USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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

FEB 12 2020

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, Food Safety and Inspection Service conducted an on-site audit of the Netherland's meat inspection system from May 6 through May 21, 2019. Enclosed is a copy of the final audit report. The comments received from The Netherlands Food and Consumer Product Safety Authority are included as an attachment to the final audit report.

For any questions regarding this FSIS audit report, please contact the Office of International Coordination, by email at InternationalCoordination@usda.gov.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN THE NETHERLANDS MAY 6 THROUGH MAY 21, 2019

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING BEEF, VEAL, PORK, AND PROCESSED EGG PRODUCTS EXPORTED TO THE UNITED STATES OF AMERICA

February 4, 2020

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's Food Safety and Inspection Service (FSIS) from May 6 through May 21, 2019. The purpose of the audit was to determine whether the Netherlands' food safety inspection system governing meat and processed egg 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-intact veal, raw-intact pork, thermally processed-commercially sterile pork, heat treated but not fully cooked-not shelf stable pork, and processed egg products.

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 OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- Netherlands Food and Consumer Product Safety Authority (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.
- The 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.
- The NVWA has not ensured egg processing facilities have met the requirements proffered in response to FSIS findings during the previous two audit cycles; establishment personnel assigned to remove eggs with dirt and foreign materials did not remove all such eggs from the production line prior to breaking occurring.

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

- The 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.

GOVERNMENT SANITATION

- The Netherlands Supervisory Authority for Eggs (NCAE) permits 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 egg shells and enter the food supply.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- The NVWA microbiological laboratory does not analyze the entire 60 pieces as required by the N60 testing methodology when the sample portion collected for Shiga toxin-producing *E. coli* is greater than the size of the prescribed test portion.

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

TABLE OF CONTENTS

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of the Netherlands' food safety system from May 6 through May 21, 2019. The audit began with an entrance meeting held on May 6, 2019, in Utrecht, Netherlands, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – the Netherlands Food and Consumer Product Safety Authority (NVWA) for meat products and the Netherlands Supervisory Authority for Eggs (NCAE) for egg products. Representatives from the CCA 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 determine whether the food safety system governing beef, veal, pork, and egg 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 is currently eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products
Raw - Non Intact	Raw ground, comminuted, or otherwise non-intact beef	Veal – All products eligible except Advanced Meat Recovery Product; Finely Textured Beef; Partially Defatted Chopped Beef; Partially Defatted Beef Fatty Tissue; 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
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 meat	Beef, Veal, Goat, Lamb, Mutton and Pork - All Products Eligible
Heat Treated but Not Fully Cooked - Not Shelf Stable	NRTE otherwise processed meat	Beef, Veal, Goat, Lamb, Mutton and Pork - All Products Eligible

Egg Products	Egg products	Dried - Egg whites (with or w/o added ingredients); Dried -Whole egg (w/wo added ingredients); Dried - Yolk (w/wo added ingredients); Pasteurized (Frozen or Liquid) - Egg products (blends of whole egg, egg whites, and/or yolks, w/wo added ingredients); Pasteurized (Frozen or Liquid) - Egg whites (w/wo added ingredients); Pasteurized (Frozen or Liquid) - Whole egg (w/wo added ingredients); Pasteurized (Frozen or Liquid) - Yolk (w/wo added ingredients); Pasteurized (Tanker/Large Totes) - Egg products (blends of whole egg, egg whites, and/or yolks, w/wo added ingredients); Pasteurized (Tanker/Large Totes) - Egg whites (w/wo added ingredients); Pasteurized (Tanker/Large Totes) - Whole egg (w/wo added ingredients); and Pasteurized (Tanker/Large Totes) - Yolk (w/wo added ingredients).

The USDA's Animal and Plant Health Inspection Service (APHIS), which regulates importation of animals and animal products into the United States recognizes the Netherlands as subject to the following restrictions. Beef (veal) imported from the Netherlands is subjected 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 (BSE) requirements specified in 9 CFR §94.18 and/or 9 CFR §94.19.

Pork imported from the Netherlands is subjected to African swine fever (ASF) requirements specified in 9 CFR §94.8, classical swine fever (CSF) requirements specified in 9 CFR §94.31, swine vesicular disease (SVD) requirements specified in 9 CFR §94.13, and FMD requirements specified in 9 CFR §94.11. Egg products imported from the Netherlands are subject to the highly pathogenic avian influenza (HPAI) and Newcastle disease (ND) requirements specified in 9 CFR §94.6 and 9 CFR §94.28.

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 the CCA through the self-reporting tool (SRT).

Prior to the on-site equivalence verification audit, the FSIS equivalence officers reviewed and analyzed the Netherlands' SRT responses and supporting documentation. During the audit, the FSIS auditors conducted interviews, reviewed records, and observed operations to determine

whether the Netherlands' food safety inspection system is being implemented as documented in the country's SRT responses and supporting documentation.

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.

Administrative functions were reviewed at NVWA headquarters in Utrecht, Netherlands and the NCAE headquarters located in Leusden, Netherlands. Additionally, site visits were made at ten local inspection offices located in establishments certified to export to the United States. 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.

The FSIS auditors visited a sample of ten establishments from a total of twenty-four establishments certified to export to the United States. This included three processed egg products establishments, two veal slaughter and processing establishments, one pork slaughter and processing establishment, one veal processing establishment, one pork processing (includes production of not ready-to-eat (NRTE) product) establishment, one pork thermally processed-commercially sterile processing establishment, and one pork and veal cold storage facility.

During each establishment visit, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that would threaten food safety. The FSIS auditors assessed the CCA'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 and 9 CFR §590.910.

