USDA

United States Department of Agriculture

Food Safety and Inspection Service

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

APR 30 2015

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

Dear Dr. Bruschke:

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

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

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

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

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

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

Sincerely,

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosures

FINAL REPORT OF ON-SITE REINSTATEMENT OF EQUIVALENCE AUDIT

CONDUCTED IN

THE NETHERLANDS

June 2 – 26, 2014

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

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a verification audit for the reinstatement of equivalence conducted by the Food Safety and Inspection Service (FSIS) from June 2 - 26, 2014, to determine the Netherlands' eligibility to resume export of egg products to the United States (U.S.) and to verify that the egg products inspection system is equivalent to that of the U.S. with ability to produce products that are safe, wholesome, and properly labeled.

The FSIS audit focused on the ability of the Central Competent Authority (CCA), the Netherlands Food and Consumer Product Safety Authority (NVWA), to implement effective inspection and control programs related to the production and export of egg products in a manner consistent with the information provided to FSIS in the Self-Reporting Tool (SRT). NVWA has delegated the implementation of most official verification activities to the Netherlands' Supervisory Authority for Eggs (NCAE), a division of the Central Agency for Quality Issues in Dairy (COKZ). COKZ is an independent official inspection foundation appointed by the Ministry of Public Health, Welfare and Sports (VWS) and is not engaged in the production of eggs.

FSIS determinations concerning the effectiveness of the inspection programs focused on performance within the following equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Chemical Residue Programs, and (5) Microbiological Testing Programs. The Netherlands' egg inspection system employs HACCP Systems at official egg products establishments as an integral part of the inspection system formed according to the EC regulations. There was one on-site audit finding summarized below and further described in the respective section of the report.

At the time of the audit, the CCA was not consistently ensuring that egg products processing establishments were breaking eggs that were free of contamination with foreign materials. The FSIS auditor observed some of the shell eggs loaded onto the breaking machines were tainted with egg yolk or stained with dark brown spots. Small fragments of shells were also observed in liquid egg product immediately after egg breaking.

In response to the FSIS finding, the CCA implemented a corrective action that meets U.S. requirements. The corrective action included an amendment of the sanitation program requirements for the establishments seeking certification for egg products export to the United States. These establishments, which usually use nest run eggs or graded eggs, are now required to break only clean and dry eggs and to take effective measures to control and eliminate the presence of shell particles in the liquid egg products. This measure ensures, through effective sorting of eggs and the implementation of effective sanitation programs that egg products exported to the U.S. from the Netherlands will not contain defects, and will achieve the same levels of quality applied in the U.S. system.

The CCA provided supporting documents during and after the exit meeting. The FSIS auditor was able to verify that the CCA has adequately implemented its corrective actions and preventive measures in a consistent manner throughout the inspection system. Therefore, FSIS has determined that the CCA is able to meet the requirements related to all equivalence components.
FSIS' evaluation of all the data collected before, during, and after the on-site audit supports that the Netherlands' egg products regulatory system achieves the level of protection required by the United States. Therefore, FSIS will reinstate the Netherlands' equivalence and allow resumption of egg products export to the United States.

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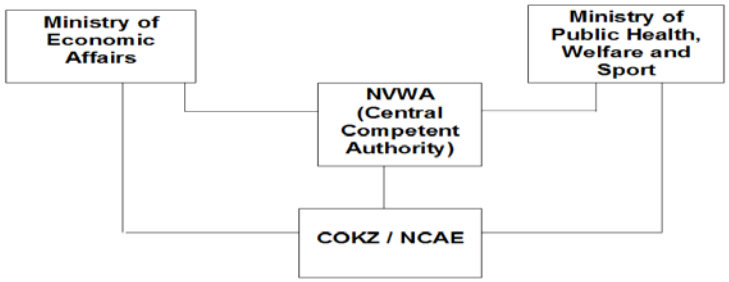
ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

APHIS	Animal and Plant Health Inspection Service
CCA	Central Competent Authority
CFR	Code of Federal Regulations
COKZ	Central Agency for Quality Issues in Dairy (*Centraal Orgaan voor Kwaliteitsaangelegenheden in de Zuivel*)
CVO	Chief Veterinary Officer
EC	European Commission
EU	European Union
EU-RLs	European Union Reference Laboratories
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Point System
ISO/IES	International Organization for Standardization/International Electrotechnical Commission
LIMS	Laboratory Information System
MEA	Ministry of Economic Affairs
NCAE	Netherlands' Supervisory Authority for Eggs (*Nederlandse Controle Autoriteit Eieren*)
NVWA	Netherlands Food and Consumer Product Safety Authority (*Nederlandse Voedsel- en Warenautoriteit*)
NRL	National Reference Laboratory
RASFF	EU's Rapid Alert System for Food and Feed
RIKILT	Institute of Food Safety
RvA	Dutch National Accreditation Body
Salmonella	*Salmonella* species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
VWS	Ministry of Health, Welfare and Sports
ZBOs	Semi-autonomous public bodies (*Zelfstandig Bestuursorganen*)

I. INTRODUCTION

The Netherlands is listed in 9 CFR 590.910(b) as eligible to export egg products to the United States (U.S.), but this eligibility has been suspended because the Netherlands has not exported egg products to the U.S. since 2002. In response to the Netherlands request for reinstatement of its equivalence for egg products inspection system, the Food Safety and Inspection Service (FSIS) conducted an on-site audit of the Netherlands' inspection system in the period from June 2-26, 2014 to verify whether their egg products inspection is equivalent to the US system and determine whether the Netherlands is eligible to resume exports of egg products to the U.S. The FSIS audit was conducted concurrently with the on-site equivalence verification audit of the Netherlands' meat inspection system.

The Netherlands Food and Consumer Product Safety Authority (*Nederlandse Voedsel-en Warenautoriteit* -NVWA) is the Central Competent Authority (CCA) overseeing the production and export of meat and egg products to the U.S. The NVWA is an independent agency commissioned by the Ministry of Health, Welfare and Sports (VWS) and the Ministry of Economic Affairs (MEA). The NVWA operates under the administrative responsibility of the MEA but functions as an executive body for both Ministries. The NVWA implements its responsibilities directly or contracts independent semi-autonomous public bodies (*Zelfstandig Bestuursorgane*-ZBOs) such as the Netherlands Controlling Authority for Dairy Products (*Kwaliteitskeuring Dierlijke Sector*-COKZ) and its subsidiary the Netherlands' Supervisory Authority for Eggs (*Nederlandse Controle Autoriteit Eieren*-NCAE). The Netherlands legislation provides for the establishment of such non-profit independent foundations to conduct, on behalf of the Ministry, official duties related to consumer safety. As of July 1, 2012, the Netherlands' CCA has designated the implementation of official verification activities for egg products to COKZ/NCAE[1]. The following chart provides an overview of the current overall organization and linkages between Ministries and the competent authority.



