



United States Department of Agriculture

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Food Safety and  
Inspection Service

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

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

Dear Dr. Bruschke:

The Food Safety and Inspection Service (FSIS) conducted an equivalence verification audit of the Netherlands' meat and processed egg inspection systems from June 2-26, 2014. The meat inspection system audit included pork and beef products. Please find the reports for these respective audits attached.

In the processed egg products report, the Netherlands' processed egg products inspection system has been determined to be equivalent to that of FSIS, and meets the U.S. level of protection. Therefore, FSIS intends to reinstate the Netherlands' eligibility to export processed egg products to the United States on the date the final audit report is published. Enclosed is the draft final audit report. Please provide comments within 60 days of the receipt of this letter. FSIS will provide the final copy of the report to you with your comments attached. The final audit report will be posted to the FSIS website, with any comments received from your government.

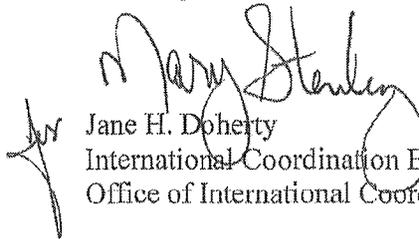
After the report is posted, FSIS will respectfully request that the Netherlands submit a list of government certified egg processing establishments. FSIS will post the establishment list on its website and the Netherlands can begin to export processed egg products to the United States. For more information, please refer to the Code of Federal Regulations (CFR) 590.900 for FSIS' processed egg products import requirements. Specifically, 9 CFR 590.915 for inspection certificate requirements, 9 CFR 590.950 and 590.955 for labeling information. Additional information on import certificate requirements can be found on the FSIS webpage found at this hyperlink: (<http://www.fsis.usda.gov/Product-Categorization.pdf>). This reference provides details on product categorization that must be included on the import certificates. Information specific to processed egg products can be found on page 14.

There were no findings for the pork aspect of the meat inspection system audit. Therefore, the Netherlands continues to maintain an equivalent meat inspection system for pork products that meets the U.S. level of protection.

However, FSIS identified concerns with the meat inspection system for beef products. In response to these findings the Netherlands proffered a corrective action plan that has been reviewed by FSIS. FSIS has determined that all concerns have been addressed. However, prior to permitting beef exports to the U.S., FSIS will conduct an audit to verify the implementation of this plan. Enclosed is the final audit report for the Netherlands' meat inspection system that will be posted on the FSIS web site. This report is combined to include both pork and beef products.

FSIS is committed to work with you on resolving issues with export of beef products to the United States. Please feel free to contact Dr. Andreas Keller at telephone number (202) 720-0082, facsimile number (202) 720-7990, or by e-mail at [InternationalEquivalence@fsis.usda.gov](mailto:InternationalEquivalence@fsis.usda.gov) if you have any questions about the enclosed materials.

Sincerely,

  
Jane H. Doherty  
International Coordination Executive  
Office of International Coordination

Enclosures

FINAL REPORT OF ON-SITE EQUIVALENCE VERIFICATION AUDIT

CONDUCTED IN

THE NETHERLANDS

June 2 – 26, 2014

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING  
THE PRODUCTION OF MEAT PRODUCTS INTENDED FOR EXPORT TO  
THE UNITED STATES OF AMERICA

Food Safety and Inspection Service  
United States Department of Agriculture

## Executive Summary

In March 2014 USDA's Animal and Plant Health Inspection Service (APHIS) issued a final rule that lifted restrictions on the importation of beef from countries classified by the World Animal Health Organization (OIE) as a "controlled risk" for Bovine Spongiform Encephalopathy (BSE). Commensurate with this change, USDA's Food Safety and Inspection Service (FSIS) decided that it would consider reinstating the eligibility to ship beef to the United States of countries affected by the APHIS rule change. To assess the equivalence of those countries, the countries would need to pass an FSIS audit of their food safety system for beef.

The Netherlands is eligible to export only pork products to the United States. This report describes the equivalence verification activities and onsite audit that FSIS conducted from June 2 – June 26, 2014, to determine whether the Netherlands is eligible to resume beef exports to the United States. Through the audit, FSIS also verified whether the Netherlands' meat inspection system for pork continues to be equivalent to FSIS's inspection system. The audit focused on six components of the Netherlands' food safety system for beef products: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. The FSIS auditor assessed the system through review of information the Netherlands' Food and Consumer Product Safety Authority (NVWA), the Central Competent Authority (CCA) provided through the Self-Reporting Tool (SRT) and performance of on-site audit activities.

The on-site audit demonstrated that the meat inspection system and control measures applied for the production and export of swine continues to be equivalent to FSIS's inspection system. The inspection program personnel assigned to pork establishments demonstrated ability to undertake their duties competently and to carry out official duties consistently. The control measures applied to the bovine inspection as implemented, however, could not guarantee the export of unadulterated beef and beef products to the U.S. on a continuous basis. The audit identified concerns related to the effectiveness of training programs for official veterinarians and auxiliary employees assigned to beef establishments. The inspection program personnel do not appear to be adequately trained to conduct effective verification measures and initiate appropriate enforcement actions when warranted. The FSIS audit findings include: Failure of NVWA inspection personnel to ensure removal of Specified Risk Materials (SRMs), particularly lingual tonsils; Failure of NVWA to ensure that in-plant inspection personnel verify whether implementation of dressing procedures during beef slaughter operations is adequate; and Failure of NVWA inspection personnel to consistently verify whether the establishments' HACCP systems are adequately controlling the presence of fecal material and ingesta on beef carcasses.

The FSIS audit findings indicate a need to improve in the government oversight functions, enhance coordination between the CCA headquarters and the team leaders in the field, ensure that supervisory reviews adequately focus on the competence of the inspection program personnel, and enhance the effectiveness of the ongoing training program of the inspection personnel assigned at bovine slaughter establishments to bring their performance to the satisfactory level exhibited in pork establishments.

While the import of pork product continues to occur under an equivalent system, the ability of the inspection system to ensure export of beef product that is safe, unadulterated, and properly labeled can be compromised if audit findings are left without remedies. Therefore, FSIS requests that the NVWA provide a comprehensive corrective action plan addressing the specific audit findings and documentation to show that corrective actions were effectively implemented.

The CCA proffered a corrective action plan and provided supporting documents during and after the exit meeting showing that the corrective actions had been implemented. FSIS's assessment of the corrective actions taken by NVWA in response to the findings of the audit indicated that the CCA has adequately addressed the identified issues of concern. Before permitting the import of beef from the Netherlands, FSIS will conduct an on-site equivalence verification audit. Through the follow-up audit, FSIS will verify whether the Netherlands' corrective actions were effectively implemented in response to FSIS's findings. The findings and Netherlands' corrective actions are described in this report, within the specific equivalence component sections. Once FSIS determines that all outstanding issues have been adequately resolved, FSIS will reinstate the system equivalence related to production of beef and re-establish the Netherlands eligibility to export beef products to the United States.

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## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

APHIS	Animal and Plant Health Inspection Service
CCA	Central Competent Authority
CFR	Code of Federal Regulations
CVO	Chief Veterinary Officer
EC	European Commission
EU	European Union
EU-RLs	European Union Reference Laboratories
<i>E. coli</i>	generic <i>Escherichia coli</i>
<i>E. coli</i> O157:H7	<i>Escherichia coli</i> O157:H7
FSIS	Food Safety and Inspection Service
IG	Inspector- General
ISO/IES	International Organization for Standardization/International Electrotechnical Commission
KDS	Quality Inspection Livestock Sector ( <i>Kwaliteitskeuring Dierlijke Sector</i> )
LIMS	Laboratory Information System
<i>Lm</i>	<i>Listeria monocytogenes</i>
NVWA	The Netherlands Food and Consumer Product Safety Authority ( <i>Nederlandse Voedsel- en Warenautoriteit</i> )
NRL	National Reference Laboratory
MEA	Ministry of Economic Affairs
OIE	World organization for animal health
HACCP	Hazard Analysis and Critical Control Point System
RASFF	EU's Rapid Alert System for Food and Feed
RIKILT	Institute of Food Safety
RVA	Dutch National Accreditation Body
<i>Salmonella</i>	<i>Salmonella</i> species
SPS	Sanitation Performance Standards
SRMs	Specified Risk Materials
SSOP	Sanitation Standard Operating Procedures
STEC	Shiga Toxin–Producing <i>Escherichia coli</i>
TPCS	Thermally processed, commercially sterile
USDA	United States Department of Agriculture
VIC	Veterinarian-in-Charge
VWS	Ministry of Health, Welfare and Sports
ZBOs	Semi-autonomous public bodies ( <i>Zelfstandig Bestuursorganen</i> )

## I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of the Netherlands' meat inspection system in the period from June 2-26, 2014. The Netherlands is currently eligible to export pork to the United States (U.S.) and seeks to re-establish its eligibility to export beef. The Netherlands' request to reinstate its equivalence for beef was based on the March 2014 lift of the restriction on import of beef from the European Union (EU) by USDA's Animal and Plant Health Inspection Service (APHIS). FSIS conducted this audit to verify whether Netherlands' inspection system for meat products is equivalent to FSIS's.

The onsite audit began with an entrance meeting held in Utrecht on June 2, 2014, at the headquarters of the Netherlands' Central Competent Authority (CCA), the Netherlands Food and Consumer Product Safety Authority (*Nederlandse Voedsel- en Warenautoriteit-NVWA*). The participants of the meeting included representatives from the CCA, the Ministry of Economic Affairs, the Ministry of Public Health, and the Embassy of the United States in the Netherlands. The FSIS auditor was accompanied throughout the audit by representatives from the NVWA. This audit was conducted concurrently with FSIS's on-site re-instatement of equivalence audit of the Netherlands' egg products inspection system for which the outcomes are reflected in a separate audit report.

The audit was conducted to assess whether the country continued to maintain an equivalent inspection system in accordance with the requirements of specific provisions of the U.S. laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to End)
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901 et seq.)

In addition, the audit verified that the inspection system implements and enforces equivalent provisions of EC regulations and directives including:

- European Commission (EC) Regulations 999/2001 *as amended*, 178/2002;; 852/2004; 853/2004; 854/2004; 882/2004; 41/2004; 396/2005; 2073/2005; 1881/2006; 1883/2006; 333/2007; 470/2009; 1069/2009; 1099/2009; 1774/2002; 726/2004; and 37/2010; and Council Directives found equivalent under the Veterinary Equivalence Agreement (VEA), 96-22 and 96-23; and
- The Netherlands' national laws, decrees, regulations, policy, and instructions issued to ensure the implementation of the overarching EC 2004 legislation and other inspection control programs governing the product and export of meat products to the U.S.

Currently, FSIS has found the following requirements and procedures employed by the Netherlands' inspection system equivalent to FSIS's requirements:

- The use of the ISO 6579 methods by official laboratories to detect *Salmonella* in meat products collected by CCA's inspection personnel.
- Establishments' testing for *Enterobacteriaceae* an indicator organism in lieu of generic *E. coli* testing program.

- Visual post-mortem inspection of market hogs, as an alternative post-mortem inspection procedure, supplemented by review and verification of the animals' Supply Chain Information.
- Use of third-party inspection personnel (*Kwaliteitskeuring Dierlijke Sector-KDS*) to perform post-mortem inspection tasks in U.S. certified establishments as a reimbursable service by NVWA.

## II. AUDIT OBJECTIVES, SCOPE, AND METHODOLOGY

The audit objective was to verify whether the Netherlands' food safety system governing inspection of meat products derived from bovine and swine is equivalent to that of the U.S., and is capable of ensuring that pork and beef products exported to the U.S. are safe, wholesome, unadulterated, and properly labeled.

In pursuit of this objective and prior to the onsite audit, FSIS conducted an extensive review of the information provided by the Netherlands through the Self Reporting Tool (SRT) and accompanying references. These documents provide a comprehensive overview of the relevant legislation, and procedures supporting the Netherlands' meat inspection system.

The FSIS auditor evaluated the CCA's official controls to ensure that all aspects of the national meat inspection system are being implemented as intended. This includes how the reorganization of the NVWA, which was completed in 2011, affected the CCA's ability to supervise and coordinate official control and verification activities. The re-organization resulted in the centralization of the CCA's functions, elimination of regional offices, establishment of team offices, and reduction of the numbers of official auxiliaries. The scope of the FSIS review and evaluation covered the CCA headquarters in Utrecht, the NVWA pork inspection team offices at Boxtel, Raalte, Apeldoorn, and the NVWA beef inspection team offices at Lichtenvoorde, Nieuwerkerk aan den IJssel, 's-Hertogenbosch and Apeldoorn.

FSIS audited nine establishments, of which three are certified to export pork products (two slaughter and processing establishments and one canning establishment), and six proposed by the CCA to be certified for U.S. beef exports (four slaughter and processing establishments, one processing establishment, and one cold storage). During the establishment reviews, the auditor paid particular attention to the extent to which industry and government interact to control hazards, and prevent noncompliance that threaten food safety, with an emphasis on the CCA's ability to provide supervisory reviews in accordance with the requirements described in Title 9 of the Code of Federal Regulations (CFR) 327.2.

The scope of the audit also included an assessment of the CCA's oversight activities of two government laboratories conducting chemical residue and microbiological official testing in conjunction with the export of product to the United States. The FSIS auditor visited the National Institute of Public Health and the Environment (RIVM) in Bilthoven, which serves as a national reference laboratory for food safety and microbiological testing, and the NVWA Food Safety Laboratory in Wageningen, which carries out routine chemical and microbiological analysis of official regulatory samples. The FSIS audit included interviews of laboratory personnel, observations, and a review of one year of laboratory data related to residue testing programs as well as microbiological testing programs for *Salmonella* in meat products. The FSIS auditor also reviewed the testing programs for *E. coli* O157:H7 and non- O157:H7 Shiga toxin-producing *Escherichia coli* (STEC) in beef, and verified that the inspection system uses

equivalent analytical methods. The Netherlands is intending to export only intact beef (veal) products to the United States.

### Audit Scope Summary

Competent Authority Visits		No.	Locations
<b>Competent Authority</b>	Central	1	<ul style="list-style-type: none"> <li>The Netherlands Food and Consumer Product Safety Authority (NVWA) - CCA Headquarters office (Utrecht).</li> </ul>
	Team offices	6	<ul style="list-style-type: none"> <li>Boxtel (pork products)</li> <li>Raalte (pork products)</li> <li>Apeldoorn (beef and pork products)</li> <li>Lichtenvoorde (beef products)</li> <li>Nieuwerkerk aan den IJssel (beef products)</li> <li>Hertogenbosch (beef products)</li> </ul>
	Local offices	6	Reviews of local inspection offices were conducted as part of the establishment reviews at Nieuwerkerk aan den IJssel, Raalte, Boxtel's-Hertogenbosch, Lichtenvoorde and Apeldoorn.
<b>Government Laboratories (Residue and Microbiological testing programs)</b>		2	<ul style="list-style-type: none"> <li>National Institute of Public Health and the Environment (RIVM) (Bilthoven)</li> <li>NVWA laboratories for food safety (Wageningen)</li> </ul>
<b>Establishments</b>			
• Meat Slaughter-processing		6	<ul style="list-style-type: none"> <li>Est. NL 9 EG, EKRO B.V. (<i>Bovine Slaughter and processing</i>)</li> <li>Est. NL 34 EG, T. Boer en Zonen B.V. (<i>Bovine Slaughter and processing</i>)</li> <li>Est. NL 49 EG, Vitelco B.V. (<i>Bovine Slaughter and processing</i>)</li> <li>Est. NL 369 EG, ESA B.V. (<i>Bovine Slaughter and processing</i>)</li> <li>Est. NL 61 EG, Vion Boxtel B.V. (<i>Swine Slaughter and processing</i>)</li> </ul>
• Meat Processing		2	<ul style="list-style-type: none"> <li>Est. NL 312 EG, Vion Apeldoorn B.V. (<i>Swine slaughter and processing</i>)</li> </ul>
• Cold Store		1	<ul style="list-style-type: none"> <li>Est. NL 939 EG, T. Boer en Zonen B.V. (<i>Bovine processing-Raw, Not Ground</i>)</li> <li>Est. NL 153 EG, Zwabenberg Food Group B.V. (<i>Swine processing-canning</i>)</li> </ul>
<b>Total</b>		9	<ul style="list-style-type: none"> <li>Est. NL 451 EG, Koel- en Vrieshuis Lintelo BV (<i>Cold storage</i>)</li> </ul>

### III. BACKGROUND

The Netherlands is a member of the EU and consequently conforms to the EC legislation and issues national regulations and procedures to address aspects of the regulations, programs or export requirements that need to be implemented and verified by the CCAs of Member States. The Netherlands is currently eligible to export meat products, exclusively pork, to the United States. The export of beef product was interrupted because of restrictions related to Bovine Spongiform Encephalopathy (BSE). On March 29, 2014, APHIS issued a final rule amending the regulations governing the importation of products derived from bovines and allowed importation of beef from EU Member States that have a controlled or negligible risk for BSE. Upon conclusion of the analysis of the references provided by the Netherlands' CCA in its response to the SRT, FSIS conducted this on-site audit of the meat products inspection system with emphasis on beef to determine whether the Netherlands is eligible to resume beef exports to the United States.

### IV. COMPONENT ONE: GOVERNMENT OVERSIGHT

The first of the six components that the FSIS auditor reviewed was Government Oversight. FSIS's import eligibility requirements state that the foreign inspection system must be designed and

administered by the national government of the foreign country, with standards equivalent to those of the meat inspection system in the United States, as described in 9 CFR 327.2. The evaluation of this component included a review and analysis of documentation previously submitted by the CCA, as support for the responses provided in the SRT, onsite record reviews, interviews, and observations made by the FSIS auditor at government offices, laboratories, and establishments.

The FSIS auditor assessed how the Netherlands' meat inspection system is organized and administered to promulgate and enforce food inspection regulations, ensure food safety, and certify meat products when they meet the requirements for export to the United States.