Additionally, two government operated laboratories, one conducting microbiological analyses and the other conducting microbiological and chemical residue analyses, and one privately operated chemical residue laboratory were audited to verify their abilities to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		**#**	**Locations**
Competent Authorities	Central—Meat	1	• NVWA, Utrecht
	Central—Egg products	1	• NCAE, Leusden
Laboratories		3	• The National Institute of Public Health and the Environment (RIVM) National Reference Laboratory for Microbiology (government operated), Bilthoven • NVWA Chemical and Microbiological Laboratory (government operated), Wageningen

		• RIKILT Wageningen University & Research Chemical Lab (private contracted), Wageningen
Beef (veal) slaughter and processing establishments	2	• Establishment NL 9, EKRO B.V., Apeldorn • Establishment NL 369, ESA B.V., Apeldorn
Swine slaughter and processing establishments	1	• Establishment NL 312, Vion Apeldorn B.V., Apeldorn
Beef (veal) processing establishments	1	• Establishment NL 939, T. Boer en Zonen B.V., Nieuwerkerk aan den Ijssel
Swine processing establishments	2	• Establishment NL 82, Vion Scherpenzeel B.V., Scherpenzeel • Establishment NL 153, Zwanenberg Food Group, Raalte
Egg product facilities	3	• Establishment EP 6063, Bouwhuis Enthoven B.V., Raalte • Establishment EP 6340, B.V. Nederlandse Industrie van Eiprodukten, Nunspeet • Establishment EP 6153, Adriaan Goede B.V., Landsmeer
Cold storage facilities	1	• Establishment NL 584, Lau van Haren Coldstores B.V., Weurt

FSIS performed the audit to verify the Netherlands' food safety inspection system met 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.] 601, *et seq*.);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, *et seq*.);
- The Meat Inspection Regulations (9 CFR §301 to the end);
- The Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*); and
- The Egg Inspection Regulations (9 CFR Part §590).

The audit standards applied during the review of the Netherlands' inspection system for beef, veal, pork, and egg 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* and includes the following:

- An ISM equivalence determination was granted for Visual Inspection Plus (VIP), a visual post-mortem inspection system for veal calves on July 12, 2018;
- An individual sanitary measure (ISM) equivalence determination was granted for the use of the Netherlands' Electronic Canalisation System (EKS) for export certification activities on March 26, 2019;
- European Commission Regulation (EC) No. 999/2001;
- Regulation (EC) No. 178/2002;
- Regulation (EC) No. 852/2004;

- Regulation (EC) No. 853/2004;
- Regulation (EC) No. 854/2004;
- Regulation (EC) No. 882/2004;
- Regulation (EC) No. 1/2005;
- Regulation (EC) No. 2073/2005;
- Regulation (EC) No. 589/2008;
- Regulation (EC) No. 1069/2009;
- Regulation (EC) No. 1099/2009;
- Regulation (EC) No. 37/2010;
- Regulation (EC) No. 16/2011;
- Regulation (EC) No. 142/2011;
- EC Directive No. 93/119/EC;
- EC Directive No. 96/22/EC; and
- EC Directive No. 96/23/EC.

III. BACKGROUND

From January 1, 2016 to December 31, 2018, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 67,447,321 pounds of meat and egg products exported from the Netherlands to the United States. The products imported into the United States included 716,702 pounds of raw-intact beef, 7,837,792 pounds of processed egg products, 629,489 pounds of not ready-to-eat (NRTE) processed pork, 50,542,367 pounds of raw-intact pork, 1,226,580 pounds of thermally processed-commercially sterile pork, and 6,492,391 pounds of raw-intact veal.

Of these amounts, additional Types of Inspection (TOIs) were performed on a total of 7,697,542 pounds of products consisting of 117,790 pounds of raw-intact beef, 929,756 pounds of processed egg products, 102,731 pounds of NRTE processed pork, 5,691,113 pounds of raw-intact pork, 86,791 pounds of thermally processed-commercially sterile pork, and 769,361 pounds of raw-intact veal, including testing for chemical residues and microbiological pathogens *Escherichia coli (E. coli)* O157:H7, and non-O157 Shiga toxin-producing *E. coli* (STEC) O26, O45, O103, O111, O121, and O145 in beef or veal and *Listeria monocytogenes* (*Lm)* and *Salmonella* in egg products.

As a result of these additional inspections, since May of 2017, 4,242 pounds of raw-intact veal were rejected at POE inspection for issues related to United States food safety requirements including, extraneous material, and STEC positive test results. Some of the veal products were also implicated in a recall by the Netherlands. An additional 89,271 pounds of meat and egg products were refused entry for non-food safety requirements due to shipping damage, missing or invalid shipping marks, etc.

The previous FSIS audit in May of 2017 identified the following findings:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- The Netherlands' inspection system for pasteurized egg products does not provide

continuous inspection coverage at egg products establishments. The FSIS auditors' onsite verification of the Netherlands' egg products inspection system indicates that the Netherlands' inspection system provides egg inspection coverage at two locations: the breaking step for shell eggs and when a batch of egg products is ready to be exported (i.e., at pre-shipment). The government inspector is not present after the breaking step, when egg products enter the processing machinery for pasteurization, further processing, drying, and packing of the final products.

- The Central Competent Authority (CCA) has not implemented a government verification plan for *E. coli* O157:H7 and non-O157 Shiga toxin-producing *E. coli* (STEC) testing for raw intact veal for intact use and exported to the United States.

GOVERNMENT SANITATION

- Multiple sanitation deficiencies were observed in the veal slaughter, pork slaughter and processing, and egg products establishments. Feathers and dirt were attached to surface of received shell eggs presented for breaking to process egg products destined to the United States export.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- Processing steps in flow charts of the veal and egg products establishments did not align with that of hazard analysis; however, it aligned with establishments' production processes.
- The CCA did not verify that specific pathogens (e.g., *Salmonella* or *Listeria monocytogenes*) known to occur in egg products were considered in the hazard analysis; however, establishments critical control points were adequately controlling these pathogens.

The FSIS final audit reports for the Netherlands' food safety inspection systems are available on the FSIS website at:
http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

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

The first of six equivalence components that the FSIS auditor 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.

The NVWA is the CCA responsible for safeguards of the health of animals and plants, animal welfare and the safety of food and consumer products. In their role as the CCA, the NVWA provides funding and oversight to the NCAE which is an independent government foundation responsible for the regulation and inspection of facilities for the production of eggs and egg products including laying farms, egg sorting/packing facilities and egg processing plants. Complete management and operational activities of a NVWA chemical and microbiological laboratory is included as part of the responsibility of the NVWA.

