United States Department of Agriculture

Food Safety and
Inspection Service

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

FEB 2 4 2016

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

Dear Dr. Bruschke,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of the Netherlands' meat inspection system from July 13 through July 23, 2015. This final audit report includes a copy of the comments received by FSIS from the Government of the Netherlands.

The Nederlandse Voedsel-en Warenautoriteit (NVWA) has informed FSIS that it has initiated implementation of corrective actions to address the audit findings and provide assurances for the improvement and monitoring of the food safety controls maintained by beef producing establishments. Consequently, FSIS concludes that reinstatement of eligibility to the Netherlands to export beef to the United States can be granted.

For technical questions regarding the FSIS audit report, please contact Mr. Vincent Fayne, Acting Director of the International Audit Staff with the Office of Investigation, Enforcement and Audit (OIEA) at (202) 690-5662, or by electronic mail at international.audit@fsis.usda.gov.

If you have any other questions, please feel free to contact me directly.

Sincerely,

for Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

THE NETHERLANDS

JULY 13 TO JULY 23, 2015

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT (BEEF) PRODUCTS

TO BE EXPORTED TO THE UNITED STATES OF AMERICA

February 18, 2016
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site verification audit conducted by the Food Safety and Inspection Service (FSIS) from July 13 to July 23, 2015, as a follow-up to the audit conducted in June 2014. The audit objective was to verify that the Netherlands' food regulatory system governing production of beef products had implemented corrective actions necessary to become equivalent to the United States system, producing products that are safe, unadulterated, and properly labeled.

The Netherlands is not eligible to export beef products to the United States (U.S.) because of restrictions imposed on those products after the detection in 1997 of Bovine Spongiform Encephalopathy (BSE) in the Netherlands. The United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has since, ruled that the Netherlands has mechanisms in place that render BSE a negligible risk. Therefore, importation of products derived from bovine could be permitted. However, before granting reinstatement of eligibility to export beef to the United States, FSIS must determine whether the Central Competent Authority (CCA), Nederlandse Voedsel-en Warenautoriteit (NVWA), maintains adequate oversight of its beef inspection and verification program.

In June 2014, FSIS conducted an audit of the Netherlands beef inspection sector. The results of that audit showed that the CCA needed to improve the performance of four of its beef inspection system components namely, Government Oversight, Sanitation, and Hazard Analysis and Critical Control Point (HACCP) Systems. The CCA proffered a plan of action that would address the audit findings. During the interim period between the June 2014 and the July 2015 audits, the CCA introduced an alternate system of post-mortem inspection at the beef establishments eligible to become certified to export to the United States. However, the CCA did not inform FSIS of this change, via the self-reporting tool (SRT) or any other communication channel, prior to the 2015 follow-up audit.

The findings reported for this audit, identified deficiencies in the four components of the system that were assessed. Sanitary deficiencies observed at the establishments indicate that the Sanitation and HACCP components of the system still do not meet FSIS's equivalence criteria. Furthermore, the CCA introduced an alternate post-mortem inspection system, but did not inform FSIS of this change, nor sought an equivalence determination on the implemented measures. The alternate post-mortem inspection system includes inspection procedures that differ from FSIS procedures. Consequently, in the absence of an FSIS equivalence determination, the introduced changes undermine the equivalence of the Government Oversight and Statutory Authority and Food Safety Regulations components of the system.

In response to the to the reported findings, the CCA initiated implementation of a corrective action plan to further provide assurances for the improvement and monitoring of the food safety controls maintained by beef producing establishments. Furthermore, the alternate post-mortem inspection system that was being implemented at beef slaughter establishments has been discontinued and the traditional inspection procedures were re-established.

Based on the adequacy of the proffered corrective actions FSIS concludes that reinstatement of eligibility to the Netherlands to export beef to the United States can be granted.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted a follow-up on-site audit of the beef production sector of the Netherlands' meat inspection system from July 13 to July 23, 2015. The audit began with an entrance meeting held on July 13, in Utrecht with the participation of representatives from the CCA –NVWA - Netherlands Food Safety Authority and an auditor from the FSIS.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This on-site audit was conducted to assess whether the CCA implemented corrective actions to address the findings reported by FSIS during the 2014 audit of the beef inspection system of the Netherlands. FSIS defined the audit scope based on an analysis of country performance within six equivalence components, data collected by FSIS from the CCA through use of the self-reporting tools (SRT), and the results of the last on-site audit of the beef inspection system conducted in June 2014.

The CCA representatives accompanied the FSIS auditor throughout the entire audit. The audit focused on performance within the four components that were identified as not equivalent during the last audit: (1) Government Oversight (Organization and Administration), (2) Statutory Authority and Food Safety Regulations (Inspection System Operations and Product Standards), (3) Sanitation, and (4) HACCP. The Government Chemical Residue Testing Programs and Government Microbiological Testing Programs components were not included in the scope of the audit because the auditor in the last FSIS audit concluded that there was a basis to find the Netherlands' system to be equivalent with respect to these components.

The FSIS auditor reviewed administrative functions at CCA headquarters and four local inspection offices. The auditor evaluated the implementation of management control systems in place, which ensure that the national system of inspection, verification, and enforcement is implemented as intended.

Five establishments were presented by the CCA as eligible to become certified to export beef products to the United States. During the establishment visits, the auditor paid particular attention to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	NVWA Headquarters/Utrecht
	Local	4	NVWA Inspection Offices at veal slaughter establishments
Laboratories			Due to the fact that this was a follow-up audit, an assessment of the technical support provided by the laboratories was not included as an audit activity
Establishments		5	Est. NL-9-EG, veal slaughter. Apeldoorn Est. NL-369-EG, veal slaughter. Apeldoorn

		Est NL-34-EG, veal slaughter. Nieuwerkerk aan den IJssel Est. NL-49-EG, veal slaughter. 's-Hertogenbosch Est. NL-939-EG, veal Cut/up – Deboning. Nieuwerkerk aan den IJssel

The audit was undertaken under the specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.),
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. Title 7), and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327).

Determinations about equivalence made by FSIS as part of the initial and subsequent reviews have been made under the provisions of the Sanitary/Phytosanitary Agreement and European Commission/United States Veterinary Equivalence Agreement (VEA).

III. BACKGROUND

The Netherlands is currently not eligible to export beef products to the United States due to restrictions imposed on those products after the detection of BSE in the Netherlands, reported in 1997[1]. In March 2014, USDA's APHIS issued a final rule that lifted restrictions on the importation of beef from countries classified by the World Organization for Animal Health (OIE) as controlled or negligible risk for BSE.

Based on the 2014 APHIS ruling on BSE, the Netherlands current classification as a country having a negligible risk for BSE, and the reinstatement of eligibility request presented by the CCA of the Netherlands' meat inspection system, FSIS initiated the process of reinstatement of equivalence of the beef inspection system of the Netherlands. However, prior to the granting of reinstatement of eligibility to export beef to the United States, the CCA would have to demonstrate to FSIS that it maintains adequate oversight of its beef inspection and verification programs.

FSIS conducted an audit of the Netherlands' beef inspection system in June 2014. The audit identified that the CCA needed to improve the performance of Government Oversight (Organization and Administration), Sanitation, and HACCP components of the beef portion of its meat inspection system. The FSIS auditors reported that the CCA needed to improve the skills of inspection personnel to verify that establishments effectively prevent direct product contamination and adequately implement their HACCP programs while maintaining acceptable recordkeeping practices to document deviations and corrective actions.

In response to the reported deficiencies, the CCA proffered a plan of action that included several strategies that were expected to correct the reported deficiencies. FSIS determined that the proffered corrective actions addressed the reported audit findings and proceeded to plan an on-

[1] Docket No. 97–034–3 Change in Disease Status of The Netherlands Because of BSE

site audit to verify whether the reported findings had been adequately corrected. This report describes the outcome of the follow-up verification activities conducted on-site from July 13 – July 23, 2015, to evaluate the proffered corrective actions and to determine the Netherlands' eligibility to resume beef exports to the United States.

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

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

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

During the June 2014 audit, FSIS auditors assessed the equivalence of this component of the beef inspection sector and reported that the CCA needed to improve the implementation of regulatory control actions as part of its regulatory oversight of the system. Veterinarians stationed at the bovine slaughter establishments that intended to be certified as eligible to export beef product to the United States required training on FSIS requirements. Specifically, training was needed on enforcement of zero tolerance for fecal and ingesta on carcasses, humane handling of cattle, removal of Specified Risk Materials (SRM), preventive measures for HACCP deviations, and sanitary dressing procedures. The CCA responded that all newly appointed official veterinarians at the NVWA receive official training, including training on United States-requirements including Sanitation Standard Operating Procedures (SSOP), Pre-SSOP, Critical Control Point (CCP) monitoring and verification, effective follow up of non-compliances, and escalated enforcement actions.

The FSIS auditor verified that the CCA has introduced measures to implement uniform regulatory oversight. The in-plant veterinarians use an automated system to choose the type of inspection procedures they perform, in accordance with public-health risk indicators that the CCA identified in the various stages of the slaughter process. The outcomes of the performed procedures are reported to headquarters via smart phones, and the data collected is used to evaluate the performance of the establishments and to determine the frequencies at which the inspection and verification assignments are to be performed at each of the establishments. The CCA has also issued Version 1.2.3 of the USA-Approval and Control of Business to present the United States requirements and to describe responsibilities and practices to be implemented to meet the mentioned requirements.

At the establishment level, the FSIS auditor verified that establishments have developed procedures to address removal of SRMs, adequate removal of tonsillar tissue from the tongues,

and handling of non-ambulatory cattle, which are prohibited from slaughter by the CCA. As it pertains to the enforcement of zero tolerance for fecal contamination, the CCA issued standardized instructions in Version 3.0 of the "*Enforcement protocol for hygienic working procedures and (fecal) contamination in abattoirs for farm animals with permanent supervision"* that establishments and inspection personnel follow. However, those instructions do not include the hygienic protocol for the prevention and control of ingesta contamination during dressing procedures.

In accordance with inspection and verification protocols, the veterinary officials are trained to provide regulatory oversight of veal production activities. The official veterinarians verify that the establishments adequately monitor the critical control points and gather and report to the CCA headquarters, information related to the adequacy of the food safety programs of the establishments. However, during the audit of the slaughter establishments, the FSIS auditor observed that the restrictions that are in place to protect electronically stored documents pose difficulties for the in-plant inspectors as they seek to verify the adequacy of the design of the establishments' written food safety programs.

At three of the audited establishments, government inspectors could not readily retrieve electronically stored HACCP documents to demonstrate the adequacy of the hazard analysis conducted by the establishment at several steps in the slaughter process where ingesta contamination occurs. Furthermore, the inspectors could not demonstrate that the establishments had written procedures to follow to prevent and control the biological hazards associated with ingesta contamination. As further discussed in the HACCP component portion of this report, establishments employ a bleeding method that severs the neck blood vessels and severs the esophagus, thus causing spillage of ingesta in the process.