The Netherlands' Food and Consumer Product Safety Authority (NVWA) is the CCA overseeing the production and export of meat products 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 Dutch legislation provides for the establishment of independent non-profit organizations (*Zelfstandig - Bestuursorganen*-ZBOs) to implement specific inspection tasks in the public interest. Non-profit organizations are led by chiefs who are nominated by, and report directly to the founding Ministry. The Quality Inspection Livestock Sector (*Kwaliteitskeuring Dierlijke Sector*-KDS) is an independent organization founded by the MEA, tasked with the performance of post-mortem inspection, and other inspection verification activities on behalf of, and under the supervision of, the NVWA official veterinarians.

KDS is considered as part of the national government commissioned under provisions of the Netherlands' legislations to perform tasks that are set jointly by multiple government entities. Its hierarchy coupled with some management autonomy, enables the establishment of collaborative partnerships between organizations within national government and between organizations belonging to different levels of government. KDS staff is employed under general civil service rules and funded mainly through allocations from the government budget and partially through inspection fees. KDS differs from NVWA in its management through a board of directors, review process through audit, and accountability through direct reporting to the founding MEA, one of the two ministries overseeing the NVWA.

The FSIS auditor verified that the CCA carries out its responsibility by inspecting food products throughout the production chain from farm to fork. The NVWA has a centralized structure that directs the implementation of its tasks for the specific year, including delegated tasks, and provides reports to the Ministries of VWS and MEA. The NVWA is headed by an Inspector- General (IG) and assisted by the Deputy IG. The CCA consists of seven sectors including 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 relevant 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 and the Agriculture and Nature 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 establishments currently certified by the CCA to export pork or proposed for certification to export beef are inspected by NVWA inspection personnel that include a Veterinarian-in-Charge (VIC) and senior controllers or assistants. The inspection personnel are supervised by the inspection team leader or by the senior systems auditor stationed in the team office, who reports directly to NVWA headquarters. The team leader or the senior systems auditor is responsible for performing periodic internal reviews of the establishments certified as eligible to produce products for export to the United States. 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 inspectors conduct post-mortem inspection procedures and other assigned verification activities in accordance with the standards set by the NVWA. In-plant inspection personnel conduct inspection activities at individual establishments at least once per shift for processing of pork in U.S. certified exporting establishments and on-line inspection during all slaughter operations in establishments that are seeking to be certified for the export of beef to the United States. A team of NVWA auditors is assigned the responsibility of conducting periodic system audit activities in a group of establishments within the territory covered by the team office.

The FSIS auditor verified that inspection personnel assigned to the establishments currently certified for pork export or stationed at the establishments proposed for certification for beef exports are full-time government-paid employees. The inspection and verification activities are conducted under the direct authority of the NVWA. The NVWA pays KDS, which distributes payments to auxiliary inspection personnel for the time they spent performing the inspection procedures. The NVWA takes measures to ensure that there are no conflicts of interest situations for the KDS auxiliary employees. NVWA sends invoices to the slaughter facility through official government channels, collects payments, and reimburses KDS annually for its services.

The FSIS auditor verified that the NVWA has the authority and responsibility to hire and assign competent, qualified inspectors to official establishments that will export products to the United States. The review of the training records, at the NVWA headquarters and the team offices, demonstrated the CCA takes control measures to ensure that its inspection personnel including official veterinarians, assistant veterinarians, and auxiliary employees have appropriate educational credentials and receive training to enable them to carry out their assigned inspection tasks. For example, the basic training of veterinarians includes general topics such as HACCP and specific requirements related to export of meat products to the United States. The specific requirements are addressed through on-the-job training at the establishment level.

The NVWA takes measures to ensure that inspection personnel are kept informed about export requirements by posting new FSIS requirements on the NVWA website. Furthermore, the training manual and current training programs are posted on the NVWA website and are readily available to the inspection program personnel. However, the CCA needs to take additional measures to ensure that its ongoing training program is effective; specifically, based on findings discussed below, the training program designed for official veterinarians assigned to bovine slaughter establishments needs to be improved and made more effective. This improvement must be coupled with measures to ensure that KDS auxiliary inspectors are proficient on the specific requirements related to U.S. exports. The FSIS auditor identified weaknesses in the inspectors' performance of the inspection activities related to the verification of the establishments' HACCP monitoring and verification procedures, removal of the SRMs, and response to incidents of contamination of carcasses (zero tolerance for feces, milk and

ingesta). The FSIS auditor did not identify similar findings or notice analogous weakness in the performance of the inspection activities at pork establishments. This difference in findings suggests a need for the CCA to develop, and ensure that its employees implement a uniform approach to the inspection activities that achieve the program objectives.

Following the FSIS audit, as part of its corrective actions, the CCA started a training program to ensure that newly appointed veterinarians receive official training that takes into account US-export requirements. The CCA also implemented a similar training program as an annual requirement for veterinarians assigned to establishments that are certified as eligible to export processed pork or that intend to be certified to export slaughtered beef products to the United States. Additionally, NVWA veterinarians are to hold regular meetings with KDS personnel. These meetings are to cover training on the US-export requirements at least twice a year. The NVWA amended its Working Manual RE-31 to include instructions for the inspection personnel on how to verify removal of SRM (lingual tonsils) and to ensure that each establishment that intends to export beef product to the U.S. conducts and documents a training program for the establishment's employees on SRM removal.

The official inspection of meat establishments is organized into national projects and includes periodic assessment of the establishments' food safety systems. The frequency of these assessments depends on the assigned risk category, production volume, and the type of establishment, but a minimum frequency of once a year is applied. The NVWA uses an approach identified as an "effective monitoring approach" to organize official controls, including inspection protocol and audit methodology, that are aimed to reduce the burden of supervisory reviews and official control of the establishments. Thus, NVWA focuses on the highest risk areas of the establishments, and targets the establishments that show a trend of non-compliance or inadequate quality assurance programs.

The auditor's assessment of the implementation of the NVWA's official program found a need for closer coordination between the CCA headquarters and the team leaders to ensure that the observations made during the periodic supervisory reviews are linked to the results of the daily inspection verification activities. Use of an analytical instrument to link this information will allow the CCA to recognize trends, identify training needs, and develop effective measures to assess the system's ability to address concerns, track progress, and determine the effectiveness of its policies.

The Netherlands provided a corrective action that addressed this finding and implemented measures to enhance coordination between the CCA headquarters and the inspection program personnel in the field. These measures include monthly supervisory reviews by the team leader and weekly meetings with the head of the section who is a part of the Management Team (MT) of the Veterinary & Import division of the NVWA. The MT, with the participation of the head of the section, meets every week and discusses the results of the supervisory reviews and the outcome of NVWA audits. The head of the section shares the MT recommendations for improvement with the team leader and inspection program personnel. These coordination measures ensure better communications between different levels of the inspection system and enhance effectiveness of the inspection control programs.

The FSIS auditor's assessment concluded that inspection program officials have adequate regulatory control to perform official inspection activities, and legal authority to enforce relevant legislation. 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. The CCA 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 that includes the reasons for the decision, the criteria the corrective actions need to meet, and the right of the establishment to appeal. However, the auditor's assessment of the implementation of the enforcement program identified situations where the inspection personnel stationed in beef establishments failed to use available tools to initiate regulatory control actions or other effective enforcement measures in response to non-compliances that resulted in direct product contamination.

The FSIS auditor verified that the inspection activities are carried out and documented in checklists and further recorded in a database system available to all NVWA inspectors. In all establishments visited, the reports of official inspection were made available to the FSIS auditor. In response to non-compliances the CCA takes action to verify that the establishment remedies the situation. However, in some instances, the in-plant inspection personnel indicated that they provided the establishments with a verbal warning or referred particular non-compliances for further action by the team lead or NVWA headquarters. The NVWA, however, did not provide a procedure to ensure effective follow-up on those non-compliances referred for further action to the team lead or NVWA headquarters.

Additionally, the NVWA did not consistently follow its procedure designed to ensure systematic follow-up of a non-compliance as part of the planning tool called the ISI database. The database automatically flags non-compliances that require follow-up verification procedures. The system provides for three possible procedures to be applied in response to incidents of noncompliance: 1) Administrative record (noncompliance records), 2) follow-up visit, or 3) fine and possible withdrawal of the establishment's approval. The procedures include instructions to the inspectors on how to carry out enforcement measures, which may include detention of product under administrative law and seizure of products from the market under criminal law. Nevertheless, the FSIS auditor identified incidents where inspectors did not follow the prescribed course of action. This failure might be attributed to flaws in the team performance.

To address these findings, as part of the overall corrective action plan, the NVWA introduced the use of the M-SPIN mobile digital system, which replaces the ISI database system, at all levels within the Veterinary & Import division. The new digital system is used to provide the inspection personnel with instantaneous records of inspection results, as well as trend analyses that cover seven inspection areas, namely: cleaning and disinfection (sanitation), animal transport, animal arrival and housing, animal stunning and killing, hygiene slaughter processes, animal by-products, and traceability. The M-SPIN system is being used as a tool that enables the inspection team to take effective enforcement measures in response to establishments' noncompliance with regulatory requirements.

The NVWA has the legal authority and responsibility to certify and de-certify establishments for export to the U.S., and the authority to approve and disapprove laboratories conducting analytical testing on products for export to the United States. The CCA's responsibilities related to establishment registration and approval processes for export are described in Article 31 of Regulation (EC) 882/2004 and NVWA regulation RE-31. The NVWA's regulation further defines the conditions that registered establishments must meet in order to be certified to export ruminant meat and other meat products to the U.S., and describes the standard inspection procedure. The FSIS auditor verified that the NVWA implements the

Working Manual (RL-159 USA certification), which provides instructions for the certification of establishments producing pork products for export to the United States. The Working Manual also describes the conditions that govern the importation of meat products to the U.S., and it identifies the monitoring to be carried out by the VIC, and the data that must be provided by the establishment to enable the NVWA to carry out its verification activities. The VIC is authorized to suspend the establishment's operation when the product safety is threatened.

The FSIS auditor assessed the effectiveness of the coordination between the different elements of the CCA, and looked closely at the CCA's ability to provide oversight through supervisory reviews conducted in accordance with the requirements described in 9 CFR 327.2. The auditor found that the Netherlands' meat inspection system provides for periodic supervisory visits by a representative of the inspection system to each registered establishment in accordance with guidance stipulated in the Working Manual RE-31. The FSIS auditor examined the inspection records at nine establishments (beef and pork) and verified that NVWA conducted periodic supervisory reviews.

The supervisory reviews were carried out every month. If results are satisfactory, the frequency changes to once every two months. In cases where outcomes continue to be consistently satisfactory, the frequency can be lowered to once every three months. The supervisory visits focused on controls for: 1) the assignment of the supervising veterinarian; 2) the establishment's prerequisite programs; and 3) the implementation of the establishment's sanitation program and its monitoring and verification activities related to the CCPs established in the establishment's HACCP systems. The results of the supervisory visit were documented in a signed audit report stating the date and time of the review, and the findings were recorded in the Inspection Information System. The team leader may designate a senior system auditor or an assistant system auditor, who is not involved in the audit of the establishment's system, to conduct and document the supervisory visit to registered establishments and report the outcome to the inspection team leader. The NVWA team leader discusses the audit results with his or her manager every three months. The written audit reports and consultations are signed by NVWA managers and filed. The NVWA's Veterinary and Import Division performs internal audits to assess the effectiveness of the monitoring and control activities, and reports the results to the head of the division.

Although the inspection system conducted periodic supervisory visits at all visited establishments, the supervisory reviews at beef establishments did not adequately focus on the competence of the inspection program personnel (e.g., knowledge of U.S. beef export requirements). The findings related to failures of the in-plant inspection to initiate effective enforcement measures, appropriate removal of SRMs, and the prevention of direct product contamination in beef slaughter establishments were either overlooked or not properly addressed through supervisory reviews. The supervisory reviews also need to be enhanced to better assess the effectiveness of the ongoing training program, and identify the training needs for the inspection personnel including KDS inspection personnel stationed in beef slaughter establishments.

The FSIS auditor verified through the review of the supporting documentation provided by the CCA, including the NVWA intranet site, that the CCA maintains a communication system that conveys the U.S. inspection requirements throughout its inspection system in a timely manner. All updates are posted to NVWA's intranet site and distributed by e-mail to inspection personnel. Additionally, all inspection personnel receive e-mail instructions on how to register on the FSIS website to receive updates and become aware of upcoming changes to the inspection procedures or control measures.

The NVWA has instructions for the inspection program personnel describing the conditions that govern U.S. exports and illustrating the verification activities that must be carried out by the NVWA including verification testing programs. The CCA maintains regulatory authority to ensure that products intended for export to the U.S. are properly labeled and packaged as part of the HACCP control and verification process. These regulatory requirements are described in Directive 2000/13/EC on labeling and the Dutch Food Act which includes requirements for the verification of net weight, retained water and the declaration of allergens as further described in VWA instruction RL-159. The FSIS auditor verified that registered establishments carry out verification activities to ensure that food intended for human consumption is adequately labeled and identified to ensure its traceability. The minimum identification for each product includes the source of the food product, any animal by-product used, and ingredients incorporated into the manufactured product in a manner that support an effective investigation and traceability of the final product by the CCA.

The CCA uses the EU's Rapid Alert System for Food and Feed (RASFF) as the primary tool to exchange information with stakeholders related to contaminated or adulterated product in commerce. RASFF provides precise information that enables the NVWA to inform FSIS about food products in commerce that could pose a threat to the public health. The CCA maintains mechanisms to record and address consumer complaints in accordance with Article 19 of the Regulation (EC) No. 178/2002, which requires establishments to remove from commerce any food products that may pose a threat to public health. The CCA maintains mechanisms to record and address consumer complaints in accordance with Article 19 of the Regulation (EC) No. 178/2002, which requires establishments to remove from commerce any food products that may pose a threat to public health.

To address FSIS's findings, the CCA needed to improve its government oversight functions, enhance coordination between the headquarters and team leaders, ensure the effectiveness of its ongoing training program for inspection personnel, and ensure that in-plant inspection personnel in cattle plants consistently initiate effective enforcement measures to prevent product contamination at beef slaughter establishments. The Netherlands sent FSIS the corrective actions discussed above in this section, and documentation showing that those corrective actions have been effectively implemented. FSIS will conduct a follow-up audit to verify that the proffered corrective actions have been effectively implemented for beef slaughter and processing inspection.

## **V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS**

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. For an inspection system to be equivalent, it must provide an appropriate regulatory framework to demonstrate equivalence with FSIS's inspection system. This framework includes, but is not limited to HACCP, sanitation, chemical residue and microbiological sampling, humane handling, slaughter, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily on-line inspections at slaughter establishments, inspection activities occurring at least once per shift in food processing establishments, and periodic supervisory visits to U. S. eligible establishments.

FSIS has determined that the European Commission's (EC) 2004 legislation is equivalent as an overarching legislation, given that the CCAs of the EU Member States address the implementation of

the legislation and other U.S. import requirements through their national laws, regulations, and policies. The FSIS's assessment of the inspection and control programs employed by the CCAs of EU Member States includes review of the country's national food hygiene control plan. The development of a National control plan is required by the EC, and used as a measure of the effectiveness of the food control regulations employed by the CCA. The national plan is updated every five years and evaluated annually. The FSIS auditor verified that the NVWA manages the Netherlands' meat inspection program in accordance with the National Control Plan for the period from 2012 to 2016. The review of the national plan is used to determine whether the official controls employed by the CCA are organized in conformity with the set criteria and the overarching EC legislation.

The Netherlands' complemented the EC 2004 food hygiene legislation through a series of statutory instruments that organize the national framework of control programs related to meat inspection including beef slaughter and processing. The current audit found that the Netherlands' meat inspection system is organized and administered by the central government, and that NVWA officials are assigned to enforce laws and regulations governing the production and export of meat at registered establishments. The CCA maintains a single standard of laws and regulations applicable to all establishments certified for export to the U.S. in accordance with the equivalence requirements of this component, as described in 9 CFR 327.2 and FSIS's equivalence determinations of the EC 2004 legislation. The framework of the inspection and control programs is established in Regulation RA-58 "Identification of porcine animals at the slaughterhouse"; Regulation RA-05 "Identification of bovine animals at the slaughterhouse"; Regulation VKI-03: "Policy guidelines on the deadline for supplying food chain information"; Regulation VKI-01: "Food chain information on domestic animals at the slaughterhouse"; Regulation WLZVL-017 "Monitoring of the welfare of ungulates at slaughterhouses; Regulation RA-91 "AM inspection at a red-meat slaughterhouse; Working Manual "RA-85 VWA-KDS Contract" clause 7 (activities of official auxiliaries) and further detailed in Regulation RA-86 "Supervision protocol". These Statutory Instruments form the basis for a regulatory oversight of meat inspection at slaughter and processing operations.

FSIS's evaluation of this component included the review and analysis of documents submitted by the CCA in the SRT, interviews with inspection officials, and observations made by the FSIS auditor during the onsite audit. The FSIS auditor verified that the CCA carried out official inspections and verification activities as outlined in the official instructions, including enforcement of the humane handling requirements, ante-mortem inspection, post-mortem inspection, control over establishment construction and facilities and equipment, and control over inedible and condemned materials.

The FSIS auditor verified through records review, interviews, and observations that NVWA official veterinarians conducted ante-mortem inspection of swine and bovine 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. In accordance with the regulatory requirements and other established inspection procedures, the official veterinarians observed all animals at rest and in motion in designated holding pens in order to determine whether they were fit for slaughter. The VICs conducted more detailed examination of suspect animals in the designated pens. The results of the ante-mortem inspection were properly documented in accordance with Regulation RA-111 "Instructions for completing the VOS form". The NVWA official veterinarians conducted animal welfare and humane handling verifications activities in accordance with the requirements of Regulation (EC) No. 854/2004 and WLZVL-17, and documented the results of their activities on the WLZVL-018 "Monitoring

Checklist of animal welfare in slaughterhouses”. The humane handling verification activities included measures to ensure that non-ambulatory disabled cattle are not slaughtered or used in meat products intended for export to the U.S. as mandated by regulation RA-72, TSE-voorschrift” chapter 3.2.1.