The NVWA also provides oversight and funds the Kwaliteitskeuring Dierlijke Sector (KDS) which is a private government contracted firm providing employees performing post-mortem examinations. The FSIS auditors verified that no changes in the staffing of governmental or other personnel directed by the NVWA has occurred since the last audit in May of 2017. However, there was one change in the organizational structure with enforcement activities and inspection activities now within separate directorates, where previously they were within the same directorate.

The NVWA assigns Veterinary Officers or Veterinary Assistants to eligible meat establishments in conjunction with staffing of the post-mortem inspection by KDS inspectors. The FSIS auditors verified that the NVWA staffing program was sufficient to ensure an effective level of oversight is maintained as described in the SRT. The NCAE assigns inspection staff to certified egg processing establishments to ensure continuous inspection of the process occurs according with the corrective action proffered in response to the FSIS May 2017 audit findings. The FSIS auditors verified that NVWA in-plant inspection personnel conduct inspection activities at least once per shift for processing establishments. The NVWA in-plant inspection personnel conduct offline verification procedures and KDS personnel conduct online carcass by carcass inspection during slaughter operations in establishments that are certified to produce meat products for export to the United States.

The FSIS auditors verified through records review and interviews that the 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, the NVWA and NCAE have the ability to take enforcement actions if a certified establishment does not meet the requirements of the NVWA or NCAE. During a site visit, the FSIS auditors reviewed records at a cold storage facility which was removed as approved for the EKS export process due to a non-compliance; corrective actions were submitted to the NVWA and after review, the approval was reinstated with an increased level of NVWA verification of the EKS process.

The NVWA ensures the inspection of product for export which may be carried out in three ways; product staged for export may be inspected by NVWA employees at a certified meat establishment, by NCAE employees at a certified egg products processing facility, or by establishment employees at EKS approved facilities under limited supervision by the NVWA. After inspection of the product, the NVWA will certify a consignment based on the information provided by the inspecting official or establishment personnel, and the NVWA will issue the export certificate allowing product to be shipped.

Certification of product for export does not occur until microbiological test results of the establishment or official NVWA or NCAE microbiological testing are received as acceptable. If a Veterinary Officer suspects or chooses to sample an animal for any chemical residues under the targeted program based on observations during ante-mortem or post-mortem inspections, that carcass is held pending acceptable test results. For testing conducted under the routine residue monitoring program however, the following findings was identified.

- 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.

The FSIS auditors verified through records review and interviews that the NVWA and NCAE employees receive training on standards applicable to their assignment including: animal welfare, ante-mortem inspection, post-mortem inspection, sanitation standard operating procedures (sanitation SOP) and sanitation performance standards (SPS), HACCP, labeling verification, export certification, import inspection to ensure source materials originate from certified establishments in eligible countries, separation of product intended for export to the United States from other product, control over condemned materials, official government sample collection practices, and enforcement of United States import requirements. However, the FSIS auditors identified that the NVWA does not ensure all United States import requirement are met.

- The NVWA considers a chemical residue test result as violative based on EU maximum residue limits which do not correspond to levels permitted by FSIS.

The NCAE requires that eggs used for production of product for both EC and United States export must meet Class A requirements and be clean, dry and meet a zero tolerance policy for presence of dirt or extraneous material at the point of breaking. NCAE inspectors visually verify that only Class A shell eggs specifically sorted and packed for United States production are received and processed for export to the United States. During the June 2014 and May 2017 audits of the Netherlands egg processing system, FSIS auditors identified failure of the NCAE to ensure the zero tolerance requirements for extraneous materials and dirt were met at the point of breaking. The FSIS auditors identified the following repeat finding.

- The NVWA has not ensured egg processing facilities have met the requirements proffered in response to FSIS findings during the previous two audit cycles; establishment personnel assigned to remove eggs with dirt and foreign materials did not remove all such eggs from the production line prior to breaking occurring.

The NVWA has the legal authority and responsibility to certify and de-certify establishments as eligible to export product to the United States. An establishment is certified as eligible through the following process; an establishment applies for certification, an off-site audit of the establishment's written programs is conducted and if the result is acceptable, an on-site audit is conducted. An additional on-site audit is conducted after a slaughter establishment is permitted to operate and document their programs as implemented; if the second on-site 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 to a slaughter facility but has only one on-site audit after which it may be certified as eligible if the results of the audit are satisfactory. The NVWA relies on the NCAE to certify an egg producing establishment as eligible to export to the United States; FSIS auditors verified through records that NCAE officials perform a comprehensive on-site inspection of a facility and their documented food safety programs prior to recommending certification and listing as eligible by the NVWA.

The FSIS auditors verified through records review and interviews that in addition to a yearly HACCP audit of each certified establishment, supervisory reviews occur as follows: Supervision 1 occurs once per month by a Team Leader, Supervision 2 occurs four times per year by a head of department, and supervision of in plant KDS employees occurs weekly by the Veterinary Officer. 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 called MSPIN.

The FSIS auditors verified through records review that NCAE officials conduct supervisory reviews on a three times per year basis at each egg processing facility. The NVWA conducts an annual oversight audit of NCAE functions, in addition to NCAE conducting an annual self-audit and a yearly independent audit by the Dutch Accreditation Council (RvA).

The NVWA provides direct oversight of government operated laboratories and approves the use of privately-owned laboratories for the analysis of official samples. The NVWA requires International Organization for Standardization (ISO) 17025 accreditation through independent audits and a yearly accreditation audit by the RvA which includes a review of mandatory competency testing completed by each laboratory. The NVWA receives copies of the accreditation and audit reports and verifies that on whether the NVWA operated laboratories and the privately-contracted laboratories continue to meet the minimum ISO standards. The FSIS auditor reviewed the most recent accreditation report available at each laboratory visited and confirmed that any identified findings were addressed in a timely manner.

The FSIS analysis and onsite verification activities indicated that the NVWA's meat and egg products inspection systems have an organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements. However, FSIS auditors identified findings regarding the certification of products for export and repeat findings regarding procedures permitted to occur at egg processing establishments as note above. Additionally, the FSIS auditors identified the potential for violative levels of chemical residues based on the Netherland's current limits, however, the FSIS auditors did not identify any affected product based on a review of available records.