FSIS observed that in accordance with the regulatory framework of the European Commission, the CCA maintains regulatory oversight of the beef slaughter establishments by utilizing employees of the NVWA and official auxiliaries who are employees of Kwaliteitskeuring Dierlijke Sector (KDS), a non-governmental organization accredited to provide inspection services in accordance with NEN-EN-ISO/IEC 17020. The CCA contracts KDS inspectors to conduct post- mortem inspection duties at the slaughter establishments under the supervision of a NVWA veterinarian. The NVWA veterinarian evaluates the performance of the KDS inspectors and makes final veterinary dispositions on retained carcasses and viscera. The terms of the contract between the CCA and the KDS inspectors stationed at the beef slaughter establishments requires that KDS provide competent, qualified, and fully trained and equipped inspectors to conduct post-mortem inspection, and that no conflict of interest situations exist between the inspectors and the establishment where they work. The CCA in turn, regularly assesses the competence of the inspectors and pays for the services they render. .

The use of non-government employees to conduct post-mortem inspection was first instituted by the CCA in 2006, after FSIS evaluated the use of KDS contracted employees to conduct post-mortem inspection at certified swine slaughter establishments and determined that it met FSIS equivalence criteria. However, FSIS has not conducted an equivalence determination for that arrangement of post-mortem inspection at young cattle slaughter establishments. Therefore, it is

incumbent upon the CCA to request that FSIS conduct an evaluation of the acceptability of the alternate post-mortem inspection system that the CCA has chosen for young cattle.

After assessing the adequacy of implementation and effectiveness of corrective actions, interviewing inspection officials, reviewing documents, and conducting observations of establishments operations, the FSIS auditor concludes that there are still several aspects of this component that need to be corrected prior to FSIS granting reinstatement of equivalence of the Netherlands beef inspection system. Specifically, the CCA's hygienic protocol for verification of contamination prevention and control implemented at the slaughter establishments does not mention prevention and control of ingesta contamination. In addition, in-plant officials experience difficulties gaining access to electronically stored documents related to the establishments' food safety programs, to review the adequacy of their design. Furthermore, concerning post-mortem inspection of young cattle, the inspection procedures being used differ from FSIS procedures, however, the CCA has not requested an equivalence determination for the measures it has introduced to conduct post-mortem inspection at young cattle slaughter establishments.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS (INSPECTION SYSTEM OPERATION AND PRODUCT STANDARDS)

The second of four equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection, and periodic supervisory visits to official establishments.

The establishments that the CCA presented for this audit, slaughter calves under eight months of age that are raised within integrated operations in which feeding and, husbandry practices are standardized. Slaughter and cutting establishments maintain control of cattle suppliers, thus allowing for traceability of animals and products throughout the entire continuum from the farms to marketing outlets.

The FSIS auditor assessed the performance of ante-mortem inspection conducted by the government veterinarians and the methods of handling of animals at receiving, including the review of documents that accompany each group of calves received that attest to their being in compliance with regulatory requirements imposed by the European Commission. The auditor's observations, interviews, and review of documents showed that official controls remain in place at the establishments. Calves younger than eight months of age arrive at the slaughter establishments accompanied by documents that describe the origin of the calves, housing conditions in which they were raised, biosecurity measures existing at the rearing facilities, and application of other required husbandry practices. The NVWA veterinarian observes the calves in the ante-mortem pens, at rest and in motion, and segregates suspects to be slaughtered at the end of the shift. Furthermore, the government veterinarian maintains records on whether the establishment euthanizes non-ambulatory calves under NVWA supervision.

During the first part of 2015, the CCA implemented an alternate system of post-mortem inspection of calves that meets the European Commission regulatory requirements. During this audit, CCA officials indicated to the FSIS auditor that the post-mortem inspection system named Visual Inspection Plus (VIP) was being used at the calf slaughter establishments. The CCA officials also indicated that the European Commission permits VIP because the establishments ensure that the calves to be slaughtered are kept under controlled housing conditions and are reared in an integrated production system. The establishments ensure that the calves are reared in an officially bovine tuberculosis-free herd, and the CCA implements regular serological and microbiological sampling of the animals at the rearing facilities. However, the CCA has not requested that FSIS determine the equivalence of that newly introduced post-mortem inspection system. Furthermore, post-mortem inspection procedures in VIP require an incision through the inside of the masseter muscles on both sides with a single straight cut and a longitudinal incision in the heart. Palpation of the retropharyngeal, bronchial, and mediastinal lymph nodes is required, but incision and examination of the sub-maxillary, retropharyngeal and parotid lymph nodes is not mandated. This protocol is not completely consistent with the post-mortem inspection procedures employed by FSIS. The FSIS protocol requires that inspectors incise and observe the medial retropharyngeal lymph nodes (both left and right).

The CCA provided to the FSIS auditor information that describes the recommendations and results of the risk analysis on tuberculosis and cysticercosis in veal calves that was conducted before the new inspection procedures to detect those zoonoses in calves were implemented, omitted, or modified at calf slaughter establishments. The risk analyses was conducted by the Bureau for Risk Assessment and Research Programming (BRARP) of the NVWA and the European Food Safety Authority, the agency of the European Union that conducts risk assessments regarding food safety. In accordance with the provided information, the incidence of tuberculosis and cysticercosis in the Netherlands, along with practices implemented at integrated calf productions systems, permits the implementation of VIP without adding public health risks. However, in order for the alternate method of post-mortem inspection to be considered equivalent, the CCA must update the information contained in its self reporting tool and request that FSIS determine if the alternate post-mortem inspection system of calf inspection beign implemented meets FSIS equivalence criteria.

The FSIS auditor conducted interviews, observations and review of documents to assess the ability of the CCA to maintain regulatory control of humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; condemned materials; establishment construction, facilities, and equipment; daily inspection, and periodic supervisory visits to official establishments. Based on the results of the assessment of this component, the FSIS concludes that the post-mortem inspection system currently being implemented at calf slaughter establishments has not been determined equivalent to FSIS. The post mortem inspection procedures used to assess the health status of calves of different ages differ from FSIS procedures. The VIP system does not include palpation, incision, and observation of lymph nodes; multiple incisions and observations of masseter muscles and the heart; observation and palpation of the liver and bile duct; and palpation, observation or incision of the mesenteric and mediastinal lymph nodes. Therefore, it is incumbent upon the CCA to request that FSIS conduct an evaluation of the visual inspection plus methodology and related

scientific support, to determine if the alternate post-mortem inspection procedures provide an equivalent level of protection of the public health.

VI. COMPONENT THREE: SANITATION

The third of the four equivalence components that the FSIS auditor reviewed was Sanitation. To be considered equivalent to FSIS' program, the CCA is to provide general requirements for sanitation, sanitary handling of products and development and implementation of SSOP.

During the audit of the beef inspection system that was conducted by FSIS in June 2014, the auditors reported several deficiencies that were related to insanitary product handling, inadequate cleaning of equipment, insanitary dressing procedures, cross contamination between hides and skinned carcasses, and contamination being transferred from overhead rails to the surfaces of carcasses. In addition, in-plant inspection officials had not taken regulatory control action nor documented identified occurrences of insanitary conditions. The CCA indicated to FSIS that it would implement an improvement plan for the sanitation and effectiveness of process control in beef slaughter establishments. Based on the response provided, FSIS conducted a follow-up audit that concentrated on evaluating the corrective actions that had been implemented by the CCA.

During the on-site audit, FSIS evaluated the adequacy of implementation of the proffered improvement plan and verified that in-plant inspection personnel had regularly evaluated the adequacy of the establishments' sanitation programs, requested corrective actions, and escalated enforcement measures to respond to inadequate corrective actions associated with repetitive sanitary deficiencies. Documents reviewed demonstrated that establishments had responded to identified sanitary deficiencies with proposals that included short and long-term measures.

During the evaluation of the sanitary conditions of the establishments in operation, the FSIS auditor observed that at three of the establishments, many carcasses in the chillers, holding coolers, and shipping areas had contamination on their surfaces. Some carcasses had a viscous dark grayish substance on the posterior quarters, and others had gray greasy stains, dried grease flakes, and black specks on several of their surfaces. This type of insanitary product handling practice was also reported by the FSIS auditors during the June 2014 audit, thus making evident that the proffered corrective actions are either ineffective or are not being properly implemented.

Additionally, during the evaluation of the production areas of one of the establishments, the FSIS auditor noted that drops of condensate that had formed on overhead structures in several production rooms were falling down creating insanitary conditions that could result in contamination of product and packaging supplies that were moved throughout the room. For both types of events, in-plant inspection personnel had formally asked the establishments to correct the identified sanitary deficiencies and had received responses that included plans to implement short and long-term corrective measures. However, the observations made during the audit indicate that the short-term measures were not adequate or were not being implemented.

The FSIS auditor discussed the above-described findings with CCA officials, and both parties agreed that the CCA will take steps to require the plants to enhance their efforts to correct the

observed inadequate implementation of their sanitation programs. It is therefore incumbent upon the CCA officials to report to FSIS the results of the official verification activities to determine whether the establishments have corrected the reported findings in an acceptable manner.

The findings that FSIS auditors reported for this component of the system in June 2014 indicated that the sanitation programs implemented by the establishments required attention. The CCA addressed the concerns expressed by FSIS and has required that establishments improve the implementation of their sanitation programs. Government records reviewed by the FSIS auditor demonstrate that the establishments have received notification on the part of the CCA concerning the inadequacy of their sanitary controls. However, the observations conducted during the audit of the establishments indicate that frequent direct product contamination and the inability of the establishments to eliminate insanitary conditions continue to be concerns that require the CCA's attention.

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

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

During the audit conducted by FSIS in June 2014, the FSIS auditors reported that there were flaws in the design and implementation of the beef slaughter HACCP plans used by the establishments that inspection personnel had not identified nor documented. Specifically, the written HACCP plan did not include in the verification activities section, direct observation of monitoring of critical control points. In addition, the corrective action records did not describe the preventive measures implemented to address recurrent deviations. Additionally, the records did not consistently document the cause of the deviations. The FSIS auditors also reported that government officials and establishments had not recognized SRM as biological hazards, and therefore, they were not ensuring the complete removal of lingual tonsils.

The CCA indicated in its response to the 2014 audit findings for this component of the system that it would issue updated work instructions for inspection personnel on how to verify compliance of the establishments with regulatory HACCP requirements. In addition, the CCA stated that it would ensure the adequacy of the implementation of the establishments' HACCP plans and would issue specific instructions to inspection personnel on how to verify the establishments' compliance with the requirements related to SRM removal. Furthermore, the CCA said that it would review and analyze the establishments' HACCP plans and would require corrective actions to address non-compliances identified during the regular establishments' audits. FSIS accepted the proffered corrective actions and notified the CCA that as a follow-up step, FSIS auditors would conduct an on-site audit to verify the adequacy of the implemented corrective actions.

During this follow up audit, the FSIS auditor verified that inspection personnel stationed at the beef slaughter establishments regularly monitor the adequacy of removal of SRMs, review establishments' HACCP monitoring records, and conduct hands on measurements of critical

limits to verify the accuracy of monitoring of the CCPs. However, the auditor identified two matters of concern. First, the bleeding method used by the establishments during the slaughter process severs the neck blood vessels along with the anterior portion of the esophagus. The FSIS auditor evaluated this bleeding practice and observed that spillage of ingesta commonly occurs during its implementation. Subsequently, the auditor reviewed the written hazard analysis conducted for the establishments and noted that they had not completely evaluated the bleeding step in the slaughter process. Furthermore, the establishments could not demonstrate that they had considered spillage of esophagus contents caused by the bleeding method as an event that required prevention or control measures.