Although the FSIS auditor verified that humane handling verification activities were performed in accordance with regulatory requirements, deficiencies were identified by the FSIS auditor in two beef slaughter establishments proposed for certification for U.S. export. First, the auditor observed that veal were held in the pens without access to water (Regulation (EC) 853/2004- Annex III, Chapter II, Section I and paragraph 7 Appendix A II R 93/119). The VIC indicated that the inspection team recognizes this situation as ongoing non-compliance. The non-compliance was discussed with the plant management during weekly meetings and documented in the inspection records, but it has not been resolved. The VIC decided to build an enforcement case and escalate this issue to NVWA headquarters. The NVWA needs several weeks and sometimes months to build an enforcement case, and, in the interim, veal lots will continue be held without access to water. This situation was an example where the NVWA failed to initiate regulatory control action or another enforcement measure to ensure immediate compliance with the regulatory requirements for humane handling of animals during slaughter. In the second incident, the FSIS auditor noticed a suspect animal held in the suspect pen without access to water. The CCA immediately responded to the auditor’s finding and took measures to ensure that the establishment implemented an appropriate corrective action. As part of the corrective action measures, the CCA incorporated a special emphasis on humane handling of animals during slaughter into the M-SPIN tool and used the tool to improve the inspection program personnel’s ability to enforce humane handling requirements and to address and verify corrective actions taken by the establishments in response to documented non-compliance.

The FSIS auditor verified through record review, interviews, and observations that KDS auxiliary inspection personnel assist with post-mortem inspection activities related to identification, proper presentation, and initial examination of carcasses while NVWA veterinarians make final disposition determinations for carcasses and parts. The design of the post-mortem inspection stations included sufficient lighting and the appropriate number of on-line KDS inspectors to perform post-mortem inspection of every slaughtered animal under supervision of the NVWA veterinarian.

The KDS inspection personnel examined the heads, viscera, and carcasses, including organs that need to be subject to inspection in bovine slaughter establishments, and conducted visual inspection of animals and parts at swine slaughter establishments according to the equivalent alternative post-mortem inspection procedure for market hogs. The visual inspection of market hogs is complemented by inspection personnel’s review and analysis of the animals’ supply chain information. This information system supports visual inspection of market hogs raised under an integrated quality control program coupled with a system of in-farm serological surveillance testing and on-site verification at the slaughter establishments. The verification activities conducted during ante-mortem and post-mortem inspection ensure that visually inspected carcasses and organs are wholesome and not adulterated. The inspection personnel conducted inspection procedures consistent with NVWA instructions, including palpation and incision of lymph nodes on carcasses of suspect hogs and those lacking proper documentation of the food chain information.

When the slaughter products are intended for export to the U.S., the portions of the carcass that are strictly inedible are identified as “inedible parts” and include the lungs, thyroid, and urinary bladder.

The NVWA ensures that carcasses determined unfit for human consumption, because of systemic diseases or violative drug residues, are condemned in accordance with Regulation (EC) 854/2004- Annex III, Section I and Chapter IV, 16, Council Directive 96/23/EC, Regulation RA-18, and Regulation RA-86. The CCA ensures that condemned carcasses are separate from inspected and passed carcasses, and are properly denatured and disposed of. The FSIS auditor also verified that the CCA ensures a complete separation of establishments that are certified for U.S. exports from those that are not certified and uses traceability to ensure that certified establishments only use products originating from an approved source.

The FSIS auditor verified that post-mortem inspection was performed in accordance with regulatory requirements described in Regulation (EC) No. 854/2004-Annex I, Regulation (EC) No 853/2004, Annex III, Regulation (EC) 1774/2002, Chapter II, Article 4, “RA-18 – Post-mortem inspection ungulates and farmed game”, and Working Manual “RA-85 VWA-KDS Contract”. However, some deficiencies were identified in a pork slaughter establishment, including the observation of a hog carcass in the cooler with the hoof not removed, and extraneous materials bound to the foot. This deficiency, which was corrected immediately, constitutes a failure of the inspectors to verify that all dirt and hoofs were removed from hog carcasses, properly disposed of, and carcasses were thoroughly washed and cleaned before making incisions for evisceration or inspection.

The FSIS auditor verified that the NVWA conducted weekly or monthly assessments of the KDS auxiliary employees’ ability to perform the post-mortem inspection procedure and other assigned verification activities. The assessment frequency depends on the total number of animals slaughtered per hour, and the total number of animals slaughtered per week. Additionally, the performance of KDS auxiliary inspectors is subject to audits by the NVWA’s auditors and, in rare cases, audits by independent organizations. The results of the NVWA periodic assessments and audits are reported to the NVWA headquarters and the MEA. However, the CCA did not provide a protocol for addressing any documented deficiencies related to inferior performance of individual KDS auxiliary employees in specific establishments or areas that may impact public health. The NVWA’s corrective action plan indicated that regular meetings will be conducted between the official veterinarian assigned at the slaughter establishments and KDS personnel to coordinate for proper execution of the inspection tasks.

The FSIS auditor verified through records review and observations whether the CCA maintains effective control to ensure disposal of condemned material in both pork and beef establishments in accordance with Regulation (EC) 854, Regulation RA-28, and Regulation DBP-20 “ABP Controls of Category 1, Category 2 and Category 3 material at slaughterhouses”. These regulations divide condemned materials and inedible animal parts 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 risky 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 and include animal hides, skin, hooves, horns, hair, and condemned parts that had no signs of infectious disease. The implementation of SRM controls in beef slaughter establishments is carried out by the NVWA veterinarians and assisted by KDS auxiliary employees.

The FSIS auditor verified through document review and observations that the CCA takes measures to ensure that meat products are safe to consume by carrying out on-line inspections during all slaughter operations, and at least one inspection activity per shift in all processing establishments. This includes

establishments that are currently certified for pork export and establishments proposed for certification to export beef to the United States.

In conclusion, the NVWA has the legal authority and the regulatory framework to impose requirements equivalent to those governing the U.S. system of meat inspection and thus meet the requirements of this component. The NVWA, however, must enhance its ongoing training program and supervisory reviews to focus on the competency of the inspection program personnel in cattle plants, including the KDS auxiliary employees, and to be able to observe and document relevant deficiencies and take the appropriate corrective actions to address such deficiencies, as related to this component. In response to FSIS requests, the Netherlands submitted corrective actions that adequately addressed the findings, and provided documentation showing that these corrective actions have been implemented. FSIS will conduct an on-site audit to verify whether the corrective actions have been effectively implemented for beef slaughter and processing inspection.

## **VI. COMPONENT THREE: SANITATION**

The third of the six equivalence components that the FSIS auditor reviewed was sanitation. To be equivalent to the U.S. inspection system, a foreign system must require that each official establishment operate in a manner to prevent insanitary conditions and to develop and implement a Sanitation SOP. The FSIS auditor's verification of this component included an analysis of the CCA's SRT responses, review of records at the government offices in the establishments, and observations at the audited establishments.

The FSIS auditor's review of regulations, official instructions, and guidelines demonstrates that the Netherlands' meat inspection system is adopting equivalent sanitation requirements. The review indicated that the CCA requires each establishment certified to export pork products or proposed for certification to export beef products to the United States to develop, implement, and maintain written Sanitation SOPs to prevent direct product contamination or the creation of insanitary conditions. An assessment of the CCA's regulatory oversight of establishment compliance was conducted in accordance with Regulation (EC) No. 852/2004; Regulation (EC) No. 853/2004; Regulation (EC) No. 882/2004; and Regulation RE 31.

The FSIS auditor reviewed the design of the establishments' Sanitation SOPs, examined the associated records, and observed the implementation of sanitation programs at certified pork establishments and at establishments proposed for certification for beef export. The auditor observed the implementation of the pre-operational sanitation at one establishment by shadowing and observing the VIC conducting pre-operational sanitation verification. The FSIS auditor reviewed the establishment's sanitation monitoring and corresponding inspection verification records, and noted that the records reflected the actual sanitary conditions of the establishment. The audited establishment was maintaining sanitation records sufficient to document the implementation of the Sanitation SOPs related to pre-operational sanitation. The establishments' employees responsible for the implementation and monitoring of Sanitation SOPs authenticated these records as directed by Regulation RE 31.

The FSIS auditor observed the operational sanitation in five bovine slaughter and processing establishments, and identified deficiencies concerning the CCA's ability to enforce sanitation requirements:

In three out of four bovine slaughter establishments, the FSIS auditor observed instances of insanitary conditions and practices. First, the auditor observed deficient sanitary dressing procedures resulting in contamination of carcasses that included:

- A mechanical hide-puller guide was rolling the hide off of the lower abdomen of carcasses without being properly sanitized between carcasses resulting in spread of contamination on carcasses as well as potential cross-contamination between carcasses.
- The hose, a non-food contact surface, of a wizard knife was repeatedly touching the hides and subsequently touching exposed surfaces of carcasses.
- Establishment employees cut open the hide and subsequently cut around the bung and the lower hind leg without sanitizing or switching knives between cuts.
- Establishment's employees cut the hides, opened and broke the hind limbs using the same knife without proper sanitation between cuts or between carcasses.

FSIS recognizes that incidental visible contamination is unavoidable in the slaughter dressing operations with any inspection system. However, such events should be rare occurrences since contamination is a preventable food safety hazard at all steps of the slaughter dressing operation. FSIS expects the CCA to take measures to ensure that the establishments' Sanitation SOPs are designed and implemented to remain effective in preventing contamination or adulteration. The sanitary dressing and process control procedures should identify the points in the operation where contamination can occur, and describe procedures to prevent contamination. The NVWA inspection personnel are expected to verify the effectiveness of the establishments' Sanitation SOPs and take enforcement action in response to each noncompliance.

The NVWA conducted an audit of all beef slaughter establishments several months prior to the FSIS audit. The NVWA analyzed results and identified zero tolerance contamination rates ranging from 6% to 22% on beef carcasses in some establishments and decided to issue penalty 'fine reports' to non-complying establishments. Additionally, the CCA rejected establishments' requests to use antimicrobial interventions during harvesting and subsequent processing. The CCA's decision was based on concerns of potential spread of contamination when applying antimicrobial solutions over improperly cleaned carcasses. Nonetheless, the measures taken in response to the internal audit findings were not effective in ensuring adequate sanitary operations in beef slaughter establishments as evident by FSIS identified deficiencies during the audit.

Second, the auditor observed poor sanitary practices after removal of hides:

- The overhead pipes above the kill floor were observed dripping over exposed carcasses. This situation was previously recognized as an issue of concern by the NVWA inspector, but no regulatory action had been taken to ensure that the establishment's corrective actions prevented recurrence.
- Carcasses on the kill floor were observed touching the inspection station platform and the cooler door. An establishment's employee picked hooks from the floor and placed them, without proper sanitation, in a cart carrying clean hooks ready to be used to hang carcasses.

The NVWA inspection personnel need to implement effective verification procedures to prevent the potential spread of bacteria from improperly sanitized tools and operators' insanitary practices.

Third, the FSIS auditor observed improper handling of carcasses during storage and transportation:

- Multiple hindquarters in the coolers of some of the visited establishments had clumps of hair, and fecal material or ingesta.
- An improperly maintained overhead rail resulted in direct product contamination with rust, black specks, and in some cases smears of black grease.
- Multiple carcasses in the chill room were touching the floor, and some of the exposed carcasses loaded into a transportation vehicle were touching pallets of boxed product as well as the inside walls of the truck. This situation may result in product contamination. Carcasses must be protected from contamination during transportation, and vehicles used to transport meat and carcasses are considered an extension of the refrigerated storage.

The NVWA inspection personnel need to verify that establishments' handling of carcasses during storage, loading, and unloading consistently prevent product contamination.

In response to the CCA's request, each of the audited establishments made changes that address the audit findings. The establishments made changes to the design of their slaughter and processing areas, modifications to their work procedures, and changes to the instruction and training that they provide to their employees. The NVWA official veterinarian assigned to each establishment has reviewed and signed the establishments' progress reports. NVWA inspection program personnel conduct routine weekly and biweekly meetings with the establishments' management to discuss the effectiveness of the establishments' sanitation programs and verify whether the establishments have implemented measures to prevent recurrence of deficiencies that affect product safety. The NVWA's decision to certify any of these establishments for export to the U.S. will be based on comprehensive analysis of the improvements by these establishments as well as the outcome of the audit of these establishments by NVWA Senior auditors.

Some of the NVWA inspection personnel stationed at beef slaughter establishments stated that they only document "issues of concern" that are likely to be repeated. The CCA must ensure that inspection program personnel document all non-compliances, and verify that establishments address them appropriately in order to identify and respond to trends of noncompliance with escalating enforcement actions sufficient to ensure compliance with regulatory requirements. Although the CCA took immediate action to address the findings related to all identified deficiencies in beef operations, FSIS requests that the CCA submit documentation showing that this issue has been effectively addressed. As part of the CCA's corrective action plan, the Veterinary and Import Division's (V&I) Management Team implemented an improvement plan for the sanitation and effectiveness of process control in beef slaughter establishments. The improvement plan included the use of a unified guidance to ensure uniform performance of the inspection and verification activities related to the establishments' sanitation programs.

Under the new approach, the inspection program personnel assess the effectiveness of the slaughtering process by conducting three daily spot checks (each involving 20 carcasses) at points both before and after the final rail inspection station. This approach also involves checks of the items on the inspection

list (Appendix 1- Questionnaire on the hygienic working methods). The inspection personnel follow Appendix 2, which provides a detailed intervention plan for dealing with sanitation deficiencies within the establishments' processes. The use of the M-Spin system as a tool for analysis of the results of the official verification activities provides accurate assessments of the slaughterhouse's performance for both veterinary inspectors and for the establishments' management. Necessary changes to the sanitation programs are implemented by personnel following Appendix 3- a summary of the draft design of the improvement plan prepared for each slaughter establishment. All three appendices are included in the CCA's response.

Furthermore, the FSIS auditor observed the operational sanitation in three swine slaughter and processing establishments, and identified deficiencies concerning the CCA's ability to enforce sanitation requirements in two slaughter establishments. The findings include:

- A hog carcass in the cooler had clumps of hair and extraneous materials.
- An establishment employee at a re-work station was using the same knife to trim multiple contaminated carcasses without proper knife sanitation between uses. KDS Auxiliary standing next to the establishment employee did not address this incident with the establishment management or report it to the Veterinarian-in-Charge (VIC).
- An establishment employee stuck a pig in the suspect examination area using a knife soiled with blood and extraneous material from previous use on other suspect animals.

The CCA took immediate action to address these audit findings, and is expected to take further measures to prevent recurrence of the same or similar findings and to ensure establishments' compliance with the regulatory requirements.

Furthermore, the NVWA needs to implement measures to ensure sanitary operations are maintained at all times, and to implement immediate regulatory or enforcement measures sufficient to preclude ongoing insanitary conditions that may result in direct product contamination or adulteration.

The FSIS auditor's review of the Sanitation SOP at one of the swine slaughter establishments found that the written program did not include effective measures to prevent direct product contamination during slaughter in accordance with Regulation (EC) 852 and RE-31. The Sanitation SOP required the plant's employees that perform animal bleeding to sanitize their knives after the 10<sup>th</sup> carcass. This sanitary measure will not prevent cross-contamination between carcasses that have not gone through post-mortem inspection, and might be deemed as "unfit for human consumption" at a later point in the process. The CCA needs to address this finding by ensuring that the establishment implements a sanitation program that prevents cross-contamination and reflects the changes in the design of the written Sanitation SOP.

As part of its corrective action plan, NVWA issued a new protocol, "interventieprotocol," which describes the interventions required by establishments to address repeated non-compliances, and instructs the inspection program personnel to ensure that establishments' corrective actions include measures to prevent direct product contamination. The CCA uses supervisory reviews and routine team correlations to ensure uniform implementation of effective enforcement measures by the inspection team assigned to official establishments.

FSIS's analysis and audit verification activities of the Netherlands' inspection system indicated that the CCA continues to meet the regulatory requirements related to this component through EU and national regulation, although there is a need to improve the implementation of the establishments' sanitation programs and the CCA verification and enforcement activity particularly at beef establishments seeking certification for export to the United States. In order for the CCA to consistently meet all of the food safety measures and objectives related to this component, NVWA must take measures to ensure that all official cattle establishments implement effective Sanitation SOPs, and other sanitation procedures that prevent direct contamination of meat products destined for the United States. In response to FSIS requests, the Netherlands submitted the corrective actions discussed above in this section to FSIS addressing these findings for beef production, and documentation showing that the corrective actions have been effectively implemented. FSIS will verify that they have been effectively implemented through an on-site audit.

## **VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEMS**

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. To be equivalent to the U.S. inspection system, a foreign system must require that each official establishment develop, implement, and maintain a HACCP system.

The auditor's review of the regulations, official instructions, and guidelines demonstrates that the Netherlands' meat inspection system is adopting equivalent HACCP requirements. The review indicated that the CCA requires that each establishment certified for export of pork, or proposed for certification beef export, to the U.S. develop and execute effective HACCP plans. The CCA continuously evaluates the effectiveness of its regulatory oversight and performs daily and periodic assessments of establishments' compliance with the regulatory requirements described in: Regulation (EC) No. 852/2004; Regulation (EC) No. 853/2004; Regulation (EC) No. 882/2004; and Regulation RE 31.

To determine whether equivalence was maintained for this component, the FSIS auditor assessed the design, and verified the implementation of HACCP programs at pork and beef slaughter and processing establishments. The assessment included a review of the establishments' HACCP records and the official records maintained by NVWA inspection personnel. Additionally, the FSIS auditor observed operations at certified pork establishments and at beef establishments proposed for certification for beef export to the United States. All visited establishments had developed, implemented, and maintained a HACCP system for products intended for U.S. export. The establishments' HACCP systems are subject to annual audits performed by the NVWA's auditors and daily inspection by NVWA in-plant inspection personnel.