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 of six equivalence components that the FSIS auditor 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 each and every carcass and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; periodic supervisory visits to official establishments; and requirements for thermally processed-commercially sterile products.

The FSIS auditors verified by review of supervisory records and interviews that supervisors from both the NVWA and NCAE conduct supervisory reviews at the stated frequencies. In addition, the FSIS auditors verified that the supervisors possessed the knowledge of EC requirements along with United States export requirements necessary for conducting supervisory reviews and establishment audits. No issues were identified with the NVWA's or NCAE's ability to conduct supervisory audits of employees and establishments.

For meat plants 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 Veterinarian-in-Charge (VIC) is able to confirm any requirements for disease statuses outlined by APHIS. In addition, the FSIS auditors verified that establishments have a recall plan in place and can trace products forward in the event of a recall as required by the NVWA.

For egg plants the NCAE inspectors verify that the identification mark is correctly attached to egg products. The packaging station code must be indicated on the pre-packaging and/or transport packaging of eggs received from packaging stations. The producer code and NCAE data must be placed on the transport packaging of eggs received directly from egg producers. In either situation, the eggs can be traced back to the farm of origin. The FSIS auditors did not have any concerns with the traceability and recall requirements in the Netherlands.

The NVWA requires ante-mortem inspection on every shipment of animals within 24 hours prior to slaughter by an NVWA veterinarian inspector. The FSIS auditor observed that the audited slaughter establishments provided a holding pen designated for observation and further examination of suspect animals. Suspect animals are examined by the VIC to determine if they are fit for slaughter and can be used to produce human food. The FSIS auditor reviewed inspection records and observed execution of ante-mortem procedures that demonstrate inspection personnel implement NVWA requirements. The FSIS auditors did not identify any areas of concern with ante-mortem inspections during the direct observations and review of records.

The FSIS auditors also observed implementation of the humane handling programs at the audited slaughter establishments. This included directly observing inspection personnel perform hands-on verification of the maintenance and conditions of the holding pens, movement of animals, access to water or feed, and proper stunning of animals. Additionally, the FSIS auditors reviewed the inspection-generated humane handling verification records documenting the results of their verification activities. Through interview and confirmation of written programs, FSIS auditors verified that the NVWA follows EC requirements which would permit the harvest of non-ambulatory animals for human consumption. The FSIS auditors identified this slaughter process permitted by the NVWA as a finding because it is not permitted by FSIS;

- The 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.

The FSIS auditors verified that government inspection personnel perform post-mortem inspection at the time of slaughter in accordance with the NVWA's requirements. The FSIS auditors directly observed the implementation of the NVWA's requirements by inspection personnel during post-mortem inspection presentation, identification, examination, and disposition of carcasses and parts. All carcasses railed out during post mortem inspection must be re-inspected by the VIC prior to being released back into the process. The FSIS auditors also directly observed the actions of KDS inspection personnel performing on-line post-mortem inspection following traditional and visual inspection methods. For both visual and traditional inspection, the VICs were observed conducting verification activities of the KDS inspectors. Review of the verification records indicated that the VICs are conducting these activities at least weekly as required by the NVWA.

In the swine and veal slaughter establishments, the KDS inspection personnel may conduct visual inspection of animals and parts according to the equivalent alternative post-mortem inspection procedure for market hogs and veal calves, respectively. For both inspection systems, the FSIS auditors observed that each and every carcass and its parts are inspected by KDS or NVWA inspectors. The verification activities conducted during ante-mortem and post-mortem inspection ensure that visually inspected carcasses and organs are wholesome and not adulterated.

The KDS inspection personnel followed the NVWA instructions for implementing visual inspection. Determination of eligibility for visual inspection is based on food chain (or Supply Chain) information, information from the Netherlands' Central Identification and Registration system which includes data about the exact age, and the whereabouts of each calf and market hogs from birth to slaughter. This information is collected and fixed to the specific slaughter line that the calf or hog is processed on. The FSIS auditors did not have any concerns with the implementation of traditional or visual inspection activities.

The NVWA requires establishments to have a CCP that ensures the absence of fecal/ingesta/milk contamination. Any visible contamination must be removed immediately by trimming. The NVWA official veterinarian verifies the effectiveness of the CCP by direct observations and

review of records daily. The FSIS auditors verified, without any concerns, that the slaughter establishments control contamination by ingesta, fecal material, or milk through a CCP in their HACCP plan with a critical limit of zero tolerance. These verifications by the FSIS auditors included directly observing the establishments implementation and the VICs verification activities including the review of records associated with zero tolerance CCPs and the verification of them.

The Netherlands is required to follow Regulation (EC) No. 999/2001, which describes requirements for the removal of SRMs in cattle. This regulation requires that tonsils and distal ileum of all cattle regardless of age must be removed. The FSIS auditors directly observed the implementation of SRM removal and disposal during veal slaughter operations. The NVWA verifies establishments' compliance with requirements for the identification, removal, segregation, and disposal of SRMs. The NVWA's procedures outline the inspection and verification activities for SRM controls. The FSIS auditors reviewed government verification records and the establishments' monitoring records concerning control and disposal of SRMs. The FSIS auditors also observed that the establishments use dedicated equipment for removing SRMs and ensuring the segregation and control of inedible materials. No issues were identified regarding the implementation of SRM controls at the establishments during the audit.

The NVWA and NCAE requires the establishments to segregate and store inedible products 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 noted that the inspection personnel have the authority and responsibility to detain, denature, and destroy inedible products in accordance with the NVWA's requirements. The FSIS auditors reviewed both inspection and establishment records, and auditors observed the disposal process of condemned and inedible materials at the audited establishments and found no concerns.

The FSIS auditors verified that the NVWA or NCAE officials carried out official inspection and verification activities as outlined in the official instructions, including verifying that establishment construction, facilities and equipment, and control over inedible products and condemned materials are all adequate.

