United States Department of Agriculture

Food Safety and
Inspection Service

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JAN 16 2018

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,

Enclosed is a copy of the final audit report for the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) on-site audit conducted of the Netherland's meat and processed egg products inspection system from May 2-19, 2017. The comments received from the Government of the Netherlands are included as an attachment to the final audit report.

In addition, FSIS acknowledges that the Netherlands Food and Consumer Product Safety Authority (NVWA) have provided documentation to address the two issues outlined below, which is also attached to the final audit report.

- **Shiga Toxin-Producing *Escherichia coli* (STEC) Government Verification Program**

At the time of the audit, the Netherlands' eligibility for raw veal products was limited to raw intact veal intended for intact use. The NVWA has submitted and implemented an equivalent government STEC verification program and as a result, the Netherlands is eligible to export raw non-intact veal and raw intact veal intended for non-intact use, such as trim derived from veal, slaughtered on and after July 15, 2017.

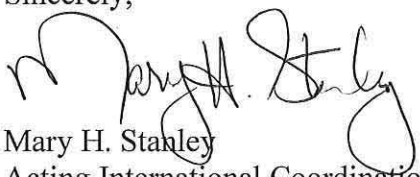
- **Continuous Inspection During Processing of Egg Products**

At the time of the audit, the Netherlands was not implementing continuous inspection during the processing of egg products for export to the United States. After the audit, the Netherlands submitted updated instructions to its inspection personnel requiring continuous inspection during the processing of egg products for export to the United States. The Netherlands has also submitted inspection records demonstrating evidence of implementation of the aforementioned instructions. Based on these submissions, FSIS is confident that the Netherlands now conducts continuous inspection of egg products.

FSIS continues to evaluate your responses and corrective actions taken to address the remaining FSIS audit findings. FSIS will be requesting additional information, which will be reviewed to assure the Netherlands' food safety system remains equivalent to that of the United States.

If you have any questions, please feel free to contact me directly at Mary.Stanley@fsis.usda.gov.

Sincerely,



Mary H. Stanley
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN THE NETHERLANDS MAY 1 - 19, 2017

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING MEAT AND PASTEURIZED EGG PRODUCTS EXPORTED TO THE UNITED STATES OF AMERICA

January 08, 2018

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from May 1 to May 19, 2017. The purpose of the audit was to determine whether the Netherlands' food safety system governing raw intact veal for intact use only, raw and processed pork products, and pasteurized 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 audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority, 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 Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors identified the following systemic findings for Government Oversight, Government Sanitation, and the Government HACCP System. However, these findings did not represent an immediate threat to public health.

Government Oversight

- 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 Points (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.

Analysis of the findings within each component raises concerns about the effectiveness of the CCA's oversight at establishments certified to export meat or egg products to the United States. During the audit exit meeting, the CCA committed to addressing the preliminary findings, as presented. FSIS will evaluate the adequacy of the CCA's proposed corrective actions and base future equivalence verification activities on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of the Netherlands' food safety system governing raw intact veal for intact use only, raw and processed pork products, and pasteurized egg products from May 1 - 19, 2017. The audit began on May 1, 2017, with an entrance meeting held in Utrecht, Netherlands, during which FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – Netherlands Food and Consumer Product Safety Authority (NVWA).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure that the food safety system governing veal, pork, and egg products maintains equivalence to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. The scope of this audit included all aspects of the Netherland's inspection system for producing and exporting meat and pasteurized egg products to the United States. The Netherlands is eligible to export raw intact veal for intact use only, raw and processed pork products, and pasteurized egg products to the United States.

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) re-inspection data, 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). Additionally, the USDA Animal and Plant Health Inspection Service (APHIS), recognizes the Netherlands as having negligible risk of Bovine Spongiform Encephalopathy and free of Foot-and-Mouth Disease, Rinderpest, Swine Vesicular Disease, and low risk of Classical Swine Fever. Furthermore, the USDA-APHIS recognizes the Netherlands free of Newcastle Disease (ND) and not affected with Highly Pathogenic Avian Influenza (HPAI).

The FSIS auditors were accompanied throughout the entire audit by representatives from the NVWA and representatives from the Netherland's Competent Authority for Egg and Egg Products (NCAE), which provides inspection oversight at certified processing establishments that are eligible to export pasteurized egg products to the United States. 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, 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 Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at the NVWA headquarters, one regional office, and seven local inspection offices. The FSIS auditors evaluated the implementation of control

systems in place, which ensure that the national system of food inspection, verification, and enforcement is being implemented as intended. At the time of this audit, there were 13 active eligible establishments exporting meat and pasteurized egg products to the United States, which consist of three veal, six pork, and four egg products establishments. Of these, the FSIS auditors examined one veal slaughter, one veal processing (raw intact for intact use only), one pork slaughter, one pork processing, and three egg products establishments. Additionally, two chemical and microbiological laboratories were audited to verify their ability to provide adequate technical support to the inspection system.

During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the NVWA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems. These requirements are outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2 and 590.910, the FSIS regulations addressing equivalence determinations for foreign country inspection systems for meat and egg products, respectively.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central/ Head Office	1	• NVWA, Utrecht
	NCAE	1	• NCAE, Leusden
Laboratories		2	• NVWA Government Laboratory, Microbiology & Chemical testing of meat products, Wageningen • Merieux (Silliker) Laboratory- Private Microbiological & Chemical testing of egg products, Pascalstraat
Pork slaughter and processing establishment		1	• Establishment NL-367-EG, Vion Groenlo B.V., Groenlo
Egg product establishments		3	• Establishment NL-6063-EP, Bouwhuis-Enthoven B.V., Raalte • Establishment NL-6340-EP, Nederlandse Industrie van Eiproducten, Nunspeet • Establishment NL-6153-EP, Adriaan Goede B.V., Landsmeer
Veal processing establishment		1	• Establishment NL-939-EG, T Boer & Zn. B.V., Nieuwerkerk a/d IJssel
Veal slaughter and processing establishment		1	• Establishment NL-9-EG, Laan van Malkenschoten, Apeldoorn
Thermally processed/commercially sterile – pork product establishment		1	• Establishment NL-129-EG, Zwanenberg Food Group (Lupack B.V.), Almelo

The audit was undertaken 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. 1901-1906);
- The Federal Meat Inspection Regulations (9 CFR Part 327.2);
- The Egg Products Inspection Act (21 U.S.C. 1031, *et seq.*);
- The Federal Egg Products Inspection Regulations (9 CFR Part 590.910); and
- Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) regulations.

The audit standards applied during the review of Netherlands' inspection system for raw intact veal products for intact use only, raw and processed pork products, and pasteurized 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 Sanitary/Phytosanitary Agreement, and includes the following alternative measures:

- Regulation European Commission (EC) No. 852/2004;
- Regulation (EC) No. 853/2004;
- Regulation (EC) No. 854/2004;
- Regulation (EC) No. 882/2004;
- Regulation (EC) No. 1099/2009;
- Regulation (EC) No. 2073/2005;
- Council Directive 93/119/EC;
- Council Directive 96/22/EC;
- Council Directive 96/23/EC; and
- Council Directive 97/747/EC.

III. BACKGROUND

The Netherlands currently exports raw intact veal for intact use only, raw and processed pork products, and pasteurized egg products to the United States. Between January 1, 2014 and December 31, 2016, the Netherlands exported approximately 43,449,539 pounds of meat and 11,136,265 pounds of pasteurized egg products to the United States. FSIS import inspectors performed 100 percent re-inspection at POE for labeling and certification on all shipments of veal, pork, and pasteurized egg products exported by the Netherlands to the United States. In addition, FSIS performed re-inspection on 1,320,276 pounds of pasteurized egg products and 5,995,174 pounds of meat products at POE in the United States for additional types of inspection (TOI). A total of 66,518 pounds of pasteurized egg products was rejected at POE due to non-public health violation (damaged containers, labeling, or export certificate issues). A total of 21,861pounds of meat products was rejected due to public health violation (off-condition).

The issuance of FSIS Notice 17-17, Sampling Imported Raw Beef Product Assigned an *E. coli* O157:H7 MT51 Type of Inspection at an Increased Level of Re-inspection, dated March 13, 2017, resulted in FSIS sampling of raw intact veal products for intact use for Non-O157 Shiga-toxin producing *E. coli* (STEC) from the Netherlands. To date, FSIS has confirmed the presence of *E.coli* O103 in three separate shipments, totaling 2,928 pounds, of intact veal products from

one veal slaughter establishment, out of two establishments eligible to export to the United States. Accordingly, FSIS issued two Public Health Alerts in May 2017 for STEC positives and subjected the Netherlands to intensified level of re-inspection. In response to FSIS POE violations with STEC positive results, NVWA, self-suspended exports of raw veal products to the United States, from the establishment implicated in the three POE violations.

The FSIS final audit report for the Netherlands' food safety inspection system will be posted on the FSIS Web site 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 (ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the FSIS auditors reviewed was Government Oversight. FSIS regulations require the foreign inspection system to be organized by the national government in such a manner as to provide standards equivalent to those of the Federal system of meat inspection in the United States. In addition, the foreign inspection system must 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 NVWA inspection personnel at establishments where products are prepared for export to the United States.

The evaluation of this component included review and analysis of the information provided by the CCA in the updated SRT and observations during the onsite audit. The FSIS auditors assessed how the Netherlands' meat and egg products inspection systems are organized and administered to promulgate and enforce food inspection regulations, ensure food safety, and certify meat and egg products when they meet the requirements for export to the United States.

The NVWA oversees the production and export of meat to the United States. The NVWA is an independent agency commissioned by the Ministry of Health, Welfare and Sports (VWS) and the Ministry of Economic Affairs (MEA). The NVWA operates under the administrative responsibility of the MEA and functions as an executive delivery body for both ministries. The Quality Inspection Livestock Sector of the Netherlands (Kwaliteitskeuring *Dierljke* Sector (KDS)) is an independent organization founded by the MEA, tasked with the performance of post-mortem inspection and other inspection verification activities under the supervision of the NVWA official veterinarians. KDS staff are employed under general civil service rules and funded mainly through allocations from the government budget and partially through inspection fees. KDS differs from the NVWA in its management through a board of directors, review process through audit, and accountability through direct reporting to the founding MEA.

The FSIS auditors verified that the NVWA carries out its responsibility by inspecting food products throughout the production chain. The NVWA is headed by an Inspector General (IG) and assisted by the Deputy IG. The NVWA consists of seven sectors: five divisions, a management staff, and a risk assessment program.

The Veterinary and Imports Division is responsible for implementing programs related to compliance with all the NVWA regulations in the areas of food safety, animal welfare, and certification of meat products. The Veterinary and Import Division collaborates with the Consumer and Safety Division, the Agriculture and Nature Division, Intelligence and Investigation Service, and Client Services Division to ensure compliance with the regulatory requirements that are shared between the divisions and directed towards food safety. The Veterinary and Imports Division is organized into five units that implement and supervise the following activities: (1) slaughterhouse controls, (2) livestock controls, (3) import controls, (4) development and evaluation, and (5) the Chief Veterinary Inspectorate.

The NVWA has control and supervision over official activities of all employees and United State-certified establishments. The NVWA has legal authority and responsibility to certify and de-certify establishments for export to the United States. The FSIS auditors verified that the NVWA mandates United States-certified establishments for meat products comply with the requirements under European legislation, as well as, the import requirements set by FSIS. If United States-certified establishments do not comply with the requirements, the NVWA official in charge of the supervision and the senior system auditors are duty-bound to advise the NVWA to withdraw United States approval. The NVWA inspectors work with a digital records system called MSPIN (mobile version for cell phones) and SPIN (for computers) to maintain written (including electronic) inspection records. The Netherlands keeps both electronic and hard copies of records consistent with requirements outlined in 9 CFR 417.5.

The establishments certified by the NVWA to export raw intact veal for intact use only or raw and processed pork products to the United States are inspected by the NVWA inspection personnel that include a Veterinarian-in-Charge (VIC) and KDS appointed auxiliaries. The team leader or the senior systems auditors are responsible for conducting periodic reviews at the United States-certified establishments. The KDS Auxiliary employees carry out post-mortem inspection and other verification activities under the supervision of the VIC. The VIC performs daily verification activities to ensure that KDS NVWA inspection personnel conduct post-mortem inspection procedures and other assigned verification activities in accordance with the standards set by the NVWA.

FSIS auditors verified that NVWA inspection personnel conduct inspection activities daily, at least once per shift for processing of raw intact veal products for intact use only or raw and processed pork products in United States-certified establishments. In addition, NVWA inspection personnel conduct carcass-by-carcass inspection during post-mortem examination in establishments that are certified to export veal or pork to the United States.

The FSIS auditors verified that NVWA inspection personnel assigned to United States-certified establishments are full-time government employees. The inspection and verification activities are conducted under the direct authority of the NVWA. The KDS receives direct payments from the NVWA and disburses payments to auxiliary inspection personnel for services rendered at slaughter establishments. The NVWA enforces measures to avoid conflict of interest situations for the KDS auxiliary employees. The NVWA sends invoices to the slaughter facility through official government channels, collects payments, and reimburses KDS annually for its services.

The FSIS auditors verified that the NVWA has the authority and responsibility to hire and assign competent, qualified inspectors to official establishments that export products to the United States. The NVWA communicates to inspection personnel throught their website the FSIS import requirements to ensure inspection personnel are kept informed about new and existing guidelines before certifying products for export to the United States. Additionally, the NVWA provides various training manuals and current training programs that are posted on the NVWA website for the inspection program personnel. The FSIS auditors verified that newly hired veterinary officers receive 200 hours of basic training on food safety and HACCP prinicples, and attend the Better Training for Safer Food (BTSF) training. The BTSF is an EC training initiative covering food and feed law, animal health and welfare, and plant health rules. In addition, veterinary officers are required to take self-study courses on FSIS export requirements annually and a refresher course on HACCP every four years.

The NVWA is authorized to require corrective actions, issue warnings, impose administrative penalties, restrict the movement of product in commerce, and withdraw establishments' approvals and certification for export. The NVWA centralized enforcement system mandates that enforcement measures taken by the inspection personnel include written notification to establishments of the reasons for the decision, the criteria the corrective actions need to meet, and the right of the establishment to appeal. The enforcement authority is based upon provisions of Administrative and Criminal Laws and uses enforcement instruments specified in Articles 54 and 55 of Regulation (EC) No. 882/2004.

While examining the NVWA enforcement activities, the FSIS auditors found the following:

- The NVWA has not implemented a government verification plan for *E. coli* O157:H7 and Non-O157 STEC testing for raw intact veal products for intact use exported to the United States as described in the document RE-36, "United States, Inspection and Supervision of USA Requirements by NVWA," for establishments certified to export to the United States.

The NVWA provides direct oversight of government operated laboratories. The Netherlands government has delegated the responsibility of quality review to an independent body, the Dutch Accreditation Council, the *Raad voor Accreditatie* (RvA). The NVWA is represented on the Supervisory Board of this independent body. RvA conducts at least one accreditation audit per year, which includes mandatory competency testing. Private laboratory conducting official testing of pasteurized egg products receives International Organization for Standardization (ISO) 17025 accreditation by the RvA. The NCAE routinely reviews the accreditation report and ensure that any audit finding is corrected. The NVWA receives copies of the accreditation and audit reports and verifies that laboratories continue to meet the accreditation requirements. RvA achieves its objectives by providing technical support to the NVWA through the delivery of valid and reliable test data. The FSIS auditors reviewed the most recent accreditation report dated October 2016 and confirmed that the laboratories addressed and corrected the findings identified by RvA.

The centrally located internal audit service office of the NVWA conducts internal annual audits of the laboratories function to evaluate their level of compliance with the standards of ISO 17025. The NVWA carries out internal quality audits of each program area, which it oversees to

improve the effectiveness of official controls. Corrective measures implemented in response to previous internal audits are also taken into account. The NVWA maintains oversight of laboratories conducting official testing of meat and egg products to be exported to the United States by ensuring that laboratories comply with the general criteria for testing laboratories provided in ISO 17025. Additionally, the NVWA requires that laboratories participate in appropriate proficiency testing schemes for food analysis and use approved equivalent and validated methods to analyze samples of product intended for export to the United States.

For the egg products inspection, the supervising body under NVWA responsible for inspecting egg products is the Netherlands Authority for Eggs and Egg Products (NCAE), which is a service within the Netherlands Controlling Authority for Milk and Milk Products (COKZ). COKZ is the Netherlands authority for the control of milk and milk products, as well as eggs, egg products and poultry meat. NCAE provides inspection oversight at egg laying poultry establishments, egg collectors and packing stations, egg processing establishments (producing egg products) and egg product traders.

The Dutch Ministry of Health, Welfare and Sport requires that the NVWA supervises and approves the NCAE working plan annually. The inspection personnel are supervised by the inspection team leader or by the senior systems auditors stationed in the team office, who reports directly to the NVWA headquarters. A team of the NVWA auditors is assigned the responsibility of conducting periodic system audit activities in all United States-certified egg products establishments. The other crucial role the NVWA plays besides conducting audits, it reviews pre-certification documents for the accuracy prior to issuing health certificate for the pasteurized egg products destined for export to the United States. The health certificates that accompany the shipments for export are issued at the NVWA level.

Through interviews conducted at the United States – eligible egg products establishments, the FSIS auditors verified that the NCAE assign qualified and trained inspectors to these facilities. The NCAE inspection personnel assigned to egg products establishments have college degrees and work experience in the field of eggs and egg products processing or related fields. New entrants to NCAE receive formal and on-the-job training prior to being assigned to egg products establishments. NCAE provides specialized training that covers specific United States import requirements. The FSIS auditors verified that ongoing training of NCAE inspectors has been conducted periodically to keep pace with developing technology and United States import requirements. The NCAE team office provided the FSIS' auditors with inspectors' on-the-job training records for the past two years, including the most recent training conducted on April 13, 2017.

While verifying the FSIS' mandatory requirements that the manufacturing of pasteurized egg products be done under continuous inspection the auditors found the following at the egg products establishments:

- The NCAE inspection system for egg products does not provide continuous inspection coverage at the egg product establishments. FSIS auditors' onsite verification of the Netherlands' egg products inspection system, shows that the Netherlands' inspection system provides inspection coverage at two locations: shell eggs breaking and when a batch of egg

products is ready to be exported (i.e., at pre-shipment). After the breaking step, the egg products enter the processing machinery. Government inspectors are not present during the steps in which the egg products are in the processing machinery. Once the egg products are packaged and labelled for shipment, the government inspectors are present during the pre-shipment review, to analyze the data and ensure the safety and quality of the finished product.

- The NCAE inspection oversight of sanitary condition during operations at egg products establishments was inconsistent. FSIS auditors observed insanitary conditions in two of the three audited establishments. In the breaking room of one establishment, FSIS auditors observed feathers and foreign materials on shell eggs and on equipment used for direct product contact surfaces of shell eggs (conveyor belt of breaking machine). At that establishment, the NCAE inspector did not take action, however the establishment management rejected the consignment for export to the United States according to FSIS auditors' observation. In the breaking room of the second establishment, FSIS auditors observed dirt and foreign materials on shell eggs and the NCAE inspector took action by rejecting the entire consignment before the onset of egg breaking. The NCAE inspection system does not require egg products establishments to wash, sanitize, or dry shell eggs before breaking. Shell eggs not washed, sanitized, and dried immediately prior to breaking may not be completely free of dirt or any extraneous material prior to entering egg breaking machine or pasteurizer.