The FSIS auditor verified through a review of the records, and onsite observations at the pork and beef establishments visited, that the in-plant inspection personnel conducted and documented official daily verification activities related to HACCP in accordance with Regulation RE 31. This encompasses the evaluation of written HACCP programs and verification of HACCP pre-requisites and plan monitoring, corrective actions, and record-keeping in accordance with Regulations (EC) No 852/2004 and Regulations (EC) No 882/2004. Furthermore, supervisory reviews (supervisory veterinary inspector and lead auditor) of HACCP verification activities by inspection personnel were well documented.

Although the FSIS auditor verified that HACCP verification activities were executed in accordance with regulatory requirements, the verification procedures in two beef slaughter establishments did not include a procedure for verification by direct observation. Therefore, the establishments' verification activities were limited to records reviews and calibration of instruments. Additionally, the corrective action records for their zero tolerance CCP did not consistently identify the cause of the deviations and the measures taken to prevent recurrence of the deviation (as required under Article 5 of Regulation (EC) No 852 and described in the EC Guidance Document Implementation of procedures based on the HACCP requirements).

The review of the certified pork establishments did not identify similar HACCP design flaws. The CCA needs to take measures to close the performance gap between inspection personnel assigned to beef establishments and those assigned to pork establishments. NVWA introduced a requirement for routine correlation sessions for inspection teams working on pork and beef establishments as one of the means to ensure consistent performance of the inspection personnel.

- At one of the swine slaughter establishments, the HACCP form used to document the corrective actions for the CCP for zero tolerance for fecal and ingesta, did not include all parts of the required corrective action. The establishment's HACCP records did not include preventive measures that needed to be taken to avoid recurrence of the same or similar deviations. This finding was not associated with a specific establishment's failure to meet the established Critical Limits (CLs) for zero tolerance for ingesta, and fecal materials in hog carcasses and parts. Nevertheless, this finding must be addressed.
- The HACCP plan of a canning establishment did not establish and implement effective monitoring procedures for the critical control point (CCP) for nitrite in canned pork luncheon meat intended for export to the United States. The establishment uses a nitrite test (paper with a color indicator that had a wide band within the target range established as the critical limits). In using such a wide band, the monitoring activity did not provide an accurate measurement to assess whether the CCP was under control, and did not provide an accurate record for future use for verification. The FSIS auditor did not identify any public health concern associated with the added amount of nitrite in the formulation of product that might result from imprecise nitrite measurements, the amount remaining in the final canned product, the maximum daily dose, and the margin of safety of added ingredient. Nevertheless, the inspection program personnel must ensure that the design of the HACCP plan in certified establishments includes critical limits that are based on substantiated evidence so that the chosen values will ensure process control.

These findings were not documented by the NVWA inspection program personnel during their most recent review of the establishments' HACCP systems. NVWA needs to implement corrective measures to ensure frequent and closer monitoring and critical review of each establishment's HACCP plans, and to take proper enforcement action when the HACCP requirements are not met. Consequently, as part of the CCA's corrective action plan, NVWA decided to methodically review and analyze the establishments' HACCP plans during the regular audits at the establishments. The establishments are now required to take immediate and ongoing measures to address non-compliances identified during the audit by NVWA inspection personnel.

Although the FSIS auditor did not identify imminent threats to the public health resulting from the HACCP design flaws, the CCA must take measures to ensure that inspection program personnel conduct a thorough review of each establishment's HACCP plan and conduct verification activities that ensure the adequacy of the HACCP system.

The CCA implemented measures described in Work Manual RE-31 to ensure that inspection program personnel assigned to official establishments carry out official verification activities to ensure the adequacy of the implementation of establishments' HACCP plans.

Moreover, the FSIS auditor found deficiencies in relation to the identification and removal of SRMs. The FSIS auditor observed the establishments' operations at four beef slaughter establishments and paid special attention to the CCA's ability to verify the implementation of the establishments' program related to the identification and removal of SRMs. The FSIS auditor's observations revealed that NVWA inspection personnel did not identify non-compliances in response to the establishments' failures to remove tonsils (including lingual tonsils), which are identified as SRMs in cattle of all ages according to EU and the U.S. requirements. Furthermore, some of the inspection personnel did not recognize tonsils as SRMs or place emphasis on their removal, and some plant employees were not familiar with the regulatory requirement for their identification and removal.

These findings were not documented in previous NVWA audit reports or records of supervisory reviews conducted prior to the FSIS audit. These findings indicated a need for improvement in the CCA's oversight functions, which include an ongoing training program, and periodic supervisory reviews of inspection activities at establishments proposed for certification to export beef products to the United States.

In response, NVWA proffered a corrective action plan that includes a modification of Working Manual RE-31 (USA – approval and control of meat establishments). The updated instruction RE-31 included changes to the instructions for the inspection personnel on how to verify the establishments' compliance with the requirements related HACCP and SRMs Removal.

In conclusion, the FSIS auditor verified that the Netherlands' meat inspection system requires operators of establishments to develop, implement, and maintain HACCP programs for each operation as set forth in accordance with U.S. regulatory requirements. The CCA has applied these standards across the meat inspection system. However, the CCA must take measures to ensure uniform implementation of these regulatory requirements through an improvement of its official controls, and verification activities related to the above described audit findings. In response to the FSIS request, the Netherlands identified the corrective actions discussed in this section taken to address the audit findings and submitted them to FSIS along with documentation showing that the corrective actions were implemented. FSIS will conduct an on-site audit to verify whether the corrective actions have been effectively implemented in cattle plants.

## **VIII. COMPONENT FIVE: CHEMICAL RESIDUES CONTROL PROGRAMS**

The fifth of the six equivalence components that the FSIS auditor reviewed was Chemical Residue Control Programs. FSIS criteria for this component require the inspection system to have a chemical residue control program designed and administered by the national government that functions to prevent chemical residue contamination of food products. To be considered equivalent to the FSIS program, the

program must include random sampling of internal organs, muscle, and fat of carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. The CCA must provide a description of its residue sampling and testing plan, and the process used to design the plan. The CCA must maintain oversight of laboratories to ensure the validity and reliability of test data.

As required by equivalent provisions the NVWA provides direction, coordination, and oversight of the residue control program in accordance with Council Directive 96/23/EC; Decision 97/747/EC; and Commission Decision 97/747/EC. Prior to the on-site audit, FSIS's residue experts thoroughly reviewed the Netherlands' 2013 National Residue Plan (NRP) as well as additional SRT responses outlining the structure of the Netherlands' chemical testing program. The auditor also conducted an onsite audit of one residue laboratory that performs analysis of products intended for export to the United States.

The design of the Netherlands NRP includes a description of the basis for the residue plan, and 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 FSIS auditor verified that the residue plan has measures in place that ensure segregation of domestic product from product destined for export to the U.S. when domestic residue tolerances are higher. The separation ensures that product that does not meet U.S. standards is not commingled with product destined for export to the United States.

The CCA issued detailed instructions for the field inspection personnel in the collection of samples of specific tissue. The instructions include procedures for handling and disposing of product that might contain violative chemical residues, and provide a description of regulatory actions to be taken against individuals or firms for food safety violations.

The FSIS auditor verified the sample collection procedures in one of the visited establishments, and confirmed proper animal identification for sample traceability. All official residue samples were sent exclusively to the National Institute of Public Health and the Environment (RIVM), which reports the result of the sample analysis to the CCA. The FSIS auditor conducted an onsite audit of the RIVM that provides technical support to the Netherlands' meat inspection system. RIVM is accredited under ISO/IEC 17025, and has established close cooperation with RIKILT- Institute of Food Safety, which is an EU and national reference laboratory. The two labs use an integrated laboratory information system. The FSIS auditor reviewed the internal SOPs (LP-05: Quality Assurance in the VWA laboratories), and verified that the sampling procedures, analytical methods, quality assurance procedures, calibration, temperature recording, and intra-laboratory check samples for this laboratory are being properly implemented and documented.

The CCA requires that laboratories analyzing product destined for the U.S. participate in appropriate proficiency testing for food analysis in accordance with Regulation (EC) No. 882/2004. The CCA conducts periodic reviews of the activities at the laboratories to ensure that the testing of product destined for the U.S. comply with the general criteria established in ISO/IEC Standard 17025:2005. CHEK, which is a *Quality assurance* independent subsidiary of the NVWA that organizes proficiency studies, distributes reference materials and help labs improve the quality of their analysis. The FSIS auditor verified that the CCA conducts direct oversight of the NVWA laboratory on an annual basis through the Central Quality Assurance and Internal Control (KIC), and ensures that obsolete documents are removed from the laboratory's intranet site and not used by the laboratory analysts. Additional CCA oversight is conducted indirectly through a third party audit. The CCA delegated the responsibility of

quality review and audit to an independent organization known as the Dutch Accreditation Council (*Raad voor Accreditatie-RvA*). The CCA is represented in the Supervisory Board of RvA. The RvA reviews include mandatory competency testing; and RvA audit reports at least once per year. The CCA receives copies of the accreditation and audit reports and verifies that the NVWA laboratories continue to meet the accreditation requirements, and achieve their objectives by providing technical support to the CCA through the delivery of valid and reliable test data.

The FSIS audit of the RIVM chemical residue laboratory, and the chemical residue control program as a whole, verified that the following areas met equivalence requirements: sample receipt and tracking, media preparation, integrity of analyses, oversight, and program activity. The FSIS auditor did not identify any deficiencies or areas of concern during the audit of this laboratory.

FSIS analysis and audit verification activities of the Netherlands' chemical residue testing program indicated that the CCA continues to meet the equivalence requirements for the Chemical Residue Control component.

## **IX. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS**

The last of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to the microbiological testing programs organized and administered by the CCA to verify that products destined for export to the U.S. are safe, wholesome, unadulterated, and meet all relevant equivalence criteria.

The evaluation of this component included an analysis of the information provided by the CCA through the SRT, review of establishments, official inspection records, and interviews with the inspection and laboratory personnel as well as observations during the on-site audit.

The NVWA requires establishments to conduct *Enterobacteriaceae* testing in cattle and pig carcasses in accordance with Regulation (EC) No 2073/2005- Annex 1, Chapter 2, Sections 2.1.1 and 2.1.2, and to perform total viable count in raw product in lieu of testing for generic *E. coli* as a measure of sanitary process control. This testing program shows that establishments maintain process control, and have been found to be equivalent to the FSIS establishment testing requirements. The FSIS auditor verified that all the establishments that are certified for pork export, as well as establishments proposed for certification for beef export to the U.S., conduct *Enterobacteriaceae* testing in accordance with the regulatory requirements, and some of the visited establishments were opting to conduct additional testing for generic *E. coli*. The FSIS auditor's reviews of the establishments' written programs, and the official inspection records did not identify any issues of concern and further confirmed that all audited establishments complied with relevant regulatory requirements.

The Netherlands, an EU Member State, participates in the EC'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, which is expected to continue, includes performance standards for *Salmonella* developed in accordance with Regulation (EC) No. 2073/2005 Chapter 3 Annex 1, Part 3.1. The FSIS auditor verified that the NVWA takes measures to ensure that inspection program personnel collect *Salmonella* samples from all classes of meat products subject to sampling (pork carcasses, beef carcasses, and minced "ground" meat products). The microbiological testing program is

conducted in accordance with Working Manual RE-29. The samples are analyzed in NVWA laboratories for Food safety using the ISO 6579-2002 method which was determined to be equivalent by FSIS. This method is described in detail in the working manual for the microbiological laboratory (MIC04-WV505).

The FSIS auditor verified that the Netherlands' meat inspection system follows procedures for the collection of samples according to the guidelines of Regulation (EC) 2073/2005- Chapter 3 Annex 1- Part 3.1, and NVWA Working Manual RE-29 using an abrasive sponge sampling method, targeting areas most likely to be contaminated (Beef: Flank, brisket, rump; Pork: Belly, ham, jowls) and covering at least total 400 cm<sup>2</sup> of the sampling area. The *Salmonella* sets for testing of animal carcasses consist of 50 samples with a maximum allowed number of 2 positives in cattle carcasses, and a maximum allowed number of 5 positives in pig carcasses. The *Salmonella* sets for testing of minced and mechanically separated ground products consist of 5 samples, and do not allow for any positive results within the sample set. The inspection program personnel received specific training for sample collection as part of the basic education program. It is also detailed in Working Manual "MON01".

The inspection system assesses the effectiveness of each establishment's process controls in reducing or controlling microorganisms on or in raw meat products. Regulation (EC) 2073/2005, Article 7 addressed measures to be initiated by the inspection program and taken by the establishment in response to unacceptable test results against the set criteria described in paragraphs 2 to 4 of the article together with other corrective actions defined in the establishments' HACCP-based procedures. In addition, establishments are required to take measures to find the cause of the unacceptable results in order to prevent the recurrence of the unacceptable test results. These measures may include a reassessment of the HACCP plan or other applicable control measures or prerequisite programs. The FSIS auditor's review of inspection records found that there have not been any *Salmonella* set failures for the past six months. The auditor's review of the establishments' and inspection records did not identify any concerns.

The NVWA has adopted a policy that considers raw, non-intact beef products or the components of these products found to have *E. coli* O157:H7 or any of six Shiga toxin-producing *Escherichia coli* (STEC) (O26, O45, O103, O111, O121, and O145) to be adulterated. The Netherlands intends to export only raw intact beef (veal) products to the United States. The Netherlands CCA has a plan in place for testing non-intact beef products such as ground beef for O157:H7 and other STECs (*NVWA Verification Activities for Escherichia coli O157:H7 in Raw Beef Products*) which matches the FSIS testing program. The current NVWA plan includes provisions for extending the testing program to include any new FSIS testing requirements.

The NVWA, as part of its intent to resume export of beef products to the U.S., has updated measures to control *E. coli* O157:H7 and other STECs in beef. NVWA requires establishments seeking certification for U.S. export to assess their HACCP plans appropriately to identify whether critical control points should be established to prevent adulteration of product. The establishments proposed for certification are required to implement validated procedures that will ensure that HACCP plans are properly implemented to ensure control of the identified hazards. The CCA considers product sampling by the establishment to be one of several activities conducted to verify the effectiveness of the HACCP systems. The CCA's lead auditor, as well as the in-plant inspection personnel, performs periodic audits of the HACCP plan to verify the design, and to ensure that it contains documentation

to address hazards that are likely to occur. The NVWA's Verification Activities for *Escherichia coli* O157:H7 in Raw Beef Products was developed based on FSIS Directive 10,010.1 Rev. 3-Verification Activities for *Escherichia coli* O157:H7 in Raw Beef Products. The manual, developed to deal with samples collected under the microbiological sampling program for the testing of STECs, addressed the implementation of STEC sampling, testing, verification and enforcement. In addition, the manual provides information on sampling of raw ground beef components other than beef manufacturing trimmings, including follow-up sampling, and explains that NVWA will continue to collect follow-up samples until 16 negative samples are collected. The FSIS auditor verified that the NVWA disseminated its policy related to testing for STECs in beef products to inspection personnel, NVWA laboratory personnel, and establishments proposed for certification for beef export to the United States. The implementation of this testing program is progressing.

The FSIS auditor conducted a verification audit of the NVWA laboratories for food safety, a government laboratory based in Wageningen that performs routine microbiological analyses verification for meat products (pork and beef). The laboratory review and audit focused on the verification of analysts' qualifications, sample receiving and handling, timely analysis, analytical methodologies, analytical controls, and recording and reporting of results. The FSIS review of NVWA laboratory operations found that the sampling plans for microbiological analysis were in place, and that the analyses were performed using equivalent methods that had been validated. There were no issues of concern identified in relation to the microbiological sampling and testing programs. The microbiological laboratory is subject to direct CCA oversight, including annual proficiency testing (Ring test) as well as indirect oversight through audits by the RvA. The FSIS auditor verified that the CCA exercises oversight over the functions of the laboratory through CHEK, which is an independent subsidiary of the NVWA. The review of past audit reports of the laboratory reveals that all internal and external audit findings were promptly corrected and verified through supervisory reviews or through follow-up audits.

The current audit found that the Netherlands' meat inspection system has a microbiological testing program that is organized and administered by the national government, and that the CCA has implemented generic *E. coli* and *Salmonella* sampling and testing programs to verify the effectiveness of its system.

The NVWA's control measures and testing programs for *E. coli* O157:H7 and other STECs are comparable to FSIS's control and testing program. FSIS's analysis and audit verification activities of the Netherlands' microbiological testing program indicated that the CCA continues to meet the equivalence requirements for the Microbiological Testing Programs component.

## **X. CONCLUSIONS AND NEXT STEPS**

The audit results indicate that the Netherlands' meat inspection system met most of the equivalence and regulatory requirements; however there were systemic findings related to the official verification of post-mortem procedures, and the enforcement of the sanitation and HACCP regulatory requirements. These findings were mostly linked to establishments proposed to export (beef), but some findings with less public health impact were connected to currently certified pork establishments. The FSIS audit findings indicate the need for improvement of the government oversight function related to the coordination between the two levels of the inspection system, improvement of the ongoing training

program, enhancement of the inspection program personnel knowledge about U.S. export requirements related to beef, and the expansion of the supervisory review to put an emphasis on the competency of the inspection program personnel including KDS auxiliary employees.

During the closing meeting held in Utrecht on June 26, 2014, the FSIS auditor presented the main findings and preliminary conclusions of the audit to the CCA. The CCA understood and accepted the findings, and made a commitment to develop a comprehensive corrective action plan that addresses the audit findings. The onsite audit findings are summarized as follows:

- The NVWA inspection personnel did not document noncompliance or initiate regulatory control action in response to the establishments' failure to remove tonsils (SRMs in cattle of all ages).
- The CCA has regulatory authority to take enforcement measures; however, in-plant inspection personnel at beef establishments failed to initiate regulatory control action or another effective enforcement measure in response to a non-compliance that resulted in direct product contamination. This included poor sanitary dressing procedures resulting in contamination of carcasses, inadequate sanitary practices after carcass dressing, and improper handling of carcasses during storage and transportation.
- The NVWA inspection personnel did not verify that the establishments' written Sanitation SOPs and associated records in one of the swine slaughter establishments, and in two of the bovine slaughter establishments included effective measures to prevent direct product contamination.
- The NVWA inspection personnel did not verify that the establishments' monitoring procedures are designed and implemented to assess whether a CCP is under control and to produce an accurate record for the verification activities that included procedures for observing the monitor performing the monitoring procedure.
- The NVWA inspection personnel did not consistently verify that the establishments' HACCP plans, and records of corrective actions taken in response to deviations from the established critical limits, included preventive measures as part of the corrective actions. In some instances, the personnel did not document the verification activities taken to assess the adequacy, and the effectiveness of the establishment's corrective actions particularly those related to failure to meet the zero-tolerance critical limits for ingesta and fecal materials on animal (beef) carcasses and parts.