FSIS concluded that the Netherland's food safety inspection system maintains the legal authority and a regulatory framework that is consistent with criteria established for this component with one finding identified above.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the NVWA and NCAE requires each official establishment to develop, implement, and maintain written sanitation SOPs to prevent direct product contamination or insanitary conditions.

The FSIS auditors noted that the NVWA requires establishments, including processed egg products plants, certified for exporting product to the United States to develop and implement sanitation SOPs. The FSIS auditors verified that each audited establishment maintains a written

sanitation program to prevent direct product contamination or adulteration. Each establishment's program included maintenance and improvement of sanitary conditions through routine assessment of the establishment's hygienic practices. The FSIS auditors confirmed that in-plant inspection personnel conduct daily verification procedures of the implementation of each establishment's sanitation program. Inspection verification activities consist in a combination of document reviews, observations, and hands-on inspections.

The FSIS auditors assessed the adequacy of the pre-operational inspection verification by observing in-plant inspection personnel conducting pre-operational sanitation verification inspection in two of the audited establishments. The in-plant 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 inspector's pre-operational sanitation verification inspection. The in-plant inspection personnel conduct pre-operational sanitation verification on a daily basis in accordance with the NVWA's established procedures.

In addition, the FSIS auditors observed the in-plant inspection personnel's verification of operational sanitation procedures in all of the audited establishments, comparing the overall sanitary conditions of all audited establishments to the NVWA's or NCAE's inspection verification documentation. The FSIS auditors' verification activities included direct observation of operations and review of the establishments' sanitation monitoring and corrective action records at all visited establishments. The FSIS auditors did not identify any concerns with the NVWA's verification of operational sanitation procedures.

The FSIS auditors' verification of sanitation SOPs included the establishments' written sanitation SOPs, the establishments' sanitation monitoring, and corrective action records, in addition to the in-plant inspection records documenting inspection verification results, noncompliances, and supervisory reviews of establishments. The FSIS auditors' review of records generated by in-plant inspection personnel (including noncompliance and verification records) showed that in-plant inspection personnel have identified and documented sanitation findings in their daily verification or periodic supervisory review records.

The FSIS auditors noted that the NVWA requires sanitary dressing procedures of livestock at slaughter establishments. As a result, each audited slaughter establishment has implemented sanitary procedures to prevent potential carcass contamination throughout the process. These included sanitary procedures to prevent carcass contamination during hide removal; to prevent direct contact between carcasses during dressing procedures; and to prevent carcass contamination with gastrointestinal contents during evisceration by tying the bung and weasand. On a daily basis, the NVWA veterinarians conduct verification of sanitary dressing procedures. The FSIS auditors did not identify any concerns with the NVWA's verification activities for sanitary dressing.

The FSIS auditors observed egg processing operations, which are verified through inspections by NCAE inspectors. During site visits to egg processing establishments, the FSIS auditors noted that the Netherlands legislation does not require egg product establishments to wash or sanitize shell eggs prior to the breaking step. During processing operations, the FSIS auditors observed the equipment system design that would lead to product contamination:

- The NCAE permits 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 egg shells and enter the food supply.

FSIS concluded that the Netherland's food safety system requires all 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 audit identified that the NCAE inspection personnel failed to correct an equipment system design potentially allowing direct microbial contamination of edible product prior to the pasteurization process. This could result in the unwholesomeness of residual egg whites through contact with unwashed egg shells. In addition, isolated noncompliances related to the verification of sanitation requirements are noted in the individual establishment checklist provided in Appendix A of this report.

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

The fourth of six equivalence components that the FSIS auditors reviewed was Government HACCP System. The food safety inspection system requires each official establishment develop, implement, and maintain a HACCP system.

The FSIS auditors noted that the NVWA requires establishments exporting to the United States to develop and implement a HACCP program. 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 in-plant inspection personnel daily verification methodology includes such activities as the evaluation of the establishment's written HACCP programs and observing the establishment personnel perform monitoring, verification, corrective actions, and recordkeeping activities. The official daily HACCP verification activities also include direct observation or record review of CCPs for all production shifts, with results of verification being entered in the associated inspection records.

The FSIS auditors conducted an on-site 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 inspector'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 inspection personnel is after post mortem inspection and in accordance with the CCAs requirements which are consistent with FSIS requirements. a

The FSIS auditors noted that veal slaughter and processing establishments certified as eligible to export to the United States addressed contamination of carcasses with STEC as a hazard reasonably likely to occur 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/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 the NVWA has verification activities in place for the establishments producing thermally processed-commercially sterile products. Establishments are required to have a HACCP plan for the thermal processing step addressing microbiological concerns that includes time and temperature. The canning establishments that produce products certified by the Netherlands for export to the United States utilize a HACCP system, with a validated HACCP plan for the thermal process. In addition to the thermal processing step, the establishment implements other CCPs and pre-requisite programs addressing aspects of canning such as tear downs, support for initial temperatures, support for the thermal process of each retort, flow of products, pressure, and incubation.

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

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that 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, and muscle of carcasses, as well as eggs and egg products for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants.

Prior to the on-site audit, FSIS residue experts reviewed the Netherlands' national Residue Monitoring Program (RMP) previous testing results, associated methods of analysis, and additional SRT responses outlining the structure of the Netherlands' chemical residue testing

program. It was noted that, as of the time of the audit, there have not been any POE violations related to this component since the last FSIS audit.

The FSIS auditors verified through records review and direct observations that the RMP is organized and administered by the NVWA which manages the national random sampling and testing program for chemical residues. Planning of the RMP is based on previous years' results as well as guidelines within EC Directives No. 96/22/EC and No. 96/23/EC. The FSIS auditors confirmed implementation of the RMP through review of records and observations at the NVWA chemical laboratory in Wageningen and the RIKILT University & Research Chemical Laboratory in Wageningen.

The FSIS auditors confirmed the RMP includes plans for the number of samples for each species, as well as locations for samples to be taken including the primary production phase (farm) and slaughterhouse. Regarding products for export to the United States, the NCAE or NVWA samples the following: eggs at the farm or packing station, bovine and porcine hair, and urine samples at the farm, and bovine and porcine urine, kidney, fat, kidney fat, retina, liver and meat at slaughterhouses. Meat samples are analyzed according to EC Directive No. 96/23EC for Category A banned substances with zero tolerance level, and Category B licensed substances with a maximum residue limit while egg products are analyzed for dioxins.