The onsite audit began with an entrance meeting at the Netherlands' CCA in Utrecht on June 2, 2014. Participants of the meeting included representatives from the NWS, NVWA, and COKZ/NCAE. The FSIS auditor was accompanied throughout the audit by representatives from the NVWA and COKZ/NCAE.

The audit verified that the country continued to maintain an equivalent inspection system by employing regulatory requirements consistent with specific provisions of the U.S. laws and regulations that were reviewed as part of the assessment process, in particular:

[1] COKZ/NCAE replaced the Control Agency for Poultry, Eggs and Egg Products (CPE) which ceased to exist.

- Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*).

- The Egg Products Inspection Regulations (9 CFR Parts 590 to End).

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

- European Commission (EC) Regulations 178/2002; 852/2004; 853/2004; 854/2004; 882/2004; 1774/2002; 726/2004; 396/2005; 2073/2005; 1881/2006; 1883/2006; 333/2007; 470/2009; 1069/2009; 1234/2007l 589/2008; 543/2008; and 37/2010; and Council Directives found equivalent under the Veterinary Equivalence Agreement (VEA), 96-22 and 96-23; and

- The Netherlands' national laws, decrees, regulations, policy, and instructions issued to ensure the implementation of the overarching EC 2004 legislation and other inspection control programs governing the product and export of meat products to the U.S. (Animals Act; Marketing Standards; Decision on animal products; and Control of animal products).

The audit standards included: (1) All applicable legislation and procedures originally determined by FSIS to be equivalent as part of the initial equivalence review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), and the European Community/United States Veterinary Equivalency Agreement (VEA).

II. AUDIT OBJECTIVES, SCOPE, AND METHODOLOGY

The audit objective was to verify whether the Netherlands' food safety system governing inspection of egg products is equivalent to that of the U.S. and is capable of ensuring that egg products exported to the U.S. are safe, wholesome, and properly labeled. In pursuit of this objective and prior to the onsite portion of the audit, FSIS conducted an extensive review of the information provided by the Netherlands through the Self-Reporting Tool (SRT) and accompanying references. These documents provide a comprehensive overview of the relevant legislation and procedures supporting the Netherlands' egg products inspection system.

FSIS determinations concerning the effectiveness of the Netherlands' egg products inspection programs focused on performance within the following components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation (Sanitation Performance Standards (SPS), (4) Chemical Residue Programs, and (5) Microbiological Testing Programs.
The FSIS auditor reviewed administrative, management, and supervision functions at the CCA headquarters in Utrecht, COKZ/NCAE team inspection offices at Raalte, Drachten, Nunspeet, and Waalwijk. The reorganization of the NVWA, which was completed in 2011, resulted in a reduction of the number of management and administrative staff, official auxiliaries, and the elimination of regional offices and the centralization of the CCA's functions. The FSIS auditor evaluated the CCA's official controls to ensure that all aspects of the national egg products inspection system are being implemented as intended.

The FSIS auditor visited five egg products plants that intend to export product to the United States. During the establishment reviews, 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 to ensure that egg products are processed, labeled, and packaged in accordance with requirements consistent with those in the United States. For example, the auditor verified whether the CCA provided continuous inspection, and enforced requirements that the facility maintain sanitary conditions.

The scope of the audit also included an assessment of the CCA's oversight activities of approved microbiology, and chemical residue laboratories. These laboratories conduct official testing in conjunction with the export of product to the U.S. in addition to testing programs required under the Netherlands' statute and the EC regulations. FSIS audited two laboratories, the NVWA Food Safety Laboratory in Wageningen, and Silliker-Netherlands B.V., a private laboratory located in Ede and contracted by COKZ/NCAE to carry out routine microbiological and chemical analyses for food safety verification for egg products. The FSIS auditor reviewed one year of laboratory data related to the collection and analysis of egg products samples for residue testing as well as microbiological testing for *Salmonella* and *Enterobacteriaceae* as required under the Netherlands' statutes. FSIS conducted onsite interviews of inspection personnel, and reviewed the CCA's audit as well as independent laboratory audit reports associated with the official testing programs. The FSIS assessment was used to verify the adequacy of the government oversight and to ensure that the inspection system uses equivalent testing methods when conducting analysis of samples to ensure that they meet FSIS requirements.

Audit Scope Summary

Competent Authority Visits		**No.**	**Locations**
Competent Authority *Oversight of egg products inspection programs*	Central	1	• The Netherlands Food and Consumer Product Safety Authority (NVWA) - CCA Headquarters office (Utrecht).
	COKZ/NCAE *Team offices*	3	• Raalte (egg products) • Nunspeet (egg products) • Waalwijk (egg products)
	NCAE *Local offices*	4	Reviews of local inspection offices were conducted as part of the establishment reviews at Landsmeer, Nunspeet, Raalte, and Waalwijk.
Laboratories (*Microbiological and Residue testing programs*)		2	• NVWA laboratories for food safety (Wageningen) - Government • Silliker Netherlands B.V. (Ede) - Private
Establishments *Egg products processing*		5	• NL EP6063 EG, Bouwhuis Enthoven B.V., Raalte • NL EP6085 EG, Van den Burg Eiproducten B.V., Waalwijk • NL EP6153 EG, Adriaan Goede B.V. , Landsmeer • NL EP6340 EG, NIVE, Nunspeet • NL EP6360 EG , Henningsen Van den Burg B.V., Waalwijk

III. BACKGROUND

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) regulates the importation of animals and animal products and guards against the introduction of animal diseases not currently present or prevalent in the United States. APHIS considers the Netherlands free of Exotic Newcastle Disease (END) and Highly Pathogenic Avian Influenza (HPAI) subtype H5N1.