The CCA has already begun to address the audit findings by implementing immediate corrective actions and preventive measures. The CCA proffered a corrective action plan that addressed all the findings related to the FSIS on-site audit. FSIS received and evaluated the Netherlands' corrective actions, as documented, and concluded that they satisfactorily addressed the audit findings. Therefore, FSIS will conduct an on-site follow-up audit to verify that corrective actions were effectively implemented for beef slaughter and processing inspection. The on-site audit is necessary because FSIS found some systemic problems with the inspection system.

**XI. ATTACHMENT TO THE AUDIT REPORT**

The Netherlands response to the FSIS audit report



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

Dr Adreas Keller  
Director International Equivalence Staff  
FSIS, USDA  
1400 Independence Avenue SW  
Washington D.C. 20250  
Verenigde Staten van Amerika

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

Visit address  
Bezuidenhoutseweg 73  
2594 AC The Hague  
The Netherlands

Postal address  
P.O. Box 20401  
2500 EK The Hague  
The Netherlands

Billing address  
P.O. Box 16180  
2500 BD The Hague  
The Netherlands

Organisation Code  
00000001003214369000

T +31 (0)70 379 8911  
[www.rijksoverheid.nl/ez](http://www.rijksoverheid.nl/ez)

Deal with by  
drs. F.J. van der Valk

T +31 (0)70 378 5035  
F +31 (0)70 378 6177  
[f.j.vandervalk@minex.nl](mailto:f.j.vandervalk@minex.nl)

Our ref.  
DGAN-DAD / 15018647

Your ref.

Encl.  
3

Date **13 FEB. 2015**  
Re Dutch veal, response to draft report

Dear Dr Keller,

Thank you for sending me the draft report of the equivalence verification audit that took place in the Netherlands from June 2 – 26, 2014, in veal and pig slaughterhouses and in a number of egg processing facilities. The report covers your findings in the veal and pig slaughterhouses, I am looking forward to also receive the FSIS report on the egg processing facilities.

The draft report in itself does not give rise to any comments regarding the accuracy of its content. This letter addresses some remarks and corrective actions that have been taken as follow-up to your draft report.

I am pleased to be able to inform you that, partly based on the observations of the auditor and partly based on improvements that had been set in motion independently by the Netherlands Food and Consumer Product Safety Authority (NVWA), the competent authority has been supervising the audited companies in accordance with FSIS standards since early November 2014. In relation to this, I would like to underline the following:

Firstly, earlier in 2014 the NVWA started a program called "Plan for Improvement of supervision in the meat production chain". The program aims at improving the NVWA inspections at slaughterhouses and the effectiveness of enforcement in case of deficiencies. You will find a summary of this plan enclosed.

Secondly, as confirmed by the auditor, the supervision by the NVWA meets FSIS standards in pig slaughterhouses. In order to improve the performance in veal slaughterhouses, NVWA staff, trained in FSIS requirements in pig slaughterhouses, have assisted the teams in veal slaughterhouses.

Thirdly, immediately after the audit took place, the audited companies and NVWA took joint action on the shortcomings. Three emails with information on the actions taken dated August 14, September 9, and October 10, 2014, have been sent to FSIS. The first two emails contained the company improvement plans, the last one is a report covering the first four weeks during which the "Improvement plan" was operational in veal slaughterhouses. The conclusion was that in a short period of time, a vast improvement of slaughtering process hygiene was accomplished in these slaughterhouses.

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

Our ref.  
DGAN-DAD / 15018647

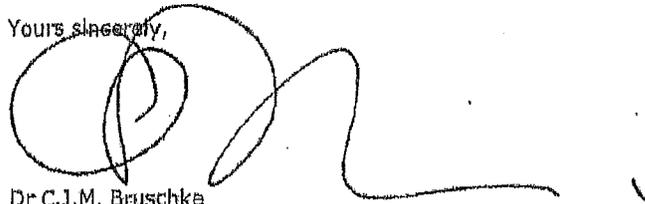
In this response we have categorized all topics that are mentioned in the report. For each topic we have indicated what action has been taken. For some items additional documentation is provided.

I trust that the answers provided in this letter demonstrate the structural improvements that have been made and will lead to a positive decision from your side on the equivalence of the Dutch system to that of the USA.

If you should consider it necessary to do so, an additional inspection may take place at any moment that suits you. Please let me know at your earliest convenience if you prefer to do so.

Mr. Keller, I look forward to make the next and final step in the process to regain market access for Dutch veal to the US market.

Yours sincerely,

A handwritten signature in black ink, consisting of a large, stylized 'D' followed by a long horizontal stroke.

Dr C.J.M. Bruschka  
Chief Veterinary Officer

## **Outline of the Plan for Improvement of supervision In the Meat Supply Chain**

### **3 February 2015**

#### **1. Objective**

The objective of the Plan for Improvement of supervision In the Meat Supply Chain is to structurally improve inspections in the meat supply chain. To this end, a method was developed that combines existing and newly developed ideas to create a substantial increase in the effectiveness of inspections. This method was primarily developed for medium-sized and small red meat slaughter houses and was subsequently also introduced in large red meat slaughter houses.

#### **2. Development**

The development of this plan is supported by two teams. A design team formulates the new work method. The design covers all aspects of the business model: operations, control & structure, ICT & resources, people & culture and knowledge. A uniformity team supports putting the design into practice and introduces the new work method within the teams. This new work method was introduced at mid-sized and small red meat slaughter houses on 18 March 2014 and on 14 July 2014 at veal slaughterhouses.

#### **3. The design**

The new design for inspections at mid-sized and small slaughter houses comprises four pillars, namely: 1. risk-based inspections, 2. inspection shortlists, 3. registration in MSPIN and 4. a prominent role for the company manager.

1. A risk-based method has been developed. This means that choices will be made and that the focus will be on those slaughterhouses and those stages in the slaughtering procedure where there are the highest risks for public health, animal welfare and animal health. These risks were divided into six risk areas, namely: animal welfare (transport & housing, and stunning & killing), cleaning and disinfecting animal transport vehicles, hygiene, animal by-products, traceability and the temperature of the meat during transport. The risk areas are established for each slaughterhouse based on indicators established for that specific risk area. This regards both operational and compliance indicators. These risk indicators comprise the risk profile for that specific risk area and as such they also specify the frequency of the inspections to be conducted for that risk area over the coming period for each specific slaughterhouse. In addition, perceived aggression and intimidation will be monitored at each slaughterhouse.
2. Inspection shortlists were prepared for the registration of the inspections. These shortlists ensure that the most logical and highest risk parameters and deviations of the relevant risk area are registered. Both the positive and negative findings are recorded. In addition to shortlists for these risk areas, there are also specific shortlists for the ante mortem inspections and the supervision of the post mortem inspections. There is also a 'caught in the act' list. This list makes it relatively easy to register the 'caught in the act' activity as incidentally observed and recognised by the supervising veterinarian.
3. Since 14 May 2014, it has been possible to implement the shortlist for the ante mortem inspection via smartphone in (M)SPIN. (M)SPIN provides options for the efficient registration of inspection data and to make these data available earlier for others. Subsequently, these data can be used to identify trends in the level of compliance, but they can also be used to conduct interventions. Since 1 July 2014, it has also been possible to complete the other nine shortlists through (M)SPIN. The data of these shortlists can be viewed via OBIEE. This supplies the company manager, the team leader and the departmental head with the required guidance information. This is an essential step forwards in establishing the new work method within the organisation.
4. The company manager plays a decisive role at mid-sized and small slaughter houses. He or she also ensures the inspection frequency for all risk areas is planned and implemented, and keeps track of whether re-inspections are required. The company manager of each slaughterhouse gets more insight as the data are not only available retrospectively, but trends can also be observed. This can be used together as input for the risk profile.

#### **4. Large slaughterhouses**

After a successful assessment in July 2014, the adjusted Improvement plan was rolled out at 22 large slaughterhouses, starting with the 4 veal slaughterhouses. On 14 July 2014, the new work method was rolled out at the veal slaughterhouses, including in-depth guidance by members of the uniformity team with respect to the hygiene inspections. On 13 October, the roll out of the new work method for all inspection areas was introduced at the 22 large slaughter houses with permanent supervision.

Based on the design for the mid-sized and small slaughter houses, the design team produced a design for the 22 large slaughter houses with permanent supervision. The same risk areas apply to the large slaughter houses. The new supervisory structure comprises three layers: daily operational supervision, periodical tactical supervision and low frequency (annual) strategic supervision. The strategic supervision is the most detailed here, while the operational supervision concerns the registration of daily established facts. There are two different operational lists, a stable inspection list and a slaughter house inspection list. The frequency of the tactical supervision is determined on a risk basis for each focus area. Two inspection lists were added for the tactical supervision, namely transport and management system. In addition, the enforcement protocol hygienic operations and faecal contamination was prepared for the large slaughter houses with permanent supervision.

#### **5. Follow-up**

By the end of 2014, the new work method had been implemented at the majority of mid-sized and small slaughter houses and at all large slaughter houses. Careful and efficient incorporation of this new work method is very important for a good long term result, which is why the members of the uniformity team will also assist staff at the red meat slaughter houses in this new supervision method during the first six months of 2015. Specifically, this means that the members of the uniformity team can visit red meat slaughter houses to provide assistance on both an announced and unannounced basis.

#### 4.1 Businesses

Hazard Analysis and Critical Control Point (third and fourth bullet)

- The description and the application of corrective measures following an exceedance of the critical limit comprises four parts:
  - Detect and eliminate the cause of the deficiency,
  - Describe how the CCP is subject to control after taking corrective measures,
  - Measures to prevent repetition (in this respect it is necessary to indicate/know the cause),
  - Prevent a harmful product from entering the market.
- The HACCP plan for veal businesses must describe the intended use of the meat. Based on the intended use, the decision tree must then be used (if the intended end product is "mince", STEC should for example be indicated as a risk – this applies to all production for export to the USA).

#### Staff education/training

A business must have written procedures for staff training, particularly a description of the education and training programmes on knowledge for supplementary US requirements.

#### 4.2.1 Slaughterhouses, cutting plants, cold stores, meat product companies, production for export

NBI Continuous Inspection during US production is not required. However, NVWA inspections must be carried out on the day of production for the US, and this primarily means supervision of the CCPs. That applies to each production shift and also in the weekends.

#### Responsibility of the team leader

The following activities must be carried out:

- o Check the operating procedure of the NVWA supervising veterinarian, this includes the measures taken by the TDA in the event of repeated deficiencies;
- o check the operating procedure of the business;
- o check several aspects via a small audit, for example, the effectiveness of the cleaning (SSOP) or the monitoring and verification (three parts see 4.1.2) of the CCPs, particularly the CCP "faecal contamination".

#### USA requirements

- KDS staff must also be trained in US requirements. This training could also be provided by the KDS itself (formally recorded in writing). There must be documentary evidence to indicate which members of staff are trained.

#### 4.2.3 Slaughterhouses and meat product businesses

The NVWA takes the following samples:

- In event of RTE (not shelf stable) products, Listeria control (RE-34), STEC (STEC manual).

The NVWA also ensures the complete removal of SRM (in the case of bovine animals).

- In the case of tongues: the tongues may not contain any lymphatic tissue or remainders of lymphatic tissue (palatine and lingual tonsils). This is considered SRM material. (see annex 1)

### 5. COMPETENCES AND RESPONSIBILITIES

#### Team Import/Export

- The Import/Export team also informs the NVWA laboratory (microbiology team) of these changes to the business list.

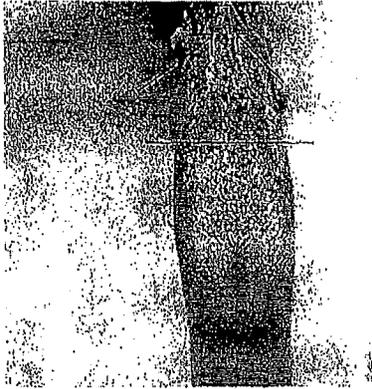
### 6. COMMENTS

In January 2015 the instruction was clarified, particularly with regard to the training of KDS staff and the business and regarding the removal of SRM (in the case of bovine animals).

Appendix 1: Identification and removal of SRM material on bovine tongues

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

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



The lower boundary of the tonsillar tissue on the tongue is indicated with the black line, at the level of the most anterior circumvallate papillae.

The upper boundary is visible to where holes in the mucosa are visible (crypts). The lingual tonsils are located here, at the depth of a few millimetres. The lingual tonsils are not located on the lateral surface of the tongue, only on the dorsum of the tongue.

A possible method is:

The removal occurs as follows: the indicated area is removed via an incision at least 5 mm deep, whereby the mucosa indicated above and underlying tissue is removed. The tongue then appears as follows:



The tissue that is cut off is considered category 1 material.

Page	Shortcomings	Corrective actions	Annex
ii,5,6,7	Ongoing effective training Knowledge of requirements FSIS, SSOP, pre-SSOP, CCPs monitoring and verification, effective follow-up of non-compliances, escalated enforcement actions.	All new appointed official veterinarians at the NVWA receive an official training, including training on the USA-requirements and all the mentioned subjects on the left column in this table. All the official veterinarians working in establishments that are suitable for the export to the USA participate in a yearly training programme. Training for all official veterinarians working at the veal slaughter houses took place in October / November 2014.  KDS personnel: regular meetings are organised between the responsible official veterinarian at the slaughter house and KDS personnel. Additional training on the USA requirements takes place two times a year during the collective meetings between KDS employees and the official veterinarians on the establishments.  Personnel of the company: Yearly training programme. NVWA verifies if a training program is in place (see also RE-31 on this).	An overview of the training program has been sent to FSIS as part of the SRT. The list of participants is available.
ii,5,16	SRM removal	Tongue cut has been re-evaluated after the FSIS audit, developed and an adjusted cut is operational since November 2014 to ensure complete removal of lymphatic material as required. Daily supervision of the correct removal of SRM (lingual tonsils) is worked out in detail in working manual RE-31.	RE-31, new parts have been translated
ii,3,6,7, 17	Coordination between CCA HQ and TL / team	Supervisory reviews by the team leader are carried out every month. Team leaders have weekly meetings chaired by the head of the section. NVWA team leaders discuss the audit results with his / her manager (head of the section) every 3 months. The head of the section is part of Management Team (MT) of the Veterinary & Import division of the NVWA. The MT meets every week. Relevant subjects are discussed at the different levels in the chain of command. In this way it is guaranteed that subjects are discussed, actions taken were needed etc on the right level of command.	Assessed reports of the different meetings are available.
4,6,14, 17	Effective analytical instrument	M-SPIN/SPIN mobile digital system (replaces ISI): at all levels within the Veterinary & Import division the results of the inspections are available for day to day actions / interventions and also to do (trend) analyses. Seven inspection areas are identified: cleaning & disinfection, animal transport, animal arrival and housing, animal stunning and killing, hygiene slaughter process, animal by-products and traceability. This system is partly (hygiene slaughter process) operational since July 14, 2014 at the veal slaughter houses. As of October 13, 2014 the implementation of the system started for the other identified inspection areas. Data analysis is carried out on M-SPIN data.	Multiple inspection lists for 7 inspection areas are available in the system for veal slaughter houses  Report with the results of hygiene controls sent to FSIS by

			email on 15 October 2014
13,14	Effective communication between the NVWA and the companies.	Regular (weekly or two weekly) meetings are organised between the NVWA and every single company. At these meetings all relevant items in relation to the slaughtering of animals are discussed (e.g. hygiene, maintenance and other non-compliances).	Assessed reports of the meetings per company are available.
ii,5,16	HACCP / CCP and HACCP-verifications	The NVWA systematically judges the HACCP plans during the regular audits at the companies. The inadequacies observed during the mission are corrected.	HACCP plan per company is available
ii,13,14	Hygiene	Establishments have trained their employees based on the detected non-conformances, have amended their working manuals and have adapted the working procedures. Supervision and enforcement are key parts of the NVWA project Plan for improvement of supervision in the meat production chain ("verbeterplan vleesketen", see email to FSIS 15 October 2014). Central elements of this project are the "design team" and the "uniformity team". The design team develops systems / methods to improve the effectiveness of the enforcement and has identified six risk areas (cleaning & disinfection, animal welfare, hygiene slaughter process, animal by-products, meat temperature and traceability). The NVWA systematically inspects all the critical points in the slaughter process by means of tailor made inspection lists in M-SPIN. The follow-up of non-compliances is laid down in the "interventieprotocol". This protocol describes the interventions for all the possible (repeated) findings. The uniformity team supports the official veterinarians to implement effective enforcement at the companies. This project started on July 14, 2014 for the veal slaughter houses.	Overview "verbeterplan vleesketen"  The "interventie protocol" has been sent to FSIS as part of the SRT.
13,14	SSOP Pre-SSOP	For every veal establishment the lists concerning monitoring and verifying SSOPs/pre-SSOPs were developed analogue to the way of working that is in place in the pig industry.	Documents per company are available.
14	Maintenance	The problems concerning improper maintenance are indentified for every establishment. At the regular meetings between the NVWA and the company the follow up concerning the shortcomings has been discussed and is agreed upon the improvements and investments to be done. For some deficiencies reconstruction is necessary. Meanwhile the problems are handled in such a manner to avoid risks and the temporary solutions have been approved by NVWA. (e.g. condense)	Every company made up an action plan and these were sent to FSIS on August 14 <sup>th</sup> 2014
10	Humane handling of animals during slaughter	Special emphasis to humane handling of animals during slaughter with the help of a form / tool in M-SPIN. The inadequacies observed during the mission are corrected.	Form in M-SPIN is available



**Appendix 1 Questionnaire on hygienic working methods and soiling (including faecal soiling)**

General details of slaughterhouse

Name of slaughterhouse:  
\_\_\_\_\_

Address: street name \_\_\_\_\_ house no. \_\_\_\_\_  
postal code \_\_\_\_\_ town/city \_\_\_\_\_

Details of owner:  
\_\_\_\_\_

Approval number:  
\_\_\_\_\_

NVWA details:

Inspector's name/number:  
\_\_\_\_\_

Inspector's name/number:  
\_\_\_\_\_

Date: \_\_\_\_\_

This inspection is a  basic inspection  re-inspection

**General**

<b>Question 1</b>	
Tick the animal (or animals) to be slaughtered during the inspection of the slaughtering process.	
cattle	<input type="checkbox"/>
calves	<input type="checkbox"/>
pigs	<input type="checkbox"/>
sheep	<input type="checkbox"/>

<b>Question 2</b>
If slaughtering is involved, enter the number of animals to be slaughtered today
..... animals
..... animals
..... animals
..... animals

<b>Question 3</b>	
Tick to indicate whether the animals are to be slaughtered stunned or unstunned	
Stunned	Unstunned
<input type="checkbox"/>	<input type="checkbox"/>



goats	
horses	
water buffalo	
other	

..... animals
..... animals
..... animals
..... animals




4. In the case of the 'other' category, give details of the species of animal to be slaughtered.

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**Basic conditions**

5. Check that adequate levels of personal hygiene are being maintained during the slaughtering process.

- no comments
- incorrect → proceed to question 5a:

5a. Give details of what was incorrect.