The second concern relates to the enforcement of zero tolerance for visible fecal contamination procedures. The CCA issued standardized instructions in Version 3.0 of the "*Enforcement protocol for hygienic working procedures and (fecal) contamination in abattoirs for farm animals with permanent supervision.*" However, those instructions do not include a requirement in the hygienic protocol for the prevention and control of ingesta contamination during dressing procedures.

The FSIS auditor observed that the implementation of HACCP systems in the beef inspection system has improved by the introduction of more effective regulatory controls, such as uniform instructions for the verification of establishments' monitoring activities and deployment of devices for the automated task assignments and data gathering. However, there is still a need for additional actions to improve the design of the establishments HACCP programs to address the actual challenges that establishments are facing. Specifically, the establishments need to completely assess all hazards associated with the bleeding method being used and implement sanitary measures that ensure prevention and control of contamination caused by spillage of ingesta during that step of the slaughter process. It is also necessary that the official verification instructions be revised to ensure that inspection personnel monitor the ability of the establishments to prevent contamination of carcasses and parts with ingesta during the dressing procedures.

VIII. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on July 23, in Utrecht with NVWA. At this meeting, the preliminary findings from the audit were presented by the FSIS auditor. The CCA understood and accepted the findings. The Netherlands is not eligible to export beef products, and the CCA has sought to obtain reinstatement of equivalence of its beef inspection system. FSIS audited the beef sector of the meat inspection system in June 2014, and reported concerns related to four of the six equivalence components of the system. The CCA proffered corrective actions, and FSIS proceeded to conduct a follow-up audit of the beef inspection sector of the system to verify the adequacy of implementation of the corrective actions.

The findings reported for this audit, identified deficiencies in the four components of the system that were assessed. Sanitary deficiencies observed at the establishments indicate that the Sanitation and HACCP components of the system do not meet FSIS's equivalence criteria. Furthermore, the FSIS auditor observed that the CCA had adopted an alternate young cattle post-mortem inspection system without notifying FSIS of the change or seeking an equivalence

determination on the implemented measures. The alternate post-mortem inspection system involves post-mortem inspection procedures that differ from FSIS inspection procedures. Consequently, in the absence of an FSIS equivalence determination, the introduced changes would undermine the equivalence of the Government Oversight and Statutory Authority and Food Safety Regulations components of the system.

In response to the to the reported findings, the CCA initiated implementation of a corrective action plan to further provide assurances for the improvement and monitoring of the food safety controls maintained by beef producing establishments. Furthermore, the alternate post-mortem inspection system that was being implemented at beef slaughter establishments has been discontinued and the traditional inspection procedures were re-established.

Based on the adequacy of the proffered corrective actions FSIS concludes that reinstatement of eligibility to the Netherlands to export beef to the United States can be granted.

Appendices

Appendix A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Ekro Laan van Malkenschoten 100 Apeldoorn, Netherlands	7/14/2015	NL-9-EG	The Netherlands
	5. NAME OF AUDITOR(S) Francisco Gonzalez		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

(04/04/2002)

60. Observation of the Establishment

Beef Slaughter (veal)

10. Monitoring of SSOPs
During the evaluation of operations at this establishment, the FSIS auditor observed that several overhead rails and rollers had accumulated black greasy residue on their surfaces that was flaking off and falling onto the carcasses that moved underneath, hung on the chain. The establishment had placed plastic covers on some of the carcasses to prevent the contamination from contacting the product. Inspection personnel have brought this issue to the attention of the establishment. In response the establishment has tried several long term and short term solutions as part of the sanitation program but inspection records and observations made show that an adequate corrective measure has not been identified. A similar finding was reported for this establishment during the 2014 FSIS audit.

17.
The establishment shares a centralized, computer based, information storage site with other establishments within the same corporation. At that site, the establishment has a description of the flow chart, hazard analysis and other written parts of the HACCP system as electronic documents that are password protected. This prevents the local government inspector from regularly verify the acceptability of the design of the HACCP system components or to verify if the written HACCP system has been reassessed, dated and signed.

22.
The entries made in the SSOP records do not describe with clarity the sanitary deficiencies identified. In a similar manner, government inspectors make entries that do not report with clarity the observed deficiencies.

55.
In accordance with European Commission regulations, EC No 1244/2007 and EC No 854/2004, the CCA has exercised its authority to implement post-mortem inspection of calves by utilizing the services of a private company to provide post-mortem inspection services. The private company inspectors conduct post-mortem inspection following procedures prescribed by the CCA that do not include incision of the head lymph nodes, since that is permitted by EC regulations. The CCA is aware of the need for FSIS to make an equivalence determination of this arrangement as was done in the past with the swine slaughter sector of the meat inspection system of the Netherlands.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Francisco Gonzalez, DVM	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Esa BV Saba 9 Apeldoorn, Netherlands	7/15/2015	NL-369-EG	The Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Francisco Gonzalez		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

(04/04/2002)

60. Observation of the Establishment

Beef Slaughter (veal)

10. Monitoring of SSOPs
During the evaluation of operations at this establishment, the FSIS auditor observed that several overhead rails and rollers had accumulated black greasy residue on their surfaces that was flaking off and falling onto the carcasses that moved underneath, hung on the chain. Inspection personnel have brought this issue to the attention of the establishment and several long term solutions have been tried as part of the sanitation program but inspection records and observations made show that an adequate corrective measure has not been identified. Inspection has issued a letter of warning to the establishment requesting an adequate corrective action.

17.
The establishment shares a centralized, computer based, information storage site with other establishments within the same corporation. At that site, the establishment has a description of the flow chart, hazard analysis and other written parts of the HACCP system as electronic documents that are password protected. This prevents the local government inspector from regularly verify the acceptability of the design of the HACCP system components or to verify if the written HACCP system has been reassessed, dated and signed.

41. The FSIS auditors and the CCA official noted that condensation drops were precipitating from overhead structures in several production rooms. Although, no direct product contamination was observed, the formation of condensate that was precipitating could potentially reach products and packaging materials that move underneath the problem areas. The establishment's records reviewed during the audit do not include reports of findings related to condensation, but the government records contain several entries reporting condensation in production areas. Inspection personnel have requested that the establishment correct this sanitary deficiency and the establishment has committed to implement short and long term corrective actions. The replacement of the cooling units throughout the establishment is scheduled for completion in August 2105. However the short term corrective measures are ineffective.

55.
In accordance with European Commission regulations, EC No 1244/2007 and EC No 854/2004, the CCA has exercised its authority to implement post-mortem inspection of calves by utilizing the services of a private company to provide post-mortem inspection services. The private company inspectors conduct post-mortem inspection following procedures prescribed by the CCA that do not include incision of the head lymph nodes, since that is permitted by EC regulations. The CCA is aware of the need for FSIS to make an equivalence determination of this arrangement as was done in the past with the swine slaughter sector of the meat inspection system of the Netherlands.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Francisco Gonzalez, DVM	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
T. Boer & zn BV '- Gravenweg 114 Nieuwerkerk aan den Ijssel, Netherlands	7/16/2015	NL-34-EG	The Netherlands
	5. NAME OF AUDITOR(S) Francisco Gonzalez		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Beef Slaughter (veal)

17.
The establishment shares a centralized, computer based, information storage site with other establishments within the same corporation. At that site, the establishment has a description of the flow chart, hazard analysis and other written parts of the HACCP system as electronic documents that are password protected. This prevents the local government inspector from regularly verify the acceptability of the design of the HACCP system components or to verify if the written HACCP system has been reassessed, dated and signed.

22.
The FSIS auditor observed one carcass with visible ingesta on the lateral surface of the hock. The in-plant official notified the establishment and an immediate corrective action was implemented. However, the record generated indicates that the establishment did not consider the presence of ingesta on the carcass as a deviation from the HACCP plan, but as an SSOP non-compliance.

55.
In accordance with European Commission regulations, EC No 1244/2007 and EC No 854/2004, the CCA has exercised its authority to implement post-mortem inspection of calves by utilizing the services of a private company to provide post-mortem inspection services. The private company inspectors conduct post-mortem inspection following procedures prescribed by the CCA that do not include incision of the head lymph nodes, since that is permitted by EC regulations. The CCA is aware of the need for FSIS to make an equivalence determination of this arrangement as was done in the past with the swine slaughter sector of the meat inspection system of the Netherlands.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Francisco Gonzalez, DVM	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
T. Boer & zn BV '- Gravenweg 114 Nieuwerkerk aan den Ijssel, Netherlands	7/16/2015	NL-939-EG	The Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Francisco Gonzalez		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Beef Cut-up (veal)

No deficiencies were identified during the audit of this establishment

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Francisco Gonzalez, DVM	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Vitelco Veemarktkade 21 's Hertogenbosch, Netherlands	7/20/2015	NL-49-EG	The Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Francisco Gonzalez		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

(04/04/2002)

60. Observation of the Establishment

Beef Slaughter (veal)

10. Monitoring of SSOPs
Implementation of the sanitation program is not adequate. Overhead surfaces had accumulated grease residue and dry flaking grease that is being transferred to numerous carcasses and major carcass portions hung in the chillers and the shipping areas. The FSIS auditor observed in several areas of the chillers that a liquid dark substance had dripped onto the hocks of the carcasses. Throughout the chilling rooms and shipping areas, there were carcasses had had dried grease particles and specks on their surfaces. There were also carcasses that had been covered with stockinets, ready for shipping, with visible greasy stains, grease drippings, and black specks on their surfaces. The establishment has been trying approaches to remedy this insanitary condition. Inspection has discussed this sanitary non-compliance with plant management and management has responded with approaches designed to address the problem. However the solution has not been found yet. Short term solutions nonetheless are not being implemented correctly.

13.
Recordkeeping for SSOPs
Government inspectors have not documented the insanitary conditions that have been observed in the holding chillers and shipping areas where carcasses are becoming contaminated with materials that fall from overhead structures, but have limited themselves to oral communications of concerns before establishment managers.

20.
Preventive actions are not stated in the slaughter HACCP plan

55.
In accordance with European Commission regulations, EC No 1244/2007 and EC No 854/2004, the CCA has exercised its authority to implement post-mortem inspection of calves by utilizing the services of a private company to provide post-mortem inspection services. The private company inspectors conduct post-mortem inspection following procedures prescribed by the CCA that do not include incision of the head lymph nodes, since that is permitted by EC regulations. The CCA is aware of the need for FSIS to make an equivalence determination of this arrangement as was done in the past with the swine slaughter sector of the meat inspection system of the Netherlands.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE

Appendix B: Foreign Country Response to Draft Final Audit Report (when available)

Ministry of Economic Affairs

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

USDA/ Food Safety and Inspection Service
Mr. Alfred V. Almanza
Deputy Undersecretary for Food Safety
1400 Independence Avenue S.W.
Washington DC
United States of America

Date: FEB - 2 2016
Subject: Draft final report veal

Directorate-General Agro and Nature
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

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

T +31 (0)70 378 5036
F +31 (0)70 378 6177
f.j.vandervalk@minez.nl

Our ref.
DGAN-DAD / 16013725

Your ref.

Encl.
1

Dear Mr. Almanza,

Thank you for your letter dated November 9, 2015 and the draft final report on the evaluation of the beef inspection system in the Netherlands attached to that letter.

With this letter I would like to respond in general to the draft report and specifically to some of the conclusions. Attached you will find a letter from the Inspector General of the Competent Authority addressed to the Chief Veterinary Officer of the Netherlands regarding the actions taken in reaction to the draft final audit report.