The Netherlands is a member of the European Union (EU) and consequently conforms to the European Commission's (EC) legislation and issues national regulations and procedures to address aspects of the regulations, programs or export requirements that need to be implemented and verified by the CCA of the Member State.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT

The first of the five components that the auditor reviewed was Government Oversight. FSIS' import eligibility requirements state that the foreign inspection system must be planned and administered by the national government of the foreign country with standards equivalent to those of egg products inspection in the United States. The evaluation of this component included a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT, onsite record reviews, interviews, and observations made by the FSIS auditor at government offices, laboratories, and official establishments producing egg products.

The FSIS auditor assessed the extent to which the Netherlands' egg products inspection system is organized and administered by the government that promulgates and enforces inspection regulations, and ensures food safety.

The NVWA oversees the production and export of egg products that would be exported to the United States. The Netherlands' CCA has designated the implementation of the majority of official verification activities to COKZ/NCAE, an independent organization founded by the Ministry of Health, Welfare and Sports (VWS). COKZ/NCAE is considered as part of the national government commissioned under provisions of the Netherlands' legislation to perform tasks that are set jointly by multiple government entities. COKZ/NCAE hierarchy coupled with management autonomy enables the establishment of collaborative partnerships between organizations belonging to different levels of government. COKZ/NCAE staff is employed under general civil service rules and funded mainly through allocations from the government budget and partially through inspection fees. COKZ/NCAE differs from NVWA in its management through a board of directors, review process through auditing, and its accountability through direct reporting to the founding VWS, one of the two ministries overseeing the NVWA. COKZ/NCAE enforces a code of conduct that does not permit outside employment without supervisory approval.

The FSIS auditor verified that the NVWA has overall responsibility of official control and compliance with the regulatory requirements and confirmed that COKZ/NCAE carries out its inspection and verification of activities within the framework of the EC legislation and the

Netherlands' national regulations under the supervision of NVWA (Commodities Act-Article 3). The NVWA approves COKZ/NCAE annual programs and receives copies of all inspection reports according to terms of formal contracts, cooperation, and procedures put in place. COKZ/NCAE is accredited to EN 45004:1995 standards that specify the general criteria for the competence of impartial bodies performing inspection activities.

The FSIS auditor verified that the CCA carries out its oversight responsibility and executes an operational plan for its inspection system that is based on a farm-to-fork approach to food safety. The approach introduces the concept of traceability of food ingredients through the chain of production and uses a Rapid Alert System for Food and Feed (RASFF) that provides rapid information on newly identified risks to the consumer. This approach is employed by granting COKZ/NCAE jurisdiction over egg producers, egg collectors, packing stations, and egg products processing establishments. The NVWA has a centralized structure that directs the execution of its tasks for the specific year including delegated tasks and reports outcomes to the Ministry of VWS as well as MEA. NVWA and COKZ/NCAE have established coordination at different levels and agreed on procedures to deal with system alerts or consumers complaints.

COKZ/NCAE is required to develop an annual work plan which is submitted to NVWA and approved every year before enactment. The operating cost of the inspection system is furnished by the NVWA as part of the approval process of COKZ/NCAE/ annual operational plan. Additional funds come from fees or charges collected in accordance with Regulation (EC) No. 882/2004-Article 27, to cover the actual costs of official control and inspection activities. The fees are collected, processed, and delivered to COKZ/NCAE through official NVWA channels. The FSIS auditor verified that COKZ/NCAE uses ID cards for official inspection personnel including program auditors that are issued under the responsibility of COKZ-NCAE Director.

NVWA ensures that COKZ/NCAE assigns qualified inspection program personnel to perform the inspection and verification activities at egg products plants that intend to export egg products to the United States. The inspection program personnel are not veterinarians. They have college degrees in agriculture and at least five years working experience in the field of eggs and egg products processing or related fields. In accordance with the requirements of Regulation (EC) No. 854/2004-Article 2, and Regulation (EC) No. 882/2004-Articles 4-6, the CCA provides specialized training that covers specific U.S. import requirements. The Inspection Academy of the NVWA is responsible for training all employees. The FSIS auditor verified that all trainings and education records are managed in the special computer system "EDU." The CCA has the authority to conduct inspections within any portion of the official facility where product is manufactured, processed, packed, or held for export to the U.S. in accordance with Regulation (EC) No 178/2002 and Commodities Act Article 2 point 10.

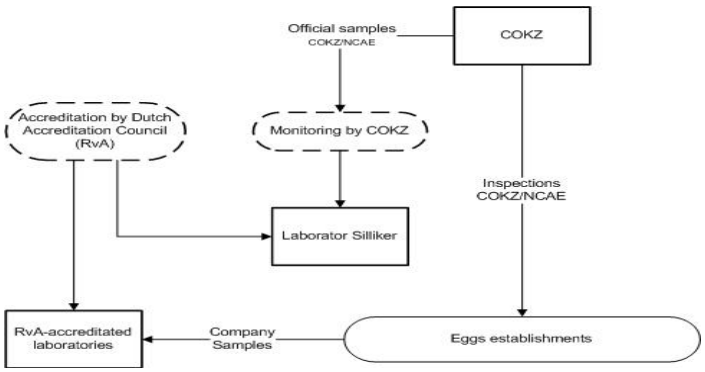
The FSIS auditor reviewed COKZ/NCAE records and verified that the inspection system is well organized and staffed to ensure uniform enforcement of the EU regulations and national laws, decrees, and regulations governing egg products inspection in official establishments proposed for certification for U.S. export. The inspection activities include performance of inspection and verification of compliance with the regulations related to sanitary operations as well as additional requirements established under the Netherlands' statutes such as the employment of HACCP systems, which includes measures for labeling of egg products in a manner that enables

traceability throughout the production chain. The CCA maintains a communication system to convey requirements related to U.S. export throughout its inspection system in a timely manner through its intranet site.

COKZ/NCAE will be responsible for certifying establishments for egg product export to the U.S. based on their ability to meet the certification requirements. Any decertification of certified establishments would be organized by NVWA based on a recommendation from COKZ/NCAE. Furthermore, COKZ/NCAE has the authority and the ability to require corrective actions in official establishments, and to take additional enforcement measures as appropriate in accordance with Regulation (EC) No 854/2004 - Article 4, Regulation (EC) No 882/2004- Articles 1-13, and NCAE-procedure INS-006, chapter 7. Elevated enforcement actions as described in Regulation (EC) No. 882/2004, Article 54, including establishment suspension and administrative penalties, are carried out in accordance with INS-006-v1-1 and coordinated by NVWA Headquarters. NVWA coordinates the assessment of penalties and the issuance of enforcement actions based on COKZ/NCAE's recommendation. COKZ/NCAE receives monthly reports that reflect the status of the recommended enforcement actions and imposed penalties. All enforcement actions are documented in an NCAE electronic inspection database (IDB).