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6. Check that no contamination is transferred from 'dirty' items to 'clean' items during the slaughtering process.

- no comments
- incorrect → proceed to question 6a:

6a. Give details of what was incorrect.

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7. Measure the temperature of at least one of the sterilisers. *Query loop runs in M-Spin until all sterilisers have been covered*

- \_\_\_\_\_ °C (open)

**Preventive measures**

8. Check what measures are taken if the live animals intended for slaughter are not sufficiently clean.

- no measures taken, all animals clean
- dirty animals are slaughtered last
- the slaughtering rate is reduced
- the animals are shaved before slaughter
- a report is sent to the company that supplied the animals
- the animals are showered before slaughter
- no measures/inadequate measures; animals are dirty



other



9. Check whether skinning and depilation are carried out correctly.

- no comments
- incorrect → proceed to question 9a:

9a. What was incorrect?

- slaughter technique
- cross-contamination
- personal hygiene
- technical failure
- other

10. Check that the stomach and intestines, the liver, heart, lungs, aorta, gullet and tongue, and the udder are removed correctly.

- no comments
- incorrect → proceed to question 10a:

10a. What was incorrect?

- soiling from stomach-intestines
- soiling by bile
- soiling by milk or colostrum
- other

#### Side effects

11. Check what measures are taken if soiling (including faecal soiling) of the carcass/meat nevertheless occurs.

- no faecal soiling found
- no measures taken
- correct measures taken (e.g. immediate trimming) → proceed to question 11a:
- incorrect measures taken (e.g. rinsing off, scraping off, insufficient effect)

11a. What correct measures were taken?

- immediate trimming
- all soiling is marked, then freshened up at a later stage in the slaughtering process
- other → proceed to question 11b:

11b. Give details of the other correct measures taken:

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#### Final measurement of soiling (including faecal soiling) of carcasses

1. Check a number of carcasses (if present) for soiling and evidence of poor slaughtering just before each carcass is presented for post-mortem inspection.

12. How many carcasses were inspected?



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13. What did you find?

- no soiling or evidence of poor slaughtering
- soiling → proceed to question 13a:
- evidence of poor slaughtering → proceed to question 13a:
- soiling and evidence of poor slaughtering → proceed to question 13a.

13a. On how many carcasses did you find soiling and/or evidence of poor slaughtering?

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Check a number of carcasses (if present) for soiling and evidence of poor slaughtering after post-mortem inspection and approval (in the refrigerated storage area).

14. How many carcasses were inspected?

- \_\_\_\_\_

15. What did you find?

- no soiling or evidence of poor slaughtering
- soiling → proceed to question 15a:
- evidence of poor slaughtering → proceed to question 15a:
- soiling and evidence of poor slaughtering → proceed to question 15a:

15a. On how many carcasses did you find soiling and/or evidence of poor slaughtering?

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Concluding questions (after inspection)

16. What corrective intervention has been implemented?

- none
- intervention in the production process → proceed to question 16a:
- mandatory action → proceed to question 16b:
- action prohibited → proceed to question 16c:
- other → proceed to question 16d:

16a. What intervention has been implemented in the production process?

- shut down (temporarily) the slaughterhouse's conveyor system
- reduce the speed of the conveyor system
- block production
- destroy production
- other



16b. What mandatory action was imposed?

- mandatory removal of soiling
- mandatory cleaning and/or disinfection, or other appropriate treatment
- mandatory identification and registration of products
- animal welfare protection measures
- introduction of procedures for *food safety, animal health and animal welfare*
- other



9. Check whether skinning and depilation are carried out correctly.

- no comments
- incorrect → proceed to question 9a:

9a. What was incorrect?

- slaughter technique
- cross-contamination
- personal hygiene
- technical failure
- other

10. Check that the stomach and intestines, the liver, heart, lungs, aorta, gullet and tongue, and the udder are removed correctly.

- no comments
- incorrect → proceed to question 10a:

10a. What was incorrect?

- soiling from stomach-intestines
- soiling by bile
- soiling by milk or colostrum
- other

### Side effects

11. Check what measures are taken if soiling (including faecal soiling) of the carcass/meat nevertheless occurs.

- no faecal soiling found
- no measures taken
- correct measures taken (e.g. immediate trimming) → proceed to question 11a:
- incorrect measures taken (e.g. rinsing off, scraping off, insufficient effect)

11a. What correct measures were taken?

- immediate trimming
- all soiling is marked, then freshened up at a later stage in the slaughtering process
- other → proceed to question 11b:

11b. Give details of the other correct measures taken:

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### Final measurement of soiling (including faecal soiling) of carcasses

2 Check a number of carcasses (if present) for soiling and evidence of poor slaughtering just before each carcass is presented for post-mortem inspection.



12. How many carcasses were inspected?

---

13. What did you find?

- no soiling or evidence of poor slaughtering
- soiling → proceed to question 13a:
- evidence of poor slaughtering → proceed to question 13a:
- soiling and evidence of poor slaughtering → proceed to question 13a:

13a. On how many carcasses did you find soiling and/or evidence of poor slaughtering?

---

3 Check a number of carcasses (if present) for soiling and evidence of poor slaughtering after post-mortem inspection and approval (in the refrigerated storage area).

14. How many carcasses were inspected?

\_\_\_\_\_

15. What did you find?

- no soiling or evidence of poor slaughtering
- soiling → proceed to question 15a:
- evidence of poor slaughtering → proceed to question 15a:
- soiling and evidence of poor slaughtering → proceed to question 15a:

15a. On how many carcasses did you find soiling and/or evidence of poor slaughtering?

---

Concluding questions (after inspection)

16. What corrective intervention has been implemented?

- none
- intervention in the production process → proceed to question 16a:
- mandatory action → proceed to question 16b:
- action prohibited → proceed to question 16c:
- other → proceed to question 16d:

16a. What intervention has been implemented in the production process?

- shut down (temporarily) the slaughterhouse's conveyor system
- reduce the speed of the conveyor system
- block production
- destroy production
- other



16b. What mandatory action was imposed?

- mandatory removal of selling
- mandatory cleaning and/or disinfection, or other appropriate treatment
- mandatory identification and registration of products
- animal welfare protection measures
- introduction of procedures for *food safety, animal health and animal welfare*
- other



16c. What prohibition was imposed?

- prohibition on the supply of animals
- prohibition on the removal, treatment or processing of products, and on their release into circulation
- other

16d. Give details of the corrective intervention that was implemented

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17. What further action (which could lead to an intervention) was taken following an inspection of this high-risk area?

- none
- report of findings (fine report, veterinary certificate, etc.) drawn up

18. Has a re-inspection date been agreed?

- no
- yes, within 6 weeks
- yes, other → proceed to question 18a:

18a. Enter week number.

\_\_\_\_\_



## Appendix 2 Detailed Interventions

This project was conducted in accordance with the 'specific intervention policy for meat' standard. This is worked out in detail below for two issues (question about hygiene during the slaughtering process and question about soiling (including faecal soiling) subsequent to the slaughtering process).

Question 13 (M-Spin 22) Inspection of carcasses at a point before the inspection platform

### **1. First occasion on which more than 5% (3 out of 60) of carcasses are found to be contaminated**

On the **first occasion** that a rate of more than 5% **per day** is recorded here, the situation is defined as **occasional** insufficiently hygienic slaughtering.

This is a class C infringement, which requires that a WW be drawn up (Word template: Report of findings).

Text block:

I noted that ... (details of slaughtering procedure in question) ... did not prevent contamination of the meat.  
This made it clear to me that the action taken was contrary to the provisions of Appendix III, Section I, Chapter IV, point 7 of Regulation (EC) 853/2004 in conjunction with Article 3, paragraph 1 of that Regulation, which is an infringement of the provisions of Article 2.4, paragraph 1(d) of the Regulation on Animal Products, in conjunction with Article 6.2, paragraph 1 of the Animals Act.

The party in question must be given assistance to achieve compliance, and their attention should be drawn to the consequences (indicated below) of corrective measures and to the consequences of repeated instances of unhygienic slaughtering (points 2 and 3 below).

**NOTE** The provision of assistance to achieve compliance should not be delayed until all 60 carcasses have been inspected. If a score in excess of 5% is recorded for the first 20 carcasses inspected (more than one carcass contaminated) then assistance to achieve compliance should be given immediately, thus giving the company an opportunity to intervene and avoid an infringement.

The company should immediately take corrective measures to ensure that the slaughtering process operates hygienically again as soon as possible (number of contaminated carcasses less than 5%). This can be done by reducing the slaughtering rate or by means of additional inspections, during which any contamination is immediately removed (at a point before the inspection platform) on the line.

If, after 60 carcasses have been inspected, the company fails to implement these measures sufficiently, immediately, or at all, then the NVWA will have to intervene. This involves reducing the speed of the



conveyor system by 50% and not increasing it again until the company is able to demonstrate that the process has been modified (less than 5% contamination). If reducing the speed of the conveyor system does not have the desired effect, then all slaughtering activities must be suspended until the company takes appropriate measures. In the latter case, the company will also receive a WW about the inadequate performance of its HACCP system.

**2. Second occasion on which more than 5% of carcasses are found to be contaminated within a series of 10 inspections**

As described above, under point 1. The situation involves occasional, repeated instances of unhygienic slaughtering.

**3. Each subsequent occasion on which more than 5% of carcasses are found to be contaminated within a series of 10 inspections**

Deep-rooted unhygienic slaughtering. This is a class B infringement (serious consequences), which requires that an FR be drawn up (Word template: Report of findings). Text block as in 1.

The party in question must be given assistance to achieve compliance, and their attention should be drawn to the consequences indicated below.

The company should immediately take corrective measures to ensure that the slaughtering process operates hygienically **and continues to do so** (number of contaminated carcasses less than 5%). If, after 60 carcasses have been inspected, the company fails to implement these measures sufficiently, immediately, or at all, then the NVWA will have to intervene. This involves reducing the speed of the conveyor system by 50%. In addition, the company will also receive a WW about the inadequate performance of its HACCP system (rule B2).

Text block:

After consulting the slaughterhouse operator, it became clear to me that he/she had done little or nothing to introduce, implement and/or enforce permanent procedures based on HACCP principles. This made it clear to me that the action taken was contrary to the provisions of Article 5, paragraph 1 of Regulation (EC) 852/2004, which is an infringement of the provisions of Article 2.4, paragraph 1(c) of the Regulation on Animal Products, in conjunction with Article 6.2, paragraph 1 of the Animals Act.

Slaughtering at the maximum rate can only be resumed once the HACCP system has been modified in such a way that the NVWA is convinced that the slaughtering process is being sufficiently well managed (perform audit in consultation with the AI (the Inspectorate SZW) team).

If reducing the speed of the conveyor system does not have the desired effect, then all slaughtering activities must be suspended until the company has modified its HACCP system.



Question 15 (M-Spln 31) Inspection of carcasses subsequent to the slaughtering process/post-mortem inspection

### **15A Discovery of faecal soiling:**

#### **1. First occasion on which faecal soiling is found on a carcass (or carcasses)**

The presence of faecal soiling subsequent to the slaughtering process has been incorporated into module D (D9) of the meat intervention policy, as a class B infringement (serious consequences). As interventions have already taken place at each of these slaughter facilities, the first step of the intervention policy (corrective measures only) can be skipped, and an FR can be drawn up immediately (Word template: Report of findings).

Text block:

I noted that the carcasses were visibly contaminated with faeces. Visible contaminants were not immediately removed by trimming or by an alternative action with an equivalent effect. This made it clear to me that the action taken was contrary to the provisions of Appendix III, Section I, Chapter IV, point 10 of Regulation (EC) 853/2004 in conjunction with Article 3, paragraph 1 of that Regulation, which is an infringement of the provisions of Article 2.4, paragraph 1(d) of the Regulation on Animal Products, in conjunction with Article 6.2, paragraph 1 of the Animals Act.

The operator should always take the corrective measures described in the company's HACCP plan:

- In terms of the product: to freshen the carcass by cutting away any soiling.
- In terms of the process: to prevent any recurrence. For example: animals clean at slaughter, focus on the various critical steps in the slaughtering process (cutting open, removing head and feet, skinning, removing stomach and intestines).

If the company takes inappropriate measures to remove soiling (including faecal soiling), such as rinsing or scraping, this should be included in the FR as an additional observation. Compel the company to freshen such carcasses properly.

#### **2. Second occasion on which faecal soiling is found on a carcass (or carcasses) within a series of 10 inspections**

As described above, draw up an FR for faecal soiling. In addition, the company must be notified that its HACCP system clearly does not provide the requisite protection. Draw up a WW for this, as described in question 13, point 3.

#### **3. Each subsequent occasion on which faecal soiling is found on a carcass (or carcasses) within a series of 10 inspections**

FR for faecal soiling, FR for HACCP system. Suspend all slaughtering activities and do not allow them to be resumed until the HACCP system has been modified, including audit in consultation with the AI team.



**15B. Discovery of non-faecal soiling:**

**1. First or second occasion on which this is found within a series of 10 inspections**

Respond to this by issuing a WW (Word template: Report of findings) + Instigate corrective measures (product, process).

Text block:

I noted that visible contaminants were not immediately removed by trimming or by an alternative action with an equivalent effect. This made it clear to me that the action taken was contrary to the provisions of Appendix III, Section I, Chapter IV, point 10 of Regulation (EC) 853/2004 in conjunction with Article 3, paragraph 1 of that Regulation, which is an infringement of the provisions of Article 2.4, paragraph 1(d) of the Regulation on Animal Products, in conjunction with Article 6.2, paragraph 1 of the Animals Act.

**2. Each subsequent occasion on which this is found within a series of 10 inspections**

Same as for 'occasional', but now draw up an FR.



### Appendix 3 Summary of draft design of meat-chain improvement plan for permanently inspected livestock slaughterhouses

The same risk areas have been identified at large calf slaughterhouses as at small and medium-sized ones. These are, successively; animal welfare, R&D, livestock transport vehicles, hygienic working methods and soiling (including faecal soiling), animal by-products, meat temperature, and traceability. In addition, there is a sharp focus on intimidation and aggression, ante-mortem inspection reports, and some data from the post-mortem inspection.

In contrast to the current situation, in which daily inspection reports are mainly recorded on paper, the aim is to use a reporting system based on mobile phones and a new database (called M-Spin).

Checklists for daily inspections are available in M-Spin: one for the animal pens and one for the slaughter hall. These lists itemise the critical components of high-risk areas. The Inspector can then immediately input and store reports of the most common deficiencies in the system. In calf slaughterhouses, for example, the spot checks made before and after the inspection platform are both included in the 'slaughter hall' operational checklist.

A list of agreed actions will also be made available, and – as with small and medium-sized slaughterhouses – there will be a 'caught red-handed' list.

The purely operational inspections are supplemented by tactical inspections. Addressing each high-risk area individually, these inspections explore the material thoroughly, delving more deeply than the operational checklists. The frequency of these tactical inspections is determined by the individual slaughterhouse's risk profile for the high-risk area in question. That risk profile takes account of the slaughterhouse's characteristics (e.g. slaughter of uniform animals intended for slaughter or of animals at the end of their working lives, as well as the identified soiling rate at a point before the inspection platform) and the history of measures taken.

Whenever a deficiency is identified, this is always followed by a re-inspection based on the tactical inspection lists. In addition to the lists for individual high-risk areas, there is a tactical list for the management system. The latter list is used only in the case of a repeated re-inspection. This is, in fact, a partial audit, which explores the slaughterhouse's system in greater depth. The purpose of this approach is to identify the reason behind the repeated infringements.

Thus, using the operational and tactical inspection lists, it will be possible to enter large quantities of inspection data from each individual slaughterhouse into the M-Spin system. An analysis of these results



provides an up-to-date picture of the slaughterhouse's performance, both for the veterinarian Inspectors and for management.

It is vital that the NVWA takes a uniform approach to its work in these slaughterhouses. In this way, companies have advance, detailed knowledge of how the NVWA operates. This is why there is an enforcement protocol for difficult topics such as slaughter hygiene and soiling (including faecal soiling). This protocol further details the intervention policy, and there is a special emphasis on corrective measures.

In the context of the meat-chain improvement plan, the Deputy Superintendent of the Veterinary and Import Division (V&I) is directly responsible for the work of the uniformity team. The team has a dedicated team leader. Its members currently monitor the various inspections set out in the improvement plan, in terms of uniformity of implementation. In the future, such uniformity will have to be monitored by the field teams themselves. For this reason it is important to focus on peer supervision, which can be carried out by the senior veterinarians, on their own teams. In time, there will also be a need for supervision. This will involve senior veterinarians from a different team, who will report to the team leader and to the head of department. During such supervision, it will be determined whether inspectors have observed the NVWA's internal rules.