After the first audit, in 2014, follow up was given to the outcome and recommendations of that report. The report of the second audit contains however observations and conclusions on certain elements of the production chain of veal that were not signalled before. Furthermore some elements were addressed in a different context in the first audit. The observations of the auditor have led to a number of actions which are aimed at resolving the issues raised. I would like to present these to you.

Firstly I suggest to revise 2 points of the report which do not reflect the actual situation:

- At page 4/5 of the draft report the KDS structure is described. In the last sentence is stated that "This approach (.....) was not in place at the time FSIS audited the beef inspection sector in 2014 but was instituted early in 2015. " However, the KDS structure has been in place for a longer period and was in place during the 2014 FSIS audit. It is correctly described in the report of the 2014 audit and mentioned there at different occasions, for instances at page 2, 3 and 4. To assess the position and tasks of KDS your 2014 report supplies important information.

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

Our ref.
DGAN-DAD / 16013725

· In the report it is mentioned on page 3 that "Specifically training was needed on(.....) handling non-ambulatory disabled cattle".
However, the finding during the inspection of 2014 did not concern non-ambulatory animals. At one of the establishments, in one of the pens, nipple drinkers were not provided. The deficiency was corrected in 2014. Nipple drinkers are now in place in all pens at calves-slaughterhouses.

In the attached table you will find the response to the conclusions of the report and our points of action.

Regarding the Visual Inspection Plus system The Netherlands will, in conformity with your conclusion on this point, formally request FSIS to determine equivalency of VIP and update the self-reporting tool (SRT) on this point.

In the meantime and depending on the outcome of that process, the traditional post-mortem inspection method for bovine carcasses, as observed and described in the audit report 2014, will be re-established for all carcasses from which meat destined for the US market will be produced.

The second paragraph of page 5 of the draft report contains concluding remarks which seem to be confusing. The use of KDS personnel on one side and the VIP system being not evaluated for equivalency by FSIS seem to be mixed up. Both points are addressed in the first paragraphs of this letter separately, and are not interlinked.

The Competent Authority and involved companies are undertaking further action to bring the HACCP to the level required by FSIS, including the assessments of all hazards relating to the bleeding method and the measures to prevent and control these hazards, such as the contamination by spilling of ingesta. The companies are responsible to include this in the HACCP and the Competent Authority are to verify if these measures both on paper and in practice are sufficient to control these risks. For this matter, an access system has been put in place to unlock the (digital) HACCP documents for government inspectors.
The working instruction for Competent Authority personnel pertaining to HACCP is further enhanced, see the attached table.

Regarding the observed shortcomings on sanitation in the report, the NVWA will continue to review the performance of the companies involved and has integrated this in the review of HACCP. Enforcement of shortcomings is part thereof.

Regarding the relation between NVWA and KDS I would like to stress that the final decision making and responsibility for post mortem inspection is assigned to the official veterinarian in charge. This situation was observed and described during the 2014 audit report.

The Dutch Competent Authority is, in the light of the conclusions of this second audit report, adapting some of its working methods to be able to keep governmental oversight on beef and veal production that meets FSIS equivalence criteria.

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

Our ref.
DGAN-DAD / 16013725

Please accept my highest regards as I look forward to a next step in this important dossier.

Yours Sincerely,

Dr. Hans Hoogeveen, JD MPA
Director-General Agro and Nature

Netherlands Food and Consumer
Product Safety Authority
Ministry of Economic Affairs

Mrs. Dr. C.J.M. Bruschke DVM, PhD
Chief Veterinair Officer
Ministry of Economic Affairs
Directie Dierlijke Agroketens en Dierenwelzijn
Bezuidenhoutseweg 73
2500 EK 'S-GRAVENHAGE

Catharijnesingel 59
3511 GG Utrecht
PO Box 43006
3540 AA Utrecht
The Netherlands
www.nvwa.nl

Contact
G.A.D.J. de Mol

T +31 (0)88 223 1883
g.a.d.j.demol@nvwa.nl

Date
January 28, 2016

Our ref. TRC/742

note

Reaction and corrective action plan related to the draft final report of an audit conducted in the Netherlands July 13 to July 23, 2015

Dear Mrs. Bruschke,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of the Netherlands' meat (beef) inspection system from July 13 through 23, 2015. Herewith you receive our reaction and the corrective action plan related to this audit.

1. Objective
The Netherlands Food and Consumer Product Safety Authority (NVWA), the Central Competent Authority (CCA), has drawn up a corrective action plan in response to the Food Safety and Inspection Service (FSIS)' audit report. It addresses the findings of the on-site audit of 2015 for the meat inspection of beef products intended for export to the United States of America. The objective of this plan is to effectively implement corrective actions.

2. Development
The Netherlands is eligible to export pork products and egg products to the United States. The on-site audit in 2014 demonstrated that the meat inspection system and control measures applied for the production and export of swine products continues to be equivalent to FSIS' inspection system.

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 as "negligible risk" for Bovine Spongiform Encephalopathy (BSE). The conducted on-site audit later that year indicated that the control measures applied to the bovine inspection needed to improve. The CCA then proffered a plan for improvement of supervision in the meat supply chain. Despite the clear improvements that were realized, additional actions were required to solve the remaining shortcomings in the Sanitation and HACCP components of the system. This was addressed by drafting the Corrective Action Plan.

3. Corrective action plan
The corrective action plan consists of three components: 1 training programs, 2 proper monitoring and enforcement and 3 additional audit-procedure.
To make sure that HACCP is fully implemented in a way to meet the FSIS criteria, training programs are initiated and these programs are directed to government inspectors as well as establishment employees. Four NVWA veterinarians received USDA-HACCP training in the USA and are responsible for training colleagues on all

veal slaughterhouses. Based on the training NVWA auditors and inspectors in charge will be able to review the adequacy of HACPP plans regarding the FSIS standards according to Rules and Regulations 9CFR part 417 from May 14, 2015. Besides the intensified government oversight, the private sector (veal companies) has introduced an intensified HACCP training program for its staff and has revisited the HACCP plans in the autumn of 2015.

The plan for improvement of supervision in the meat supply chain, which was introduced in 2014, is supported by two teams. A design team develops new working methods and a uniformity team that supports putting the design into practice. Both teams will help to address all parts of HACCP. The government inspectors in charge are familiar with all relevant parts of the HACCP-plans of the establishments and are able to retrieve (electronically stored) HACCP-documents at any moment. Special attention will be given to corrective actions when the SSOP's have failed to prevent direct product contamination or adulteration. Establishments are directed to add the specific issue of the bleeding method to their HACCP-plans and are instructed to reconsider this bleeding method in relation to FSIS Directive 6410.1 if they intend to export beef products to USA in the near future. Criteria concerning the contamination with ingesta during dressing procedures are, in line with other CCP's added to the "Enforcement protocol for hygienic working procedure". Furthermore the NVWA has developed an approach to ensure frequent and closer monitoring of the establishment sanitation and take proper enforcement action when sanitary requirements are not met.

In January 2016 the CCA introduced an additional audit procedure for slaughterhouses that intend to export to the USA. An audit-team consisting of at least one USDA HACCP-trained inspector (out of four) verifies that the Sanitation and HACCP components of the system function properly. The audit-team conducts off-site and on-site audits. The establishments must submit a written document covering all the necessary improvements. When the document has been approved at least two on-site audits will be conducted to ensure that improvements are structural.

Yours sincerely,

Dr. ir. H. MPA Paul
Inspecteur-generaal
The Netherlands Food and Consumer Product Safety Authority (NVWA)

(Page in Final 2015)	Shortcoming	Annotation
1 (i,4,5,6,7)	**Visual Inspection Plus (VIP)** Method VIP: not equivalent; adopted without notifying FSIS	Immediate action: the traditional post-mortem inspection method will be resumed for all carcasses from which meat destined for the US market will be produced. Next step: process for equivalence will be started; SRT: up-load of method and supporting documents. FSIS will also be informed by a separate letter and supporting documents. There has been miscommunication or misinterpretation how to inform FSIS in a correct way. Neither information by letter was given nor an update of the SRT was performed. Additionally we would like to inform you about the evidence based scientific study indicating this method is an even more sanitary slaughtering process step than cutting into lymph nodes.
2 (i,5)	**Auxiliaries (KDS)** Post mortem inspection performed by auxiliaries (KDS).	The assignment of auxiliaries of the KDS is no new phenomenon. Auxiliaries of the KDS performed the post mortem inspection also in 2014. The option for auxiliaries to perform post mortem inspection is laid down in Regulation 854/2004/EC, Annex 1, Section 3. The KDS structure has been in place for a longer period and was in place during the 2014 FSIS audit. This structure is correctly described in the report of the 2014 audit and mentioned there at different occasions and correctly so, for instance at page 2, 3 and 4. To assess the position and tasks of KDS your 2014 report supplies important information. The CCA would like to emphasise that they are and will be responsible for the final inspection decision.
3 (i,4,5,9)	**HACCP 1** HACCP components do not meet FSIS criteria.	At the end of January 2016, the CCA implemented the USA-HACCP method for verification of Dutch establishments by assembling an audit-team: 2 x senior auditor, 1 x USDA-educated expert on HACCP, 1 x in plant NVWA veterinarian responsible for daily routine. Adequate training of government inspectors and establishment employees has started to meet the FSIS criteria. Four NVWA veterinarians already received an USDA-HACCP training in the USA (two of them in 2015) and are responsible for the training of colleagues on all veal slaughtering establishments. Based on the training NVWA auditors and NVWA inspectors in charge will be able to review the adequacy of HACCP plans regarding the FSIS standards according Rules and Regulations 9CFR part 417 [Docket No. FSIS-2009-0019] from May 14, 2015. This means CCA involvement in scientific or technical design of the data and a follow up by routine in plant verifications.
(13)	No requirements for prevention and control (bleeding method and contamination)	Emphasis on addressing all parts of HACCP, particularly with regard to prevention, will be part of the training. Establishments are directed to add the bleeding method as CCP to be a specific issue into their HACCP-plans and reconsider this method in relation to FSIS Directive 6410.1 (http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/PHIS_6410.1.pdf?redirecthttp=true) Criteria concerning the contamination with ingesta during dressing procedures are, in a similar way to other CCPs, added to the "Enforcement protocol for hygienic working procedure".
4 (i,4,5)	**HACCP 2** Government inspectors could not readily retrieve electronically stored HACCP-documents	At all slaughterhouses for the export to the USA the government inspectors can retrieve (electronically stored / web-based) HACCP-documents. The government inspectors in charge are familiar with the relevant parts of the establishments HACCP-plans. Additionally even CCA on central level has access to the HACCP plan on one particular plant for scientific / theoretical / experts input.

5 (3)	**Animal Welfare (2014)** Specifically training was needed for handling non-ambulatory disabled cattle	This is not correct: the finding during the inspection of 2014 wasn't regarding non-ambulatory animals. In one of the establishments, in one of the pens, no nipple drinkers were provided. The deficiency was remedied in 2014. Nipple drinkers are in all pens at calves-slaughterhouses.