The FSIS analysis and onsite verification activities indicated that the Netherlands' meat and egg inspection systems have an organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements. However, the Netherlands' egg products inspection system does not meet FSIS's statutory and regulatory requirements for continuous inspection. Specifically, FSIS expects inspection personnel to be on premises during operations, and to conduct activities that may include sanitation verification, review of various monitoring records, and verification of time/temperature at critical points in the operation.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY, 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 auditors reviewed was Government Statutory Authority, Food Safety, and Other Consumer Protection Regulations. The system is to provide for, but is not limited to, humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; periodic supervisory visits to official establishments; and requirements for thermally processed/commercially sterile products. The evaluation of this component included a review and analysis of the information provided by the NVWA in the updated SRT and observations during the onsite audit.

The FSIS auditors verified through records review, interviews, and observations that the NVWA official veterinarians conducted ante-mortem inspection of calves and swine on the day of slaughter by reviewing the incoming animal registration, food chain information, and identification documents that provide traceability of the animals to their source. The NVWA official veterinarians conducted animal welfare and humane handling verification activities in accordance with the requirements of Regulation (EC) No. 854/2004, "Laying Down Specific Rules for the Organization of Official Controls on Products of Animal Origin Intended for Human Consumption," and Regulation (EC) No. 1099/2009, "On the Protection of Animals at the Time of Killing." The NVWA has adapted these regulations into document-WLZVL-17 "Monitoring Welfare of Ungulates Slaughterhouses." The results of their verification activities are documented in the document WLZVL-018 "Monitoring Checklist of Animal Welfare in Slaughterhouses." The humane handling verification activities include measures to ensure that non-ambulatory disabled cattle are not slaughtered or used in meat products intended for export to the United States. The FSIS auditors did not identify any concerns related to humane handling of livestock destined for slaughter.

In accordance with the regulatory requirements and inspection procedures, the VIC observed all animals at rest and in motion in designated holding pens in order to determine whether they were fit for slaughter. The VIC conducted more detailed examination of suspect animals in the designated pens. The results of the ante-mortem inspection were properly documented in accordance with the NVWA document RA-111, "Instructions for Completing the Summary Schedule of Tests on Slaughter Animals (VOS) Form"

The FSIS auditors verified through record review, interviews, and observations that KDS auxiliary inspection personnel perform post-mortem inspection activities related to identification, proper presentation, and inspection of carcasses while the NVWA veterinarians make final disposition determinations for retained carcasses and parts. The requirements of post-mortem inspection are stipulated in Regulation (EC) No. 854/2004, section IV, chapter I through IV. The Netherlands developed the document "XIV supervision on KDS toezichtprotocol VWA op werkzaamheden KDS-EN-edit_final04-08, for the inspectors to follow while conducting post mortem inspection.

In the veal slaughter establishments audited, the KDS inspection personnel inspected heads, viscera, and carcasses. The auditors observed KDS inspectors were correctly incising head lymph nodes, palpating viscera and lungs, incising heart and bronchial lymph nodes while checking for pathological lesions in accordance with the NVWA's requirements outlined in the document referenced above. The auditors further observed that inspectors were inspecting each carcass for the presence of feces, milk, and ingesta, and diverting carcasses to separate line if needed for trimming lesions or any contaminated parts. Carcasses that do not require veterinary dispositions such as fecal contamination or injuries are retained and channeled to salvage station for appropriate trimming. Prior to releasing retained carcasses, KDS inspectors or NVWA veterinarian re-inspect before entering the final wash station. The design of the post-mortem inspection stations included sufficient lighting and the appropriate number of on-line KDS inspectors to perform carcass-by-carcass post-mortem inspection under the supervision of the NVWA veterinarian.

In the swine slaughter establishment, the KDS inspection personnel conducted visual inspection of animals and parts according to the equivalent alternative post-mortem inspection procedure for market hogs. 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 palpation and incision of lymph nodes for suspect carcasses and those lacking proper documentation. The FSIS auditors verified that the slaughter establishments control contamination by ingesta, fecal material, or milk through a Critical Control Point (CCP) in their HACCP plan with a critical limit of zero tolerance.

The FSIS auditors verified that the NVWA provides provisions to control and segregate condemned carcasses or parts from inspected and passed products. Inspectors verify that carcasses and parts determined unfit for human consumption, because of systemic diseases or violative drug resides are condemned in accordance with the NVWA issued documents RA-18, "Post-Mortem Inspection of Domestic Ungulates and Farmed Gam" and RA-86, "Inspection Arrangement, Amended Items Concerning Visual Inspection." The FSIS auditors verified through records review and observations that the NVWA maintains effective control and disposal of condemned material in both pork and veal establishments, in accordance with the document DBP-20, "Controls Animal By-products of Category 1, Category 2, and Category 3 material at slaughterhouses."

According to DBP-20, condemned materials and inedible animal parts are categorized into three categories based on the risks they pose to public health. Materials identified as Category 1 include the highest risk materials, such as specified risk materials (SRMs), and Category 2, includes other risk materials, such as carcasses and parts condemned for infectious animal diseases or for violative levels of chemical residues. The materials of low risk are put into Category 3, which includes animal hides, skin, hooves, horns, hair, and condemned parts that had no signs of infectious disease. The NVWA veterinarians who are assisted by KDS auxiliary employees carry out the implementation of SRMs controls in veal slaughter establishments.

FSIS auditors verified documentation that the NVWA inspectors verify that each United States-certified meat product establishment maintain complete separation either in time or space when product for the export is being prepared. Inspectors routinely review chain of custody documents to verify that only products originating from approved sources are being used for the United States export. At the veal and pork establishments, the FSIS auditors reviewed a sample of periodic supervisory reviews, which were conducted in the last 90 days by the NVWA team leaders.

At the egg product establishments, the FSIS auditors verified documentation that the NCAE inspectors verify that each United States-eligible egg products establishment maintain complete separation, either in time or space, when product for the export is being prepared. The FSIS auditors verified that the pasteurized egg products destined for the United States export are derived from Grade A shell eggs. Candling of shell eggs occur at the packing stations and no additional candling procedures were carried out before egg breaking. The NCAE inspectors routinely review chain of custody documents to verify that shell eggs used for pasteurized egg products are originating from European Union approved sources. The FSIS auditors reviewed a

sample of periodic supervisory reviews, which were conducted in the last 90 days by the NCAE supervisory staff. The FSIS auditors did not identify any issues with these reviews.

The FSIS auditors concluded that the NVWA and the NCAE have the legal authority and the regulatory framework to impose requirements equivalent to those governing the United States system of meat and egg products inspections to meet the requirements of this component.

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 CCA requires each official establishment to develop, implement, and maintain written SSOP to prevent direct product contamination or insanitary conditions.

The FSIS auditors reviewed regulations, official instructions, and guidelines that included Regulation (EC) No. 852/2004; Regulation (EC) No. 853/2004; Regulation (EC) No. 854/2004; and the NVWA document RE-3, "USA – Approval and Control of Meat Establishments." The FSIS auditors examined one veal slaughter, one veal processing (raw intact veal, for intact use only), one pork slaughter, one pork processing, and three pasteurized egg products establishments to verify the implementation of SSOP and official verification activities at the audited establishments. The FSIS auditors verified the operational sanitation at both pork and veal slaughter establishments, and identified several sanitation deficiencies. The FSIS auditors found the following:

- The pork slaughter and processing establishments had numerous white plastic cutting boards that were cracked, frayed and in need of repair;
- In one thermally processed/commercially sterile products establishment, several non-food contact surfaces were dirty creating insanitary conditions.

The FSIS auditors observed the implementation of pre-operational sanitation at one veal establishment and verified inspection activities performed by the NVWA personnel. The FSIS auditors observed numerous product particles from the previous day's production on the blue overhead ceiling structure in the meat processing department. Establishment personnel promptly corrected the findings and implemented long-term corrective measures to prevent further recurrence of similar issues. NVWA inspection personnel verified corrective actions for both operational and pre-operational sanitation non-compliances. The FSIS auditors concluded that the establishment was maintaining records sufficient to document the implementation of the SSOPs related to pre-operational and operational sanitation.

The FSIS auditors verified that each egg product establishment has a written sanitation program that is being implemented as written. Establishments' employees maintained records of monitoring activities and implementation results. At one egg products establishment, the FSIS auditors observed the implementation of pre-operation sanitation by the establishment's employees and verification by the NCAE inspector. The FSIS auditors concluded that the

establishment was maintaining records sufficient to document the implementation of its sanitation program related to pre-operational and operational sanitation.

The packing stations are not located at the egg product establishments; they are off-site. Based on documents review including inspectors' reports of packing stations and interviews with the NCAE officials, the packing stations receive shell eggs and perform sorting, grading, identification, removing dirt and feathers, candling, and labeling. The FSIS auditors determined that NCAE inspectors visit egg packing stations once per month to conduct verification activities or whenever there is consignment of egg products destined for the United States. The NCAE requires that shell eggs processed for United States export must meet zero tolerance policy for presence of dirt or extraneous material. Before egg breaking, NCAE inspector visually verifies that only Grade A shell eggs are eligible for use to produce pasteurized egg products intended for export to the United States.

At the egg products establishments, the FSIS auditors found the following:

- Numerous pieces of feathers and dirt were attached to the surface of shell eggs presented for breaking to be processed for pasteurized egg products destined to the United States. The FSIS auditors observed that egg products establishments do not wash, sanitize, or dry shell eggs before breaking.
- In the breaking room for eggs, feathers and foreign material were observed on direct product contact surfaces (conveyor belt). In the absence of immediate wash, sanitizing and dry of eggs prior to breaking, the potential for product contamination is of concern.
- During pre-operational sanitation at an egg products establishment, the elbows and fittings in the egg breaking machine connecting to pasteurizer had heavy build-up of organic residues from previous day's production.
- The NCAE inspection personnel are not routinely requiring establishment to disassembling hard to clean equipment.

The FSIS verified that the meat and egg product inspection system of the Netherlands requires that all certified establishments develop, implement, and maintain sanitation programs, including SSOPs, to prevent the creation of insanitary conditions and direct product contamination. However, FSIS auditors noted multiple deficiencies in the enforcement of sanitation standards in both egg and meat products establishments.

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

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

The FSIS auditors observed operations at United States-certified raw veal for intact use only, raw and processed pork, and pasteurized egg products establishments exporting to the United States. The FSIS auditors verified that all visited establishments had developed, implemented, and maintained a HACCP system for products intended for United States export in accordance with the NVWA document RE-31 "USA – Approval and Control of Meat Establishments." In each

certified establishment visited, the FSIS auditors assessed the design of HACCP program, evaluated plan monitoring, hazard analysis, flow charts, corrective actions, recordkeeping, and verified HACCP implementation in accordance with the relevant provisions of Regulations (EC) No. 852/2004 and Regulations (EC) No. 882/2004. Furthermore, the FSIS auditors reviewed the establishments' HACCP records and the official daily verification activity records generated and maintained by the NVWA inspection personnel.

At the time of this audit, the NVWA had not implemented a sampling program for STEC as described in the document RE-36 "United States, Inspection and Supervision of USA requirements by the NVWA." However, the NVWA requires veal establishments to describe the intended use of the veal products in their HACCP plan. Based on the intended use, the establishments must subsequently perform an analysis to classify the products as low risk or high risk. The establishment has to address STEC in its HACCP system as a hazard reasonably likely to occur, if the veal product is for non-intact use.

The NVWA considers all raw non-intact veal and raw intact veal for intact use in raw non-intact product to be adulterated if it is contaminated with *E. coli* O157:H7 and the six non-O157 STEC serotypes, including O26, O45, O103, O111, O121, and O145. The NVWA requires veal establishments to control the pathogen or prevent the potential pathogen from becoming reasonably likely to occur through preventive control measures, such as testing of raw intact veal product for *E. coli* O157:H7 and the six non-O157 STEC. The audited veal slaughter establishment had implemented STEC testing program of intact veal products at the frequency of five samples per month. The FSIS auditors reviewed samples of analytical results of STEC testing; however, no documents were available pertaining to corrective actions in response to positive results. The NVWA requires certified establishments exporting raw intact veal for intact use to have a contractual agreement with United States importers to ensure that products are intended for intact use only, however, these contractual agreements do not address the product intended for non-intact use.

Veal and pork slaughter and processing, establishments certified to export products to the United States must perform pre-shipment review of all records generated during production of relevant shipments. The pre-shipment inspection document must be signed (not initialed) by the employee. These documents include records of monitoring and verification of CCPs and corrective actions in response to any deviations.

At the veal establishments, the FSIS auditors found the following:

- The NVWA has not implemented a government verification testing plan for *E. coli* O157:H7 and non-O157 STEC for the veal products exported to the United States;
- In both veal establishments visited, auditors observed that the processing steps in flow charts did not accurately correspond to steps in the hazard analysis; however, it aligned with establishments' production processes.
- Inadequate STEC verification program in one veal slaughter establishment, which recently had three POE violations.

At egg products establishments, the FSIS auditors verified that NCAE assigned inspectors to review the HACCP plan design, hazard analysis, flow chart, and finished product examination,

which includes pre-shipment review as part of the establishment HACCP system verification. The egg products establishments systems are subject to annual audits performed by each of the NCAE and NVWA officials. Additionally, the NCAE inspectors that verify the implementation of HACCP and EC hygiene requirements carry out quarterly audits.

At the egg products establishments, the FSIS auditors found the following:

- In the review of the hazard analysis of an egg products establishment, establishment personnel:
    - Did not consider specific pathogens, for example *Salmonella* or *Listeria monocytogenes*, known to occur in egg products; and
    - Did not maintain records for the pressure gauge valves during pasteurization process; however, the CCPs for pasteurization and drying (time and temperature) were met and adequately controlling *Salmonella* and *Lm*. Furthermore, the CCA requires certified establishments to perform *Salmonella* and *Lm* testing on each batch of egg products exported to the United States. Only batches that test negative are certified for export to the United States.
- The above findings were not noted by the NCAE inspection program personnel during their most recent review of the establishment's HACCP systems;
- The processing steps documented in the flow charts of egg products establishments did not accurately align with the steps in the hazard analysis; however the process steps observed during operations were aligned with that of the flow charts.

In conclusion, the FSIS auditors verified that the Netherlands' meat and egg products inspection systems require the operators of establishments to develop, implement, and maintain HACCP program for each operation to meet the Netherlands' regulatory requirements. The NVWA and NCAE have not consistently applied these standards across the meat and egg products inspection systems.

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 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, muscle of carcasses, and hen eggs for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants.

Prior to the onsite visit, the FSIS auditors reviewed the Netherlands' National Residue Monitoring Plan (NRMP) issued in March 2017 and supplemental SRT responses outlining the structure of the NVWA chemical residue testing program. There have not been any POE violations related to chemical residue testing since the last FSIS audit.

The provisions in Council Directive 96/23 /EC, which outlines the requirements to monitor certain substances and residues in live animals and animal products, govern the NRMP.

Commission Decision 2002/657 /EC establish the criteria for analytical methods, interpretation of results, methods validation, and determination of residue limits.

Article 5 of Council Directive 96/23/EC mandates that the country update the NRMP for the following year based on the results of the previous year in order to consider changes in chemical group and detection measures. The design of the NVWA NRMP includes a description of the basis for the residue plan, the process used to develop it, and the various sampling schemes; lists the selected matrices for each compound; and includes a rationale and process for adding and removing chemical compounds. The MEA and VWS prepare the Residue Monitoring Plan in concert with the department for Legal Affairs of the NVWA and the Institute of Food Safety, which is the National Reference Laboratory (NRL) for most residues. The NVWA coordinates the implementation of the monitoring plan for residues. The FSIS auditors verified that the residue plan has measures in place that ensure segregation of domestic meat and pasteurized egg products from products destined for export to the United States when domestic residue tolerances are higher.

The sampling is done by or under the responsibility of veterinarians or inspectors of the NVWA. The analysis of samples is performed in the NVWA laboratories. The NVWA is responsible for gathering testing results and reporting to the European Commission. Substantial administrative sanctions are imposed when an animal is presented for slaughter that contains a residue(s) exceeding the Maximum Residue Level (MRL). The supervision on the quality and the uniformity of the analysis is the responsibility of the NRL.

In case of non-compliant results testing for hormones, beta-agonists or banned substances in samples collected on the farm or in the slaughter establishments, the farms are subjected to investigation by NVWA. Animals present at the holding pens are marked and movement restrictions are enforced. The animals at the farm are sampled at the owner's expense. Article 23 of the Council Directive 96/23/EC instructs member countries that animals tested positive for the presence of residues above the MRL should be destroyed. Repeated non-compliant violators are subjected to an intensified control.

The FSIS auditors verified that the NVWA-assigned government inspectors collect the samples under the NRMP project for 2017. The FSIS auditors observed NVWA inspection personnel simulated the entire process from sample collection to sample sealing. The FSIS auditors further verified that the NRMP is meeting its testing schedule for the second quarter of this year. The NVWA veterinarians and inspectors are authorized to sample suspect animals with clinical signs or injection sites during ante-mortem or pathological lesions during post-mortem inspection.

In-plant residue samples are analyzed using Nouws Antibiotic Test (NAT). The NAT-screening test comprises five test plates to identify tetracycline, beta-lactam, macrolides, quinolones, sulfonamides, and aminoglycosides. The NAT meat or kidney post-screening method is based on the analysis of kidney and/or meat fluid. Post screening confirmation is only performed on a positive NAT screening result. For egg products, the NRMP samples for chloramphenicol, nitro furans, nitroimidazoles, coccidiostats, polychlorinated biphenyl, and antibiotics. The number of samples included in the NRMP is based on the production volume of the species or product concerned in the preceding year. The number of samples is calculated in accordance with the

requirements of Commission Decision 97/747/EC. The Netherlands' NRMP complies with the minimum requirements concerning the number of samples to be monitored for all food producing animal species including hen eggs.

The FSIS auditors reviewed the chemical residue testing program at the NVWA government laboratory located in Wageningen. The NVWA laboratory outsources approximately 15 percent of the samples for analysis at the RIKILT laboratory in Wageningen. The FSIS' audit of the laboratory included interviews with the officials and document reviews, and concluded with a site visit to the chemical testing portion of the laboratory. This laboratory is accredited annually by the RvA, in the specific areas of testing, according to ISO 17025 standards. The FSIS auditors reviewed the most recent accreditation audit report of the laboratory. The last accreditation audit of the laboratory by RvA took place in October 2016. The accreditation review identified minor issues which laboratory remedied and submitted the corrective actions, which were already accepted.