The CCA maintains oversight of laboratories conducting official testing of egg products to be exported to the U.S. by ensuring that laboratories comply with the general criteria for testing laboratories provided in ISO/IEC Guide 17025. Additionally, the CCA ensures that laboratories participate in appropriate proficiency testing schemes for food analysis and use approved equivalent and validated methods to analyze samples of product intended for export to the U.S.

COKZ/NCAE has an agreement with Silliker Netherlands B.V. in Ede to perform official analysis of egg products samples to verify that they meet established microbiological standards related to control of *Enterobacteriaceae* and *Salmonella*. The Silliker-NCAE Service Level Agreement (SLA) states that the Silliker laboratory must be accredited by the Dutch Accreditation Council "Raad voor Accreditatie" (RvA) for NEN-EN-ISO/IEC 17025. The SLA ends automatically once the laboratory loses its accreditation (appendix G1 SLA Silliker-NCAE, Article 18). Each year COKZ performs an audit of Silliker (Silliker-NCAE SLA-Article 10). Additionally, biannual administrative assessments are conducted to verify the validity of the accreditation, review the validation of the used methods, and review the results of proficiency testing for the analysts.



NVWA has delegated the responsibility of quality review of laboratories to an independent body, the RvA. The competent authority is represented by the Supervisory Board of RvA, which is

authorized to approve or disapprove laboratories. COKZ/NCAE oversees the degree of compliance with the conditions laid down in the SLA. Substantial noncompliance could force an immediate termination of the SLA (Silliker-NCAE SLA-Article Article 3).

NVWA has mechanisms to ensure that product exported to the U.S. is below established Maximum Residue Limits (MRLs) in the U.S. or have non-detectable levels for those compounds for which MRLs have not been established in the United States. The Netherlands' inspection system conducts official residue testing on eggs and egg products that may include inspector generated samples. Additionally, official egg products processing establishments are required to conduct their own testing program as part of their HACCP system to address potential chemical hazards.

NVWA controls the issuance of export certificates for egg products destined for the U.S. based on COKZ/NCAE verification records accompanying each consignment. NVWA has instructions for inspection program personnel that describe the conditions that govern exports to the U.S., and the verification activity that must be carried out by inspection personnel including specific verification testing. The CCA maintains regulatory authority to ensure that products intended for export to the U.S. are properly labeled and packaged. These regulatory requirements are described in Directive 2000/13/EC on labeling and fully implemented in the Dutch Food Act. The FSIS auditor verified that establishments are required to ensure that food intended for human consumption placed in commerce is adequately labeled and identified to facilitate product traceability through relevant documentation or information collected in accordance with the regulatory requirements.

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

The audit verified that the Netherlands' egg products inspection system is organized and administered by the government, and that the CCA officials are assigned to enforce the laws and regulations governing production and export of egg products at establishments proposed for certification for U.S. export. Thus, the official control system implemented in the Netherlands to ensure continuous inspection during egg product processing and the official measure taken to verify and certify the production and export of egg products to the U.S., are meeting the equivalence requirements of this component.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the five equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. For an inspection system to be equivalent, it must provide an appropriate regulatory framework to demonstrate equivalence with FSIS' inspection

system, including but not limited to sanitation, chemical residue and microbiological sampling, establishment construction, facilities, equipment, continuous inspection and periodic supervisory visits to U.S. eligible establishments.

FSIS has determined that the European Commission's (EC) 2004 legislation is equivalent as an overarching legislation, provided that the CCAs of EU Member States address the implementation of the regulation and other import requirements through their national laws, regulations, and policies. FSIS verified that the NVWA has developed, as required under the EC regulations, a National Control Plan for the period from 2012 to 2016. The plan is used to manage the Netherlands' egg products inspection program.

The Netherlands' has implemented the EC food hygiene legislation through a series of statutory instruments that lay out the national framework for the inspection program related to egg products inspection. The framework of the inspection program is established by: The Animals Act; Control of animal products; The NCAE Procedure for Approval and Inspection; The Decree on the Hygiene of Foodstuffs (WHL); "EXA-01": Working Manual General Certification.; Working Manual RE-31 (Approval and Control/Supervision of Establishments); The Decree on Preparation and Handling of Food (WBBL, Food Safety Criteria); and COKZ/NCAE Quality Manual-KHN-001. KSP-101 is the procedure for inspector training, for testing inspector knowledge and skills, as well as for assessing inspector performance. MON-004 is the procedure for sampling powdery egg products. These statutory instruments form the basis for a regulatory oversight of egg products inspection.

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

New establishments are inspected by COKZ/NCAE in accordance with work plan HP-DBP NCAE 2014 before they are permitted to operate. COKZ/NCAE audit activities include performing one announced annual audit and two unannounced annual audits and inspectors conduct continuous inspection. The audit covered points related to construction, facilities and equipment. It is conducted using COKZ/NCAE's standardized Assessment List for egg products processing establishments.

The CCA has made a commitment, through a letter from the CVO, to provide for direct and continuous official inspection of the processing of egg products intended for export to the United States. This measure will be fully implemented once reinstatement of equivalence is granted, and the establishments are certified. Continuous inspection of products produced for export to the U.S. will be conducted throughout all hours of operation and phases of processing covering breaking eggs as well as filtering, mixing, blending, pasteurizing, stabilizing, cooling, freezing or drying, or packaging egg products. The FSIS auditor verified that COKZ/NCAE inspection personnel have the ability to conduct continuous official inspection activities that are supervised by the team leader or field service manager. The official inspection procedures are carried out in accordance with the instructions provided by the Policy and Decisions Department (Flow-chart INS-006, point 3, 4 and 5.) and documented using INS-006_v1-1. The results of the inspection

activities are reported through the supervisory channels to the COKZ/NCAE Director. The COKZ/NCAE Director oversees the implementation of the inspection programs and ensures that these programs are carried out in accordance with the annual work plan approved by the NVWA (Workplan HP-DBP NCAE 2014). The FSIS auditor's review established that NVWA takes measures that include review and approval of the annual work plan as well as periodic coordination with COKZ/NCAE Director to ensure that COKZ/NCAE maintains enough competent and qualified inspection personnel to perform direct continuous official inspection of processing activities for egg products on the days they produce product for export to United States.