The FSIS auditors verified that in-plant NVWA inspection personnel collect routine residue samples and NVWA veterinarians 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 the NVWA Wageningen laboratory which initially receives all samples. Approximately 15 percent of residue samples are then transferred to the RIKILT laboratory; both the NVWA and RIKILT laboratories are housed within the same building, which allows for immediate transfer of samples to RIKILT facilities under controlled conditions. Receipt of samples, tracking of samples, handling and analysis, and reporting of results were reviewed by the FSIS auditors at both facilities. The NVWA and RIKILT laboratories are both ISO 17025 approved facilities and are also accredited by the RvA. The FSIS auditors verified that both laboratories have been audited within the past year in accordance with ISO requirements; in each case, the laboratory responded to correct any findings identified during the audit process.

The FSIS auditors confirmed that, when a carcass is tested for routine RMP monitoring, there is no government requirement to hold the tested carcass pending receipt of acceptable test results; this observation is identified as a finding in Component One: Government Oversight. NVWA officials indicated that this procedure for routine monitoring is based, in part, on the controls in place with the required food chain information program. The food chain information program includes: tracking of an animal from birth to arrival at the slaughter plant, any medical treatment of the animals with withdrawal times for medication administered, disease history of the farm of origin, health condition of animals and the region of origin of the animals. If all food chain information is not provided with the animal at arrival for slaughter, the official veterinarian may prohibit slaughter of the animal or require all carcasses to be held pending receipt of the food chain information. If the food chain information is not received, the animals would be rejected from slaughter or the carcasses would not be permitted to enter the human food supply.

Results of laboratory analysis are reported to NVWA headquarters, with acceptability of results based on Regulation (EC) No. 37/2010 which identifies banned substances with zero tolerance levels and substances with maximum residue levels permitted in food stuffs. The FSIS auditors identified in Component One that the NVWA does not currently identify chemical residue test results as violative based on FSIS import requirements.

The FSIS analysis and on-site verification activities indicate that the NVWA continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and ensuring controls of the presence of residues of veterinary drugs and contaminants in meat and processed egg products destined for human consumption.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last of six equivalence components that 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 and processed egg products prepared for export to the United States are safe and wholesome.

Prior to the on-site visit, FSIS microbiologists reviewed the Netherland's national microbiological sampling and testing programs, laboratory methods of analysis, and additional SRT responses outlining the structure of NVWA's microbiological verification sampling and testing programs. Since the last FSIS audit, the NVWA has implemented STEC testing of veal products and has also required certified establishments to develop a STEC testing program as a verification program in response to the FSIS 2017 audit findings. The FSIS auditors noted that there have not been any POE violations for STEC in beef (veal) since July of 2017 which is when the NVWA implemented a government STEC verification testing program and required certified establishments to develop their own STEC testing programs.

The FSIS auditors verified that NCAE employees perform sampling of processed egg products for *Salmonella* and *Lm* with a scheduled 2019 sampling plan of 106 samples analyzed for each microorganism. The FSIS auditors also verified that each egg processing establishment performs sampling of finished products for *Salmonella* and *Enterobacteriaceae*. At each egg processing facility visited, the establishment has written programs regarding the sampling techniques used to obtain a sample and for analysis using on-site ISO 17025 accredited private laboratories. NCAE official employees review the microbiological test results for acceptability prior to pre-certification of the consignment for export to the United States. After NCAE employees perform the pre-certification, the establishment receives the export certificate from the NVWA, and product may then be shipped to the United States.

The FSIS auditors verified that the NVWA ensures establishments follow Regulation (EC) No. 2073/2005 regarding process hygiene criteria testing and analysis for carcasses. Establishments are required to conduct indicator organism testing on carcasses for aerobic colony count (ACC) and *Enterobacteriaceae,* and to analyze the data using standards set as lower limit (m) and upper limit (M) based on the species. The FSIS auditors verified establishments adhere to the sampling

frequencies as per NVWA requirements and take actions when an individual test is beyond the upper limit (M) or a trend is determined based on levels above the lower limit (m). The FSIS auditors also verified that NVWA officials perform indicator organism testing of carcasses for verification twice yearly on 10 carcasses with four locations per carcass sampled and analyzed for ACC and *Enterobacteriaceae* by NVWA laboratories.

The NVWA has developed *Salmonella* official sampling and testing programs for chilled carcasses using two programs which are implemented by NVWA employees and the NVWA microbiological laboratory. Routine testing is performed according to NVWA guidelines with testing conducted once every four weeks. Targeted sampling consists of a set of 55 consecutive samples for swine or 82 consecutive samples for veal and is conducted according to NVWA guidelines at least once every three years or is initiated if three consecutive positive test results are returned from the routine testing program. The FSIS auditors did not identify any concerns regarding sample collection procedures or NVWA testing methods regarding the *Salmonella* sampling programs.

The NVWA policy is that all veal product found to be contaminated with *E. coli* O157:H7 or eight other non-O157 STEC (eight identified by the Netherlands includes the six identified as adulterants by FSIS) is ineligible for export to the United States. Currently, the Netherlands is exporting only intact veal products to the United States however, the NVWA and each establishment considers that all product exported may be used for non-intact finished product. NVWA officials follow NVWA guideline *Verenigde Staten, Verification and Sampling Activities for STEC in Raw Beef* (RE-33) regarding verification and sampling activities for STEC in veal products destined for export to the United States.

NVWA officials perform STEC verification sampling at the frequency of four times per month in accordance with procedures as per RE-33. NVWA in-plant inspection personnel also observe establishment sampling procedures at least once per month as a verification procedure. The FSIS auditors reviewed 2018 test results at the NVWA microbiological laboratory in Wageningen; 188 samples were taken by NVWA officials with two samples returned as positive for STEC. If a positive test result is obtained through NVWA routine sampling (four times per month sampling), follow-up sampling is immediately scheduled at the same facility and the slaughter house (if product was sourced from another facility) and conducted in accordance with RE-33 guidelines.