The FSIS auditors interviewed the analysts to assess their technical competency, training, and knowledge of the analytical methods used on the samples to detect chemical residues. The FSIS auditors' review also included an evaluation of management system documents and internal audit reports. The review of proficiency testing records revealed that all results reviewed were acceptable. During the visit to the facility, the FSIS auditors observed the laboratory personnel at the sample receipt area who were receiving samples, checking sample integrity and security, assigning the identification, and storing the samples in accordance with the laboratory's standard operating procedure. No concerns arose as a result of the laboratory audit.

FSIS auditors verified that the NVWA and NCAE's chemical residue testing program for meat or egg products is consistent with the criteria established for this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditors reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that meat and egg products produced for export to the United States are safe and wholesome.

The NVWA requires United States-certified establishments to conduct *Enterobacteriaceae* and Aerobic colony count testing in veal and pork carcasses, in accordance with Regulation (EC) No. 2073/2005-Annex I, Chapter 2, Sections 2.1.1 (cattle) and 2.1.2 (pigs) in raw product. This testing program is in lieu of testing for generic *E. coli* as a measure of establishments' sanitary process control. The FSIS auditors verified that all the establishments that are certified for veal and pork export conduct testing in accordance with the above referenced regulatory requirements. The government verification of establishment microbial sampling procedures and frequencies is to demonstrate that establishment process controls are effectively preventing contamination.

The NVWA has implemented requirements outlined in Regulation (EC) No. 2073/2005 Chapter 3, Annex 1, Part 3.1, pertaining to European Commission's *Salmonella* reduction program in meat slaughter and processing establishments and conducts a sampling and testing program for *Salmonella* in raw meat products. The testing program includes performance standards for *Salmonella* developed in accordance with the above regulation. The FSIS auditors verified that the NVWA takes measures to ensure that inspection personnel collect *Salmonella* samples from all classes of meat products subject to sampling (pork and veal carcasses). The NVWA takes *Salmonella* samples from a randomly selected carcass once every four weeks, following the instruction in the document RE-30, "United States, Salmonella, Screening." The samples are taken in the cooler after the carcass has been chilled for 12 hours. Pork samples are taken for 55 consecutive days and veal samples for 82 consecutive days, in accordance with the instructions in the document RE-29, "United States, Salmonella, Targeted Samplings," these samples are collected by establishments' personnel. The samples are analyzed in the NVWA laboratories for food safety using the ISO 6579 method, which FSIS has determined to be equivalent.

- At the time of this audit, the FSIS auditors found that the NVWA has not implemented government verification plan for STEC testing for the raw veal products exported to the United States. The NVWA informed FSIS auditors that it has developed a STEC testing program, which will be implemented in the near future.

At the time of exit meeting, NVWA and FSIS were in communication and had begun the process of reviewing, providing feedback and revising the government STEC verification sampling program. Additionally, the NVWA will require STEC sampling program at certified establishments for veal products. FSIS has completed its review of the Netherlands' raw veal STEC verification activities and has determined that the Netherlands is eligible to export raw non-intact veal and raw intact veal for non-intact use (FSIS Notice 36-17).

The auditors verified that the Netherlands' egg products inspection system requires all official establishments to sample and test pasteurized liquid, frozen, and dried pasteurized egg products for *Enterobacteriaceae*, *Salmonella,* and *Listeria monocytogenes.* This requirement is supported by Regulation (EC) No. 2073/2005-Annex I-Chapter 1-Item 1.4 - Egg Products. Official microbiological sampling by NCAE is performed to verify certified establishment's controls. In the past year, NCAE collected 115 samples for *Salmonella* and 14 samples for *Listeria* from all certified egg product establishments, there were no confirmed positive sample results.

The NVWA work plan, "Work Plan HP-DBP NCAE 2015" provides procedures for sampling and analyzing liquid egg products, and the document MON-003-V1-3 annex R18b, "Sampling and Analysis of Powdered Egg" provides sampling and analysis procedures for powdered egg products and outlines techniques on sample collection, sample integrity, and reliability. The microbiological method employed to test egg products for *Enterobacteriaceae, Salmonella*, and *Listeria* are ISO 21528, ISO 6579, and ISO 11290-1, respectively.

The FSIS auditors verified that analyses of *Salmonella, Enterobacteriaceae,* and *Listeria* are performed by an accredited private laboratory (Merieux), which is ISO 17025 accredited and is audited on a yearly basis by the RvA. The NCAE has a Service Level Agreement with Merieux laboratory and has access to RvA reports. Merieux laboratory simultaneously reports test results

related to the official verification of microbiological control programs to the NCAE and the regulated establishments.

The Merieux laboratory located in Ede was audited for microbiological testing of egg products. Merieux laboratory participates in inter-laboratory proficiency testing (PT); the FSIS auditors reviewed all test results under the program and concluded that the PT met the tests' standards. This private laboratory is contracted by the NCAE to test samples collected from all United States-certified egg products establishments. The FSIS auditors verified that the laboratory conducts microbiological testing on samples for official verification on product destined for United States export, specifically for *Salmonella, Listeria,* and *Enterobacteriaceae*.

The FSIS auditors reviewed the recent ISO 17025 accreditation report issued by RvA. The laboratory has corrected the concerns identified by the accreditation body and presented the corrective actions for review for their acceptance. The FSIS auditors interviewed analysts and reviewed their qualification and training records. The review determined that all analysts received required training to conduct analytical testing. No concerns were identified as a result of the laboratory audits.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on May 19, 2017, in Utrecht, Netherlands, with the NVWA. At this meeting, the FSIS auditors identified the following systemic findings for Government Oversight, Government Sanitation, and the Government HACCP System. However, these findings did not represent an immediate threat to public health.

Government Oversight

- The Netherlands' inspection system for pasteurized egg products does not provide continuous inspection coverage at egg product 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 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 Points (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.

Analysis of the findings within each component raises concerns about the effectiveness of the CCA's oversight at establishments certified to export meat or egg products to the United States. During the audit exit meeting, the CCA committed to addressing the preliminary findings, as presented. FSIS will evaluate the adequacy of the CCA's proposed corrective actions and base future equivalence verification activities on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklist

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., Laan van Malkenschoten 100, Apeldoorn	05/16/2017	NL-9-EG	Netherlands
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
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.	X
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. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

FSIS Auditors identified the following:

10/51
In the main processing room, white plastic cutting boards were rough, nicked, and fissured. The blue conveyer belt has two broken and missing plastic segments. The metal frame of a working table has numerous welded spots with uneven surfaces. The edges of white conveyor for boxed products is cracked and has rusty corners. The painting of walls adjacent to the packaging machine is chipping. The hanging blue cover of overhead structure has multiple small pieces of food particles from previous day's production. The plastic cover of packaging machine (sealing machine) was repaired and glued together by orange duct tape.

15/ 51
The processing steps in HACCP flow charts of this establishment did not align with that of hazard analysis; however it aligned with establishments' production processes.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/02/2017

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 (Lupack B.V.) Sluisweg 7, Almelo.	05/08/2017	NL-129-EG	Netherlands
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
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. Enforcement	X
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	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

FSIS auditors observed the following deficiencies in the processing department:

10/51
- Rust present inside cans closing machine (Cameron machine)
- Peeling paint at the receiving area by while tiles wall
- At the entrance of tumbling room there is dirt, black residue discoloration, and grease accumulation.
- Area between seasoning and wash room, there is dirt accumulation at the junction of wall and ceiling; the seal around an exit pipe is missing in one location.
- Unused metal agar was left on the floor of catwalk without any labeling indicating its sanitation status.
- In the spice room, there was dust and moisture accumulation
- Large exhaust vent and pipes at the sterilization room ceiling was covered with black residue and dust.

13/51
No records to show daily operation sanitation performed during production. Upon checking the written SSOP, there was no section referring to ongoing operational sanitation.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/02/2017

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Vion Groenlo B.V. Den Sliem 8 Groenlo	05/02/2017	NL367EG	Netherlands
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
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	X
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. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment
FSIS auditors identified the following deficiencies:

10/ 51
- Inner plastic lining of boxed product were torn
- Smear of grease on one carcass leg
- Sides or edges of few blue plastic containers/ tots used to transport pork products were chipping off.
- Hams in holding area with obvious black hair on skin

44
Work or cleaning cloth was left unattended on top of cabinet/ locker in employee dressing room

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/02/2017

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 & Zn. B.V.,'s-Gravenweg 350, Nieuwerkerk a/d IJssel	05/15/2017	NL-939-EG	Netherlands
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [X] 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.	X
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. Enforcement	X
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	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

FSIS auditors identified the following:

15/ 51
The processing steps in flow charts of this establishment did not align with that of hazard analysis; however it aligned with establishments' production processes.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/02/2017

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. Aakstraat 14, Raalte	05/10/2017	NL-6063-EP	Netherlands
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
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. Enforcement	X
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	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

FSIS auditors identified the following deficiencies:

13/51
- Daily records generated by government auxiliary employee verifying hygiene and sanitation inspection at egg packing station or egg breaking department is not signed or dated.
- HACCP plan did not identify specific pathogen that is reasonably likely to occur in egg products such as *Salmonella* and *Listeria monocytogenes.*

16/51
Pressure gauge of pasteurization unit is cloudy and not clear to read to record pasteurization pressure of egg products.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/02/2017

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., Scheepsbouwersweg 3, Landsmeer, Netherlands	05/12/2017	NL-6153-EP	Netherlands
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	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.	X	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.	X	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

FSIS auditors identified the following deficiencies:

10/51
- During pre-operational sanitation review and observation, there was excessive biofilm formation from previous day's production inside stainless steel pipes-fitting of the breaking machine which carry egg products to pasteurization room. Disassembling of clean-in-place pipes or hard-to-reach section of breaking machine is not part of government inspection routine activity.
- Shell eggs received at the breaking room were not clean and covered with dirt, feathers, marks, dried yolk, or black smears.

13/51
- Daily records generated by government auxiliary employee verifying hygiene and sanitation inspection at egg packing station or egg breaking department are not signed or dated.
- Daily records for operational sanitation verification were not available at the time of this audit. Plant records of sanitation checks do not include section for corrective action when deficiencies are identified during pre-operational sanitation.

15/51
HACCP plan did not identify specific pathogen that is reasonably likely to occur in egg products such as *Salmonella* and *Listeria monocytogenes.*

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/02/2017

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
Nederlandse Industrie van Eiproducten (NIVE), Energieweg 9, Nunspeet	05/11/2017	NL-6340-EP	Netherlands
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
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.	X
16. Records documenting implementation and monitoring of the HACCP plan.	X
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.	X
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. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

FSIS auditors identified the following deficiencies:

10/51
- Shelled eggs received at the breaking room, destined for United States export, were covered with excessive feathers and dirt.
- Overhead structure just above the breaking machine was not properly connected with the ceiling leaving gaps, which could be a source of pest entry or dirt falling on production surfaces.
- Overhead structure that houses electric cables in the pasteurization department is rusty. A major white duct in the same room shows evidence of dried water of reddish rusty residue on outer surface of the duct.

13/51
Daily records generated by government auxiliary employee verifying hygiene and sanitation inspection at egg packing station or egg breaking department is not signed or dated.

15/51
HACCP plan did not identify known specific pathogen that is reasonably likely to occur in egg products such as *Salmonella* and *Listeria monocytogenes.*

16/18/51
Records of pasteurization pressure at beginning, during, or end of cycle were not available or routinely kept on file or digitally.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/02/2017

Appendix B: Foreign Country Response to 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
Mrs. Mary Stanley
1400 Independence Avenue, SW
Washington, DC
20250

Directorate-General Agro and Nature
Animal Supply Chain and Animal Welfare Department

Visit address
Bezuidenhoutseweg 73
2594 AC Den Haag
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The Netherlands

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T.J.D. van Riet

T +31 (0)70 378 6521
F +31 (0)70 378 6177
t.j.d.vanriet@minez.nl

Our ref.
DGAN-DAD / 17197091

Your ref.

Encl.

Date 12 DEC 2017

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

Dear Mrs. Stanley,

With this letter I will give an official response to the draft audit report and corresponding letter which were received October 26, 2017. The Food Safety and Inspection Service (FSIS) conducted a routine onsite ongoing equivalence audit of the Netherlands' veal, pork and egg products from May 1-19, 2017. After the audit, some additional documentation has been sent to FSIS to address some of the issues which were discussed during the visit.

The Netherlands is glad that FSIS concluded the Netherlands is eligible to export non-intact veal and raw intact veal for non-intact use, derived from veal slaughtered on and after July 15, 2017. As was mentioned in your letter, the NVWA has submitted and implemented an equivalent government STEC verification programme. The two supporting documents will be posted as a part of the audit report.

FSIS also determined to be confident the Netherlands maintains continuous inspection of egg products. With reference to my letters, with reference numbers DGAN-DAD/17095147 and DGAN-DAD/17049329, I would, once again, like to make clear that the Netherlands inspection system for egg products was equivalent to that of the United States as was concluded in the final report of FSIS dated April 30, 2015. Concerning continuous inspection we had follow-up discussions, which resulted in an accomplished optimisation of the inspection system. The supporting documents in casu quo the updated instructions and US export programme were sent shortly after the audit, and will be posted as annexes to the audit report.

During the audit, the FSIS inspectors identified various findings for government oversight, government sanitation and the government HACCP system. However, none of these findings did represent an immediate threat to public health.

Enclosed with this letter you will find the more detailed response of the Netherlands to the draft audit report. The first document consists of comments

Directorate-General Agro and Nature
Animal Supply Chain and Animal Welfare Department

Our ref.
DGAN-DAD / 17197091

regarding the information in the report. In the second and third document the corrective actions undertaken by respectively the NVWA and NCAE, in reaction to the audit findings, are schematised.

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

Sincerely yours,

E.M. Kannekens DVM
Deputy Chief Veterinary Officer

Ministerie van Landbouw,
Natuur en Voedselkwaliteit

Comments regarding the information in the FSIS draft report of the routine onsite ongoing equivalence audit of the Netherlands' veal, pork and egg products from May 1 – 19, 2017

Page	Text/description	Comment	Replacement/addition
1, 5th paragraph	One regional office	Correction	the office of NCAE, the competent authority for egg products
2, 1st paragraph	...four egg products establishments.	Correction	...five egg products establishments.
2, table	Laan van Malkenschoten	Correction, the address is mentioned instead of the name of the establishment	EKRO
4, 5th paragraph	*Dierlijke*	Typo	*Dierlijke*
5, 2nd paragraph	...employees and US certified...	Typo	...employees at US certified...
6, 1st paragraph	...through their website...	Addition	...through their website, and with email notifications
8, 2nd paragraph	The NCAE inspection system....before breaking.	Addition	Shell eggs for US egg products must be of grade A quality and free of dirt. This is laid down in specific NCAE procedures and requirements. Washing of eggs is no practice in the egg industry in the Netherlands.
9, 4th paragraph	...veal slaughter establishments...	Correction	...veal slaughter establishment...
8, 2nd paragraph and NL6153EP 10/51 2nd	Shell eggs covered with....black smears.	Correction	At the time of the inspection it was noticed that the eggs were not sufficiently clean for breaking for US egg products, but no feathers and black smears were present. The eggs were disapproved to the assessment of the NCAE inspectors instead of the FSIS inspectors. In the Netherlands it is obliged for grade A eggs to have marks on the eggs.
NL6340EP 10/51 1st	Shelled eggs...feathers and dirt.	Correction	The deviation of the norm for the quality of eggs (which is captured in the NCAE procedures) was detected by the NCAE inspector. And for that reason the eggs were disapproved for US egg product production.

Draft report FSIS May 1-19, 2017 meat and pasteurized egg products US

Corrective actions and comments concerning pasteurized egg products destined for US

		Corrective actions
Summary 1e ● IV,p. 8 3e paragraph X Conclusions 1e ●	NCAE executes continuous inspection as assessed and approved by FSIS during inspection 2014. NCAE inspectors are present every production during the most critical production steps.	Based on recommendations FSIS 2017 NCAE inspects additional steps in the process as confirmed in letter FSIS Oct 26 2017. July 1 2017 inspection of additional process steps is implemented. See annex 1 and 2 added with the FSIS report.
Summary 4e, 5e ● VII p.14 2e paragraph NL 6340 EP 15/51	HACCP	During follow up inspection of the concerning egg product producer fundamental review of the HACCP will be required and enforced.
VI p.12 4e paragraph NL 6153 EP 10/51 1e-	".. enforcement of sanitation standards .."	Improvement of NCAE inspection list in which more explicitly the pre-sanitairy inspection of the breaking installation is required. See annex 1 and 2 added with the FSIS report.
NL 6063 EP 13/51 1e – NL 6153 EP 13/51 1e – NL 6340 EP 13/51	Daily records hygiene - sanitation inspection not signed	The record form has been expanded with signing each record.
NL 6063 EP 16/51	Pressure gauge of pasteurization cloudy and not clear	This gauge was not of the pasteurization equipment, but of the concentrating / fermenting process step before Ultra Filtration. This gauge is not directly relevant for food safety. Improvement immediately during FSIS inspection has been demonstrated.
NL 6153 EP 13/51 2e-	Plant records sanitation checks not including corrective actions	Records for sanitation checks are expanded whith recording corrective measurement in case of deviations.
NL 6340 EP 10/51 2e – 10/51 3e -	Overhead structure above breaking machine. Overhead structure electric cables pasteurization department …	Fundamental review by the establishment on basic hygiene requirements of production areas and installation will take place. A masterplan has been submitted by the establishment July 2017. The progress of implementation will be inspected by NCAE on regular basis.
NL 6340 EP 16/18/51	Records pasteurization pressure	During the each day pressure test initial and end-pressure will be recorded. During follow up inspection by NCAE this will be verified.
NL 6063 EP 13/51 2e- NL 6153 EP 15/51 NL 6340 EP 15/51	Salmonella and Listeria monocytogenes not identified in HACCP	In the HACCP besides Salmonella also Listeria monocytogenes is identified as relevant pathogen in the HACCP analysis of the 3 establishments. At places where generally "pathogens" are mentioned this is specified with Salmonella and Listeria monocytogenes.

Netherlands Authority for Eggs and Egg Products
Leusden, 8 December 2017
Ref.: AM\ei-c\VS\gcreactieFSIS2

COMPONENT	DEFICIENCY	CORRECTIVE ACTIONS/CURRENT SITUATION
COMPONENT ONE: GOVERNMENT OVERSIGHT	Veal: The NVWA 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.	NVWA has submitted and implemented an equivalent government STEC-verification programme.
COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY, FOOD SAFETY, AND OTHER CONSUMER PROTECTION REGULATIONS	No deficiencies	
COMPONENT THREE: GOVERNMENT SANITATION	The pork slaughter and processing establishments had numerous white plastic cutting boards that were cracked, frayed and in need of repair; In one thermally processed/commercially sterile products establishment, several non-food contact surfaces were dirty creating insanitary conditions.	Veal, pork, meat processing: all establishments has taken corrective actions; NVWA veterinarians in charge have verified that all necessary actions have been taken. [1]
COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS ANDCRITICAL CONTROL POINTS (HACCP) SYSTEM	1. The NVWA has not implemented a government verification testing plan for E. coli O157:H7 and non-O157 STEC for the veal products exported to the United States; 2. In both veal establishments visited, auditors observed that the processing steps in flow charts did not accurately correspond to steps in the hazard analysis; however, it aligned with establishments' production processes. Inadequate STEC verification program in one veal slaughter establishment, which recently had three POE violations.	1. See answer to component 1 2. The establishments have provided flow-charts consistent with their hazard analysis. A senior system auditor of NVWA has checked the adequacy of these flow-charts. Some flow-charts, connected with the future STEC-sampling programs of the establishments, will be provided (and verified by NVWA) once the sampling programs are approved by NVWA.[1] 3. The establishment suspended the export of veal to the USA. NVWA reapproved the export in July 2017, after the necessary corrective actions were taken by the establishment. All veal/veal products exported to the USA has to be sampled for STEC (at all establishments concerned) till the establishments has implemented adequate STEC-sampling programs, approved by NVWA.