The Netherlands' inspection system for egg products provides for periodic supervisory visits and audits of the food safety system. A representative of the inspection system visits each establishment proposed for certification for U.S. export. The official audits (comparable to FSIS Food Safety Assessments) are carried out regularly in accordance with the requirements of Regulation (EC) No 882/2004- Article 3. Scheduling of the audits takes into account risks associated with the product, the ingredients, and the activity or operation that may affect food safety. The audit focuses on the effectiveness of official controls at all production and processing steps and distribution. COKZ/NCAE ensures that periodic reviews and audits are conducted by staff that is free from any conflict of interest, have access to an adequate laboratory capacity for testing, and have the legal powers to carry out official controls and initiate enforcement action when necessary. The audit procedures are described in in Workplan HP-DBP NCAE 2014 and documented in the Review List of Egg Processing Industry HP DBP_DEF and NCAE Inspection List for Egg Products -USA Export.

The FSIS auditor verified through records review and observations that the CCA conducts verification activities to ensure that official plants take effective measures to ensure destruction of condemned material (including denaturing of product). The regulatory requirements are described in Article 4 of Regulation (EC) No 853/2004 and Article 6 of Regulation (EC) No 852/2004, which states that destruction of condemned materials shall be carried out under conditions which prevent cross-contamination and, if appropriate, in a dedicated part of the establishment. Additionally, Regulation (EC) No 1774/2002 specifies health rules concerning animal by-products not intended for human consumption and further describes strict public health rules for the collection, transport, storage, handling, processing and use or disposal of all animal by-products. The requirements described in Article 3.1 of the Dutch law addressing control of animal products are implemented through COKZ/NCAE bulletin (Checklist for Animal By-products in the Egg Sector) and documented accordingly (Review List of Egg Processing Industry -HP-DBP_DEF). NVWA maintains control over condemned materials leaving egg product processing plants and destined for rendering facilities.

The FSIS auditor verified that the CCA ensures complete separation of establishments intending to export to the U.S. from those that are not certified or seeking certification to export to the United States. The inspection and verification activities conducted at establishments seeking certification for egg products export to the U.S. follow a distinct inspection list (COKZ/NCAE Inspection List for Egg Products to USA). The list is used to verify that egg products processing plants regulatory requirements are consistent with those in the U.S. and that documented results indicate whether or not all the specific requirements are met. COKZ/NCAE maintains an

electronic inspection database (IDB), which documents the establishments' profiles, the results of inspection activities, and the establishments' responses to each noncompliance or enforcement action. Additionally, the inspection system implements mechanisms to verify that egg products processed at more than one egg products facility come from an approved source and are processed under conditions that meet requirements for export to the United States. The verification mechanisms are based on a traceability system for eggs and egg products throughout the production and supply chains. The CCA has written protocols to address potential deviation and failures of any establishment's HACCP system, required under the Netherlands' regulatory system, which could affect the ability of the establishment's food safety systems to prevent shipment or export of adulterated product (Notification Instruction of Unsafe Food). The Notification Instruction of Unsafe Food includes a decision tree and instructions for the inspection personnel to initiate notification upon identification of unsafe product.

The FSIS auditor noticed that egg products processing establishments do not conduct onsite candling or maintain candling records indicating that ineligible eggs or eggs with cracked shells, leakers, and eggs with interior defects were detected and removed. The inspection system, however, provides for candling according to Regulation (EC) No 589/2008 - Article 5, at the egg packers using adequate facilities for sanitation. COKZ/NCAE inspection personnel verify the effectiveness of the candling of eggs as part of primary production as specified in Article 3(17) of Regulation 178/2002, and Annex I, Part A, point I (1) of Regulation 852/2004. The primary production is identified as the steps that include the egg collection, transport between buildings, and storage of eggs at the production site, provided that these steps do not alter their nature. The packaging of eggs, either at the site of production or at a separate packing establishment, falls outside the activities of official plants. These activities are conducted under supervision of COKZ/NCAE, which verifies their compliance with the relevant requirements of Annex II to Regulation (EC) No 852/2004, of Annex III, Section X of Regulation (EC) No 853/2004, Article 5 of Regulation (EC) 589/2008, and of Article 116 and Annex XIV of Regulation (EC) No 1234/2007, establishing a common organization of agricultural markets and on specific provisions for certain agricultural products (9 CFR 590.510). As a result, egg products processing establishments are not required to perform sanitation and candling in the transfer room since they only receive shell eggs that have already been sanitized and candled.

In response to a FSIS observation, COKZ/NCAE modified its verification procedures to ensure that the records documenting candling results occurring at the egg packing establishment are included as part of the supply chain information that accompanies batches of eggs destined for egg products processing establishments. The records include a written statement to declare that, at the time of exporting egg products to the U.S., 100% candling is to be performed as part of the processing procedure, verified by COKZ/NCAE inspection personnel, and documented in the Review List Egg Processing Industry- HP-DBP_DEF. The CCA has the authority to access the records of the producer of the egg products intended for export to the U.S. in accordance with Regulation (EC) No 178/2002 Article 19 point 4, as implemented through and contained in the Commodities Act-Preparation and Handling of Food, Article 2 point 10, and to ensure that product exported to the U.S. meets the requirements of 9 CFR 590.510 related to classifications of shell eggs used in the processing of egg products. Egg products processing establishments perform visual inspection of eggs for physical defects before breaking eggs, typically on the same day of receiving.

The FSIS auditor verified that the Netherlands' egg products inspection system provides operating requirements for the breaking room, freezing, and defrosting facilities and equipment as well as drying, blending, packaging, and heat treatment rooms in accordance with Regulation (EC) No. 853/2004- Annex III - Section X - Chapter II. Additionally, the Netherlands' egg products inspection system complies with Regulation (EC) No. 852/2004- Annex II-Chapters I, II and IX, which requires premises to be kept clean and maintained in good repair and condition, and Regulation (EC) No. 852/2004-Article 5, which requires establishments to implement and maintain a permanent procedure or procedures based on HACCP and Article 4, which addresses compliance with temperature requirements.