Nederlandse Voedsel- en
Warenautoriteit
Ministerie van Economische Zaken

Divisie Veterinair & Import
Catharijnesingel 59
3511 GG Utrecht
Postbus 43006
3540 AA Utrecht
www.nvwa.nl

Audit USA HACCP en USA-eisen

Versie 2.0, 29 januari 2016

INLEIDING

In het kader van het mogen exporteren van roodvlees naar de USA dient een bedrijf ge-audit te worden om te zien of het naast de naleving van de Europese Regelgeving met betrekking tot het veilig produceren van levensmiddelen van dierlijke oorsprong ook kan voldoen aan de aanvullende eisen die de USA stelt. Deze aanvullende eisen zijn vastgelegd in de instructie RE-31 van de Nederlandse Voedsel- en Warenautoriteit (NVWA). De auditprocedure bestaat uit twee onderdelen. Eerst wordt op basis van de door het bedrijf aangeleverde documentatie en de reeds bij de NVWA beschikbare gegevens een off-site audit uitgevoerd. Nadat die met goed gevolg is doorlopen volgen minimaal twee on-site audits om vast te stellen dat het bedrijf structureel aan de gestelde eisen voldoet.

Bij het bedrijf *XXXXXXXX*, een XXXXXXXX met nummer NL-xxx-EG is een off-site uitgevoerd. Bedrijf XXXXXXXX heeft op XX-XX-201X het verzoek tot audit en bijhorende documentatie aangeleverd. De off-site audit is uitgevoerd op XX-XX-201X.

Op basis van de off-site audit heeft het auditteam geconcludeerd dat bedrijf XXXXXXXX (niet volledig) voldeed aan de gestelde eisen. (De NVWA heeft op de volgende onderdelen tekortkomingen geconstateerd: ..... Bedrijf XXXXXXXX dient aanpassingen in de bedrijfsvoeringen door te voeren. Nadat de NVWA een nieuw verzoek heeft ontvangen met schriftelijke onderbouwing van de aangebrachte verbeteringen, voert de NVWA een nieuwe audit uit.)

BEDRIJFSGEGEVENS

Naam:	x
Adres:	x
Plaats:	x
Telefoon:	x
Fax:	x
@:	x
www:	x
Bedrijfscategorie:	x
Producten:	x
Bedrijfsomvang:	x
Certificaten:	x

AUDITGEGEVENS

Off-site / In-plant audit
Plaats: x
Datum: x

Teamsamenstelling NVWA:

Naam	*Functie*
Naam	*Functie*
Naam	*Functie*

Gesprekspartners van het bedrijf:

Naam	*Functie*
Naam	*Functie*
Naam	*Functie*
Naam	*Functie*

De audit richtte zich op de eisen gesteld in Europese regelgeving, betreffende voedselveiligheid en dierenwelzijn, voor alle activiteiten vallend onder de erkenningsnummer NL-XXX-EG van het bedrijf XXXXXXXX, als ook op de aanvullende eisen die gesteld worden door de USA.

Referentiekader audit:

EU regelgeving
- HACCP / basisvoorwaardenprogramma (Verordening (EG) nr. 852/2004 en 853/2004); de EU Guideline HACCP (als verplicht) toepassen
- de op HACCP gebaseerde procedures uit artikel 2 van Sectie II van Bijlage II van Verordening 853/2004
- traceerbaarheid en meldingsplicht (Verordening (EG) nr. 178/2002)
- merking (Verordening (EG) nr. 1337/2013) Verordening (EG) nr. 1760/2000 en Verordening (EG) nr. 1825/2000
- microbiologische controles (Verordening (EG) nr. 2073/2005)
- dierlijke bijproducten (Verordening (EG) nr. 1069/2009 en 142/2011)
- dierenwelzijn (Verordening (EG) nr. 1099/2009)

USA regelgeving
- 9 CFR 300 ff., betreffende HACCP 9 CFR Part 417

NVWA voorschriften
- USA Toelating bedrijven (RE 31)
- USA-Doelgericht onderzoek Salmonella (RE 29)
- USA-Screening Salmonella (RE 30)
- USA-Microbiologisch Verificatie Onderzoek (RE 32)
- USA - Species Testing (vleesproducten)
- USA - Listeria (waar van toepassing) (RE 34)
- USA – STEC-Manual (waar van toepassing)

Er is een rondgang gemaakt over de werkvloer tijdens werkzaamheden.

Nederlandse Voedsel- en
Warenautoriteit
Ministerie van Economische Zaken

Mededelingen tijdens inleidend gesprek:

Vraag	**Toelichting**
1 Voldoet de bouwkundige staat van het bedrijf aan de eisen?	Voor deze bedrijven zijn de algemene inrichtingseisen voor alle exploitanten van levensmiddelenbedrijven van toepassing. Zie hiervoor Bijlage II van Verordening (EG) nr. 852/2004 en Bijlage III van Verordening (EG) nr. 853/2004. Het is niet de bedoeling om de inspectietaken van het project 'Erkenning-verlening en -onderhoud' te herhalen. De resultaten van de inspecties in het kader van de erkenning-verlening in combinatie met de resultaten van een globale rondgang door het bedrijf resulteren in een oordeel over de bouwkundige staat/inrichting van het bedrijf.
1 a Zijn in het verleden bevonden non-conformiteiten binnen de vastgelegde tijd verholpen	Zie 1
2 Voldoen de overige basisvoorwaarden aantoonbaar* aan de eisen?	Onder de overige basisvoorwaarden vallen de volgende onderwerpen: de goede hygiënepraktijken (artikel 4, lid 4 van de Verordening (EG) 854/2004), opleiding en bekwaamheid van het personeel en de behandeling van de dierlijke bijproducten in het bedrijf. Bijvoorbeeld: Markering en tracering; Ongedierte wering c.q. bestrijding; Drinkwaterkwaliteit; Zorgen dat geen condens op het product, medewerkers, instrumenten of verpakkingsmateriaal valt etc. * "aantoonbaar": gedocumenteerd, incl. corrigerende maatregelen en preventie etc.
2a Worden bij afwijkingen correctieve en preventieve maatregelen etc. beschreven	Guidance document EU verplicht toepassen als zijnde wet
3 Voldoet het bedrijf aan de hygiëne eisen?	Zie de hygiënevoorschriften in de Ver. 852/2004, bijlage II en Ver. 853/2004 bijlage III. Geef hierbij een oordeel op basis van de resultaten van inspecties in het kader van erkenningsonderhoud die recent zijn uitgevoerd in combinatie met een globale rondgang door het bedrijf.
4 Heeft het bedrijf een door derden gevalideerd HACCP-plan?	**§ 417.4** (1) Door wie en wanneer is de validatie uitgevoerd? ("60-dagen-eis" en beoordelaar mag niet zijn betrokken geweest bij het opzetten van het HACCP plan)
5 Zijn alle gevaren onderkend die tot een aanvaardbaar niveau gereduceerd moeten worden?	De gevarenanalyse houdt in het onderkennen van elk gevaar dat voorkomen, geëlimineerd of tot een aanvaardbaar niveau gereduceerd moet worden (artikel 5, lid 2 onder a van de Verordening (EG) nr.852/2004).

6 Zijn alle processtappen in processchema`s (hoofd- en deelprocesschema`s) weergegeven?	9CFR §417.2 A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified http://www.fsis.usda.gov/wps/wcm/connect/3cd0a6a5-fcff-4809-a298-030f3cd711a9/Meat_and_Poultry_Hazards_Controls_Guide_10042005.pdf?MOD=AJPERES Voorbeeld: In het verleden vroeg men ook de weergave van de CCP`s in de processchema`s om de plaatsen van monitoring en verificatie te kunnen controleren.
7 Is STEC in de gevarenanalyse meegenomen?	STEC (Shiga-toxine producerende E. coli) in levensmiddelen. De NVWA heeft hiervoor in 2014 een beleidslijn opgesteld. Bedrijven moeten het risico van STEC meenemen in hun HACCP- plan en als dat nodig is voor het productieproces: • beheersmaatregelen instellen; • daarop controleren; • actie ondernemen bij aantreffen. Voor hoog risico producten voor de export naar de USA is het "STEC manual" bij het team import-export NVWA beschikbaar[1]
8 Zijn de kritische controlepunten geïdentificeerd?	Het bedrijf is verplicht tot het identificeren van de kritische controlepunten in het stadium of de stadia daarna waarin controle essentieel is om een gevaar te voorkomen of te elimineren dan wel tot een aanvaardbaar niveau te reduceren (artikel 5, lid 2 onder b van de Verordening (EG) nr. 852/2004).
9 Zijn bij de kritische controlepunten de kritische grenswaarden vastgesteld?	Het bedrijf heeft de verplichting om kritische grenswaarden voor de kritische controlepunten vast te stellen teneinde te kunnen bepalen wat aanvaardbaar en wat niet aanvaardbaar is op het vlak van preventie, eliminatie, of reductie van een onderkend gevaar (artikel 5, lid 2 onder c van de Verordening (EG) nr. 852/2004).
10 Zijn de kritische grenswaarden op een aanvaardbaar niveau vastgesteld?	Het bedrijf heeft de verplichting om kritische grenswaarden voor de kritische controlepunten vast te stellen teneinde te kunnen bepalen wat aanvaardbaar en wat niet aanvaardbaar is op het vlak van preventie, eliminatie, of reductie van een onderkend gevaar (artikel 5, lid 2 onder c van de Verordening (EG) nr. 852/2004).
11 Zijn voor alle CCP's bewakingsprocedures omschreven?	Het bedrijf is verplicht om efficiënte bewakingsprocedures op de kritische controlepunten vast te stellen en toe te passen (artikel 5, lid 2 onder d van de Verordening (EG) nr. 852/2004).
12 Zijn in alle bewakingsprocedures de vereiste onderwerpen beschreven?	De volgende items moeten beschreven zijn in de bewakingsprocedures: werkwijze bewaking, frequentie, kritische limieten, corrigerende actie en registratie. FSIS vraagt bij alle corrigerende acties ook preventieve maatregelen en het aanpassen hiervan als een omissie optreedt en dus de tot nu beschreven preventieve maatregelen niet voldoende blijken te zijn. Dit betreft niet alleen de CCP's.