[1] The corrective actions taken by establishment and local NVWA will be/have been* part of the annual NVWA -audit on the US-requirements at all establishments with a registration for the export of veal, pork and/of meat products to the USA.
*some of the annual audits have already taken place as scheduled.

COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS	No deficiencies	
COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS	At the time of this audit, the FSIS auditors found that the NVWA has not implemented government verification plan for STEC testing for the raw veal products exported to the United States. The NVWA informed FSIS auditors that it has developed a STEC testing program, which will be implemented in the near future.	See answer to component 1

NCAE Export programme egg products US

1. General

This export programme relates to the pre-certification of egg products, for the purposes of obtaining an NVWA export certificate for egg products destined for the US. This export programme connects into the NVWA instruction DPDLH-164 USA, eggs and egg products.

2. Register

- Registration of egg products and egg product manufacturer takes place in ANEVEI / MEA.
- MEA reports the egg product manufacturer to the US.
- ANEVEI / MEA report the egg product manufacturer to NVWA and NCAE
- Export certificates can only be provided to US registered egg product manufacturers.

http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/eligible-foreign-establishments%B7

3. Registering batches of egg products to be produced

- The egg product manufacturer agrees with the NCAE a day and time at which eggs will be broken for the production of egg products for the US *and further will be processed to egg product for US*. Each week the egg product manufacturer must provide a plan to the NCAE.

4. Inspection

4.1 Eggs intended to be used for the production of egg products must be A-quality and dry and clean that before breaking 0% contamination is achieved. If sorting is carried out by a third party, there must be a statement for a packing station under the supervision of the NCAE which indicates that the eggs were sorted into A-quality, have been marked and that the eggs are sufficiently clean and dry. This statement (original) must be available before the egg product manufacturer's breaking process begins.

4.2 In the event of foreign eggs

- an official statement (original) from a veterinary authority must be available, showing that the origin of the eggs fulfils the requirements of the US (see NVWA instruction). This statement must be available before the start of the egg breaking process for the relevant batch.
- with respect to transporting the eggs, the packing station mentioned in 4.1 must comply with a protocol agreed between the egg product manufacturer and the packing station.

4.3 Inspection of the establishment *is executed on all relevant steps in the process on the basis of the established inspection list: Presanitary inspection, breaking of the eggs and separating of the fluid egg product in egg yolk, whole egg and/of egg white; concentrating; desugering (as a minimum present during start-up)*; filtering and cooling fluid egg product; compositing fluid egg product, addition of additives and standardisation; pasteurization fluid egg product; freezing (as a minimum present during start-up)* drying; grinding and seaving; packaging and labeling; hotroom (as a minimum present at filling the (hotroom, the end of the heat treatment and emptying of the hotroom)**

** The NCAE inspector as a minimum is present during start of the process-step. The (intermediate) product will not go on to the next step without precence of the NCAE inspector.*

4.4 End product verification takes place when the batch is ready and a request for an NCAE pre-exportcertificate is done. In addition to 4.3 on the basis of the inspectionlist (extra) verification takes place of:

- Traceability of used and broken eggs suitable for destination in the US egg-product.
- Realisation of pasteurisation with respect to produced batch
- Results of microbiology check (Salmonella n=5, c=0, Enterobacteriaceae m=10, M=100, n=5, c=2.)
- Clean and sound packaging

- Content of veterinary statement for origin and transport in case of foreign eggs (at the offices of NCAE)

5. Measures

- If serious, multiple and/or repeated shortfalls are identified during inspection, a certificate will not be issued. In the event of repetition, with the understanding that shortfalls that are not in line with agreement are eliminated.
- In the event of shortfalls in relation to export check a pre-certificate will not be issued for NVWA for the relevant batch.

Netherlands Authority for Eggs and Egg-products
Leusden, 21 June 2017
Ref.: AM\module\gbappendixVSeiproductENG (NL: gbappendixVSeiproduct)

INSPECTION LIST FOR EGG PRODUCTS TO USA

This inspection list is intended for inspection of the egg processing establishment in case of production of egg products for export to the USA.

In case of production of a batch of egg product intended for USA the Netherlands Competent Authority, NCAE (Netherlands Authority for Eggs and Egg products) inspector, is present *at*:
- Presanitairy inspection of the establishment before start of the production of egg product for the USA. The eggs are inspected (11) and the breaking area and installation (21, 31, 41) during which also the equipment inside will be inspected.
- Breaking of the eggs *and separation of the fluid egg product in egg yolk, whole egg and/or egg white*
- Concentrating
*- Desugaring (as a minimum present during start-up)**
- Filtering and cooling of the fluid egg product
- Compositing of the fluid egg product, adding additives and standardisation
- Pasteurisation of the fluid egg product in which the realized time and temperature of the concerning batch will be reported
- Freezing (as a minimum during initial phase of freezing)
- Drying
- Grinding and seaving
- Packaging and labeling
*- Hotroom (as a minimum present during filling of the hotroom, at the end of the heat treatment and emptying of the hotroom in which the realized time and temperature will be reported)**
** The NCAE inspector as a minimum is present during start of the process-step. The (intermediate) product will not go on to the next step without presence of the NCAE inspector.*
-At time the batch is ready to be exported. Thus when laboratory results are available.
~~In practice this means that per batch 2 separate verification visits are being carried out.~~ The ~~second~~ inspection *of the final product* takes place during the check for the pre-export certification.

~~The NCAE-audit consists of a sanitation control, verification of heating step (hotroom or pasteurization) and verifying the results of laboratory analysis.~~
~~The inspection points (see below) are to be inspected during the 2 verification audits. The process of breaking eggs will be inspected during the first visit. The control of the batch, hotroom or pasteurization registrations and results of the lab tests will take place during the second visit. The remaining points are distributed over the 2 control visits.~~

Reference of this inspection list is found in the EU hygiene package and animal by-products regulations whose requirements are set out in a NCAE inspection list of egg processing. The additional and specific requirements in relation to USA egg products are added in this inspection list.

~~The general principle is: Eggs are raw material and not (liquid) egg products.~~

* reference is NCAE assessment list HP/DBP

Nr	*Question*	*Notes*	*Reference **	
10	**Eggs**			
11	The eggs intended for production of egg products meet the physical quality requirements?	Basic requirement is that the shells of eggs used in the manufacture of egg products must be fully developed and contain no breaks.	405	
12	Are the eggs for breaking clean and dry?	Eggs destined for the production of egg products must be of grade A quality and dry and clean that during breaking 0 % dirty eggs will be reached.	407	

Nr	*Question*	*Notes*	*Reference* *	
13	Is there a statement available at the egg product establishment that indicates that the relevant batches of eggs intended for the production of USA-egg product fulfil the requirements of the USA?	If candling takes place at third party's there has to be a truthfully filled in statement from the packing station – under supervision of the NCAE –that the eggs are candled for grade A quality, marked and sufficient clean and dry.		
14	If candling of eggs takes place at a packing station: Is the packing station - delivering the relevant batches of eggs – an approved packing station and on a list of the NCAE with respect to export to the USA?			
15	Does the establishment have, for each batch of eggs destined for production of egg products for the USA, a written statement indicating the origin of these eggs? If so, which country(ies) are the breaking-eggs coming from?			
16	In the event of foreign eggs being used for USA-egg products: is thera an official statement indicating that the eggs fulfil the requirement in the NVWA instruction clause 3 on the USA exportcertificate for egg products?	Assessment of the text of this statement will be done by the NCAE department exportcertificates.		
17	Is the fluid egg product visual or whith equipment assessed on contamination?			
20	**Business Premises**			
21	Are the preparation areas clean and well-maintained? Is the prevention of vermin sufficient?	- good state of maintenance and cleaning; - no accumulation of dirt; - the end up of particles and contaminants in egg product is prevented; - formation of condensation or undesirable mold(fungi) is prevented - implementation of good hygienic practise; - pollution/contamination during and between the acts of preparation; The floors, walls, ceilings, windows and doors are well maintained and clean.	501-507 701-703	
22	Are the areas for storage of eggs and egg products clean and well maintained?	-good state of maintenance and cleaning; - no accumulation of dirt; - the end up of particles and contaminants on eggs and egg products is prevented; - formation of condensation or undesirable mold(fungi) is prevented; The whole operation shall be in a such way that good hygienic practice is possible.	511	
23	Eggs and egg products are clean, dry and free of extraneous odors stored? The eggs are protected from shocks and direct sunlight? The eggs are stored at constant and correct temperature?	Eggs must be stored at such a temperature that optimal maintenance of the hygienic quality is possible. The optimum storage temperature is between 15 and 25 C.	512	
24	The toilets are clean and hygienic?		521	

Nr	*Question*	*Notes*	*Reference* *	
25	Are the hand washing and sanitation clean and hygienic?		522	
26	The changing rooms are clean and hygienic?	Staff involved in preparation of products must have adequate changing rooms where a hygienic separation is between own clothing/footwear and industrial and occupational clothing. These facilities must be clean.	523	
30	**Installations**			
31	Are surfaces of equipment, in particular those in contact with product, well maintained and clean?	The equipment is smooth, washable and resistant to corrosion. Besides visual inspection also the breaking installation must be internally inspected and couplings and other openings must be opened for inspection. Production of USA-egg product must start after full cleaning of installation and storage tanks. Is has to be assured that no egg product – not destined for USA – comes into USA-egg product	601	
40	**Cleaning and disinfecting**			
41	Are the installation and production areas cleaned and disinfected in accordance with the laid down programmes?	Also during production cleaning has to be done in accordance with the cleaning and disinfection programme. The realization and intern control of the cleaning and disinfection must be recorded. In case of deviations the corrective measurements have to be recorded.	701 - 704	
50	**Pest prevention/combat**			
51	Is the prevention and, if necessary, the control of vermin in the production, storage and other areas sufficient?	There are no rodents/pests observed. When mouse droppings, flies, etc. are observed this is insufficient. Supply of eggs can mean that pests arrive with the eggs. This needs a system of monitoring on the basis of which corrective actions are taken related to the supplier	901	
60	**Waste/animal by-products**			
61	Are food waste, (by) products not intended for human consumption and other waste removed as quickly as possible from the processing area's?	Accumulation of waste should be avoided. As soon as possible after the production of (by) products not intended for human consumption these must be identified (see 2000), be removed and stored separately	1001	
62	Is food waste, (by) products not intended for human consumption and other waste stored in lockable containers or waste bins? Containers are appropriately constructed, well maintained, easy to clean and they are clean?		1002	
63	There are facilities for the disposal of waste from food, (by) products not intended for human consumption and other waste? To do this, the storage facilities are designed and managed in such a way that they are clean and free of harmful organisms?		1003	

Nr	*Question*	*Notes*	*Reference* *	
64	The waste is removed on hygienic and environmentally friendly manner and this is not a source for pollution and or recontamination?		1004	
70	**Personal hygiene and training**			
71	Adequate personal hygiene by the employees is taken into account? Clean working clothes shall be worn?	In preparation areas with open end product must: - a bonnet that covers hair completely; - clean corporate clothing is worn. This corporate clothing should not be worn in other areas when this is not justified from a hygienic point of view; In general, the following applies: - hygienic hand washing; - when entering different hygienic levels in the plant hygienic measures should be taken in such a way that this is justified from the point of view of hygiene. There are several options: e.g. change footwear; hand disinfection; gloves; footwear disinfection baths; - no smoking, spitting, eating and drinking in premises;	1101	
72	Is clear that personnelle is sufficiently informed and trained in relation to the specific requirements of export of egg products to USA?			
80	**Cross-Contamination**			
81	During breaking contamination of the eggs product is restricted to a minimum?		1301	
82	Is cross-contamination during all stages of production, storage and expedition avoided?	Critical points to be checked include - condensation on ceilings, pipes, etc. above open product. Leaked liquids from transport pipes above open product. - good separation between wet and dry zones - products other than egg products intended for human consumption are no risk for cross contamination. Products with a lower hygienic status may not be stored between products with higher level of hygiene. If necessary, storage is in separate areas. - if products other than egg products intended for human consumption are stored in the same storage room, they must be of known quality and hygiene, and stored in relation to the egg products in such a way that cross contamination is not possible (the degree of separation depends on the hygienic quality).	1304	

Nr	*Question*	*Notes*	*Reference* *	
83	Products which are not suitable and intended for human consumption and waste are stored separately enough and in a similar way and indicated as such (waste and or not fit for human consumption.)?	- Egg products not intended for human consumption (category 3 material): must clearly be indicated as "category 3 material, not for human consumption" Also on bags stacked on a pallet this indication must clearly readable per bag. - Egg products not intended for human consumption must not be stored in the same storage room as egg products intended for human consumption, unless they are good and hygienically packed, marked, sufficiently separated and are stored in a particular part of the storage space. - Dried egg powders not intended for human consumption and not demonstrably equivalent of quality intended for human consumption must be well separated from the products intended for human consumption. This may certainly not be stored between the food consignments. This may be in a separate and designated areas of the same storage space and in such a way that there is no risk of cross-contamination is (also in terms of handling, material handling, etc.). - Also in terms of internal transport etc. care is taken that there should be no cross-contamination.	1305	
90	**Specific processing requirements and heat treatments.**			
91	Are after breaking all parts of the liquid egg immediately processed?	From a microbiology point of view after breaking all parts of the liquid egg should be processed as quickly as possible. Excluded for the requirement of immediate processing/heat treatment is the protein that is intended for dried or crystallized albumin which undergoes a heat treatment in a later stage of processing.	1402	
92	Fulfils the heat treatment process laid down as CCP or relevant safety measurement the minimum requirements? Fluid egg product: Streaming pasteurisation Batch wise pasteurisation Powdered egg product: Hotroom	Voor explanation see 1406 of the inspection list egg product production. Report the realized pasteurisation of the relevant batches egg product for USA. Report the realized temperature and time of the batch.	1406	
100	**Packaging and labeling**			
101	The packaging material for immediate or secondary packaging cannot be a source of contamination to the product?		1702	
102	Packaging material for immediate packaging is stored in such a way that it is not contaminated?	Immediate packaging material must be stored dry and dust-free.	1703	

Nr	*Question*	*Notes*	*Reference* *	
103	The packaging shall be carried out in such a position that avoids contamination and/or (re)contamination of the product? Is the relevant batch/lot clean and properly packed?	Special attention must be given that during and after packing/filling the packaging remains clean.	1704	
104	Is the identification mark applied correctly? Are consignments of egg products labeled indicating on which temperature the egg product should be stored and the shelf life at this temperature? If applicable, raw egg fluid product must bear the correct labeling	On the consignments of egg products the storage temperature and shelf life must be indicated. In addition on raw fluid egg product the following indication must be mentioned "unpasteurised fluid egg product – to be treated on the place of destination". Also the date of breaking eggs has to be mentioned.	1706 1708 1710	
110	**Microbiological results batch**			
111	The results of the microbiological test of the batch meet the official (and USA) requirements?	1. Salmonella absent in 25 grams, n = 5, c = 0 2. Enterobacteriaceae: Cfu/ml m = 10, M = 100, n = 5, c = 2. To be checked at the end of the production process. In case of deviation extra verification of the control of the pasteurization process; investigation of the risk of recontamination. If these criteria are not met the specific batch is excluded for export to US. The number of the 5 incremental samples are taken out of 5 of the batches and per individual sample examined. Minimally 1x per month microbiological analysis is executed by an accredited laboratory.	1911	
120	**Traceability/batch information**			
121	Are all the traceability data of the produced USA batch of egg product available?	The establishment supplies the traceability data from the broken eggs to the finished egg product per produced batch intended for USA. At least the following data are available: - Broken eggs: total weight of the eggs broken; identification data of these eggs. - Quantity of egg product obtained from these broken eggs (weight and identification). - Further identification of the batch in the successively process steps. - Number of units in great packaging: bags or boxes and weight units; party/lot/batch encoding; approval number; - Realized time and temperature of pasteurization per batch of egg product.		

Nr	*Question*	*Notes*	*Reference* *	
122	The necessary information to identify the batch is available?	- Party/Lot/batch number - Order Number - Article Number - Item Description - Packing unit/package contents - Production date/production period - Best before date/shelf life period - Approval number and name manufacturer on packaging - Total weight		

Ref.: AM\module\reglement\VS\gbinspectielijstVSeng

SAMPLING VERIFICATION ACTIVITIES FOR SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* **(STEC)** IN RAW BEEF

Based on FSIS DIRECTIVE 10,010.1

Contents

ACRONYMS and ABREVIATIONS

BB	Administrations Manager of the NVWA for an establishment, at slaughterhouses this is an official veterinarian ("Bedrijvenbeheerder")
SIA	Senior Inspector Auditor
STEC	Shiga toxin-producing *E. coli* (STEC)—STEC may also be referred to as Verocytotoxin-producing *E. coli* (VTEC)
TL	Team leader(s)
TO Import-Export	NVWA Team development concerning Import and Export Affairs
VIC	Veterinarian(s) in charge

PREAMBLE

This instruction describes the current development proposal concerning STEC verification sampling at veal/cattle slaughterhouses and beef processing facilities in the Netherlands, eligible for the export of raw veal/beef (intact and non-intact) to the USA.
This instruction belongs only to activities at establishments with an export registration beef/veal to the USA. The instruction does not belong to establishments if all of the finished product groups are intended for RTE only.

CHAPTER I - GENERAL

I. PURPOSE

A. This document provides instructions in the frame of STEC-verification to VIC for collecting and submitting samples of raw beef products under the routine and follow-up sampling programs for Shiga toxin-producing *Escherichia coli* (STEC) for the export to the USA.

B. Instructions concerning STEC verification activities other than NVWA sampling are contained in "NVWA Verification Activities STEC Raw Beef[1]"; the document is based on Directive 10,010.2.

C. HEP: At this moment establishments in the EU are not bound to sample regularly/daily for STEC. However, the two slaughterhouses with an registration for the export of veal to the USA are recently started with daily sampling, extensive testing and research for STEC. Criteria for HEP (STEC percentages for local and for systemic HEP) has to be determined for the respective slaughterhouses depending on the current results and will be subjected to adjustments according to future results. At certain testing stages HEP criteria has to be analyzed and if applicable adjusted.

D. The export of non-intact veal/beef will not start before the STEC-sampling procedures of the establishments and NVWA are evaluated with positive results.