During the on-site audit of one of the veal slaughter establishments, the FSIS auditors observed and verified proper N60 sample collection methodology by the establishment's quality control personnel and in-plant inspection personnel. The FSIS auditors confirmed that veal slaughter establishments have implemented a STEC testing program in accordance with NVWA guideline *United States, requirements for companies* (RE-31); establishments test each lot of product destined for export and hold product pending test results. If the product tests positive for STEC, it is not eligible for export to the United States regardless of the product type or intended use. Establishment programs identified products to be tested (product destined for export), lot size (microbiologically separate and no more than one day of production which is typically less than 40,000 Kg), size and number of slices (N60 methodology), method of collection (exterior carcass

material, throughout the production run), and sample handling and analysis (validated testing method).

The FSIS auditors visited the NVWA microbiological laboratory located in Wageningen. The RvA conducts an annual technical review of this laboratory to maintain the ISO 17025 accreditation. The NVWA microbiological laboratory is responsible for screening and confirmation analyses of official samples and uses testing methodologies for official analysis of *E. coli* O157:H7, non-O157 STECs, and *Salmonella* in accordance with their ISO accreditation. During the laboratory visit, the FSIS auditors reviewed documents pertaining to the sample receipt, timely analysis, analytical methodologies, data capture, sample storage, equipment calibration, media preparation and storage, analytical controls, and reporting of results. The FSIS auditors identified the following finding;

- The 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 analysis and onsite verification activities indicate that the NVWA continues to maintain the legal authority to implement its microbiological sampling and testing programs to ensure that meat and processed egg products are safe and wholesome. FSIS concludes that the NVWA meets the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on May 21, 2019 in Utrecht, Netherlands with the NVWA and NCAE. At this meeting, the FSIS auditors presented the preliminary findings from the audit. The FSIS auditors identified the following systemic findings:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- Netherlands Food and Consumer Product Safety Authority (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.
- The 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.
- The NVWA has not ensured egg processing facilities have met the requirements proffered in response to FSIS findings during the previous two audit cycles; establishment personnel assigned to remove eggs with dirt and foreign materials did not remove all such eggs from the production line prior to breaking occurring.

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

- The 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.

GOVERNMENT SANITATION

- The NCAE permits 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 egg shells and enter the food supply.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- The 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.

During the audit exit meeting, the NVWA committed to address or respond to the preliminary findings as presented. FSIS will evaluate the adequacy of the 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
Bouwhuis Enthoven B.V. (Eggs) Raalte	05/08/2019	EP6063	Netherlands
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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.	
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	X
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.	

60. Observation of the Establishment

45; Lid of product storage tote was broken/cracked.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	5/8/2019

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
Adriaan Goede B.V. (Eggs) Landsmeer	05/13/2019	EP6153	Netherlands
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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.	X
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.	
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.	

60. Observation of the Establishment

13; FSIS auditors observed that establishment records of operational sanitation did not include documentation of sanitation checks if multiple monitoring throughout the day was required by their program.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	5/13/2019

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
B.V. Nederlandse Industrie van Eiprodukten (NIVE) (eggs) Nunspeet	05/10/2019	EP6340	Netherlands
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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.	
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	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	O
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.	

60. Observation of the Establishment

22- The critical limit monitor did not record the actual time the monitoring of the sieve was taking place in the Green Room.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	5/10/2019

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	05/14/2019	NL 9	Netherlands
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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.	X
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.	
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	X
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	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

60. Observation of the Establishment

13; FSIS auditor observed that establishment did not maintain records documenting completion of clean-up procedures to ensure separation of non-U.S. product from that of product destined for U.S. export.

46; Rail dirt was observed on carcasses within cooling chambers, carcass breaking room and cut up room; establishment took actions to ensure removal of rail dirt from carcasses prior to removal from the hanging line in the cut up/deboning room.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	5/14/2019

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 Scherpenzeel	05/16/2019	NL 82	Netherlands
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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.	
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	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
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.	

60. Observation of the Establishment

39- Two holes were observed in a ventilation duct above production line one in the raw cut up area. No product or food contact surface contamination was observed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	5/16/2019

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
Zwanenberg Food Group . Raalte	05/17/2019	NL 153	Netherlands
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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	O
34. Species Testing	
35. Residue	O
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.	

60. Observation of the Establishment

22- The establishment was not documenting the time the calibration of process monitoring instruments is taking place.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	5/17/2019

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 NL 312 . Apeldoorn	05/14/2019	NL 312	Netherlands
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
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			

60. Observation of the Establishment

41- Beaded condensate was observed overhead in the spray cool tunnel area prior to entering tunnel. The condensate droplets were to numerous to count and spread over a 10 foot by 3 foot area. Condensation was not observed falling on any products.

45,46 – Rail dust and grease was observed in several areas of the establishment. The grease and/or rail dust was observed in multiple areas of the establishment on the rails over pork carcasses. Grease was observed on 2 carcasses during the government inspectors zero tolerance verification activities. Any grease observed on product was identified and the establishment took corrective measures including the removal or grease and/or rail dust.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	5/14/2019

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
ESA BV NL 369 Apeldoorn	05/16/2019	NL 369	Netherlands
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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.	
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.	
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	
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. Other	X
58.	
59.	

60. Observation of the Establishment

57; Establishment did not maintain adequate supporting documentation for decisions in their hazard analysis; establishment was routinely not following a pre-requisite program according to their written requirements. No evidence of product adulteration.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	5/16/2019

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
Lau van Haren Coldstores B.V. Weurt	05/09/2019	NL 584	Netherlands
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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.	
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	
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.	

60. Observation of the Establishment

No observations of non-compliance.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	5/9/2019

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. . Nieuwerkerk aan den Ijssel	05/15/2019	NL 939	Netherlands
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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.	
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.	
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	O
34. Species Testing	O
35. Residue	O
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.	