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION T. Boer en Zonen B.V. 's-Gravenweg 350, 2911 BK Nieuwerkerk aan den IJssel ( <i>Veal processing-cutting/raw intact</i> )	2. AUDIT DATE 6/10/2014	3. ESTABLISHMENT NO. Est. NL 939 EG	4. NAME OF COUNTRY The Netherlands
	5. NAME OF AUDITOR(S) Faiz Agarib, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

**12/51 and 56 Sanitation**

FSIS auditor observed a trailer backed to the loading dock that had exposed carcasses with no exterior protection loaded into the front of the trailer with pallets of boxed product loaded behind the exposed carcasses with extensive contact between the exposed carcasses and packaged product on pallets. This poses the potential for contamination of exposed product.

These findings indicate that the establishment's sanitation program, *as designed*, is not preventing direct product contamination or the program was not properly implemented (*e.g. employees training and supervisory oversight*)

These findings were not documented by the establishment or NVWA inspection program personnel. Article 5 of Regulation (EC) 852 and RE-31 delineated the general and specific hygiene requirements for each establishment to operate in a manner to prevent insanitary conditions. The official controls shall be performed by NVWA personnel to ensure the verification of compliance with the food law, animal health and animal welfare rules is covered in Regulation (EC) No. 882/2004 [9 CFR 416.13, 9CFR 416.1]. NVWA may need to look into means to ensure frequent and closer monitoring of the establishment sanitation and take proper enforcement action when the sanitary requirements are not met.

The findings are to be corrected by the establishment and verified for adequacy by the inspection program personnel.

**Observation**

**Traceability and Recall procedure:** FSIS auditor verified that the establishment has an established mechanism to trace the product throughout all stages of production, processing and distribution in accordance with Article 18 of Regulation EC/178/2002. The establishment has a recall plan on file. The identification of the origin of food ingredients and food sources is of prime importance for the protection of consumers, particularly when products are found to be faulty. Traceability facilitates the withdrawal of foods and enables consumers to be provided with targeted and accurate information concerning implicated products.

61. NAME OF AUDITOR  
Faiz Agarib, DVM

62. AUDITOR SIGNATURE AND DATE

*Faiz Agarib*

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Est. NL 369 EG, ESA B.V. Saba 9, 7332 BH Apeldoorn	2. AUDIT DATE 06/05/2014	3. ESTABLISHMENT NO. Est. NL 369 EG	4. NAME OF COUNTRY The Netherlands
	5. NAME OF AUDITOR(S) Faiz Agarib, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Est. NL 369 EG, ESA B.V. Saba 9, 7332 BH (Bovine Slaughter and processing), Apeldoorn

**10/56 SSOP:**

- During the evaluation of the establishment's operational sanitation, FSIS auditor noticed that some of the carcasses are touching the standing platform and the doors of the cooler this may expose the product for contamination or cross contamination when smear on contaminated surface. Rails should be located and passageway space provided so that exposed product does not come in contact with posts, walls, and other fixed parts of the building, or with barrels, boxes, and other containers trafficked through holding and operating areas.
- During the tour of the establishment, FSIS auditor observed one of the establishment's employees touching the skinned surface of carcasses with hands to remove visible contamination without using hooks which may cause the spread of bacteria from the operators' hands.
- During the tour of the establishment, FSIS auditor noticed that the overhead rails are rusty and not properly maintained to prevent direct product contamination.
- The hide puller includes a roller that applies counter pressure to each carcass during stimulation. The roller contacts the carcass along the midline and then rolls up to the lower abdomen before being retracted. There is no sanitizing of the roller between carcasses which poses the distinct risk of cross-contamination between carcasses.
- The hose for a wizard knife operator was observed to repeatedly contact outer hide and subsequently exposed surface tissue on each carcass. There were no procedures to avoid cross-contamination.

These findings were not documented by the establishment or NVWA inspection program personnel. Article 5 of Regulation (EC) 852 and RE-31 delineated the general and specific hygiene requirements for each establishment to operate in a manner to prevent insanitary conditions. [9 CFR 416.13, 9CFR 416.1].

The findings are to be corrected by the establishment and verified for adequacy by the inspection program personnel.

**13/51 SSOP:**

- The establishment's written sanitation program and corrective actions records did not address measure to be taken to prevent the recurrence of direct contamination of product in accordance with Article 5 of Regulation (EC) 852 and RE-31. [9CFR 416.15(b) and 416.16(a),]

FSIS recognizes that incidental visible contamination is unavoidable in the slaughter dressing operation. Such events should be rare occurrences because contamination is a preventable food safety hazard. Contamination is expected to be prevented at all steps in the slaughter dressing operation. As such, the establishment's Sanitation SOP must be designed and implemented to remain effective in preventing contamination or adulteration.

A prudent establishment would also have written procedures for sanitary dressing as a means to describe how contamination will be prevented to the maximum degree practical and to provide the greatest assurance of meeting the regulatory requirements of 9 CFR 416. By having a written program, the establishment is capable of evaluating both "real time" and "after the fact" results when determining if their program was being implemented as intended. A written program is a more optimal means of demonstrating that the establishment is effectively preventing contamination than an undocumented system, which is especially important when establishments compare their sanitary dressing practices to their pathogen control performance documentation.

Sanitary dressing procedures should identify the points in the operation where contamination can occur, describe procedures the establishment will take to prevent contamination from occurring, describe the procedures for what constitutes compliance/non-compliance at each point, frequency of verification at each point, documentation of verification at each point, corrective action, and training of assigned employees in hygienic sanitary dressing practices.

## 60. Observation of the Establishment

**Est. NL 369 EG, ESA B.V. Saba 9, 7332 BH (Bovine Slaughter and processing), Apeldoorn**

10/56

## HACCP:

- **Observation:** During the review of the establishment's records for the monitoring of zero tolerance, FSIS auditor noticed that the CCP deviation records do not fully described the finding in relation to the location and possible cause of the contamination. This may hinder the establishment's efforts to implement effective measures to preventive recurrence of the same or similar findings. This is an area where the establishment may need to improve its documentation.
- When the auditor inquired as to decision-making regarding SRMs the response was that the establishment only slaughtered beef less than 12 months of age so there was no concerns. The establishment, and NVWA, failed to recognize that there was no written program to address SRMs for all cattle including tonsils and distal ileum. The distal ileum and viscera were routinely denatured and sent to inedible rendering and records documenting disposal were available but there was no written program to address removal of tonsils, including lingual tonsils. Harvested tongues were observed on racks in preparation for packaging and no removal of lingual tonsils had occurred nor was it planned.
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**Observation**

**Traceability and Recall procedure:** FSIS auditor verified that the establishment has an established mechanism to trace the product throughout all stages of production, processing and distribution in accordance with Article 18 of Regulation EC/178/2002. The establishment has a recall plan on file. The identification of the origin of food ingredients and food sources is of prime importance for the protection of consumers, particularly when products are found to be faulty. Traceability facilitates the withdrawal of foods and enables consumers to be provided with targeted and accurate information concerning implicated products.

61. NAME OF AUDITOR  
Faiz Agarib, DVM

62. AUDITOR SIGNATURE AND DATE

*Faiz Agarib*

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Vitelco B.V. Veemarktkade 21, 5222 AE 's-Hertogenbosch ( <i>Veal Slaughter/Processing-raw intact</i> )	2. AUDIT DATE 6/11/2014	3. ESTABLISHMENT NO. Est. NL 49 EG	4. NAME OF COUNTRY The Netherlands
	5. NAME OF AUDITOR(S) Faiz Agarib, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Est. NL 49 EG, Vitelco B.V. (Bovine Slaughter and processing), 's-Hertogenbosch

**10/51/56 SSOP:**

- During the observation of the operational sanitation in the kill floor, the hide puller was observed in operation. The puller contacts the skinned hocks, exposed tissue, and clamps the suspended carcass by the hind legs at the hocks of each animal. The puller is designed to provide a low pressure rinse of water between animals but this was not sufficient to ensure effective sanitation of the contact surfaces as it was not thorough coverage and was not defined to ensure sanitation through temperature, sanitizers, or any other measure or procedure. As a result this equipment can result in cross-contamination between carcasses throughout the slaughter shift.
- During slaughter operations overhead pipes were observed dripping onto the floor and very near dehidated carcasses moving on the rail. The NVWA veterinarian and establishment described it as condensation for which measures had already been implemented. Beaded droplets were visible and dripping from an area of overhead pipes. The establishment acknowledged that the amount of dripping was consistent with leakage rather than condensation. An establishment employee responded to the area with a squeegee covered with soft material and proceeded to wipe the overheads where he was observed to knock droplets onto carcasses passing by on the rail and pieces of solid material from the soft cover were also observed falling on or near carcasses that continued to move on the rail. No action was taken by either the establishment or NVWA to halt operations while restoring sanitary conditions and therefore the immediate actions resulted in direct product contamination. Subsequent discussion identified that the establishment had taken incremental actions attempting to address this specific problem and had scheduled movement of the overhead pipes in approximately four weeks. The temporary measures implemented by the establishment were ineffective in protecting product from contamination and NVWA activities failed to ensure appropriate corrective actions were implemented to protect product from contamination.
- During the dehidating process the hind leggers were observed making cuts to open the hide and subsequently proceed to skin around the bung and lower hind leg without sanitizing or switching knives between cuts. Even though observed at length and with the establishment operations manager present the employees continued the insanitary practice. After notifying the establishment management of the sanitary dressing concern he reported that he provided instruction to the employees to implement two knives, one to open the hide followed by switching to a sanitized second knife to skin.
- The auditors observed the evisceration process and identified an evisceration employee with an approximately one foot diameter area of digestive tract contents heavily soiling the lower apron. In addition the evisceration employees were using long plastic sleeves extending to the armpit region as well as gloves. The sleeves were made of thin material such that many folds were present. The evisceration area had a small sink but no hose or other measure to ensure that aprons, hands and sleeves were thoroughly cleaned between animals or even when heavily soiled with gastrointestinal contents. From the location observed no direct product contamination was observed but this practice is not consistent with effective sanitation procedures designed to ensure product is protected from contamination during the slaughter process. During subsequent discussion the establishment indicated that this had already been an area redesigned by an architect but the remodeling project was not slated until later in the year. The auditor explained that until that time the sanitation procedures must be designed to protect product from contamination during the process.
- The establishment has implemented a rail-out loop near final inspection to ensure adequate trimming of carcasses for localized pathology and contamination including zero tolerance (fecal material, ingesta). Observation of this area identified that the carcasses were manipulated onto the rail-out rail by an employee with bare hands who touched repeated carcasses without implementing any hand washing procedures. In addition, when multiple carcasses were railed out there was extensive contact between carcasses. Both observed practices are not sanitary and fail to prevent contamination. The NVWA veterinarian reported that she had identified the same concerns and had repeatedly notified the establishment of the cross-contamination concerns with the rail-out loop and the establishment acknowledged that they were aware of the issue but had not yet identified a solution. In the meantime the insanitary practices continued.

These findings indicate that the establishment's sanitation program, *as designed*, is not preventing direct product contamination or the program was not properly implemented (*e.g. employees training and supervisory oversight*)

60. Observation of the Establishment

**Est. NL 49 EG, Vitelco B.V. (Bovine Slaughter and processing), 's-Hertogenbosch**

These findings were not documented by the establishment or NVWA inspection program personnel. Article 5 of Regulation (EC) 852 and RE-31 delineated the general and specific hygiene requirements for each establishment to operate in a manner to prevent insanitary conditions. The official controls shall be performed by NVWA personnel to ensure the verification of compliance with the food law, animal health is covered in Regulation (EC) No. 882/2004 [9 CFR 416.12(a); 416.2(d)(1) and 416.4(d)]. NVWA may need to look into means to ensure frequent and closer monitoring of the establishment sanitation and take proper enforcement action when the sanitary requirements are not met.

The findings are to be corrected by the establishment and verified for adequacy by the inspection program personnel.

**18/51 and 19/51 HACCP**

The establishment has identified, and implemented, a critical control point for zero tolerance of fecal materials and ingesta. However, the establishment has addressed monitoring of the CCP through defined “verification” procedures such that the required ongoing verification activity to verify direct observation of monitoring and corrective actions are not defined and have not been implemented. The establishment is implementing review of records but is confused by designating monitoring “verification”. In addition, the establishment has ensured the accuracy of process monitoring instruments, thermometers, for CCP 2 and was able to produce documentation but has failed to define the written verification procedure and frequency. Because the establishment failed to properly define the above they also fail to meet the recordkeeping requirements for documenting the results of verification in accordance with Article 5 of Regulation (EC) 852 and Regulation (EC) No. 882/2004 [9 CFR 417.2(c)(7) and 9 CFR 417.5(a)(3)].

**Observation**

**Traceability and Recall procedure:** FSIS auditor verified that the establishment has an established mechanism to trace the product throughout all stages of production, processing and distribution in accordance with Article 18 of Regulation EC/178/2002. The establishment has a recall plan on file. The identification of the origin of food ingredients and food sources is of prime importance for the protection of consumers, particularly when products are found to be faulty. Traceability facilitates the withdrawal of foods and enables consumers to be provided with targeted and accurate information concerning implicated products.

<p>61. NAME OF AUDITOR Faiz Agarib, DVM</p>	<p>62. AUDITOR SIGNATURE AND DATE <i>Faiz Agarib</i></p>
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## Foreign Establishment Audit Checklist

<b>1. ESTABLISHMENT NAME AND LOCATION</b> T. Boer en Zonen B.V. 's-Gravenweg 114, 2911 CJ Nieuwerkerk aan den IJssel (Veal Slaughter/Processing-raw intact)	<b>2. AUDIT DATE</b> 6/10/2014	<b>3. ESTABLISHMENT NO.</b> Est. NL 34 EG	<b>4. NAME OF COUNTRY</b> The Netherlands
<b>5. NAME OF AUDITOR(S)</b> Faiz Agarib, DVM			<b>6. TYPE OF AUDIT</b> <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

**Est. NL 34 EG, T. Boer en Zonen B.V. (Bovine Slaughter and processing), Nieuwerkerk aan den IJssel**

**10/56 SSOP:**

- During the evaluation of the establishment's operational sanitation, FSIS auditor noticed that
  - The establishment employees are making cut into the hide and breaking the hind limbs using the same knife without proper sanitation between cuts or between carcasses;
  - The electric sensor used to guide the hide removal machine touches the smaller side veal in the breast region and move up and potentially contaminates the skinned part of the carcass. The electric sensor is immersed in water at room temperature and not sanitized in any other way.
- During the evaluation of the establishment's operational sanitation, FSIS auditor noticed that:
  - Many carcasses (hind quarters) in the cooler are contaminated with grease or hair clumps.
  - Exposed product ready to be shipped to a sister establishment is placed in plastic totes with openings along the sides and only the top row of containers on a pallet are covered with plastic sheeting. The plastic sheet dispenser is placed low to the floor and the plastic was observed to incidentally touch the floor while being dispensed.
  - Exposed product placed in a cart in the cooler is touching the side and the wheels of the cart.
  - Overhead rails and switches were observed with excessive grease in areas and carcasses in the cooler were observed to have extensive black grease contamination on the hindquarters and rounds, some of the hind quarters were observed to have extensive contamination with rail dust, hair, flakes of blackish unidentified foreign material, and fecal material.
- During the tour of the establishment, FSIS auditor observed one of the establishment's employees touching the skinned surface of carcasses with hands to remove visible contamination without using hooks which may cause the spread of bacteria from the operators' hands.

These findings indicate that the establishment's sanitation program, *as designed*, is not preventing direct product contamination or the program was not properly implemented (*e.g. employees training and supervisory oversight*)

These findings were not documented by the establishment or NVWA inspection program personnel. Article 5 of Regulation (EC) 852 and RE-31 delineated the general and specific hygiene requirements for each establishment to operate in a manner to prevent insanitary conditions. The official controls shall be performed by NVWA personnel to ensure the verification of compliance with the food law, animal health and animal welfare rules is covered in Regulation (EC) No. 882/2004 [9 CFR 416.13, 9CFR 416.1]. NVWA may need to look into means to ensure frequent and closer monitoring of the establishment sanitation and take proper enforcement action when the sanitary requirements are not met.

The findings are to be corrected by the establishment and verified for adequacy by the inspection program personnel.

**13/51 SSOP:**

- The establishment's written sanitation program and corrective actions records did not address measure to be taken to prevent the recurrence of direct contamination of product in accordance with Article 5 of Regulation (EC) 852 and RE-31. [9CFR 416.15(b) and 416.16(a),]

FSIS recognizes that incidental visible contamination is unavoidable in the slaughter dressing operation. Such events should be rare occurrences because contamination is a preventable food safety hazard. Contamination is expected to be prevented at all steps in the slaughter dressing operation. As such, the establishment's Sanitation SOP must be designed and implemented to remain effective in preventing contamination or adulteration.

A prudent establishment would also have written procedures for sanitary dressing as a means to describe how contamination will be prevented to the maximum degree practical and to provide the greatest assurance of meeting the regulatory requirements of 9 CFR 416. By having a written program, the establishment is capable of evaluating both "real time" and "after the fact" results when determining if their program was being implemented as intended. A written program is a more optimal means of demonstrating that the establishment is effectively preventing contamination than an undocumented system, which is especially important when establishments compare their sanitary dressing practices to their pathogen control performance documentation.

Sanitary dressing procedures should identify the points in the operation where contamination can occur, describe procedures the establishment will take to prevent contamination from occurring, describe the procedures for what constitutes compliance/non-compliance at each point, frequency of verification at each point, documentation of verification at each point, corrective action, and training of assigned employees in hygienic sanitary dressing practices.

## 60. Observation of the Establishment

**Est. NL 34 EG, T. Boer en Zonen B.V. (Bovine Slaughter and processing), Nieuwerkerk aan den IJssel****16/51 HACCP:**

The design of the establishment's HACCP plan, particularly the part addressing the CCP for zero tolerance for fecal and ingesta contamination of carcasses seems to be mixing up between the concepts of monitoring and verifications. The design of the HACCP Plan seems to be allowing for monitoring of the CCP in different locations. NAWA seems to accepting the establishment's HACCP plan.