E. VIC, responsible for collecting raw beef samples at establishments that produce raw beef products, are to be provided up to two hours of official regular time to read this instruction and also a training (on-site/off-site, depending on the experience and needs of the VIC).

NOTE: For the purposes of this instruction, when the instruction references "raw beef" it includes veal and not-ready-to-eat (NRTE) beef; when the instruction references "establishments" it includes also establishments applying for a registration for the export of beef/veal products to the USA.

II. CANCELLATIONS

NVWA Verification Activities for Escherichia coli O157:H7 in Raw Beef Products v 2014

III. BACKGROUND

A. NVWA considers all product, contaminated with STEC O157:H7 and the following 8 non-O157 STEC: O26, O45, O103, O104, O111, O121, O145 and O174 (Dutch top 9), and stx, and eae/aagR+aaiC genes present, to be ineligible for export to the USA..

B. Sampling verifies that an establishment's food safety procedures and controls adequately address STEC.

C. Establishments are required to hold or maintain control of raw beef products that NVWA has tested for STEC pending negative results.

[1] Instruction *NVWA Verification Activities STEC Raw Intact* is extended for raw non-intact.

CHAPTER II – ELIGIBILITY CRITERIA FOR FSIS STEC SAMPLING

I. SAMPLING at establishments, eligible for the export of raw beef to the USA

A. VIC are to be aware that they have to sample and test eligible raw beef products produced under inspection, including inspected source materials that are subsequently used in retail operations conducted onsite.

B. Establishments that slaughter and further process raw beef product may be eligible for multiple raw beef products. These establishments may produce veal, organs, marrow bones, tenderized veal, ground product, beef manufacturing trimmings, bench trim, and other raw ground beef or beef patty components. These establishments may use purchased product (only from establishments with a registration, for the product concerned, for the export to the USA) to produce bench trim or raw non-intact products. Therefore, VIC may have to take samples for multiple sampling tasks.

C. In the event of a positive sample from any of the routine sampling programs, follow-up samples will be scheduled at the establishment. The purpose of scheduling these follow-up samples is to determine whether the establishment effectively addresses STEC.

D. STEC sampling has to be part of Supervision 1 (team leader supervision) at least once a year.

II. SAMPLING FREQUENCIES FOR ROUTINE SAMPLING PROGRAMS

VIC have to sample each establishment that produces:

1. Raw ground beef products; and
2. Bench trim, other raw ground beef components, or beef manufacturing trimmings for each product.

Frequency: at least four times per month.

III. INTENDED USE AND SAMPLING ELIGIBILITY

A. The product's intended use is a key factor in determining whether NVWA collects samples. NVWA samples products intended for use in:
1. Raw non-intact product (e.g. ground, mechanically tenderized, needled, vacuum marinated),
2. Intended Use is unclear.

B. VIC are *not to sample*[2] product that:
1. The establishment intends for use in intact or ready-to-eat product,
2. Product that will receive other full lethality treatment at another establishment.

If the product is to receive a full lethality treatment at another establishment, VIC are to verify that the establishment's hazard analysis and flow chart show that the product is intended for

[2] However, the verification activities, as detailed in "NVWA Verification Activities STEC Raw Beef", are still applicable.

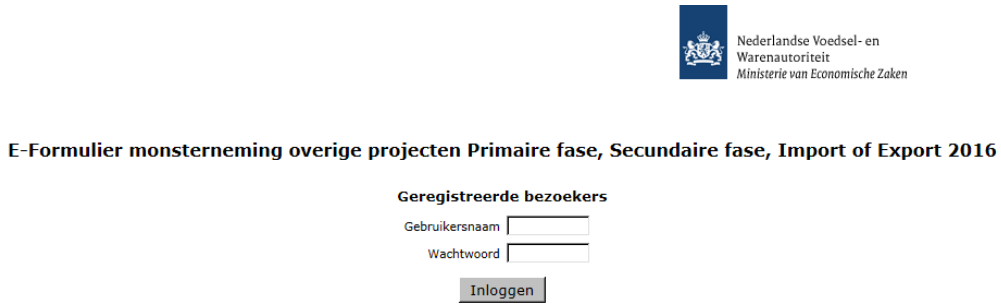
one of these controlled uses, and that the establishment has controls that ensure that the product is used as intended. If not, VIC are to collect the sample.

C. When establishments do not maintain clear records concerning the intended use of raw ground beef product, beef manufacturing trimmings, bench trim, or other raw ground beef components, VIC are to consider that these products are intended for use in the production of raw non-intact products. Such products are subject to NVWA sampling and testing for STEC.

D. If a product is subject to being sampled, VIC are to sample the product even if the establishment decides to change the product's intended use (e.g., to cook all the product represented by the sample or to send the product to another establishment to cook the product after NVWA has collected the sample). In this situation, VIC are to proceed with submitting the sample to the NVWA-laboratory for analysis.

CHAPTER III – Digital Sampling form

VIC are to use the "E-formulier monsterneming overige projecten Primaire fase, Secundaire fase, Export of Import" (E-form sampling other products for project in primary phase, secondary phase, export or import) . As detailed in instruction: "Werkvoorschrift digitaal monsterregistratieformulier" (Dutch only).



1. Follow the procedure for packaging of the sample(s) and completing of the digital sample registration form as detailed in instruction "MON01-10 Werkvoorschrift digitaal monsterregistratieformulier".
2. Complete the digital sample registration form:
- category: encircle "verification"
- kind of product: kind of animal of origin;
- identification: "microbiological verification test";
- tick off "microbiological testing STEC";
On account of: establishment
3. The whirl bags containing the samples has to be kept cooled in a refrigerator.
4. The transport of the monsters has to take place at a temperature of max. +/- 5°C by cooled sampling transport of the NVWA-laboratory Wageningen.

CHAPTER IV - SAMPLE COLLECTION PREPARATION

I. PREPARING TO COLLECT A SAMPLE OF RAW PRODUCT FOR STEC VERIFICATION TESTING

A. Verification sampling will takes place unannounced; VIC are to plan the sampling tasks (risk-) based on their knowledge of the establishment's practices.
VIC has to inform the establishment that it is responsible for supporting its basis for defining the production lot represented by the sample (i.e., the sampled lot); and
VIC has to inform the establishment that it is required to hold or maintain control of the sampled lot when FSIS collects samples for STEC until negative results become available.

B. VIC are to be aware that NVWA, concerning products for the export to the USA, does not recognize "Clean-up to clean-up" alone as a supportable basis of distinguishing one portion of production from another portion of production.

C. VIC are to be aware that factors or conditions that may determine the sampled lot include:
1. Any scientific, statistically based sampling programs for STEC that the establishment uses to distinguish between segments of production;
2. Sanitation Standard Operating Procedures (Sanitation SOPs) or/and any other prerequisite program used to control the spread of *E. coli* O157:H7 cross-contamination between raw beef components during production.
The following may lead to the cross-contamination between raw beef components during production:
    a. Improper sanitary dressing procedures;
    b. Insanitary product contact surfaces on equipment such as machinery and employee hand tools;
    c. Improper employee hygiene;
3. Processing interventions that limit or control STEC contamination; and
4. Beef manufacturing trimmings and raw beef components or rework carried over from one production period to another.

D. If multiple lots of raw ground beef product were produced from source materials from the same production lot from a single supplier, and some of this product was found positive for STEC, VIC are to be aware that a scientific basis is necessary to justify why any raw ground product produced at the grinder from those source materials should not be considered to be adulterated.

E. If VIC have questions concerning the establishment's definition of the sampled lot, they are to contact a SIA or TO Import Export. If VIC have questions concerning the establishment's support for the sampled lot, they are to contact their team leader.

NOTE: When VIC are assigned to an unfamiliar establishment, they are to discuss sampling with the establishment during the entrance meeting.

II. SAMPLING SUPPLIES

VIC are to care for sufficient stock of N60 supply kits and additional supplies for N60 sampling, including packaging materials to be able to execute the sampling immediately at any time.
NVWA provides the sampling and packaging materials.

III. GENERAL SAMPLING INSTRUCTION FOR ROUTINE STEC SAMPLING

A. VIC are to notify establishment management about collecting samples. VIC are to inform the establishment of the reason they are collecting the sample (e.g., routine NVWA verification testing or follow-up sampling in response to an STEC positive from NVWA-testing).

B. VIC are to use a method for randomly selecting the production lot for sampling. VIC are to randomly select a day, shift, and time. VIC are to collect samples from all shifts the establishment operates and include, where applicable Saturdays, even Sundays, in the random selection.
There needs to be an equal chance that sampling will occur during any particular shift.

C. VIC may be assigned more than one sampling task in an establishment that produces raw ground beef product, beef manufacturing trimmings, other raw ground beef or beef patty components, and trim or raw non-intact product from purchased product.
1. VIC are not to collect a raw ground beef sample from the same lot of source materials (i.e., beef manufacturing trimmings, bench trim, or other raw ground beef components) that already have been sampled by NVWA.
2. If the establishment produces 1,000 pounds of product or less on a daily basis, or only on an intermittent basis, VIC are only to collect one sample.

D. VIC are to collect fresh and not frozen product for STEC sampling. VIC are only to collect a sample of frozen product if the establishment has a critical control point (CCP) for freezing in its HACCP plan, and freezing is an active process that achieves a reduction in STEC (e.g., a spiral freezer).

E. VIC are to collect the sample after the establishment has completed production of a lot (as defined by the establishment) and applied all antimicrobial treatments to the product to be sampled.
NOTE: Application of an antimicrobial treatment (other than a treatment that achieves a full-lethality) does not exempt the product from routine sampling.

F. If the product is to receive a full-lethality, VIC are to verify that the establishment's hazard analysis and flow chart show that the product is intended for this use, and that the establishment has controls that ensure that the product is used as intended. VIC are to verify, through records review, that the establishment maintains sufficient documentation to support its assertion that product receives an intervention off-site. If so, VIC are not to sample the product.
EXAMPLE: The establishment receives letters of guarantee showing that all product receives a full-lethality treatment and maintains records documenting on-going communication with the receiving establishment to verify that all its product is being treated with the intervention.

G. VIC are to collect a sample even if an establishment has already tested the production lot for STEC.

I. If the establishment intends to test the product for any of the adulterant STEC before completing pre-shipment review, VIC are not to wait for the establishment to receive the test results before collecting the sample. Each time VIC collect samples tested for STEC, they are to verify that establishments are holding or maintaining control of the sampled lot.

IV. ALTERNATIVE LOTTING FOR RAW GROUND BEEF PRODUCT, BEEF MANUFACTURING TRIMMINGS, OTHER RAW GROUND BEEF COMPONENTS AND BENCH TRIM SAMPLING

An establishment may request to reduce its lot size to one combo bin or some other unit (e.g., box) for samples of raw ground beef, beef manufacturing trimmings, other raw ground beef components, and bench trim on the day that NVWA collects samples.

In this case, VIC are to verify that the establishment:
1. Has a validated intervention for STEC at a CCP in the HACCP plan under which the beef manufacturing trimmings or other raw ground beef components are produced or requires its suppliers to have a CCP where a validated intervention is applied to the source materials used to manufacture the raw ground beef product or bench trim; and
2. Samples and tests every production lot for STEC and generally collects its samples of raw ground beef, beef manufacturing trimmings, other raw ground beef components, or bench trim across multiple combo bins or other sample units.
If an establishment meets the criteria in here above and reduces its lot size of ground product or bench trim from source materials, beef manufacturing trimmings, or other components to a single combo bin or sample unit when NVWA samples the product, VIC are to collect a sample from the single combo bin or sample unit. If the establishment does not meet the criteria, VIC are to collect the sample as described Chapter V - “SAMPLE COLLECTION PROCEDURES”.

V. GATHERING SUPPLIER INFORMATION

VIC are to gather information about the source materials and suppliers at the time they collect a routine raw ground beef and bench trim sample, as well as when they do follow–up sampling to these programs. Establishments has to provide VIC the supplier and source material information at the time VIC collect raw ground beef and bench trim samples for STEC. This information enables NVWA to trace the raw material back to the original slaughter establishment. VIC can keep the actual label from empty packages. For imported source materials, VIC are to record the Inspection certificate number and to verify the registration of the establishment of origin for the export of the source materials to the USA.

CHAPTER V – SAMPLE COLLECTION PROCEDURES

I. GENERAL

A. The establishment may be eligible for more than one sampling program. VIC are to sample beef components, beef manufacturing trimmings, and bench trim separately following the instructions provided in this Chapter. When the establishment produces multiple types of trim or components, VIC are to randomly select beef manufacturing trimmings, bench trim, and beef components. For a given sampling event, VIC are to collect only one type of trim or component type, whenever possible. The intent is that, through random selection, all eligible products the establishment produces that are subject to sampling will likely be selected over time.

B. VIC are to collect samples of a lot according to the establishment’s lotting practices.

C. NVWA-instructions containing step-by-step sample collection procedures by sampling program are available. See for sample collection procedures for

- **Beef manufacturing trimmings and bench trim** (N60 sample collection procedure): Directive 10,010.1, Attachment 2
- **Raw ground beef product:** NVWA-instruction "MRNT 17109, Gehakt vlees en vleesbereidingen" and also Directive 10,010.1, Attachment 4.
- **Other raw ground beef components:** Directive 10,010.1, Attachment 3
- **Frozen components:** Directive 10,010.1, Attachment 5.

II. FINAL PACKAGING

A. VIC are to collect raw ground beef products in their final package whenever possible. VIC are to collect the appropriate number of packaged products so that the sample equals two pounds (2lb).

B. VIC are to place the product collected in its final packaging in the larger, non-sterile bag provided with the sampling supplies. VIC are not to use the Whirl-pak® bags when collecting products in its final packaging.

III. N60 SAMPLING METHOD

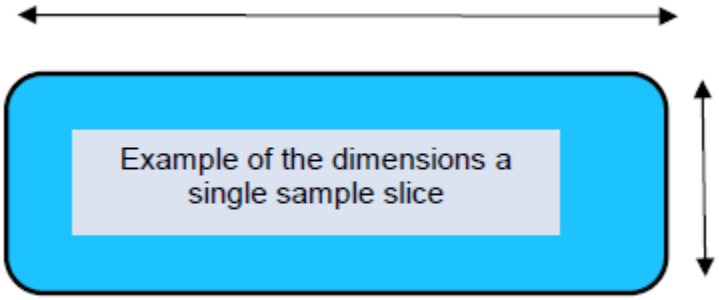
A. N60 sampling is the sample collection method VIC are to use when collecting samples of beef manufacturing trimmings and bench trim, provided the establishment produces beef manufacturing trimmings and bench trim in amounts that are large enough to be sampled using the N60 method. VIC assigned to establishments that produce beef manufacturing trimmings and bench trim of sufficient size to be sampled using the N60 method and trim too small to be sampled using the N60 method are to collect samples from the product that lends itself to N60 procedures. If the establishment commingles both types of trim, whenever possible, VIC are to collect samples from the product that lends itself to N60 procedures before commingling.
NOTE: If the establishment only produces beef manufacturing trimmings and bench trim that is too small to be sampled using the N60 method, VIC are to collect a sample by taking aseptic grab samples (see Section IV in this chapter).

B. VIC are to not to use the N60 method when collecting other raw ground beef component samples. VIC are to collect other raw ground beef component samples by taking aseptic grab samples (see Section IV in this chapter).

C. N60 sampling involves collecting 60 thin slices from the external surface of beef tissues. Each sample slice should be about 3 inches long by 1 inch wide and 1/8th inch thick (ca[3]. 6.5cm x 2.5cm x 0.3 cm), as shown below. It is important to collect thin slices because the surface of the beef carcass can be contaminated through improper sanitary dressing procedures. VIC are to collect only one sample slice from each of the 60 individual pieces of trim. VIC are not to take multiple samples from a single piece of beef manufacturing

[3] Precisely: (6.72cm x 2.54cm x 0.32cm)

trimmings unless the production lot consists of less than 60 individual pieces. Collecting thin slices from the external surface maximizes the amount of surface area sampled, which increases the likelihood of finding pathogens if they are present.



D. VIC are to use the 3 Whirl-Pak bags when collecting samples using N60 procedures. VIC are to place 30 pieces in each of two Whirl-Pak.
NOTE: When cut to the correct size, 30 sample slices should fill one Whirl-Pak bag to the fill line. In the third Whirl-Pak bag, VIC are to aseptically collect samples of trim from the same production lot by using a grab sample technique. For larger trim pieces, VIC are to cut the trim piece so that it fits in the Whirl-Pak bag with at least 2-3 inches (5-7cm) of space at the bag.

-> 60 pieces + "grab-sample"

E. VIC are to randomly select one production lot according to the establishment's lotting practices with each lot having an equal chance of being selected regardless of product location.
1. If an establishment's specific production lot is greater than 5 containers, VIC are to select randomly 5 containers for sampling with each container having an equal chance of being selected; and
2. If the establishment's specific production is 5 or less containers, VIC are to refer to Table 1 to determine the number of sample pieces to collect from each container.

Table 1: Number of Sample Pieces to Collect per Container

Number of containers in each specific lot	Number of samples to select from each container
5	12 pieces
4	15 pieces
3	20 pieces
2	30 pieces
1	60 pieces

3. If the establishment reduces its lot size to one container and meets the alternative lotting in Chapter IV, Section V. VIC are to collect samples from that container.

F. Some slaughter establishments may transfer beef manufacturing trimmings to another establishment with a different EG number that is in the same, complex and/or company

as the slaughter establishment or separated from the slaughter facility by only a wall. VIC are to sample the beef manufacturing trimmings at the slaughter establishment, just as if an establishment would send this product to a more distant location.

G. VIC are to use the N60 method to collect samples from primal and subprimal cuts that are used to produce mechanically tenderized products before tenderization if VIC can safely do so.

H. If the establishment does not have the capability to temporarily shut off components for sampling activities (by example tenderizing components), or does not agree to do so, no product produced in/with this component is eligible for the export to the USA. Upon request a company has to show full cooperation to the NVWA according to 882/2004/EC (on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules).

IV. ASEPTIC GRAB SAMPLING

A. VIC are to aseptically collect grab samples and are not to use the N60 sample method when collecting other raw ground beef component samples.

B. VIC are to aseptically collect grab samples when raw ground beef product is not available in its final packaging, or the package is too large.

C. For aseptic grab samples, VIC are to collect a sufficient quantity of product to fill each of the three Whirl-Pak bags to the fill-line. For larger components, such as hearts, VIC are to collect one or more pieces or enough to fill each of the 3 Whirl-Pak® bags above the fill line but leaving at least 2-3 inches (5-7cm) of space at the top of the bag when collecting samples of raw ground beef products other than trim.

V. PACKING THE SAMPLE

VIC are to use only the packaging materials provided by the NVWA.

VI. ACCESSING TEST RESULTS

A. VIC are to obtain sample results by accessing the dossier of the respective establishment at: T:\nvwa\Veterinair-Import\Bedrijvendossier V&I. The laboratories will report the results for all adulterant STECs (*E. coli* O157:H7 and non-O157 STEC) for each sample there.

B. “Not acceptable” positive test results for adulterant STEC are reported as soon as each analysis is completed and reviewed. If the sample confirms positive for STEC, NVWA laboratory Wageningen will display the specific STEC serogroups that are positive.