The operating requirements include measures to ensure that eggs are not broken unless they are clean, sufficiently dry, and are broken in a manner that minimizes contamination (Review List Egg Processing Industry- HP-DBP_DEF). COKZ/NCAE inspection personnel verify compliance and ensure that proper corrective actions are taken in response to a non-compliance (Regulation (EC) No 882/2004- Articles 1-13, and NCAE-procedure INS-006).

The inspectors verify that the plant maintains an adequate separation from other operations, and ensure that cracked eggs are processed as soon as possible. After egg breaking, each component of the egg product must undergo processing as quickly as possible to eliminate or reduce microbiological hazards to an acceptable level. If processing of egg products is not carried out immediately after egg breaking, liquid egg must be stored either frozen or at a temperature of not more than (4°C/39.2 °F). The storage period before processing must not exceed 48 hours. However, these requirements do not apply to products that are to be de-sugared if the de-sugaring process is performed as soon as possible. Each batch of egg product that has been insufficiently processed may immediately undergo processing again in the same plant if by doing so it can be rendered unadulterated. Once a batch is found to be unfit for human consumption, it must be destroyed for human food purposes under the supervision of an inspector and denatured using sufficient amount of denaturant (Working Manual DBP-20).

The FSIS auditor verified that the Netherlands' egg product inspection system provides for, and verifies, the operating requirements for spray process drying facilities and albumen flake drying facilities, ensures that processing equipment is kept clean and maintained, and is kept in good repair and condition. COKZ/NCAE inspection personnel conduct inspection and verification activities to ensure that: 1) operations are carried out by implementing and maintaining a permanent procedure or procedures based on HACCP principles; 2) the drying facilities are constructed to allow thorough cleaning and are equipped with approved intake filters; 3) the driers are constructed and equipped to prevent excess accumulation of powder in the drier, 4) bags and powder conveyors draw air from sources free from foul odors, dust, and dirt; and 5) sifters are constructed in a manner such that accumulations of large particles or lumps of dried eggs can be removed continuously, while the sifters are in operation. These requirements are verified in accordance with the procedure described in the Notes Egg Products Hygiene Package and documented in the Review List for Egg Processing Industry.

The FSIS auditor verified that the CCA consistently conducts inspection and verification activities to ensure that pasteurization facilities meet the operating requirements for equipment, and operations (including minimum temperature requirements and minimum holding times) in accordance with Regulation (EC) No 852/2004-Annex II- Chapter XI. COKZ/NCAE implements control and verification measures described in the Notes Egg Products Hygiene Package- Section 14: Specific Processing Requirements and Heat Treatments. The CCA also verifies that egg product processing establishments meet operating requirements for the heat treatment of dried egg whites, including temperature and holding time requirements. Moreover, COKZ/NCAE routinely verifies that egg products processing establishments sample and test pasteurized liquid, frozen, and dried egg products for *Salmonella* in accordance with Regulation (EC) No. 2073/2005- Annex I- Chapter 2- Item 2.3 and Regulation (EC) No 178/2002- Article 17. Additionally, the CCA takes official product samples, analyzes them at the NVWA laboratory, and compares the results of official samples with the results of the establishments' samples as a measure to verify the effectiveness of the establishments' microbiological control programs. The CCA requires and routinely verifies that egg products that would be exported to the U.S. are pasteurized or heat-treated, following required minimum temperature and minimum holding times, and are *Salmonella* negative.

The Netherlands' egg products inspection system includes requirements to ensure that establishment construction, facilities, and equipment are adequate; provides for continuous inspection; and provides for periodic supervisory review of official establishments. The inspection system provides for official controls over condemned material until destroyed or removed; requires and verifies complete separation of certified establishments from those that are not certified; and provides for equivalent operation requirements to those applied to products produced in the United States. In conclusion, the CCA has the legal authority and the regulatory framework to impose measures equivalent to those that govern the United States' egg products inspection system, and thus meets the requirements of this component.

VI. COMPONENT THREE: SANITATION

The third of the five equivalence components that the FSIS auditor reviewed was sanitation. To be equivalent to the U.S. inspection system, a foreign system must require that each egg products plant operate in a manner to prevent insanitary conditions and to ensure that product is not adulterated. The FSIS auditor's verification activity for this component included an analysis of the CCA's SRT responses, review of records at government offices in the establishments, and observations at the audited egg products processing establishments.

The FSIS auditor's review of the regulations, official instructions, and guidelines supports that the Netherlands' egg products inspection system adopted sanitary controls equivalent to the Sanitation Performance Standards (SPS). The U.S. inspection system has no requirement for implementing Sanitation SOPs in domestic egg products establishments, and is consequently not required of foreign inspection systems or establishments. However, the Netherlands' egg product inspection system requires egg product establishments to operate under a written Sanitation SOPs as a foundation for HACCP that is required under the statutes of the Netherlands. The assessment of the CCA's regulatory oversight and establishment compliance was conducted in

accordance with: Regulation (EC) No. 852/2004; Regulation (EC) No. 853/2004; Regulation (EC) No. 882/2004; and Regulation RE 31.

The CCA requires, and routinely verifies, that the structure of the facility is maintained in a sound condition in accordance with the requirements of Regulation (EC) No 852/2004- Article 4 and annex I, II and V and Regulation (EC) No 853/2004 – Annex III - Section X - Chapters II. The verification procedures are described in the work plan HP-DBP NCAE 2014, and documented in the Review List of Egg Processing Industry HP DBP_DEF and NCAE Inspection List for Egg Products - USA Export. The FSIS auditor verified that COKZ/NCAE routinely conducts verification activities to ensure that plants meet additional sanitation performance standard requirements such as ventilation, condensation control, structural integrity, and that all food contact surfaces and non-food contact surfaces of facilities, equipment and utensils are cleaned and sanitized as frequently as necessary to prevent product contamination or adulteration (Review List of Egg Processing Industry HP DBP_DEFAssessment points: 701-705). The inspection and verification activities conducted by COKZ/NCAE include daily assessments of the overall sanitary and hygiene condition of the establishment (premises and equipment).