**52/51 Humane Handling:**

- **Observation:** During the review of the establishment's Ante-mortem and humane handling verification activities, FSIS auditor noticed that the animals in the pens do not have access to water. The veterinarian assigned to the establishment stated that he raised this issue with the plant management and documented it in the inspection records. The establishment response states that the animals in the pen (Veal) are not used to drink from buckets and can only use nipples. However, the animals are held such short time to be able to learn how to use the watering system of the establishment structure. Therefore, the establishment's the watering system off since the plant management determined that the system will not be used any way. This lead veterinarian was not satisfied with the establishment's answer and has decided to continue documenting this non-compliance in order to build a case to escalate this issue to a high level.

**Observation**

**Traceability and Recall procedure:** FSIS auditor verified that the establishment has an established mechanism to trace the product throughout all stages of production, processing and distribution in accordance with Article 18 of Regulation EC/178/2002. The establishment has a recall plan on file. The identification of the origin of food ingredients and food sources is of prime importance for the protection of consumers, particularly when products are found to be faulty. Traceability facilitates the withdrawal of foods and enables consumers to be provided with targeted and accurate information concerning implicated products.

61. NAME OF AUDITOR

Faiz Agarib, DVM

62. AUDITOR SIGNATURE AND DATE

*Faiz Agarib*

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION EKRO B.V. Laan van Malkenschoten 100, 7333 NP Apeldoorn	2. AUDIT DATE 06/04/2014	3. ESTABLISHMENT NO. Est. NL 9 EG	4. NAME OF COUNTRY The Netherlands
	5. NAME OF AUDITOR(S) Faiz Agarib, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.	x	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

**Est. NL 9 EG, EKRO B.V. (Bovine Slaughter and processing), Apeldoorn**

**10/56 SSOP:**

- During the tour of the establishment, FSIS auditor observed one of the establishment employees loading carcasses and parts into the rails of transportation vehicle. The auditor noticed that one of the carcasses was not raised to a level that makes it free of the floor of the cooler. Carcasses in the chill-room, must hung on rails clear of the floor. Additionally, the auditor noticed that some of the carcasses loaded to the truck were touching the inner sides of the transportation vehicle which may cause contamination of carcasses. Vehicles for transporting meat and carcasses should be considered as an extension of the refrigerated storage. Personnel handling carcasses during loading and unloading operations should follow the strictest rules regarding their personal hygiene and clothing and should handle carcasses as little as possible to avoid contamination.
- During the tour of the establishment, FSIS auditor observed one of the establishment's employees picking hooks from the floor and place them in a location intended for hooks to be used to handle carcasses and parts without proper washing and sanitation. Additionally, some of the carcasses were noticed to have black specks from the overhead rail. These are example of poor hygiene after carcass dressing which may cause the spread of bacteria from improperly sanitized tools and operators' hands.
- Multiple carcass hindquarters in the cooler were observed to have numerous black specks from the overhead rail, areas of black grease smears up to 2 inch diameter, multiple hairs including small clumps of hairs, and multiple quarters with zero tolerance contamination (fecal material or ingesta) were observed at various points in the cooler.

These findings were not documented by the establishment or NVWA inspection program personnel. Article 5 of Regulation (EC) 852 and RE-31 delineated the general and specific hygiene requirements for each establishment to operate in a manner to prevent insanitary conditions. The official controls shall be performed by NVWA personnel to ensure the verification of compliance with the food law, animal health and animal welfare rules is covered in Regulation (EC) No. 882/2004 [9 CFR 416.13, 9CFR 416.1].

These findings are to be corrected by the establishment and verified for adequacy by the inspection program personnel.

**13/51 SSOP:**

- The establishment's written sanitation program and corrective actions records did not address measure to be taken to prevent the recurrence of direct contamination of product in accordance with Article 5 of Regulation (EC) 852 and RA-31. [9CFR 416.15(b) and 416.16(a)]

The establishment is slaughtering beef of a size that results in carcasses dragging along the face of foot platforms at the scale, evisceration, and other areas (including KDS inspection stand) during slaughter with no procedures to prevent cross-contamination between carcasses or to clean or sanitize the surfaces, not defined or treated as food contact surfaces. In addition, at least one carcass in the cooler was observed with the neck no more than one inch off the flooring. The NVWA explained that netting was applied to the neck and this indicated that it would be trimmed during processing. The auditor explained that it is not adequate to allow product contamination to occur with the justification it would later be trimmed but rather the process must be designed to prevent contamination and, if it occurs, promptly remove it

FSIS recognizes that incidental visible contamination is unavoidable in the slaughter dressing operation. Such events should be rare occurrences because contamination is a preventable food safety hazard. Contamination is expected to be prevented at all steps in the slaughter dressing operation. As such, the establishment's Sanitation SOP must be designed and implemented to remain effective in preventing contamination or adulteration.

A prudent establishment would also have written procedures for sanitary dressing as a means to describe how contamination will be prevented to the maximum degree practical and to provide the greatest assurance of meeting the regulatory requirements of 9 CFR 416. By having a written program, the establishment is capable of evaluating both "real time" and "after the fact" results when determining if their program was being implemented as intended. A written program is a more optimal means of demonstrating that the establishment is effectively preventing contamination than an undocumented system, which is especially important when establishments compare their sanitary dressing practices to their pathogen control performance documentation.

Sanitary dressing procedures should identify the points in the operation where contamination can occur, describe procedures the establishment will take to prevent contamination from occurring, describe the procedures for what constitutes compliance/non-compliance at each point, frequency of verification at each point, documentation of verification at each point, corrective action, and training of assigned employees in hygienic sanitary dressing practices.

60. Observation of the Establishment

**Est. NL 9 EG, EKRO B.V. (Bovine Slaughter and processing), Apeldoorn**

**20/51 HACCP**

Review of the HACCP records documenting corrective actions for CCP-1, zero tolerance, the auditor identified that corrective actions were indicated by filling in bubbles on a checklist such that they were not specific and did not identify the cause nor measures to prevent recurrence in accordance with Article 5 of Regulation (EC) 852 and described in the EC Guidance Document Implementation of procedures based on the HACCP Principles, [9 CFR 417.3(a) and (c)].

The auditor observed that during processing the tongues at packaging that did not have lingual tonsils removed. During discussion the NVWA and plant indicated that they were aware tonsils were identified as specified risk materials (SRMs) in all cattle but the establishment failed to address removal of all SRMs. The HACCP system is inadequate to ensure SRMs are properly identified and removed from edible product.

**Observation**

**Traceability and Recall procedure:** FSIS auditor verified that the establishment has an established mechanism to trace the product throughout all stages of production, processing and distribution in accordance with Article 18 of Regulation EC/178/2002. The establishment has a recall plan on file. The identification of the origin of food ingredients and food sources is of prime importance for the protection of consumers, particularly when products are found to be faulty. Traceability facilitates the withdrawal of foods and enables consumers to be provided with targeted and accurate information concerning implicated products.

61. NAME OF AUDITOR  
Faiz Agarib, DVM

62. AUDITOR SIGNATURE AND DATE

*Faiz Agarib*

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Vion Boxtel B.V. Boseind 10, 5281 RM Boxtel  (Swine slaughter/processing)	2. AUDIT DATE 6/23/2014	3. ESTABLISHMENT NO. Est. NL 61 EG	4. NAME OF COUNTRY The Netherlands
5. NAME OF AUDITOR(S) Faiz Agarib, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	X	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

**Est. NL 61 EG, Vion Boxtel B.V. (Swine slaughter/processing), Boxtel**

**13/51 and 10/56 SSOP:**

- The establishment’s written sanitation program did not include effective measures to prevent the recurrence of direct contamination of product during slaughter in accordance with Article 5 of Regulation (EC) 852 and RE-31. [9CFR 416.15(b) and 416.16(a),]

FSIS recognizes that the establishment’s SSOP instruct the plant employees to sanitize their knives after each 10<sup>th</sup> carcass. This sanitary measure will not ensure sanitary dressing or prevent cross contamination between carcasses that have not gone through post mortem inspection and might be deemed an “unfit for human consumption” at a later point in the process. The purpose of the SSOP plan is to prevent contamination at all steps in the slaughter and dressing operation. As such, the establishment’s Sanitation SOP must be designed and implemented to remain effective in preventing contamination or adulteration. A prudent establishment would also have written procedures for sanitary dressing as a means to describe how contamination will be prevented to the maximum degree practical and to provide the greatest assurance of meeting the regulatory requirements and training of assigned employees in hygienic sanitary dressing practices.

- During the tour of the ante-mortem areas of the establishment, FSIS auditor observed an establishment employees sticking a pig in the area designated for suspect/emergency slaughter. The employee was using a knife soiled with blood and other contaminants from previous use on other suspect animals. The establishment decided to condemn the suspect animal after completion of bleeding and instructed the establishment employee to sanitize the knife immediately and after each use.

These findings were not documented by the establishment or NVWA inspection program personnel. Article 5 of Regulation (EC) 852 and RE-31 delineated the general and specific hygiene requirements for each establishment to operate in a manner to prevent insanitary conditions. The official controls shall be performed by NVWA personnel to ensure the verification of compliance with the food law, animal health and animal welfare rules is covered in Regulation (EC) No. 882/2004 [9 CFR 416.13, 9CFR 416.1]. NVWA may need to look into means to ensure frequent and closer monitoring of the establishment sanitation and take proper enforcement action when the sanitary requirements are not met.

**16/51 HACCP:**

The establishment’s HACCP plan design, particularly the part addressing the corrective action CCP for zero tolerance for fecal and ingesta did not ensure that all parts of corrective action are met. The review of the corrective action records indicated that the route cause of the deviation was not identified and preventive measures were not put in place to avoid recurrence of the same or similar deviations. NAWA did not have records of this finding during the last review of the establishment’s HACCP plan and records.

These findings are to be corrected by the establishment and verified for adequacy by the inspection program personnel.

**Notes:**

*Est. NL 61 EG, Vion Boxtel B.V. has an approval in place from NVWA for the use of alternative post-mortem inspection procedure that does not require incision of lymph node. The veterinarian(s) station at the establishment are using Food Chain Information and professional judgment to determine if a selected group of animals should be slaughtered at the end of the day using slow speed and traditional post-mortem inspection procedure.*

Regulation (EC) No 853/2004, Chapter V, Chapter 2 (b): During cutting, boning, trimming, slicing, dicing, wrapping and packaging, the meat is maintained at not more than 3°C for offal and 7°C for other meat, by means of an ambient temperature of not more than 12°C or an alternative system having an equivalent effect. *Establishment NL 61 EG, Vion Boxtel has an approval in place from NVWA to ship “energy reduced” carcasses at 70 °C or 50 °C.*

61. NAME OF AUDITOR  
Faiz Agarib, DVM

62. AUDITOR SIGNATURE AND DATE

*Faiz Agarib*

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Vion Apeldoorn B.V. Laan van Malkenschoten 77, 7333 NP Apeldoorn <i>(Swine slaughter/processing)</i>	2. AUDIT DATE 6/24/2014	3. ESTABLISHMENT NO. Est. NL 312 EG	4. NAME OF COUNTRY The Netherlands
	5. NAME OF AUDITOR(S) Faiz Agarib, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	X
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

**Est. NL 312 EG, Vion Apeldoorn B.V. (Swine slaughter/processing), Apeldoorn**

**55 Post-Mortem inspection /10/51 SSOP:**

- During the tour of the establishment, a hog carcasses part (ham) was found in the cooler with hoof. FSIS auditor observed one of the inspection program personnel taking the ham to the rework station where he removed the hoof from the ham but left the hoof in the floor of the rework area and did not place it the inedible container for Catogery-2 animal byproducts “not suitable for human or pet consumption”. All hair, scurf, dirt, hoofs and claws shall be removed from hog carcasses and proper disposed, and the carcasses shall be thoroughly washed and cleaned before any incision is made for inspection or evisceration. [*§310.11 Cleaning of hog carcasses before incising*]
- During the tour of the establishment, FSIS auditor observed an establishment employee trimming contaminated hog carcasses at rework station with moving line in the kill floor. The establishment’s employee was using the same knife to trim multiple contaminated carcasses without proper sanitation in between. There was a KDS employee standing next to the establishment employee verify adequacy of the rework performed. KDS did not address this finding with the establishment management or NVWA veterinarian in charge.

The establishment implemented immediate corrective action to address the above two findings. The VNWA inspection team is expected to verify that the adequacy documentation of the corrective action

Observations:

NVWA veterinarian observed the following non-compliance and initiated proper enforcement actions:

- A hog carcass was found in the cooler without proper removal of the hooves. It is NVWA expectation hog carcasses be free of hair, scurf, dirt, hoofs and claws before making any incision is made for inspection or evisceration.
- The forelimbs of hog carcasses were touching the edge of the CCP monitoring station and create insanitary conditions. The side of the stand of the station are not considered product contact surface and result in contamination and cross-contamination of inspected meat product.
- A hog carcass has an inflamed shoulder and should have been derailed for further evaluation and proper disposition. Additionally, two carcasses were observed in the reprocessing and further veterinary disposition station bearing the mark of inspection. Carcasses should not bear the mark of inspection unless they are thoroughly evaluated and deemed fit for human consumption and all trimming and reprocessing is conducted by the establishment and verified by the inspection program personnel.

**Note:** *Est. NL 312 EG, Vion Apeldoorn B.V. has an approval in place for the use of alternative post-mortem inspection procedure that does not require incision of lymph node. The veterinarian(s) station at the establishment are using Food Chain Information and professional judgment to determine if a selected group of animals should be slaughtered at the end of the day using slow speed and traditional post-mortem inspection procedure.*

<p>61. NAME OF AUDITOR Faiz Agarib, DVM</p>	<p>62. AUDITOR SIGNATURE AND DATE <i>Faiz Agarib</i></p>
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### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Zwanenberg Food Group B.V. Westdorplaan 225 8101 PN RAALTE <i>(Thermally processed, commercially sterile pork luncheon-canning)</i>	2. AUDIT DATE 06/18/2014	3. ESTABLISHMENT NO. Est. NL 153 EG	4. NAME OF COUNTRY The Netherlands
	5. NAME OF AUDITOR(S) Faiz Agarib, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .	X	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.	X	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

**Est. NL 153 EG, Zwanenberg Food Group B.V. (Processing- Thermally processed, commercially sterile -Canning), Raalte**

Establishment NL 153 EG, Zwanenberg Food Group B.V., has chosen to address the food safety hazards associated with microbiological contamination associated with producing canned product in its HACCP plan

**14 and 18/51 HACCP**

- During the tour of the establishment and, FSIS auditor noticed that the establishment has not established and implementing effective monitoring procedures at critical control point for control of Nitrite in pork luncheon intended for export to the U.S. The establishment is using strip paper with color indicator. However, the standard used to determine the actual value has a wide range “using *Degrees Brix (symbol °Bx) which is the solid content of an aqueous solution. One degree Brix is 1 gram of solid in 100 grams of solution and represents the strength of the solution as percentage by weight (% w/w). If the solution contains dissolved solids other than pure sucrose, then the °Bx only approximates the dissolved solid content.*” The observation does not provide accurate measurement to detect loss of control at critical points and provide information in time for corrective action to be taken in response to deviation of the critical limits. Critical limits correspond to the extreme values acceptable with regard to product safety. They separate acceptability from unacceptability. They are set for observable or measurable parameters which can demonstrate that the critical point is under control. They should be based on substantiated evidence that the chosen values will result in process control. Article 5 of Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs requires food business operators to put in place, implement and maintain a permanent procedure based on Hazard Analysis and Critical Control Point (HACCP) principles.

**20/51 HACCP**

- The establishment applies HACCP principles in accordance with Article 5 of Regulation (EC) No 852/2004 which requires food business operators to put in place, implement and maintain a permanent procedure based on Hazard Analysis and Critical Control Point (HACCP) principles. FSIS auditor, however, noticed that the establishment’s verification procedures included review of HACCP records and calibration of equipment but it did not include direct observations of the person(s) responsible for monitoring the CCPs. The establishment based this decision on the use of continuous monitoring devices. The use of continuous **monitoring** devices and data loggers to **monitor** a critical limit is common and encouraged. The establishment does not need to observe the device. The establishment, however, needs to observe its employees performing procedures associated with **monitoring** the critical control point (**CCP**). Inspection program personnel (IPP) need to be familiar with the HACCP plan's list of **monitoring** procedures, the frequency at which **monitoring** is to occur, and the documents supporting the **monitoring** and frequency to determine whether the establishment needs to perform an ongoing verification. The verification should be carried out by someone other than the person who conducts the monitoring.

These findings were not documented by the establishment or NVWA inspection program personnel. Article 5 of Regulation (EC) 852 and RE-31 delineated the general and specific hygiene requirements for each establishment to operate in a manner to prevent insanitary conditions. The official controls shall be performed by NVWA personnel to ensure the verification of compliance with the food law, animal health and animal welfare rules is covered in Regulation (EC) No. 882/2004 [9 CFR 417.2, 417.3, and 417.4.]. NVWA may need to look into means to ensure frequent and closer monitoring of the establishment sanitation and take proper enforcement action when the HACCP requirements are not met.

**Observation**

**Traceability and Recall procedure:** FSIS auditor verified that the establishment has an established mechanism to trace the product throughout all stages of production, processing and distribution in accordance with Article 18 of Regulation EC/178/2002. The establishment has a recall plan on file. The identification of the origin of food ingredients and food sources is of prime importance for the protection of consumers, particularly when products are found to be faulty. Traceability facilitates the withdrawal of foods and enables consumers to be provided with targeted and accurate information concerning implicated products.

**Incubation:** the establishment incubates at least one container from each batch to watch for any abnormality and keeps three containers at room temperature for 2-3 year to ensure safety and quality of product throughout the shelf life of the product.

61. NAME OF AUDITOR

Faiz Agarib, DVM

62. AUDITOR SIGNATURE AND DATE

*Faiz Agarib*