C. After receiving the STEC test results, VIC are to advise an establishment that is holding product that it does not need to continue to hold that product if it has tested negative for STEC.

D. Sample discard: if NVWA-Laboratory discards a sample submitted for STEC testing, VIC are to notify establishment management so that product may be released. BB/VIC are to take appropriate action, based on the reason for the sample discard when applicable. VIC are to review the reason for sample discard and make the necessary adjustments in how the

samples are collected, sealed, packed and transported to ensure that the laboratory does not discard future samples because of improper handling or packaging.
NOTE: There may be reasons for sample discards that are beyond VIC control.

CHAPTER VI –FOLLOW-UP SAMPLING PROCEDURES

I. GENERAL

A. VIC are to collect follow-up samples in response to NVWA positives as soon as possible after the positive results were obtained. The purpose of follow-up sampling is to determine whether the establishment's process is effectively addressing STEC.

B. VIC are to collect follow-up samples from the same type of product that tested positive, if available. If the establishment is not producing the product requested, VIC are to collect follow-up samples from beef manufacturing trimmings if the establishment is producing them.

C. In the event that the establishment does not produce the product that tested positive or beef manufacturing trimmings, VIC are to collect follow-up samples from other raw ground beef components or bench trim, if available.

D. VIC are not to wait until the establishment takes corrective actions or has confidence that its corrective actions are effective to collect follow-up samples.

E. VIC are to continue collecting samples for a follow-up sampling task until the set is complete. Specifically, VIC are to continue collecting follow-up samples until the applicable number of samples (16 or 8 consecutive negative samples, see Section II.C. of this chapter) have been collected for each follow-up sampling set triggered.

F. Follow-up sampling has to be done in response to each positive from NVWA's routine sampling programs at the establishment that received the positive result.

G. NVWA also schedules follow-up sampling sets at supplying slaughter establishments in response to a positive from raw ground beef sample from and a bench trim positive at an establishment sampled for off-site product.
Supplier follow-up sampling sets are discussed in more detail in Section II of this chapter.

H. NVWA may also schedule a follow-up sampling set outside these follow-up sampling projects, e.g., in response to an outbreak or recall.

I. Each positive result in a follow-up sampling set triggers another follow-up sampling set.

J. VIC are to contact NVWA-laboratory at Wageningen if they have questions concerning sampling.

K. VIC has to detail the intended follow-up sampling as required in this chapter in a written action plan (e.g. kind of product, frequency, activities concerning supplier/purchaser etc.). The team leader has to verify if VIC acted as required in this instruction and "NVWA STEC verification" (based on Directive 10,010.2).

II. FOLLOW-UP SAMPLING AT SUPPLIERS

A. If the originating slaughter establishments supplied more than one type of source material used in the positive ground beef or bench trim sample, NVWA has to generate sampling tasks for each type of source material.

B. VIC are to collect a single follow-up sample or multiple follow-up samples at supplier establishments as assigned. NVWA does not assign follow-up sampling tasks at establishments that only bone or fabricate beef primal or subprimal cuts but do not slaughter.

C. If NVWA determines that an originating slaughter establishment was the only supplier, or that any of the originating slaughter establishments were suppliers that had previously been identified within approximately 4 months (or 120 days) of the current raw ground product or bench trim positive result, NVWA assigns 16 (or 8 in response to an establishment produces less than 1,000 pounds per day of the product that tested positive) follow-up sampling tasks for the originating slaughter establishments. The follow-up samples has to be identified for each component used in the positive raw ground beef or bench trim product.

NOTE: Follow-up samples of raw ground beef product are to be collected from the grinders that used purchased source materials.

III. SPECIAL INSTRUCTIONS FOR FOLLOW-UP SAMPLING OF INTACT BEEF COMPONENTS THAT WERE NOT INTENDED FOR USE IN RAW NON-INTACT PRODUCT

A. If intact product was used as a component in raw ground beef product or was sampled as bench trim that NVWA finds positive for STEC, VIC are to select a carcass (rather than the component of the carcass) at the originating slaughter establishment for follow-up sampling under the following conditions:
1. HACCP plan records and purchase specification records for product produced at the originating slaughter establishment show that the intact product was not intended for grinding or non-intact product, and that the establishment informed purchasers that the product was not intended for grinding; and
2. The establishment derived intact product from the carcass in a manner to minimize commingling with other product, and the establishment packaged the product separately from other product without commingling (e.g., boneless chucks were placed on a conveyor belt and were then off-loaded for packaging without being commingled with other product).

B. VIC are to verify that that the conditions in A. above are met. If the conditions in A. above are met, VIC are to collect the samples at the originating slaughter establishment from one or more carcasses hanging in the cooler before fabrication, according to the establishment's lotting practices.
1. VIC are not to wait until the establishment breaks the carcass down into primal and subprimal cuts to collect follow-up samples.
2. VIC are to use the N60 method to collect slices from the carcass surface from the same part of the carcass used to produce the raw ground beef product or bench trim, if known.
   a. If the location on the carcass is not known, then VIC are to sample:
      i. Inside round;
      ii. Outside round;
      iii. Navel plate;
      iv. Brisket; and
      v. Foreshank

b. If the slaughter establishment designates more than 1 carcass as a lot, then VIC are to collect samples from more than 1 carcass as follows:

TABLE 2: Number of Sample Pieces to Collect Per Carcass	
number of carcasses in each specific lot	number of sample pieces to collect from each carcass
5 or more	12 pieces
4	15 pieces
3	20 pieces
2	30 pieces
1	60 pieces

c. VIC are to cut enough slices off the surfaces of the carcass to equal 2 pounds (1kg).

C. If both conditions in A. above are not met, VIC are to sample the intact components that were used to produce the positive raw ground beef or bench trim products using the N60 method.

D. If the NVWA sample collected is positive in B., generally only the sampled carcass is implicated because STEC contamination is generally point-source contamination that occurs sporadically as a consequence of handling during hide removal and dressing of the carcass. However, if the establishment does not prevent carcasses from being commingled or does not have adequate controls to prevent cross contamination among carcasses, it will not be able to designate a single carcass lot for sampling.
1. The establishment may decide to destroy the implicated carcass or to use it to produce products that will be processed to destroy the pathogen (e.g., by cooking).
2. Because establishments remove the head and cheek meat, weasand, hearts or offal during the slaughter process and process them separately from the rest of the carcass, NVWA will not consider these parts associated with the positive STEC result, unless there is cross-contamination, inadequate sanitary dressing procedures, or inadequate controls to prevent contamination.

Chapter VII - Attachments

I. Important Information and Material for training purposes

See the FSIS film: STEC Sampling of Domestic Raw Beef Products

See the Attachments II – IV of FSIS Directive 10,010.1 about sampling techniques.

NVWA Verification Activities for STEC in Raw Beef Products

Based on **FSIS DIRECTIVE 10,010.2 Verification Activities for Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef Products**

Contents

Acronyms and Abbreviations

BB	"Bedrijvenbeheerder" (Administrations Manager of the NVWA for an establishment, at slaughterhouses this is an official veterinarian)
CSI (PM):	Coördinerend Specialist Inspecteur (coordinating specialist inspector - product manager)
Division C&V	NVWA- Division Consumer & Safety (Consument & Veiligheid)
Division V&I	NVWA-Division Veterinary affairs & Import(-Export) (Veterinair & Import)
HAV	Hazard Analysis Verification
KCC	"Kennis en Contact Centrum" Centre for information and contact, part of KCDV
KCDV	Klant Contact en Dienstverlening
NR	Non-compliance Record
NRLTO	Not Reasonably Likely To Occur
RIVM	Rijksinstituut Volksgezondheid en Milieu (National Institute for Public Health and Environment)
RLTO	Reasonably Likely To Occur
RTE	Products that are consumed raw
RvB	"Rapport van Bevindingen" (Non-compliance report)
STDA	"Senior Toezichthoudend Dierenarts"((Senior) supervisory Veterinarian)
STEC	Shiga toxin-producing *E. coli* (STEC)—STEC may also be referred to as Verocytotoxin-producing *E. coli* (VTEC)
VIC	NVWA-Veterinarian in charge (slaughterhouse cutting establishment)

CHAPTER I – GENERAL

I. PURPOSE

A. This working manual provides instructions to inspection program personnel (IPP)[1] on the verification activities.
B. BB/VIC responsible for performing HACCP verification tasks and SIA responsible for performing Hazard Analysis Verification (HAV) tasks in establishments that produce raw beef products are to be provided up to three hours of time to read this directive; a one day training[2] has to be scheduled before performing official STEC-verification tasks.
C. STEC-verification tasks are to perform at an establishment that has a registration for the export of beef/veal to the USA.

NOTE: For the purposes of this working manual, when the working manual references raw beef, veal and not-ready-to-eat (NRTE) beef are included.

II. CANCELLATIONS

NVWA Verification Activities for STEC in Raw INTACT Beef Products

III. POSITIVE STEC VERIFICATION SAMPLE

BB's are to verify that products that tested positive for STEC from NVWA or establishment testing received appropriate disposition; see Chapter III.I.A1.

IV. BACKGROUND

- **A.** NVWA considers all product, contaminated with STEC O157:H7 and the following 8 non-O157 STEC: O26, O45, O103, O104, O111, O121, O145 and O174 (Dutch top 9), and stx, and eae/aagR+aaiC genes present, to be ineligible for export to the USA. Therefor the establishment has to control the pathogen or prevent the potential pathogen from becoming reasonably likely to occur through preventive measures.

B. STEC contamination is a food safety hazard during the slaughter and processing of raw intact and raw non-intact beef products. The establishment (with an export registration for beef/veal to the USA) may use a multi-hurdle approach and incorporate multiple controls and preventive measures to address the pathogen in its HACCP system. Thus, the establishment may control the pathogen through one or more CCP's in its HACCP plan or prevent the potential pathogen from becoming reasonably likely to occur through preventive measures in its SSOP's or through other prerequisite programs, or a combination of these mechanisms. Nonetheless, establishments have to sample/test for STEC as detailed in instruction "RE-31 USA, requirements concerning establishments, Appendix 2"[3] (instruction about requirements concerning establishments eligible for the export of meat/beef to the USA).

[1] BB, VIC, SIA
[2] By a STDA of a SIA who has followed the FSIS training
[3] Detailed in Annex STEC sampling

C. BB's are to be aware that an establishment producing raw beef product needs to make sure that it effectively addresses the hazard.
An establishment may determine that its controls or preventive measures for E. coli O157:H7 effectively control or prevent non-O157 STEC. Interventions validated to control E. coli O157:H7 should be effective in controlling the non-O157 STECs when properly implemented as described in the establishment's supporting documentation unless data such as multiple non-O157 STEC sample results indicate otherwise. This has to be validated and is therefore only acceptable after a certain timeline where all relevant STEC types (E. coli O157:H7 and non-O157 STEC) are sampled. See instruction RE-31, requirements concerning establishments, Appendix 2.

CHAPTER II – IPP HACCP VERIFICATION ACTIVITIES

I. GENERAL

SIA's and BB's are to verify that establishments that produce raw intact and non-intact beef products meet HACCP regulatory requirements by performing Hazard *Analysis* Verification Tasks (SIA's) and HACCP Verification Tasks (BB's).

II. PERFORMING THE HAV TASK

A. SIA's are to perform annually the HAV task; this is part of the annual export registration audit. They use the instructions in Table 1 when performing Raw Intact and Raw Non-Intact Hazard *Analysis* Verification Tasks. Table 1 will be incorporated in the existing NVWA checklist[4] (HACCP) for USA export registration.

TABLE 1: STEPS IN PERFORMING THE HAZARD ANALYSIS VERIFICATION (HAV) TASK IN RAW INTACT AND RAW NON-INTACT BEEF PRODUCTS

Step	Description	Verification Questions	Regulatory Citation (9 CFR)
Step 1	Review flowchart and compare to production process. Determine whether the establishment has identified the product's intended use (see Chapter II, NVWA Sampling	• Has the establishment described all of the steps of each process and product flow?	417.2(a)(2)

[4] Steps already are part of the NVWA checklist

	Verification Activities for Shiga Toxin). (NVWA checklist, step 6)		
Step 2	Review the hazard analysis and consider guidance in the FSIS Meat and Poultry Hazards and Controls Guide available on FSIS's website and Chapter IV, Section IV of this document[5]. (NVWA checklist, step 7) Become familiar with any prerequisite programs the establishment uses as preventive measures support hazard analysis decision that STEC is not reasonably likely to occur (NRLTO) for the specific product type. (NVWA checklist, step 7)	• Has the establishment addressed possible hazards from STEC in its hazard analysis?	417.2(a)(1), 417.5(a)(1)
Step 3	For each hazard that the establishment considers RLTO, verify that the HACCP plan includes one or more CCPs to control it. (NVWA checklist, steps 8-17) *If the HACCP plan includes no CCP's for hazards considered RLTO, see Step*	• If the establishment considers STEC a hazard RLTO (Reasonably Likely To Occur), has the establishment included one or more CCPs to control the hazard either at that step or a later step? • Is the establishment's HACCP plan designed to ensure that it includes the monitoring procedures and frequencies that it uses to monitor the CCPs? • If the establishment has included its antimicrobial intervention control measures as a CCP, has the establishment	417.2(c)(2) 417.5(a)(2) 417.2(c)(4)

[5] Part of the NVWA checklist (HACCP) for the annual audits of establishments with USA-export registration

	3a *If no hazards are reasonably likely to occur, skip to step 4.* See Chapter IV, Section IV of this document.	incorporated the critical operating parameters (e.g., carcass and product coverage) into its written monitoring procedures? NOTE: SIA's are to use the information in Attachment 1 to assist them in reviewing the establishment's scientific support for antimicrobial treatments that establishments apply as part of a CCP, SSOP, or other prerequisite program. •If the establishment performs STEC testing, does the establishment have support for its sampling and testing procedures and the frequency for the procedures? • Does the establishment use the instructional or disclaimer statement as a control or CCP to address STEC? NOTE: This represents noncompliance with 417.5(a)(1) (See Chapter IV of this directive) and is not allowed for products for the export to the USA.	417.2(c)(2), 417.5(a)(2) 417.2(c)(4) 417.5(a)(2) 417.5(a)(1)
Step 3a	If the HACCP plan includes no CCP's for hazards considered RLTO, has the establishment supporting documents which prove CCP's for the hazards to be unnecessary?		
Step 4	For each hazard, the establishment considers NRLTO, determine what evidence the establishment uses to support the decision. See Chapter IV, Section IV of this directive.	• If the establishment determines that STEC is NRLTO in its product, does it prevent STEC through a prerequisite program or its SSOP? Proceed to step 5. • Does the establishment determine that STEC is NRLTO in its product *based on data concerning customary consumer*	417.5(a)(1)

	(NVWA checklist, step 18.1)	*preparation practices in conjunction with its purchase specifications* and its own preventive measures employed during further processing that are incorporated as part of a prerequisite program? For example, certain cuts of meat contain a large amount of connective tissue, so consumers need to cook the product for a long time to make the product palatable (e.g., a brisket for use in corned beef). Other cuts of meat (e.g., "Philly" style cheese steaks) are thin and are cooked thoroughly quickly. Proceed to step 6.	417.5(a)(1)
Step 5	Review prerequisite programs and other supporting programs, including written programs, records, and employee activities. Verify the implementation of prerequisite programs. (NVWA checklist, steps 29-31)	• Does the establishment use prerequisite programs to support hazard analysis decision-making? • Does the establishment's antimicrobial intervention preventive measures on incoming raw materials incorporate the critical operating parameters (e.g., product or carcass coverage) identified in the establishment's scientific support? NOTE: SIA's are to use the information in Attachment 1 to assist them in reviewing the establishment's scientific support for antimicrobial treatments that establishments apply as part of a CCP, SSOP, or other prerequisite program. • If the establishment has incorporated its antimicrobial intervention preventive measures or other STEC preventive procedures in a prerequisite program, does the establishment implement the antimicrobial intervention or other STEC preventive measures according to its supporting documentation? • If the establishment has determined that its prerequisite programs for E.coli O157:H7 adequately prevent non-O157 STEC, does the establishment implement its preventive measures according to its support?	417.5(a)(1) 417.5(a)(1) 417.5(a)(1) 417.5(a)(1) 417.5(a)(1)

		• Are the prerequisite programs consistently being implemented as written? • Do the prerequisite programs support the establishment's hazard analysis decision-making on an ongoing basis?	417.5(a)(1) 417.5(a)(1)
Step 6	Review other supporting documentation. NVWA checklist, steps 17/18	• Does the establishment use data concerning customary consumer preparation practices information in conjunction with its purchase specifications and its own preventive measures employed during further processing as part of a prerequisite program to support its hazard analysis decisions? • Do the establishment's hazard analysis decision-making documents describe the basis for the establishment's determination that these practices constitute customary preparation?	417.5(a)(1) 417.5(a)(1)
Step 7	Review establishment validation documents, including scientific supporting documents and validation data.	• Does the in-plant validation data show that the establishment can implement its CCPs and prerequisite programs consistent with the scientific support to effectively control or prevent STEC?	417.4(a)(1)
Step 8	Verify reassessment requirements. Check the most recent signature and date for each HACCP plan. (NVWA checklist, step 18a3) (NVWA checklist, step	• If an establishment that identifies non-O157 STEC in its hazard analysis as NRLTO because its preventive measures for E. coli O157:H7 are adequate for non-O157 STEC receives a non-O157 STEC positive result, has the establishment reassessed its HACCP plan and documented the reassessment? • Has the establishment reassessed its HACCP plan when information (e.g.,	417.3(b), 417.4(a)(3) 417.4(a)(3)

	17,18)	repetitive ongoing positive STEC results) indicates the HACCP plan is no longer adequate?	

TABLE 2: STEPS IN PERFORMING THE HACCP VERIFICATION TASK IN RAW INTACT AND RAW NON-INTACT BEEF PRODUCTS

A. BB's are to use the instructions in Table 2 when performing Raw Intact and Raw Non-Intact HACCP Verification Tasks (frequency: initially once in a month in combination with sampling[6]).
The sampling frequency will be evaluated and determined after the test phase.