The FSIS auditor verified through records review and observation that the CCA ensures that each establishment intending to export to the U.S. develops and implements written standard operating procedures for sanitation that identify areas of risk of direct product contamination. COKZ/NCAE inspection personnel routinely use the Review List of Egg Processing Industry HP DBP_DEF-Assessment point 300, to verify that the establishments' written plans identify the cleaning procedures, including frequency, and that accountability for cleaning is properly implemented. In response to a non-compliance, a corrective action, in accordance with Regulation (EC) No 852/2004 – Article 5, is taken, documented by the establishment, and further verified by the inspection personnel (Review List of Egg Processing Industry HP DBP_DEF-Assessment points: 204, 206). The corrective actions taken at all audited establishments include proper handling of contaminated product, restoration of sanitary conditions, and measures to prevent recurrence of the same or similar sanitation deficiencies (Review List of Egg Processing Industry HP DBP_DEF-assessment points: 300, 314, 315, and 2000).

The CCA requires and routinely verifies that establishments take action to prevent product contamination and take corrective actions when insanitary conditions or contaminated products are found. It instructs the inspection program personnel to follow procedure INS-006_V1-1, to document non-compliances, and it establishes a timeframe for the establishment to complete corrective actions and preventive measures. However, the auditor observed at two of the five egg products processing establishments that:

- The inspection program personnel did not consistently ensure that establishments only use shell eggs free of contamination and foreign materials. Some of the previously candled eggs loaded onto the egg breaking machines were tainted with egg yolk and stained with dark brown material. Additionally, small fragments of egg shell particles were observed in liquid egg, immediately after egg breaking.

FSIS requires egg products to be protected from contamination during processing, handling, storage, loading, and unloading during transportation by the official establishment. The

inspection program personnel are to verify that plants break only eligible clean and sanitized shell eggs and ensure that eggs are sufficiently dry at the time of breaking to prevent contamination or adulteration of the liquid egg product from free moisture on the shell. Additionally, inspection program personnel are to verify that shell particles accidentally falling into the liquid egg products are being removed with a spoon or other approved instrument.

COKZ/NCAE stated that Article 26 of Regulation (EC) No 589/2008 establishes a tolerance for quality defects at the packing center just before dispatch to the egg products processing establishment, allows for up to 5% of egg quality defects (including eggs tainted with egg yolk, smeared with fecal materials, or soil). These eggs are nest run eggs or graded eggs and do not include any restricted eggs, and therefore, there is no risk of breaking ineligible eggs. However, since these eggs are not washed, candled, or sanitized at the egg breaking facility, the CCA decided to address this finding as one of the special conditions identified in the EC regulations that EU Member States have to address through their national regulations when certified establishments prepare product for export to the United States.

Consequently, the CCA initiated and implemented a corrective action plan that included an adjustment to the sanitation program requirements for establishments seeking certification for U.S. export. The adjusted sanitation program requires that establishments producing egg products for export to the U.S. break only clean and dry eggs and take measures to control, and eliminate the presence of shell particles in liquid egg products. Egg products processing establishments that encounter sanitation deficiencies are to take corrective measures that include measures to restore sanitary conditions and ensure that adulterated products do not enter commerce. These requirements are verified by COKZ/NCAE inspection personnel as part of the assessment conducted to determine an establishment's eligibility to be certified to export product to the United States.

The CCA implemented the corrective actions proffered in response to the above finding by following a procedure described in INS-006_V1-1 and verified the effectiveness of the established control measures using assessment points 204, 205 of the Review List of Egg Processing Industry HP DBP_DEF. The FSIS auditor verified that COKZ/NCAE has effectively implemented this newly established requirement throughout the inspection system. The new requirement was coupled with the routine verification activities designed to ensure that each official establishment routinely evaluates its Sanitation SOP and to ensure maintenance of effective procedures for sanitation, as described in INS-006_V1-1. COKZ/NCAE inspection personnel are to take enforcement actions, including suspension and withdrawal of inspection, in response to an establishment's failure to prevent product contamination or take appropriate corrective actions.

FSIS' analysis and audit verification activities of the Netherlands' egg product inspection system found that the CCA meets the equivalence requirements for this component. These requirements include the inspection system being able to address the audit findings related to the sanitation of shell egg used for breaking, for which the inspection system took immediate action and implemented effective corrective actions and preventive measures as verified by the FSIS auditor. Therefore, the Netherlands' egg products inspection system meets the equivalence criteria for the Sanitation component.

VII. COMPONENT FOUR: CHEMICAL RESIDUES CONTROL PROGRAMS

The fourth of the five equivalence components that the FSIS auditor reviewed was Chemical Residue Control Programs. FSIS criteria for this component require the inspection system to have a chemical residue control program designed and administered by the national government that functions to prevent chemical residue contamination of food products. To be considered equivalent to the FSIS program, the CCA must provide a description of the design of its residue sampling and testing plan. The CCA must maintain oversight of laboratories to ensure the validity and reliability of test data.

As required by equivalent provisions, the NVWA provides direction, coordination, and oversight in accordance with Council Directive 96/23/EC; Decision 97/747/EC; and Commission Decision 97/747/EC. The Netherlands' National Residue Control Plan (NRCP) has been implemented for the execution of Council Directive 96/23/EC on measures to monitor certain substances, and residues thereof in live animals and animal products including egg products. FSIS' residue experts thoroughly reviewed the Netherlands' 2013 residue testing plan as well as additional SRT responses outlining the structure of the Netherlands' chemical testing program. The FSIS auditor also conducted an onsite audit of one residue laboratory that performs analysis of products intended for export to the United States.

NVWA is centrally organized and hence policy, management decisions, and operational planning are initiated and implemented at the central level following sampling procedures (Sampling NP primary productions). The NVWA laboratory formulates the sampling allocation for the NRCP and issues sampling requests to the NVWA-teams responsible for sampling, the frequency of which is determined by the type of product.

The FSIS auditor verified that the design of the NRCP includes a description of the basis for the residue plan and the process used to develop it, the various sampling schemes, and lists the selected matrices for each compound. The NRCP includes a rationale and process for adding and removing chemical compounds. The operations of the residue plan put measures in place that ensure segregation of domestic product from product destined for export to the U.S. when domestic residue tolerances are higher. The CCA has the authority and resources to remove violative product from the human food chain, take control of products with violative chemical residue, and take regulatory action against individuals who attempt to introduce violative products into the human food chain.