[1] De op het moment beoogde producten voor de export naar de USA eisen geen onderzoek op STEC op basis van eisen USA

13 Beheersen de bewakingsprocedures doeltreffend de risico's voor de voedselveiligheid?	De bewakingsprocedures moeten gericht zijn op het te beheersen risico voor de voedselveiligheid. Zie ook hier boven – wordt alles in acht genomen en (schriftelijk) vastgelegd
14 Worden alle bewakingsprocedures ook uitgevoerd zoals ze zijn beschreven?	De bewakingsprocedures moeten worden uitgevoerd zoals deze door het bedrijf zijn vastgesteld Wat doet het bedrijf als blijkt dat ze niet, zoals vastgesteld of helemaal niet, worden uitgevoerd?
15 Zijn de corrigerende maatregelen doeltreffend?	**§ 417.3 Corrective actions.** (a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure: Dit betekent ook dat bij afwijkingen/omissies de preventieve maatregelen moeten worden aangepast. (c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with § 417.4(a)(2)(iii) and the recordkeeping requirements of § 417.5 of this part.
15a1 Is de oorzaak geïdentificeerd en geëlimineerd?	**§ 417.3 Corrective actions.** (1) The cause of the deviation is identified and eliminated;
15a2 Is de CCP nadat de corrigerende maatregelen zijn genomen onder controle?	(2) The CCP will be under control after the corrective action is taken;
15a3 zijn preventieve maatregelen beschreven?	(3) Measures to prevent recurrence are established;
15a4 Wordt voorkomen dat producten onveilig (of op ander manier niet voldoende) in de handel komen?	(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.
15 b Bij voorkomende afwijkingen die niet beschreven staan door correctieve maatregelen of bij andere onvoorziene gevaren onderneemt het bedrijf actie:	If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:
15b1 Wordt in geval van non-conformiteit het product apart gehouden?	(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met

15b2 Wordt en review gedaan om te bepalen of het betreffende product, en met welke bestemming, in de handel kan?	(2) Perform a review to determine the acceptability of the affected product for distribution;
15b3 Wordt ervoor gezorgd dat het product, als het niet voldoet, niet in de handel komt?	(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;
15b4 Wordt door een person, met voldoende kennis (opleiding), een re-assessment doorgevoerd om te bepalen of de geconstateerde afwijking/gevaar in het HACCP-plan opgenomen moet worden?	(4) Perform or obtain reassessment by an individual trained in accordance with § 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.
16 Zijn er verificatieprocedures om na te gaan of het HACCP plan naar behoren functioneert?	Het bedrijf heeft de verplichting om procedures vast te stellen om na te gaan of de bedoelde maatregelen onder a t/m e van artikel 5, lid 2 van de Verordening (EG) nr. 852/2004 naar behoren functioneren (artikel 5, lid 2 onder f van de Verordening (EG) nr. 852/2004). Zijn deze procedures doeltreffend? Worden ze aangepast als ze niet doeltreffend zijn? Is een re-assessment van deze procedures beschreven? § 417.2 (7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with § 417.4 of this part.
17 Hoe heeft het bedrijf invulling gegeven aan de verificatie op STEC?	Bij slachthuizen wordt STEC met name veroorzaakt door fecale bezoedeling. Het niet aanwezig zijn van fecale bezoedeling op karkassen is een basisvoorwaarde. Indien blijkt dat STEC wel voor komt, dient nagegaan te worden of in het HACCP plan hiervoor procedures zijn opgenomen om dit te voorkomen en of deze procedures door het bedrijf ook worden uitgevoerd. De Nederlandse Beleidsnormen t.a.v. STEC zijn bindend!
18 Worden de omschreven verificatieprocedures uitgevoerd?	Het bedrijf heeft de verplichting om procedures vast te stellen om na te gaan of de bedoelde maatregelen onder **§ 417.4 en** a t/m e van artikel 5, lid 2 van de Verordening (EG) nr. 852/2004 naar behoren functioneren (artikel 5, lid 2 onder f van de Verordening (EG) nr. 852/2004). Het bedrijf dient deze procedures ook daadwerkelijk uit te voeren. <u>9 CFR Part 417</u> **§ 417.4 Validation, Verification, Reassessment.** (a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented. (3)(i) **Reassessment** of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and

	whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with § 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of § 417.2(c) of this part.(ii) Each establishment must make a record of each reassessment required by paragraph (a)(3)(i) of this section and must document the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment. For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination.(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.
18 A1 Heeft de validatie na het opstellen van het HACCP-plan plaatsgevonden?	**§ 417.4 Validation, Verification, Reassessment.** (1) **Initial validation**. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.
18 A2 Worden de verificaties uitgevoerd?	(2) **Ongoing verification activities**. Ongoing verification activities include, but are not limited to:(i) The calibration of process-monitoring instruments;(ii) Direct observations of monitoring activities and corrective actions; and(iii) The review of records generated and maintained in accordance with § 417.5(a)(3) of this part.

18A3 Vindt tenminste jaarlijks een re-assessment van het HACCP-plan plaats?	(3)(i) **Reassessment** of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with § 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of § 417.2(c) of this part.(ii) Each establishment must make a record of each reassessment required by paragraph (a)(3)(i) of this section and must document the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment. For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination.(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.
19 Record keeping	§ 417.5 Records. (a) The establishment shall maintain the following records documenting the establishment's HACCP plan:(1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;(2) The written HACCP plan, including decision making documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented

	in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.(d) Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.(e) Record retention. (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.(f) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.
20 Kan men aantonen dat het beschreven HACCP-plan daadwerkelijk wordt toegepast?	Het bedrijf moet de beschikking hebben over documenten van registraties, waaruit blijkt dat het beschreven HACCP-plan daadwerkelijk wordt toegepast.
21 Heeft de NVWA toegang tot de relevante delen van het HACCP-plan en de bijhorende documenten?	Inzichtelijk systeem en/of nodige ondersteuning door bedrijf
22 Wordt de NVWA bij veranderingen van het HACCP-plan op tijd geïnformeerd?	"Wordt de NVWA over relevante veranderingen in het HACCP-plan geïnformeerd? Indien ja, hoe en wanneer?" Voorbeelden:
23 Zijn nieuwe gevaren en risico in het proces, product, grondstof of bij de gebruiker, (EG en USA) opgenomen? Is het bedrijf betreffende USA-regelgeving proactief bezig (moet niet eerst door NVWA op veranderingen worden aangesproken)	Nieuwe gevaren, risico's of wijzigingen in het proces, product, grondstof of gebruiker moeten in de laatste versie van het HACCP-plan zijn opgenomen. (artikel 5, lid 4 onder b van de Verordening (EG) nr. 852/2004 en 9 CFR Part 417). "Hebben er in de afgelopen periode wijzigingen in de USA regelgeving plaatsgevonden, die invloed hebben op HACCP-plannen van USA geregistreerde bedrijven? Wie van het bedrijf checkt dit en hoe vaak? Wat zijn dan de wijzigingen? In hoeverre is het HACCP-plan van het bedrijf n.a.v. de wijzigingen in de USA regelgeving aangepast"

24 Garanderen de HACCP procedures dat producten van dierlijke oorsprong voldoen aan specifieke eisen?	Het bedrijf moet beschikken over HACCP procedures die de garantie bieden dat producten van dierlijke oorsprong voldoen aan de genoemde criteria in artikel 4, lid 5 van de Verordening (EG) 854/2004. Daar staat: Bij de audits van de op de HACCP gebaseerde procedures wordt nagegaan of de exploitanten van levensmiddelenbedrijven deze procedures **voortdurend en naar behoren toepassen**, waarbij er vooral voor gezorgd wordt dat de procedures de garanties bieden die gespecificeerd worden in sectie II van bijlage II bij Verordening (EG) nr. 853/2004. Meer in het bijzonder wordt nagegaan of de procedures, voor zover mogelijk, de garantie bieden dat producten van dierlijke oorsprong: a) voldoen aan de microbiologische criteria van de communautaire regelgeving; b) voldoen aan de communautaire regelgeving inzake residuen, contaminanten en verboden stoffen en c) geen sporen van fysische risico's zoals vreemde lichamen vertonen.
25 Zijn er HACCP procedures die garanderen dat de juiste dieren op het slachthuis worden aanvaard?	Het bedrijf moet beschikken over HACCP procedures die garanderen dat elk dier cq. elke groep dieren die op het terrein van het slachthuis worden aanvaard, aan de eisen voldoen genoemd in artikel 2 van Sectie II van Bijlage II van Verordening (EG) nr. 853/2004. **Deze procedures gaan over:** *a) de dieren zijn naar behoren **geïdentificeerd**;* *b) de **relevantie informatie** van het in sectie III bedoelde bedrijf van herkomst is bij het binnenbrengen van de dieren aanwezig;* *c) de dieren komen niet van een bedrijf of een gebied waarvoor met het oog op de gezondheid van mens en dier een **verplaatsingsverbod** dan wel een andere beperking geldt, tenzij de bevoegde autoriteit daarvoor toestemming gegeven heeft;* *d) de dieren zijn **schoon**;* *e) de dieren zijn **gezond**, voor zover dit door de exploitant van het levensmiddelenbedrijf kan worden beoordeeld,* *en* *f) het **welzijn** van de dieren bij aankomst in het slachthuis is bevredigend."* Voor **USA** specifiek relevant is de herkomst van de dieren (born and bred, betreffende kalveren is dit: [2]). Hoe voert het bedrijf een aantoonbare controle hierop uit? Is er steeds (op ieder tijdstip) een NVWA'er aanwezig bij aanvoer van dieren? Heeft bedrijf dit ook beschreven?

[2] Voor de kalveren is dit niet born and bred. Echter, omdat er nog geen certificaat is afgesproken, is het nog niet vastgelegd wat de eisen/landen zijn.

26 Zijn de HACCP eisen van de FSIS bekend bij bedrijf?	9 CFR Part 417
27 Worden de CCP's door bedrijf bewaakt zoals beschreven in RE-31	Bij overschrijdingen van kritieke limieten van CCP's moet het bedrijf de volgende corrigerende maatregelen nemen: ▪ De oorzaak opsporen en elimineren. ▪ De CCP door een correctieve actie weer onder controle brengen. ▪ **Preventieve actie(s)** ondernemen, **beschrijven**, om herhaling te voorkomen (bij ieder overschrijding/corrigerende actie). ▪ Actie(s) uitvoeren zodat er geen afwijkende producten in de handel/consumenten kunnen komen. Dit houdt onder andere in dat voor ieder verlading de temperatuur gecontroleerd wordt. Gebeurt dit ook buiten de gewone werktijden_ Naast de verificatie van het HACCP-systeem voert het bedrijf dagelijks een **verificatie van de monitoring van de CCP's** uit door een andere persoon dan die de monitoring uitvoert en bestaat uit: - Verificatie fysieke uitvoering monitoring CCP, - Schaduwcontrole door eigen meting en een vergelijking van die twee controles, - Verificatie vastlegging monitoringslijsten, - Controle op corrigerende maatregelen.
28 Wordt pre-shipment zoals beschreven in RE-31 uitgevoerd?	Ook in de weekeinden of buiten openingstijden? Het bedrijf moet een geschreven procedure voor de registraties van controles hebben waarin het bedrijf aangeeft hoe bij verzending van een partij of product een (papieren) controle plaatsvindt op de beheersing van de CCP's tijdens die productie. **Voor de duidelijkheid – er moet een aantoonbaar link tussen de te verzenden partij en de gecontroleerde CCP monitoringsgegevens bestaan.** De uitvoerder van de pre-shipment controle was niet betrokken bij de monitoring van de CCP's.

§ 417.6 Inadequate HACCP Systems.
A HACCP system may be found to be inadequate if:
(a) The HACCP plan in operation does not meet the requirements set forth in this part;
(b) Establishment personnel are not performing tasks specified in the HACCP plan;
(c) The establishment fails to take corrective actions, as required by § 417.3 of this part;
(d) HACCP records are not being maintained as required in § 417.5 of this part; or
(e) Adulterated product is produced or shipped.