Step	Description	Verification	Regulatory Citation (9 CFR)
Step 1	Select the product type and specific production.	• BB's are to review the list of products, to ensure **all product types**[7] are selected over time.	
Step 2	Verify the monitoring requirements.	• If the establishment has included its antimicrobial intervention control measures as a CCP, BB's are to verify that the establishment implements the procedure as written. • If the establishment has determined that its CCPs for E. coli O157:H7 adequately control non-O157 STEC, BB's are to verify the establishment implements its procedures according to its support.	417.2(c)(4) 417.5(a)(2)
Step 3	Verify the verification requirements	• If the establishment performs STEC testing, BB's are to: --Observe the establishment's employee collecting the sample and determine whether the sampling procedures are being performed as written. --Review sample results (including any non-O157 STEC results the	417.4(a)(2)

[6] As detailed in NVWA Sampling Verification Activities for Shiga Toxin
[7] Random sampling of all components

		establishment conducts in addition to E. coli O157:H7) and verify that the establishment takes corrective actions in response to positive results that meet the requirements of 9 CFR 417.3 (see step 5).	
Step 4	Verify the recordkeeping requirements	• BB's are to review sampling records to determine whether the establishment collected the number of samples at the frequency documented in its program.	417.5(a)(3)
Step 5	Verify the corrective action requirements. See Chapter III, Sections I and II for more information.	• BB's are to verify that the establishment: --Has included corrective actions as part of its HACCP plan and --Takes corrective action in response to STEC positive results from establishment or NVWA testing.	417.3
Step 6	Verify the pre-shipment review requirements. See Chapter III, Section III and Chapter IV of this directive for more information.	• BB's are to verify that product for the export to the USA bears no instructional or disclaimer statements	417.5(c)
Step 7	Consider the implications of any noncompliance. See Chapter III, Section I.B. for more information.	• BB's are to document noncompliance(RvB) and consider the findings in the context of the establishment's food safety system.	Regulation 178/2002/EC

CHAPTER III – BB's RESPONSIBILITIES RELATED TO POSITIVE STEC SAMPLE RESULTS

I. BB's RESPONSIBILITIES WHEN AN ESTABLISHMENT RECEIVES A POSITIVE STEC SAMPLE RESULT FROM NVWA

A. Verify the corrective action requirements (Step 5 in Table 2):

1. BB's are to verify that products that tested positive for STEC from NVWA or establishment testing received are considered unfit for the export to the USA and to be properly canalised in one of the following ways:

a. The positive product is shipped to another official establishment for disposition (e.g., cooking); in this case BB is to verify that the establishment adequately addresses in the accompanying documents the pathogen in the product and the subsequent requirement of giving the product a (STEC-) lethality treatment.
NOTE: BB's are to be aware that a voluntary instructional "For Cooking Only" statement is not a sufficient control.

b. The positive product is shipped to an official rendering establishment for rendering or destruction. In such case the BB is to verify that the establishment adequately addresses the product by verifying the right EU mandatory documentation was used for this shipment.

2. Under no condition the product is to be shipped to and stored in a cold storage facility. The product is to be transported non-stop to the establishments mentioned under 1a and 1b.

NOTE: establishments has to hold or maintain control of product that NVWA tests for adulterants pending receipt of acceptable test results.

B. Consider the implications of any noncompliance based on the positive NVWA result (Chapter 1A) (Step 7 in Table 2):

1. BB's are to document a report of findings ("Rapport van Bevindingen") in light of art. 14 of 178/2002/EC for the confirmed positive result from NVWA testing, if the corrective actions as laid down in chapter III.I.1.A are not met. BB's are to ensure, if applicable, recall and proper treatment of the respective batch.

2. If NVWA finds the product to be positive for non-O157 STEC or *E. coli* O157:H7, and the establishment also tested the product, BB's are to check establishment test results to determine whether the establishment also found the sampled product positive for *E. coli* O157:H7 or non-O157 STEC.

3. If BB's have concerns about the adequacy of the HACCP system, they are to discuss their concerns with their supervisors.

II. BB's RESPONSIBILITIES WHEN AN ESTABLISHMENT HAS A POSITIVE STEC SAMPLE RESULT FROM ITS OWN TESTING

A. When performing the HACCP verification task (step 3 in Table 2), BB's are to review the records associated with any STEC testing conducted by an establishment (see table 2 . If BB's find presumptive positive or confirmed positive STEC results in the testing records, they are to verify that the establishment is implementing corrective actions (step 5 in Table 2). When an establishment tests product, a presumptive positive or positive result alone does not warrant a NR. BB's are only to issue an NR in response to an establishment's presumptive positive or positive finding if the establishment fails to take the appropriate actions in accordance with its HACCP system to meet the requirements.

B. BB's are to verify that the establishment addresses the product as if it had tested positive, if an establishment is only performing screening tests (e.g., a presumptive positive) and does not follow up with additional testing to determine whether STEC is isolated from the product. The establishment cannot use negative results for a second screening test for STEC as a means to support food safety because a screening test is not a conclusive (specific) test for the pathogen.

C. When performing a HACCP verification task (step 3 in Table 2 above), BB's are to verify that establishment employees conducting sampling for STEC do not sample sterile product that could not be contaminated with STEC (e.g., product taken from the interior of a carcass). If BB's observe such sampling, they are to document noncompliance.

D. If establishment records show testing of trim and other raw ground beef components for STEC, but the establishment never finds any positives, BB's are to notify the TO SP. In addition, if establishment records show multiple positives for STEC in its own testing, evidencing a potential systemic problem, BB has to issue an extraordinary audit by a SIA and TO specialist to review the establishment's trim and other raw ground beef components sampling and testing methods for trim for STEC.

III. ESTABLISHMENTS CONDUCTING PRE-SHIPMENT REVIEW, AWAITING STEC ANALYSIS, FOR PRODUCT THAT IS NOT AT THE PRODUCING ESTABLISHMENT

When performing a HACCP verification task (step 6 in Table 2), BB's are to be aware that some establishments analyze samples for STEC while they are moving the product, but the product is still under the establishment's control. BB's are to be aware that NVWA provides establishments the flexibility to move their product before export certification when the establishment is conducting testing for STEC and maintains control of the product (e.g., through NVWA provenance documents ("geleidebiljetten")). Export is not possible until the negative sample result is affirmed.

CHAPTER IV – VERIFICATION PROCEDURES INVOLVING INSTRUCTIONAL OR DISCLAIMER STATEMENTS CONCERNING STEC

I. GENERAL

Product for export may not bear either an instructional or a disclaimer statement.

NOTE: A statement that the establishment does not intend to use the product in ground product or other non-intact product is not an instructional or disclaimer statement (e.g., "not intended for grinding" or "not intended for raw ground"). These types of statements **may not be used at all** on product labels.

Contact: TO Import-Export (export@nvwa.nl)

Attachment 1

CRITICAL OPERATING PARAMETERS FAMILIARIZATION

SIA's are to use the examples provided in this attachment to assist them in reviewing the establishment's scientific support for antimicrobial treatments that establishments apply as part of a critical control point (CCP), SSOP, or other prerequisite program**.**

EXAMPLE:

FSIS test results show that the percent positive for STEC in trim produced from veal appear to be higher than trim produced from other cattle slaughter classes. Following up on these results, FSIS conducted a review of Food Safety Assessments (FSAs) and onsite visits to veal slaughter establishments in the USA to identify concerns unique to veal slaughter. The results of the review in the USA indicate a common deficiency. Specifically, veal slaughter establishments, in applying their antimicrobial interventions, failed to achieve carcass coverage because of the practice of suspending carcasses from the rail system with both hind limbs on a single hook (see Figure 2). Because of this practice, spray interventions did not reach all parts of the carcasses. Carcass coverage –ensuring that the entire carcass surface is treated -- is necessary for the intervention to operate effectively. As a

result of the incomplete carcass coverage, interventions were likely less effective than intended, and this ineffectiveness may have contributed to the production of products contaminated with STEC.

In addition, during on-site visits to beef fabrication establishments in the USA, FSIS found that those establishments, when applying their antimicrobial intervention, also failed to achieve product coverage. Reasons for inadequate application of the antimicrobial intervention to all product surfaces included the stacking of products and the folding of longer pieces, particularly loins (Figures 3 and 4). These actions prevented antimicrobial sprays from reaching all product surfaces. Additionally, establishment personnel failed to address these actions by adjusting the conveyor belt timing, properly designing spray applications, and ensuring that product was single-stacked and lying flat so that all product surfaces received the antimicrobial spray. Product coverage – ensuring that all of the product is treated – is necessary for the intervention to operate effectively and as intended.

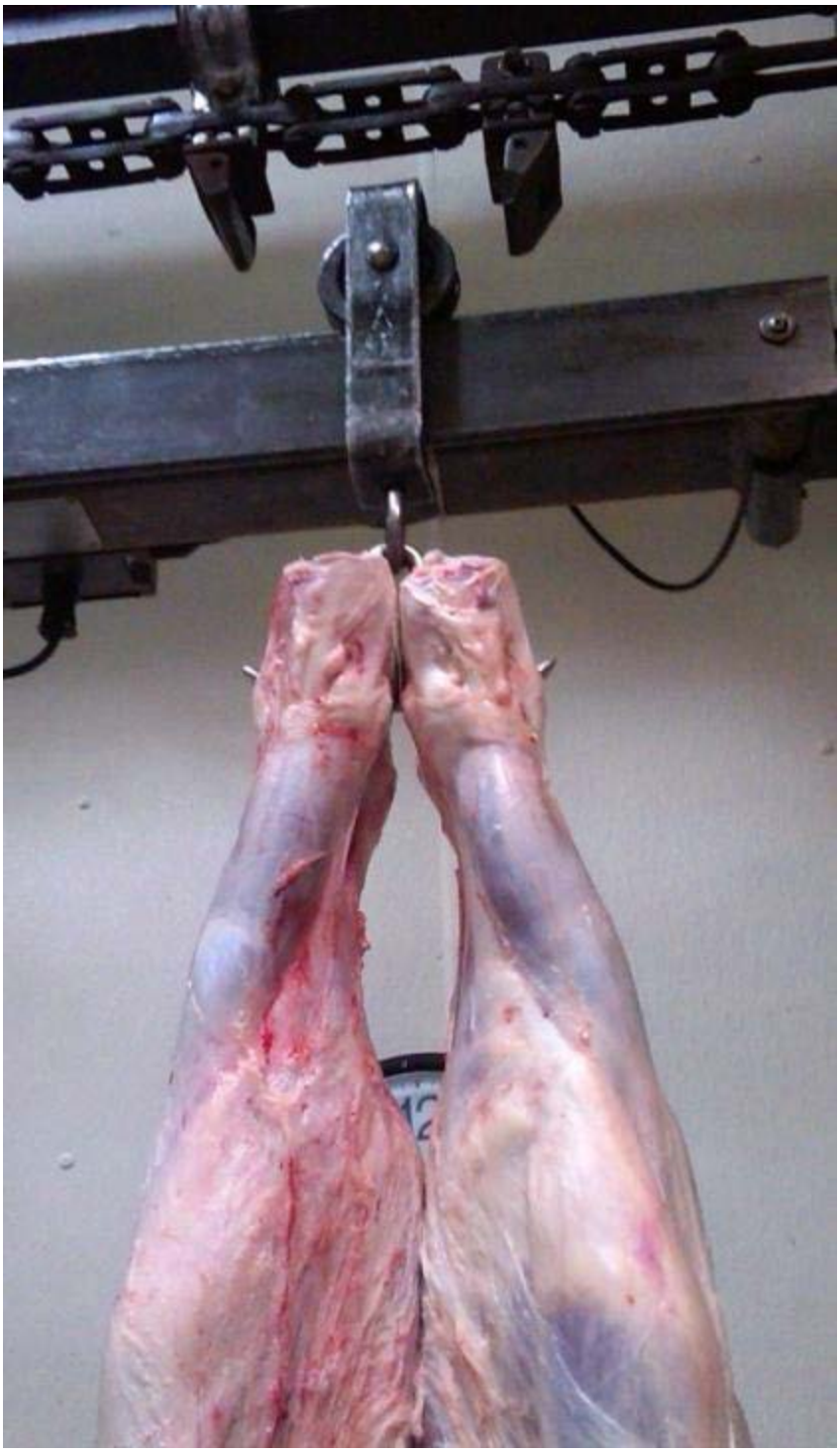


Figure 2. Example of a veal carcass with both hind limbs suspended from a single hook. This practice prevented the antimicrobial treatment from achieving full carcass coverage, a critical operating parameter.

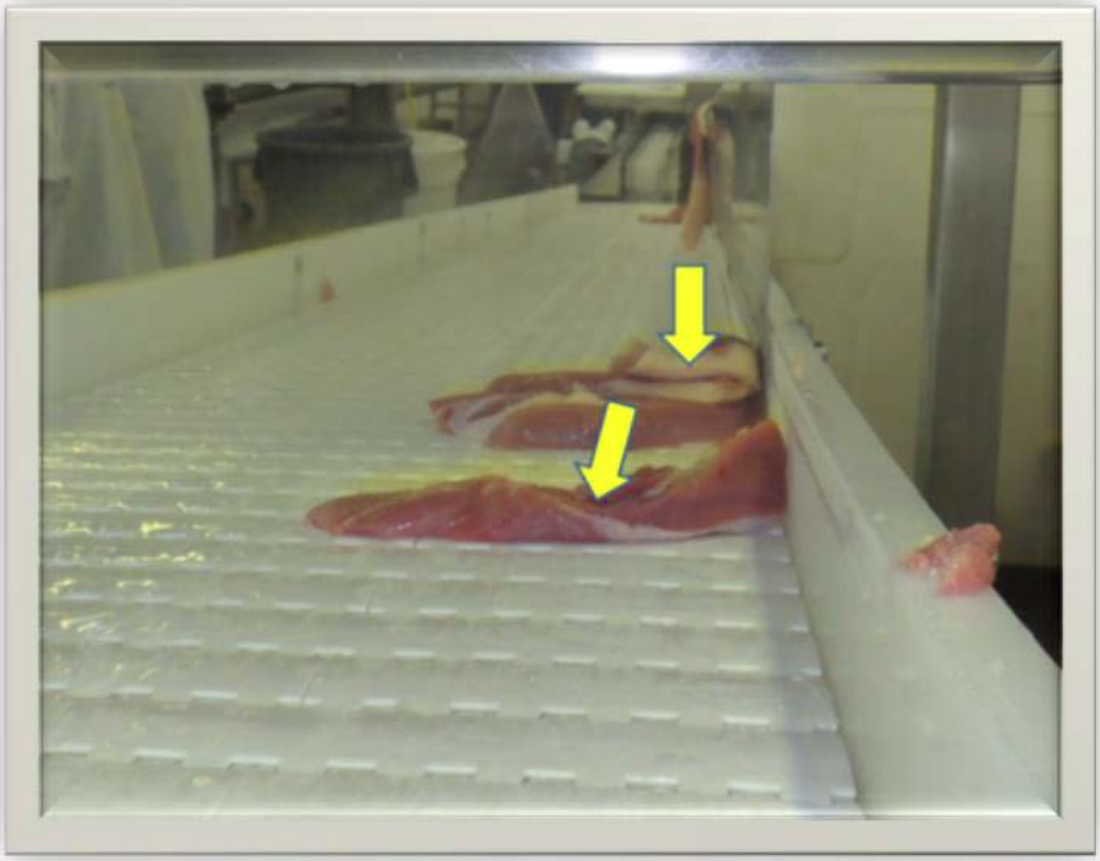


Figure 3. Product is folded as the antimicrobial treatment is applied, which prevents the antimicrobial treatment from achieving full product coverage, a critical operating parameter.

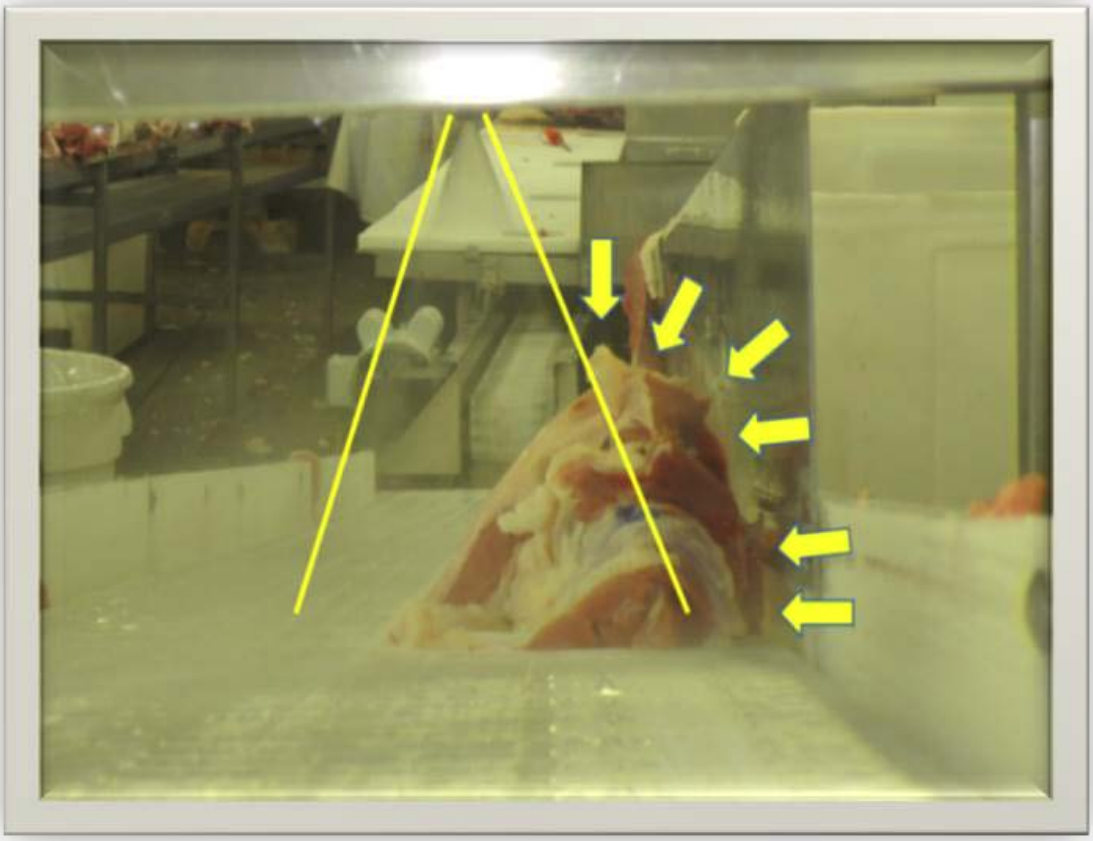


Figure 4. Product is stacked and folded and some of the product is outside the arc of the antimicrobial treatment. As a result, the antimicrobial treatment does not achieve full product coverage, which is a critical operating parameter.

Source: FSIS Directive 10,010.2

Supporting documents

- HACCP checklist
- Meldwijzer Onveilige Levensmiddelen
- "Afhandeling routine veiligheidsmeldingen vlees" (dealing with routine food safety alerts) – document will be sent after translation into English.
- NVWA Sampling Verification Activities for Shiga Toxin

1. PURPOSE AND SCOPE OF APPLICATION

- This instruction describes the requirements which companies must meet in order to be registered for the export of fresh meat of ungulates and/or derived meat products to the USA.
  Note: the inspection and supervision of these companies by the NVWA is detailed in instruction RE-36 United States, NVWA supervision of USA requirements.