60. Observation of the Establishment
No observations of non-compliance.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	5/15/2019

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

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

Directorate-General Agro

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
T.J.D. van Riet

T +31 (0)70 378 6521
t.j.d.vanriet@minlnv.nl

Our ref.
DGA / 19307598

Your ref.

Encl.
1

Date 31 JAN 2020

Re Official response to draft audit report on veal, pork and egg products

Dear Dr Catlin, dear Michelle,

With this letter I will give an official response to the draft audit report and corresponding letter which were received October 23, 2019. The Food Safety and Inspection Service (FSIS) conducted a routine onsite ongoing equivalence audit of the Netherlands' veal, pork and egg products inspection system, from May 6 through May 21, 2019.

I appreciated your positive response on the extension of the response time, as communicated per e-mail.

FSIS identified six findings within the six system equivalence components. None of these deficiencies represented an immediate threat to public health.

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

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

Sincerely yours,

Hendrik-Jan Roest, DVM, PhD
Deputy Chief Veterinary Officer

Annex:
Official reaction to the FSIS draft audit report

COMPONENT	DEFICIENCY	REACTION THE NETHERLANDS CORRECTIVE ACTIONS/CURRENT SITUATION
COMPONENT ONE: GOVERNMENT OVERSIGHT	Netherlands Food and Consumer Product Safety Authority (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. The 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.	NL has participated in the webinar "test and hold", which was organized between FSIS and the European Union on January 16, 2020. During the webinar, FSIS explained their requirements for test-and-hold and also the corresponding equivalence procedure. We have experienced the webinar as a helpful instrument. First, NL was reluctant regarding implementation of the test-and-hold-requirement. The concerns related to the announcement to the slaughterhouse of which specific carcass has been tested for the National Residue Monitoring Plan. The common practice in NL is that it is not announced to the slaughterhouse which specific carcass has been tested. The reason for this is that, in cases of non-compliance, the primary farm will be visited by the competent authority for investigation. If the slaughterhouse knows which carcass was violative, it is simple to know the primary farms where the carcass originates from because of the Information and Registration system which is in place for all slaughter animals in the Netherlands. Because of this, carcasses are sampled without notice, so the slaughterhouse is not able to inform the primary farm, who is then able to destroy evidence before investigation by the competent authority and so disturb investigations. In this way the FSIS requirement could undermine the system of the national residue monitoring plan.

		Bearing this in mind, we had to take a further look into this testing system related to the FSIS requirement. Because we do not want to disturb the trade of meat to the US, NL will implement the FSIS test-and-hold requirement for the US. Carcasses sampled, either by NVWA in the frame of National Residue Plan or the company for their own purposes, will be declared unfit for the export to the USA and therefor nor the carcasses nor meat and organs of these carcasses will be exported to the USA. This method will be adopted in the work instructions, and will be implemented by March 1, 2020. Although we are now taking on board the test-and-hold-requirement, we would, given the argumentation above, like to discuss this requirement during a future visit. NL has a National Residue Monitoring Plan in place, which is required by Council Directive 96/23/EC. The National Residue Monitoring Plan is a monitoring plan conducted by the government. It aims at detecting illegal treatment of food-producing animals, controlling compliance with the maximum residue limits for veterinary medicinal products, the maximum residue levels for pesticides and the maximum levels for contaminants. This concerns EU authorized substances and EU MRL's. The results give an overview of non-compliances in the different sectors and show trends. FSIS requires the CCA to maintain an official government chemical residue control program that ensures that all chemical residues that are considered adulterants by the United States are not present in products exported to the United States. Because it is not possible to add the chemical substances which are considered adulterated by FSIS, to the EU-based National Residue Monitoring Plan, the responsibility for compliance with this requirement has to be laid down at the (slaughtering) establishments eligible to export to the USA. Dutch establishments should always have the choice to

		produce for export to the USA or not. In order to comply with the FSIS requirement, the branch organization, together with the relevant establishments, is scrutinizing the differences between the chemical substances which are considered adulterants by FSIS and by the EU. For chemical substances which are considered adulterants by FSIS and not by EU, and where Maximum Residue Limits of FSIS are lower than required by NL/EU, they will develop a complementary sampling plan, including on-farm monitoring and verification by pre-harvest testing on said substances. NVWA is willing to verify the sampling system; however details concerning the verification can only be laid down when this sampling plan of the industry has reached an acceptable level. As soon as this sampling plan is available, it will be shared with FSIS.
	The NVWA has not ensured egg processing facilities have met the requirements proffered in response to FSIS findings during the previous two audit cycles; establishment personnel assigned to remove eggs with dirt and foreign materials did not remove all such eggs from the production line prior to breaking occurring.	As communicated to you by letters, reference numbers DGA-DAD / 19187003 and DGA / 19249938, dated July 29th and October 30th, 2019, the procedure Sanitary and microbiological quality of eggs destined for US egg products has been amended. Assessment of test runs per establishment and subsequent decision by the Netherlands Control Authority for Eggs (NCAE) for approval production for US.
	The 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.	As communicated to you by letter, refence number DGA / 19219109, dated, September 11th 2019, veal of non-ambulatory veal calves is precluded from export to the United States. This is laid down in the related NVWA instructions (RE-31 and RE-36).

COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY, FOOD SAFETY, AND OTHER CONSUMER PROTECTION REGULATIONS		

COMPONENT THREE: GOVERNMENT SANITATION	The Netherlands Supervisory Authority for Eggs (NCAE) permits 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 egg shells and enter the food supply.	The hygienic design of the breaking installation, concerning transport of egg shells after breaking, is such that it is prevented that the residual egg white comes into contact with the outside of the eggshells. If this is insufficiently prevented the residual egg white will not come into egg product destined for USA. This is implemented in the NCAE inspection list point 81. The statement is an annex to the letter with reference number DGA-DAD / 19187003, dated July 29th 2019.
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	The NVWA microbiological laboratory does not analyze the entire 60 pieces as required by the N60 testing methodology when the sample portion collected for Shiga toxin-producing *E. coli* is greater than the size of the prescribed test portion.	As agreed in December 2019, a sensible approach has to be discussed / developed in a conference call, among laboratory experts of FSIS and the Netherlands. This conference call will be organized on short term.