Anders dan HACCP	
29 SSOP etc. Zie RE-31	Voor de toezichtwerkzaamheden op USA-geregistreerde bedrijven geldt dat controlelijsten van het bedrijf en de NVWA volledig ingevuld moeten zijn. Het schoonmaakplan van de bedrijven moet op schrift staan. Op de controlelijsten moeten de volgende gegevens te worden vermeld: ▪ Datum. ▪ Tijdstip van de controle. ▪ Aard van de tekortkoming. ▪ Actie op de tekortkoming. ▪ Hercontrole met tijdstip. ▪ Handtekening van de controleur. ▪ Handtekening van de NVWA-controleur. ▪ Controlelijsten van bedrijf en NVWA moeten aantoonbaar met elkaar vergeleken worden.
30 Worden door het bedrijf bij afwijkingen alle nodige maatregelen genomen	Bij afwijkingen bij (pre-)SSOP's moet het bedrijf volgende corrigerende maatregelen nemen: • Schoonmaken (ruimte, materiaal) en/of opknappen, flamberen product. • Preventieve actie(s) uitvoeren om herhaling te voorkomen (betekend deze (nieuwe) preventieve acties ook beschrijven). • Nagaan of overig product gecontamineerd kan zijn en zo ja, actie(s). • Re-evaluatie en indien nodig modificatie van SSOP's.
31 Training	§ 417.7 Training Hebben alle medewerkers een "USA opleiding"?

EINDOORDEEL[3]

Het bedrijf xxx (EG xxx) wordt wel of niet voorgedragen voor landenregistratie – USA.

De USA landenregistratie van het bedrijf xxx (EG xxx) wordt wel of niet verlengd (*toepassen bij jaarlijkse audit*).

Het bedrijf xxxx (EG xxx) dient het aangetroffen systeem op de volgende punten aan te passen:

[3] **§ 417.8 Agency verification**
FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:(a) Reviewing the HACCP plan;(b) Reviewing the CCP records;(c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;(d) Reviewing the critical limits;(e) Reviewing other records pertaining to the HACCP plan or system;(f) Direct observation or measurement at a CCP;(g) Sample collection and analysis to determine the product meets all safety standards; and(h) On-site observations and record review

AFSPRAKEN

Het bedrijf xxx (EG xxx) zal schriftelijk in kennis gesteld worden van de tekortkomingen zoals die aan het licht zijn gekomen tijdens deze audit.

Welke afspraken zijn gemaakt n.a.v. de geconstateerde tekortkomingen?
xxx.

Wie voert de her-inspectie uit en op welke datum?
xxx.

Welke interventie uit het interventiebeleid is toegepast?
[NVT / MW / SW / PV / BR / Corrigerende interventie / Andere interventie]

Diverse stukken ter onderbouwing:

FSIS 5000 serie:
http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/5000-series/5000-Series

FSIS: Meat and Poultry Hazards and Controls Guide
http://www.fsis.usda.gov/wps/wcm/connect/3cd0a6a5-fcff-4809-a298-030f3cd711a9/Meat_and_Poultry_Hazards_Controls_Guide_10042005.pdf?MOD=AJPERES

Suggested General Verification Questions for Most Process Steps
This set of general questions should be asked when evaluating the production process in light of the relevant process steps. It is intended to assist inspection personnel in verifying the adequacy of the establishment's approach to each processing step. Individual processing steps in this Guide include additional questions that are specific to each processing step.

- Has the establishment included this process step in the flow chart and hazard analysis?
- Does the establishment have a prerequisite program that addresses this step?
- Has the establishment identified any hazards associated with this step?
- Is this process step a CCP?
- Is the establishment following all procedures identified in the hazard analysis?
- Does the establishment maintain records associated with this step?
- Do records contain information that indicates a reassessment of the hazard analysis or HACCP plan is necessary?
- Are records made available to FSIS?
- Is the equipment used clean, sanitary, and well maintained?

Nederlandse Voedsel- en Warenautoriteit
Ministerie van Economische Zaken

Veterinary & import division
Catharijnesingel 59
3511 GG Utrecht
The Netherlands
Postbus 43006
3540 AA Utrecht
The Netherlands
www.nvwa.nl

USA audit HACCP and USA requirements

Version 2.0, 29 January 2016

INTRODUCTION

As part of the process to obtain authorisation to export red meat to the USA, a business must be audited to verify whether, in addition to complying with the European regulations governing safe production of food products of animal origin, the business can also meet the additional requirements that the USA demands. These additional requirements are listed in the Netherlands Food and Consumer Product Safety Authority's (NVWA) instruction RE-31. There are two components to the audit procedure. First, the Authority conducts an off-site audit based on the documentation supplied by the business and the information already available to the Authority. This audit, if passed, is followed by at least two on-site audits to establish that the business is capable of meeting the set requirements on an ongoing basis.

An off-site audit of the business *XXXXXXXX*, an XXXXXXXX with number NL-xxx-EG, has been conducted. On XX-XX-201X, business XXXXXXXX submitted a request for audit and accompanying documentation. The off-site audit was conducted on XX-XX-201X.

Based on the off-site audit, the audit team concluded that business XXXXXXXX was in compliance/is not fully in compliance with the set requirements. (The Authority observed irregularities in the following aspects: ..... Business XXXXXXXX must implement changes in its operational procedures. After the Authority has received a new request with substantiation in writing of the improvements implemented, it will conduct a new audit.)

COMPANY DETAILS

Name:	x
Address:	x
City/town:	x
Telephone:	x
Fax:	x
@:	x
www:	x
Business category:	x
Products:	x
Company size:	x
Certificates:	x

AUDIT INFORMATION

Off-site/In-plant audit
City/town: x
Date: x

Composition of the team from the Authority:
Name *Job title*
Name *Job title*
Name *Job title*

Contact persons for business:
Name *Job title*
Name *Job title*
Name *Job title*
Name *Job title*

The audit was focused on the requirements set under European regulations concerning food safety and animal welfare, for all activities falling under approval number NL-XXX-EG for the business XXXXXXXX, as well as the additional requirements set by the USA.

Audit reference framework:

EU regulations

- HACCP/basic conditions programme (Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs and Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption); application of EU Guideline HACCP (as mandatory)
- the HACCP-based procedures of Article 2,Section 2,Annex 2 of Council Regulation (EC) 853/2004
- traceability and reporting obligation (Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety)
- indication and labelling (Commission Implementing Regulation (EU) No 1337/2013of 13 December 2013 laying down rules for the application of Regulation (EU) No 1169/2011 of the European Parliament and of the Council as regards the indication of the country of origin or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry), Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 and Commission Regulation (EC) No 275/2007 of 15 March 2007 amending Regulation (EC) No 1825/2000 laying down detailed rules for the application of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the labelling of beef and beef products
- microbiological criteria (Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (Text with EEA relevance))
- animal by-products (Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived

products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) and Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive Text with EEA relevance)

- animal welfare (Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (Text with EEA relevance))

USA regulations

- 9 CFR 300 ff., concerning HACCP 9 CFR Part 417

Authority instructions

- USA – Approval of businesses (RE-31)
- USA – Targeted salmonella investigation (RE-29)
- USA – Salmonella screening (RE-30)
- USA – Microbiological verification investigation (RE-32)
- USA – Species Testing (meat products)
- USA – Listeria (where applicable) (RE-34)
- USA – STEC Manual (where applicable)

An on-site walk-through was conducted at the time of the audit activities.

Information provided during initial meeting:

Question	**Explanation**
1 Is the state of the business's building(s) in compliance with the requirements?	These companies are subject to the general architectural and layout requirements for all operators of food business operators. For these requirements, see Annex 2 of Council Regulation (EC) No 852/2004 and Annex 3 of Regulation (EC) no. 853/2004. It is not the intention to repeat the inspection tasks of the project 'Erkenningverlening en -onderhoud' ('Acceptance granting and acceptance maintenance'). The results of the inspections in the context of the acceptance granting in combination with the results of a general walk-through in the business produce an evaluation of the state of the physical facilities (building) and layout of the business.
1a Have irregularities observed in the past been remedied within the stipulated period?	See 1
2 Do the other basic conditions demonstrably* meet the requirements?	'Other basic conditions' refers to the following subjects: good hygiene practices (Article 4, paragraph 4 of Council Regulation (EC) No 854/2004), training and competence of the personnel and the handling of animal by-products in the business. For example: Identification and tracing, Pest prevention/control; Potable water quality, ensuring that no condensation falls on the product, personnel, equipment or packaging material, etc. * 'demonstrable': documented, including corrective measures and prevention, etc.
2a In the event of irregularities, are creative and preventive measures, etc., defined?	Obligatory application of EU guidance document as if by law
3 Is the business in compliance with hygiene standards?	See the hygiene instructions in Council Regulation (EC) 852/2004, Annex 2, and Council Regulation (EC) No 853/2004, Annex 3. Give an opinion based on the results of inspections for the purposes of approval maintenance recently carried out in combination with a general walk-through in the business.
4 Does the business have an HACCP plan validated by third parties?	**Paragraph 417.4** (1) When was this validation carried out, and by whom? ('60-day requirement' and evaluator must not have been involved in setting up the HACCP plan)
5 Have all hazards that must be reduced to an acceptable level been identified?	The hazard analysis involves the identification of every hazard that must be prevented, eliminated or reduced to acceptable levels (Article 5, paragraph 2(a) of Council Regulation (EC) No 852/2004).

6 Have all process steps been mapped out in process diagrams (primary and sub-process diagrams)?	9CFR §417.2 A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified http://www.fsis.usda.gov/wps/wcm/connect/3cd0a6a5-fcff-4809-a298-030f3cd711a9/Meat_and_Poultry_Hazards_Controls_Guide_10042005.pdf?MOD=AJPERES Example: In the past, it was also a requirement to diagram the CCPs in process diagrams to establish the points for monitoring and verification.
7 Has STEC been incorporated into the hazard analysis?	STEC (Shiga toxin-producing E. coli) in food products. TheAuthority drafted a policy guideline for this area in 2014. Companies must include the risk of STEC in their HACCP plan and, where necessary, for the production process: • implement control measures • check for STEC • take action where encountered For high-risk products intended for export to the USA, there is a 'STEC manual' available from the Authority's import-export team.[1]
8 Have the critical control points been identified?	The business is obliged to identify the critical control points at the stage or stages in which inspection is essential for preventing or eliminating a risk or reducing it to an acceptable level (Article 5, paragraph 2(b), Council Regulation (EC) No 852/2004).
9 Have the critical limits for the critical control points been established?	The business has the obligation to establish critical limits for the critical control points in order to determine what is and is not acceptable in the areas of prevention, elimination or reduction of an identified hazard (Article 5, paragraph 2(c), Council Regulation (EC) No 852/2004).
10 Have the critical limits been set at an acceptable level?	The business has the obligation to establish critical limits for the critical control points in order to determine what is and is not acceptable in the areas of prevention, elimination or reduction of an identified hazard (Article 5, paragraph 2(c), Council Regulation (EC) No 852/2004).
11 Have monitoring procedures for all CCPs been described?	The business is obliged to define and apply efficient monitoring procedures for the critical control points (Article 5, paragraph 2(d), Council Regulation (EC) No 852/2004).
12 Do all monitoring procedures include a description of the required subject areas?	The monitoring procedures must include a description of the following items: monitoring method, frequency, critical limits, corrective action and registration. For all corrective actions, FSIS also requires preventive measures and their adjustment wherever an omission occurs, which in turn means the preventive measures described up to that point proved are inadequate. This refers not only to the CCPs.

[1] The products currently intended for export to the USA do not require inspection for STEC under USA requirements.