2. LEGAL BASIS

2.1. EU regulations

- Regulation (EC) No 999/2001
- Regulation (EC) No 852/2004
- Regulation (EC) No 853/2004
- Regulation (EC) No 854/2004
- Regulation (EC) No 1069/2009
- Regulation (EU) No 142/2011

2.2. National legislation

- Dutch Animal Health and Welfare Act (*Gezondheids- en welzijnswet voor dieren*), Section 79
- Dutch Animals Act (*Wet dieren*)

2.3. USA regulations

- 9 CFR 300ff

2.4. Other

- Instruction RE-29 United States, Salmonella, targeted sampling of carcasses
- Instruction RE-30 United States, Salmonella, screening of carcasses
- Instruction RE-32 United States, Microbiological verification of carcasses and meat
- Instruction RE-34 United States, Listeria sampling (only for Ready-to-Eat products, not shelf-stable)
- Instruction RE-36 United States, NVWA supervision of USA requirements
- Instruction RL-159 United States, pork and beef (issuing health certificates)
- NVWA STEC Verification Activities for Raw Beef
- NVWA Sampling Verification Activities for Shiga Toxin (for raw beef products)
- NVWA project protocol “Audit of USA registered companies’ (registration audits and annual audits of USA registration); this is an internal NVWA document; the targets of the audit are detailed in RE-31 and RE-36)
- USA Audit checklist (SPIN, please refer to the NVWA website[1] as well)

3. DEFINITIONS

FSIS	: Food Safety and Inspection Service
Pre-SSOP	: Pre-Sanitation Standard Operation procedures
SSOP	: Sanitation Standard Operation Procedures
HACCP:	: Hazard Analysis and Critical Control Point; HACCP is a food safety system according to the 7 principles of the Codex Alimentarius, principles and application of the HACCP system, Alinorm 93/13.
HAV	Hazzard Analysis Verification
CCP	: Critical Control Points (please refer to the Codex Alimentarius).
Ready-to-eat	:
Products (RTE) – not	: Ready-made products: foodstuffs intended to be consumed without

[1] https://www.nvwa.nl/onderwerpen/export-dieren-dierlijke-producten/inhoud/landeneisen-voor-dierendierlijke-producten/verenigde-staten-van-amerika-exporteisen-veterinair/verenigde-staten-van-amerikaexporteisen-vlees-en-vleesproducten

shelf-stable:	the requirement of further heat treatment, or treatment or processing with a similar effect (examples: cooked and fermented sausages, corned beef, sliced ham and luncheon meat, carpaccio). Listeria examination required.
RTE (not shelf-stable) – fully cooked:	: (examples: cooked and fermented sausages, corned beef, sliced ham and luncheon meat). Listeria examination required.
Not Ready-to-eat: (NRTE) – not shelf-stable	: foodstuffs that require heating before being consumed – the required heating must be clearly indicated on the packaging, otherwise the USA will consider them to be RTE/not shelf-stable and require a Listeria examination.
Thermally processed	: Products that undergo heat treatment in their final packaging. This heat treatment forms a critical control point within the HACCP and has to be validated (example: canned meat).

Product categories
The USA uses various product categories; please refer to the table below. When a company is registered for the USA, the audit documents must state which products to be exported are subject to the audit. FSIS will be informed of the products and the product category/categories. As soon as an already registered company wishes to add a new product for export to the USA, the company has to be re-audited for the relevant product. FSIS will be informed of the product being added and the category to which the new product of the company belongs.

For a detailed list of products and the associated USA Import Codes for certification purposes, please refer to Instruction RL-159 'United States, pork and beef'.

Finished Product Types by Process Category				
Process Categories	Finished Products			
	Raw Product	NRTE Product	RTE Products	Thermally Processed Product
Slaughter	*			
Raw/Non-Intact (Raw/Minced)	*			
Raw/Intact (Raw/Not-Minced)	*			
Thermally Processed/Commercially Sterile				*
Not Heat-Treated/Shelf-Stable		*	*	
Heat Treated/Shelf-Stable		*	*	
Fully Cooked/Not Shelf-Stable			*	
Heat Treated but Not Fully Cooked/Not Shelf-Stable		*		
Product with Secondary Inhibitors/Not Shelf-Stable		*	*	
Eggs/Egg Products Not Applicable				

4. WORKING METHODS

4.1. Companies
In order to be allowed to export to the USA, companies must meet the following additional requirements. In addition to the EU regulations, these are the additional requirements of the FSIS (USA).

All companies (slaughterhouses, cutting plants, cold and frozen stores, and meat product companies) have implemented:

Pre-SSOP and Sanitation Standard Operating Procedures (SSOPs)
- a written, complete cleaning and disinfection plan and registrations with regard to the

application thereof, demonstrably approved and dated by the company manager or branch manager;
- registrations on checklists with regard to cleaning and cleanliness prior to commencement of the activities;
- registrations on checklists with regard to hygiene during the activities;
- verification plan for cleaning procedures and their execution;
- corrective and preventive measures if the results are insufficient, in order to prevent a product from being contaminated;
- daily registration and documentation of inspections, noting the date, time and initials, a description of the shortcoming, the corrective action taken and re-inspections noting the date, time and initials.

Hazard analysis and Critical Control Point
(an obligation under Article 5 of Regulation (EC) No 852/2004)

- HACCP plan demonstrably approved and dated by the company manager or branch manager;
- demonstrable implementation of the HACCP plan in practice;
- this plan must be validated 60 days after being implemented, by an external expert or an expert of a sister company who is not involved in the HACCP team of the relevant company;
- the description and application of corrective measures in connection with the exceeding of the critical limit value consists of three parts:
  - finding the cause of the shortcoming and eliminating it;
  - describing how the CCP is controlled after taking corrective measures;
  - taking measures to prevent the problem from recurring (to this end, the cause has to be identified and known).
- The HACCP plan has to include STEC as a risk. (See for more details “NVWA STEC-verification Activities, HAV, table 1)

In addition to the verification of the HACCP system, the company has to verify the monitoring of the CCPs on a daily basis. This verification has to be performed by someone other than the person performing the monitoring and should consist of:
- verification of the physical execution of the CCP monitoring;
- duplicate inspection on the basis of a company's own measurement and a comparison of those two outcomes;
- verification of the monitoring list records;
- control of the corrective measures.

Pre-shipment Inspection
The company must have a written procedure for the registration of inspections in which it indicates how, before a batch is dispatched, a (paper) inspection is performed of the CCP management during the production of the relevant batch. The pre-shipment inspection must be signed (not initialled) by the employee.

All inspection records must be initialled by the employee involved. The following details must be indicated: date and time of the shortcoming being identified/the inspection, the nature of the shortcoming, and the date and time of corrective measures and re-inspections. The corrective measures and re-inspections must be initialled as well. The company must have available a current list of all the initials of the trained employees involved.

Procedures with regard to the education/training of employees
The company must have written procedures as regards the training of the employees and, in particular, a description of the education/training provided with respect to the additional USA requirements.

Other requirements for slaughterhouses, cutting plants, cold and frozen stores, and meat product companies:
Animals, carcasses, meat and meat products, not suitable for the USA, must be processed

separately in terms of space or time. Where applicable, the company must lay down the working methods in writing.

Moreover, additional requirements apply for certain companies:

Slaughterhouses and cutting plants

- must have procedures for checking the origin of the animals.
- Procedures with regard to the collection, storage, separation and disposal of category 1, 2 and 3 materials, as laid down in Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011. In particular the removal of the lingual and palatine tonsils. For a possible working method, please refer to Appendix 1 'Identification and removal of SRM material on beef tongues'. The resulting administration must be kept for at least two years.
- must have a microbiological verification programme in accordance with Regulation (EC) No 2073/2005;
- The establishment has to address STEC in its HACCP-system. In the case of a veal slaughterhouses and/or cutting plants the establishments are required to have a NVWA approved STEC sampling protocol according to appendix 2 of this instruction. NVWA considers all product, contaminated with STEC O157:H7 and the following 8 non-O157 STEC: O26, O45, O103, O104, O111, O121, O145 and O174 (Dutch top 9), and stx, and eae/aagR+aaiC genes present, to be ineligible for export to the USA. Therefor the establishment has to control the pathogen or prevent the potential pathogen from becoming reasonably likely to occur through preventive measures.

4.2. Sampling

The NVWA takes the samples required by the USA. For more information on this, please refer to: Instruction RE-36 'United States, NVWA Monitoring of USA requirements', the specific instruction referred to in section 2.4.

The costs associated with the USA samples will be charged to the relevant company. For details on sampling for 'species testing', please refer to Appendix 5 of Instruction RL-159 'United States, meat and beef'; for details on sampling for 'pff management', please refer to Appendix 6 of Instruction RL-159.

5. POWERS AND RESPONSIBILITIES

For the activities of the NVWA regarding the registration of companies for export to the USA and the NVWA inspection and supervision of companies that are already registered, please refer to RE-36 'United States, NVWA Monitoring of USA requirements'.

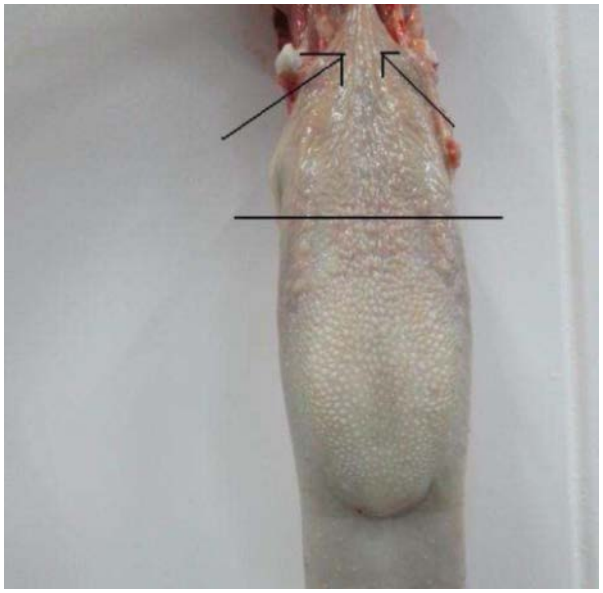
6. EXPLANATION

In anticipation of the future functional separation between inspection and enforcement, some of the information formerly included in the export project protocols has been moved to this instruction. This ensures that the information is available to every supervising veterinarian and to the companies.
There is still an export project protocol (VYNT XX04) which regulates the export registration audits in respect of the export of meat and beef to the USA and of the annual audits of establishments with export registrations. For to the extent possible, the export project protocol refers to this instruction and to Instruction RE-36 'United States, NVWA Monitoring of USA requirements'. The export project protocol only contains the information that is exclusively relevant to the auditor.

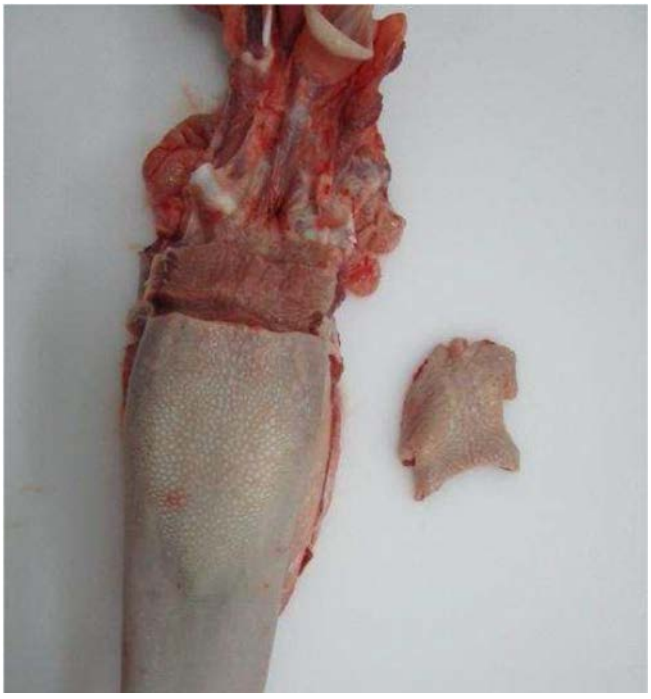
Appendix 1: **Identification and removal of SRM material on beef tongues**

Tonsils (oral) can be found in four anatomical locations: palate, pharynx, buccal tongue and lingual tongue.

The removal of lingual tonsils, minimum requirements (removal of visible tonsil tissue).



The lower limit for tonsillar tissue is indicated by the black line, around the vallate papillae that are closest to the back of the tongue. The upper limit is drawn where there are visible holes in the mucous membrane (the crypts). The lingual tonsils are found here, down to a depth of several millimetres. These tonsils are not located on the side of the tongue, only at the top. A possible working method is to remove the indicated area by means of an incision of at least 5 mm deep, taking away all the mucous membrane as described above along with the underlying tissue. After this procedure, this is what the tongue will look like:



The part removed is considered category 1 material.

Appendix 2: **STEC sampling protocol**

Each veal slaughterhouse and/or cutting plant is required to work according to its own written STEC sampling protocol. This protocol needs to be send to export@nvwa.nl for approval by the NVWA and will only be valid if signed by the head of the TO import/export department after approval. All STEC sampling protocols will be evaluated and only approved if in line with US legislations.

The STEC sampling protocol should address the following:

- **Products to be tested**
  This should at least contain all (bench)trimmings and other materials that can be used as source material for ground beef and other products. The use of only carcasses as a tested product is not allowed.

- **Lot size**
  The establishment should define how much product is going to be grouped together to constitute a "lot" (e.g., combo bins of trimmings; boxes of packaged head meat or cheek meat). This lot definition is not to be changed on the results of testing. Lots should be microbiologically independent from each other. A lot is never allowed to constitute more than one day of production.

- **Statistical sampling methods for selecting lots**
  Define which lots are to be sampled and with what frequencies. Each individual lot should be sampled and tested.

- **Slice size and number of slices**
  Define the size of the sample by specifically defining the size of each slice and the amount of slices taken.

- **Collection method for selecting samples**
  With all collection methods, specifications should be designed to ensure that a high percentage of the collected product that is to be used for testing consists of exterior surface tissue. The establishment should describe a collecting method that selects product at multiple sites within the lot or multiple production intervals within a given lot, for it to be more likely to detect pockets of contamination than a sampling plan that samples at fewer sites or production intervals. Potential contaminants will be on the exterior surface of the product that was exposed during the slaughter and dressing process. Therefore, collection methods must also provide more surface area for the test increase the sensitivity of the sampling.

- **Procedures for preparing a sample analysis**
  The establishment should clearly describe the procedures for the collecting of the samples with easy to follow clear instructions.

- **Sample size analysed in a laboratory**
  Which part of the sample size will be analysed in a laboratory. Pooling is optional but must be validated.

- **Laboratory testing method used**
  The laboratory test must be:
  1. Validated for testing relevant foods by:
     a. a recognized independent body (i.e., AOAC, AFNOR, MicroVal, NordVal), or
     b. a U.S. regulatory body (i.e. FSIS MLG or FDA BAM),or
     c. the NVWA, or
     d. or an ISO method

2. The validated method should be:
    a. Fit for the intended purpose and application, and
    b. Performed under validated conditions by a laboratory that assures the quality of the analytical results.

- **Actions taken when samples are positive**
  Corrective actions should be written down in this protocol. The actions are towards both the sampled lot, it's destination, CCP if applicable and the process. Corrective actions should include identifying and eliminating the cause of the deviation and/or reassessing the HACCP plan and determining whether changes to it are necessary. Additional corrective actions should be written down in the case of a High Event Period.

For further assistance in developing a STEC sampling protocol the establishment can use FSIS Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers

Until this protocol is approved, the currently exporting establishments are only allowed to export raw intact veal to the USA and are required to sample each batch of product exported to the USA according to the N60 method (see FSIS directive 10.010.1, attachment 2) with lab test according to ISO 13136. (e.g. exporting 20 different products in one shipment requires 20 N60 samplings with negative results).

Appendix 3: **KEY POINTS**

The establishments and the laboratories involved has to meet the following requirements:

1. **Sampling method:** N60 has to be used for sampling both beef manufacturing trimmings and bench trim; ground beef/ground beef products: see "NVWA Sampling Verification Activities for Shiga Toxin", Chapter 5.
2. **Sample size:** at least 325g (beef/veal, organs);
   Ground beef: 2lb (ca.900 gram) sample of ground beef product from the current day's production in final packaged form
3. **Testing method:** equal to ISO/TR 13136:2012
4. **E.coli serogroups:** O157:H7 and the following 8 non-O157 STEC: O26, O45, O103, O104, O111, O121, O145 and O174 (Dutch top 9), and stx, and eae/aagR+aaiC genes present.
5. **Detection limit:** The detection limit of the method of the NVWA was determined to be **3CFU/25g;** the laboratories, testing for the establishments, has to reach at least the same detection limit.
6. **HEP:** Positive rate statistically significantly greater than 5%,

Table 1: HEP Criteria when Establishment test more than 60 samples per Day or local HEP for 10 consecutive samples

Unacceptable # Positives	Number of Samples	Confidence	Observed Percentage of Positive
3	10	98.8%	30.0%
8	61	98.9%	13.1%
9	74	98.9%	12.2%
10	86	98.9%	11.6%
11	100	98.9%	11.0%
12	113	98.9%	10.6%
13	127	98.9%	10.2%
14	141	98.9%	9.9%
15	155	98.9%	9.7%
16	169	98.9%	9.5%
17	184	98.9%	9.2%
18	198	98.9%	9.1%
19	213	98.9%	8.9%
20	228	98.9%	8.8%

In the event the establishment has not (yet) developed or appropriated supported HEP criteria, **the specific HEP criteria NVWA will use during traceback and oversight (audit and HAV) are:**

1. **For a local HEP**: 3 or more STEC (or virulence markers) positive results out of 10 consecutive samples from production lots containing same source materials; that is, the trim was produced from one or more carcasses slaughtered and dressed consecutively or intermittently within a defined period of time (e.g., shift); and

2. **For a systemic HEP**: 7 or more STEC (or virulence markers) positive results out of 30 consecutive samples from production lots containing same source materials.

7. **Kind of product sampled:**
   Establishments: intact/non-intact products according to prior consultation with NVWA, as laid down in their NVWA approved STEC-plan according to RE-31, Appendix 2.
   NVWA: STEC-verification In the frame of the intended NVWA STEC-verification the whole range of products an establishment, registered for the export to the USA, is allowed to export to the USA will be sampled. See for details about the intended program: “NVWA STEC verification Activities Raw Beef” (based on Directive 10,010.2) and “Sampling Verification Activities for Shiga Toxin” (based on Directive 10,010.1) .
8. **Frequency:**
   Establishments: daily
   NVWA: verification at least four times per month (intact); for non-intact veal the sensible frequency has to be evaluated at a later date, when export of non-intact veal is under reasonable consideration. However, it will be for non-intact at least the same frequency as for raw intact products, which is at least four times per month.

9. **Activities concerning Supplier/retail:** See “NVWA STEC verification Activities Raw Beef” (based on Directive 10,010.2) and “Sampling Verification Activities for Shiga Toxin” (based on Directive 10,010.1).
10. **Control of tested product:** NVWA requires establishments to hold or maintain control of product that is tested for STEC pending receipt of acceptable test results. See chapter III.I.A.1. “NOTE” in document “NVWA STEC verification Activities Raw Beef” about appropriate disposition and the requirement in the context of hold or maintaining control of product by the establishment.
11. **Regularly actions (STEC positives):** See “NVWA STEC verification Activities Raw Beef” (based on Directive 10,010.2) and “Sampling Verification Activities for Shiga Toxin” (based on Directive 10,010.1).