13 Do the monitoring procedures effectively control the risks to food safety?	The monitoring procedures must be designed to control the risks to food safety. See above: all aspects must be observed and documented.
14 Are all monitoring procedures being carried out as described?	The monitoring procedures must be carried out as adopted and established by the business. What does the business do if it becomes apparent that they are not being carried out as defined, or not being carried out at all?
15 Are the corrective measures effective?	**§ 417.3 Corrective actions.** (a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure: This also means that in the event of irregularities/omissions, the preventive measures must be adjusted. (c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with § 417.4(a)(2)(iii) and the recordkeeping requirements of § 417.5 of this part.
15a1 Has the cause been identified and eliminated?	**§ 417.3 Corrective actions.** (1) The cause of the deviation is identified and eliminated;
15a2 Has the CCP been reviewed after the implementation of the corrective measures?	(2) The CCP will be under control after the corrective action is taken;
15a3 Have preventive measures been described?	(3) Measures to prevent recurrence are established;
15a4 Is the marketing of unsafe (or otherwise inadequate) products successfully being prevented?	(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.
15 b Where irregularities not described by corrective measures arise, or in the event of other unforeseen hazards, does the business take action:	If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:
15b1 In the event of irregularity, is the product isolated?	(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met
15b2 Is a review conducted to determine whether the product in question can enter the market, and if so, with what destination?	(2) Perform a review to determine the acceptability of the affected product for distribution;

15b3 Are steps taken to ensure that any unsatisfactory product does not enter the market?	(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;
15b4 Does a person with sufficient knowledge/training conduct a re-assessment to determine whether the irregularities/hazard observed must be incorporated into the HACCP plan?	(4) Perform or obtain reassessment by an individual trained in accordance with § 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.
16 Are there verification procedures in place to ascertain whether the HACCP plan is functioning properly?	The business has the obligation to define procedures to verify whether the measures described under a up to e inclusive of Article 5, paragraph 2(c), Council Regulation (EC) No. 852/2004, are functioning effectively (Article 5, paragraph 2(f), Council Regulation (EC) No 852/2004). Are these procedures effective? Where not effective, are they adjusted? Is a reassessment of these procedures called for? § 417.2 (7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with § 417.4 of this part.
17 What is the business's implementation of inspection for STEC?	In slaughterhouses, the primary cause of STEC is faecal contamination. The elimination of faecal contamination on carcasses is a primary condition. If STEC is identified, the HACCP plan must be reviewed to determine whether appropriate procedures are in place to prevent this and whether these procedures are actually being implemented by the business. The Dutch policy standards on STEC are binding!
18 Are the verification procedures described being carried out?	The business has the obligation to define procedures to verify whether the measures described under **paragraph 417.4 and** a up to e inclusive of Article 5, paragraph 2(c), Council Regulation (EC) No 852/2004, are functioning effectively (Article 5, paragraph 2(f), Council Regulation (EC) No 852/2004). The business must also be actually implementing these procedures. 9 CFR Part 417 **§ 417.4 Validation, Verification, Reassessment.** (a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented. (3)(i) **Reassessment** of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an

	individual trained in accordance with § 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of § 417.2(c) of this part.(ii) Each establishment must make a record of each reassessment required by paragraph (a)(3)(i) of this section and must document the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment. For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination.(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.
18 A1 Has the validation following the drafting of the HACCP plan been carried out?	**§ 417.4 Validation, Verification, Reassessment.** (1) **Initial validation**. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.
18 A2 Are the verifications being carried out?	(2) **Ongoing verification activities**. Ongoing verification activities include, but are not limited to:(i) The calibration of process-monitoring instruments;(ii) Direct observations of monitoring activities and corrective actions; and(iii) The review of records generated and maintained in accordance with § 417.5(a)(3) of this part.

18A3 Is a reassessment of the HACCP plan being carried out at least once a year?	(3)(i) **Reassessment** of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with § 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of § 417.2(c) of this part.(ii) Each establishment must make a record of each reassessment required by paragraph (a)(3)(i) of this section and must document the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment. For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination.(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.
19 Record-keeping	§ 417.5 Records. (a) The establishment shall maintain the following records documenting the establishment's HACCP plan:(1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;(2) The written HACCP plan, including decision making documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented

	in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.(d) Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.(e) Record retention. (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of a NVWA employee's request.(f) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.
20 Can the business demonstrate that the HACCP plan as described is actually being implemented?	The business must have documents and records available showing that the HAACP plan as described is actually being implemented.
21 Does the Authority have access to the relevant sections of the HACCP plan and its accompanying documentation?	Transparent system and/or necessary support by business
22 Is the Authority being informed of changes to the HACCP in a timely manner?	'Is the Authority informed of relevant changes to the HACCP? If so, how and when?' Examples:
23 Are new hazards and risks in the process, product, raw material or at the user end (EC and USA) included? Is the business staying on top of relevant US regulations (without having to first be notified of changes by the Authority)?	New hazards, risks or changes in the process, product, raw material or user must be included in the most recent version of the HACCP plan. (Article 5, paragraph 4(b) of Council Regulation (EC) No 852/2004 and 9 CFR Part 417). In the recent past, have there been any changes in US regulations that are of impact on HACCP plans of USA-registered companies? Who within the business is checking this and how often? What are the changes? To what degree has the business's HACCP plan been adapted to the changes in the USA?

24 Do the HACCP procedures guarantee that products of animal origin meet specific requirements?	The business must have HACCP procedures that offer a guarantee that products of animal origin meet the criteria specified in Article 4, paragraph 5 of Council Regulation (EC) No 854/2004, which reads: Audits of HACCP-based procedures shall verify that food business operators apply such procedures **continuously and properly**, having particular regard to ensuring that the procedures provide the guarantees specified in Section 2 of Annex 2 to Council Regulation (EC) No 853/2004. They shall, in particular, determine whether the procedures guarantee, to the extent possible,that products of animal origin: a) comply with microbiological criteria laid down under Community legislation; b) comply with Community legislation on residues, contaminants and prohibited substances; and c) do not contain physical hazards, such as foreign bodies.
25 Are there HACCP procedures that guarantee that the correct animals are being accepted at the slaughterhouse?	The business must have in place HACCP procedures to guarantee that every animal/group of animals accepted on the slaughterhouse site meets the requirements specified in Article 2 of Section 2 of Annex 2 of Council Regulation (EC) No 853/2004. **These procedures stipulate that:** *a) the animals are properly **identified*** *b) the **relevant information** from the holding of provenance referred to in Section 3 is available upon the arrival of the animals* *c) the animals do not come from a holding or area subject to a **movement prohibition** or other restriction for reasons of animal or public health, accepting where the competent authority so permits* *d) the animals are **clean*** *e) the animals are **healthy**, as far as the food business operator can judge and* *f) the **welfare** of the animals is satisfactory upon arrival at the slaughterhouse.* Specifically relevant for the **USA** is the origin of the animals (born and bred, as regards calves this means: [2]). How does the business exercise demonstrable monitoring of these aspects? Is there someone from the Authority present at all times (at every moment) when animals arrive? Has the business also identified this?

[2] For the calves, this is not born and bred. However, because no certificate has yet been agreed, it has not yet been established what the requirements/countries are.

26 Is the business familiar with the HACCP requirements of the FSIS?	9 CFR Part 417
27 Are the CCPs as described in RE-31 monitored by the business?	In the event of excess of critical limits of CCPs, the business must take the following corrective steps: ▪ Identify and eliminate the cause. ▪ Get the CCP back under control by means of a corrective action. ▪ Undertake and **describe preventive action(s)** in order to prevent repetition (upon each individual irregularity/corrective action). ▪ Perform action(s) to ensure that no inadequate product is able to enter the market/reach consumers. This means, in part, that the temperature of every loaded batch is checked, even outside ordinary business hours. Alongside the verification of the HACCP system, the business has daily **verification of the monitoring of the CCPs** performed by a person other than the one performing the monitoring, this verification consisting of: - Verification of physical performance of monitoring of CCP - Shadow control by means of independent measurement and a comparison of the two measurements - Verification of logging of monitoring lists - Verification of corrective measures
28 Is pre-shipment as described in RE-31 being carried out,	even on weekends or outside business hours? The business must have a written procedure for the logging of controls and monitoring. In this procedure, the business must indicate how upon shipment of a batch or product, paper-based control and inspection of the CCPs is carried out during production. **To be absolutely clear: there must be a demonstrable link between the batch to be shipped and the verified CCP monitoring data.** The person who performed the pre-shipment control was not involved in the monitoring of the CCPs.

§ 417.6 Inadequate HACCP Systems.
A HACCP system may be found to be inadequate if:
(a) The HACCP plan in operation does not meet the requirements set forth in this part;
(b) Establishment personnel are not performing tasks specified in the HACCP plan;
(c) The establishment fails to take corrective actions, as required by § 417.3 of this part;
(d) HACCP records are not being maintained as required in § 417.5 of this part; or
(e) Adulterated product is produced or shipped.

Other than HACCP	
29 SSOP etc. See RE-31	For the supervisory activities concerning USA-registered businesses, both the business's own control lists and the Authority's control lists must be fully completed. The business's cleaning plan must be in writing. The control lists must state the following information: ▪ Date ▪ Time of control ▪ Nature of irregularity ▪ Action taken on irregularity ▪ Second control, with time ▪ Signature of person performing control ▪ Signature of controller from the Authority ▪ Control lists of the business and the Authority must demonstrably compared against each other.
30 In the event of an irregularity, does the business take all necessary steps?	In the event of irregularities in SSOPs/pre-SSOPs, the business must take the following corrective steps: • Cleaning (space, material) and/or refurbishing, flaming product. • Taking preventive action(s) to avoid repetition (also means describing these [new] preventive actions). • Examining whether remaining product may be contaminated and if so, action(s). • Reevaluation and, if necessary, modification of SSOPs.
31 Training	Paragraph 417.7 Training Have all personnel taken a 'USA training'?

FINAL ASSESSMENT[3]

The business xxx (EC xxx) is or is not recommended for country registration – USA.

The USA country registration for business xxx (EC xxx) is or is not renewed (*use for annual audit*).

The business xxxx (EC xxx) must adjust the following aspects of the system as encountered:

COMMITMENTS

The business xxx (EC xxx) will be notified in writing of the irregularities as revealed during the course of this audit.

What commitments have been made based on the irregularities observed?
xxx.

Who will conduct the reinspection, and on what date?

xxx.

What intervention from the intervention policy has been applied?
[nNVT/MW/SW/PV/BR/Corrective intervention/Other intervention]

Various supporting documentation:

FSIS 5000 serie:
http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/5000-series/5000-Series

FSIS: Meat and Poultry Hazards and Controls Guide
http://www.fsis.usda.gov/wps/wcm/connect/3cd0a6a5-fcff-4809-a298-030f3cd711a9/Meat_and_Poultry_Hazards_Controls_Guide_10042005.pdf?MOD=AJPERES

Suggested General Verification Questions for Most Process Steps
This set of general questions should be asked when evaluating the production process in light of the relevant process steps. It is intended to assist inspection personnel in verifying the adequacy of the establishment's approach to each processing step. Individual processing steps in this Guide include additional questions that are specific to each processing step.

- Has the establishment included this process step in the flow chart and hazard analysis?
- Does the establishment have a prerequisite program that addresses this step?
- Has the establishment identified any hazards associated with this step?
- Is this process step a CCP?
- Is the establishment following all procedures identified in the hazard analysis?
- Does the establishment maintain records associated with this step?
- Do records contain information that indicates a reassessment of the hazard analysis or HACCP plan is necessary?
- Are records made available to FSIS?
- Is the equipment used clean, sanitary, and well maintained?