The CCA issued a sampling guide that provides detailed instructions for the field personnel collecting samples. The FSIS auditor observed and verified the sample collection procedures in the visited establishment and confirmed proper identification of samples for the purpose of traceability. The CCA instructions include procedures for handling and disposing of product that might contain violative chemical residues. Enforcement actions are conducted at the central level by NVWA, and they include regulatory actions (penalties) against individuals or firms for food safety violations in accordance with the procedure described in Sampling NP Primary Productions Procedure (chapter 4.2)

The FSIS auditor reviewed NVWA laboratory internal SOPs and verified that the sampling procedures, analytical methods, and quality assurance procedures and calibration, temperature

recording, and intra-laboratory check samples for this laboratory are being properly implemented and documented. The NVWA laboratory prepares a monthly report on the progress of the sampling and conducts investigations as part of the NRCP. Corrective actions are taken when samples fail to arrive on time, and the remaining sampling scheme is adjusted accordingly. The laboratory informs all relevant authorities about noncompliant results. The NVWA is responsible for the collection of NRCP results and issues the annual report that includes test results. The NVWA also investigates the abuse of illegal substances in farm animals. These investigations are conducted on a risk-based approach.

In addition to the NVWA sampling, COKZ/NCAE conducts additional sampling and analysis on residues and contaminants based on the risk assessment. For example in 2014, monitoring of organochlorine compounds, including PCB's (dioxins and PCBs), was performed by COKZ/NCAE- NVWA (survey-project). The results of residue samples in egg products are provided to COKZ/NCAE on a yearly basis. Besides monitoring by NVWA and verification managed by COKZ/NCAE, official egg products processing establishments in the Netherlands are required to implement monitoring of residues and contaminants at a frequency that is based on hazard analysis conducted using HACCP-principles. COKZ/NCAE oversees the implementation of the establishments' sampling plan (Review List-Egg Processing Industry-assessment-points 404, 413, 1941). FSIS has no requirement for plants to conduct a residue testing program. These activities were only assessed since they are considered as integral parts of the Netherlands' residue control program that exceeds FSIS requirements.

Two laboratories provide analytical services under the NRCP: NVWA laboratory and RIKILT laboratory. Both laboratories have been accredited to ISO 17025 and report the results of the sample analyses to the CCA. Since 2010, RIKILT serves as the National Reference Laboratory (NRL). The accreditation is renewed every four years by the RvA. The CCA is represented in the Supervisory Board of RvA. The CCA requires laboratories analyzing product destined for the U.S. to participate in proficiency testing schemes for food analysis, in accordance with Regulation (EC) No 882/2004. The RvA reviews include: 1) mandatory competency testing; and 2) RvA audit reports at least once per year. The CCA receives copies of the accreditation and audit reports and verifies that the NVWA laboratories continue to meet the accreditation requirements and achieve their objectives by providing technical support to the CCA through the delivery of valid and reliable test data. The CCA also conducts periodic reviews of the laboratory activities to ensure that laboratories testing product destined for the U.S. comply with the general criteria for testing laboratories in accordance to ISO/IEC Standard 17025. Residue samples collected by COKZ/NCAE based on risk assessments are sent to Silliker Netherlands, a private laboratory contracted by COKZ/NCAE to carry out routine analyses and verification for egg products.

The FSIS audit of the Netherlands' chemical residue laboratory and the review of the chemical residue control program verified that the following areas met equivalence requirements: sample receipt and tracking, media preparation, integrity of analyses, oversight, and program activity. The FSIS auditor did not identify any deficiencies or concerns during the laboratory audit.

FSIS' analysis and audit verification activities of the Netherlands' chemical residue testing program demonstrated that the CCA meets the equivalence requirements for this component.

VIII. COMPONENT FIVE: MICROBIOLOGICAL TESTING PROGRAMS

The last of the five equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to the microbiological testing programs organized and administered by the CCA to verify that products destined for export to the U.S. are safe, wholesome, and not adulterated and meet all relevant equivalence criteria.

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

The auditor verified that the Netherlands' egg products inspection system requires all official establishments to sample and test pasteurized liquid, frozen, and dried egg products for *Salmonella*. This requirement is supported by Regulation (EC) No 2073/2005-Annex I- Chapter 1-Item 1.4-Egg products, excluding products manufactured using a process or product formulation that will eliminate the *Salmonella* risk; Regulation (EC) No 178/2002- Article 17 requires establishments involved in all stages of production, processing, and distribution to ensure that their food products comply with the requirements of the respective food law relevant to their activities. These establishments must take measures, including sampling, to verify that such requirements are met.

Official governmental sampling by COKZ/NCAE is performed and compared to the establishment's own sampling and test results to verify the effectiveness of the establishment's food safety system. Work plan HP-DBP NCAE 2014 provides procedures for sampling and analyzing liquid egg products, and MON-003_V1-3 provides sampling and analysis procedures for powdered egg products and ensures sample collection integrity and reliability. The frequency of sampling events, and samples per event, provides meaningful data for evaluating the presence of pathogens in product exported to the United States. The sampling methodology, including the matrices and tools used, are effective for generating meaningful and consistent data.

The table below includes information for microbiological testing and methods approved by the CCA for establishments intending to export egg products to the US.

Target Microorganism	Matrix Origin	Test Portion (g/ml)	Testing Method Type
Enterobacteriaceae	Egg Products	cfu / ml m = 10, M = 100, n = 5, c = 2.	ISO 21528
Salmonella	Egg Products	Absent in 25 g, n = 5, c = 0	EN/ISO 6579
Listeria	Egg Products	Absent in 25 g, n = 5, c = 0	EN/ISO 11290-1

n = number of units comprising the sample c = maximum number of samples where the presence of microorganism can be detected.
Enterobacteriaceae in egg products: satisfactory, if all the values observed are ≤ m; acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m; unsatisfactory, if one or more of the values are > M or more than c/n values are between m and M.

The FSIS auditor verified that analysis of *Salmonella*, *Enterobacteriaceae*, and *Listeria* is performed by an accredited private laboratory (Silliker), which is NEN-EN ISO/IEC 17025 accredited and is overseen on a yearly basis by the RvA. COKZ/NCAE has a Service Level Agreement with Silliker (Silliker-NCAE SLA). The Accreditation Council reports its findings to the relevant laboratory. During its annual audit at Silliker, COKZ/NCAE has access to RvA reports. Silliker simultaneously reports test results related to the official verification of microbiological control programs to the COKZ/NCAE and the regulated establishment (Working

Manual RE-29-*Salmonell*a-targeted inspection and Working Manual RE-30-*Salmonella*-screening).

The FSIS auditor visited the Silliker laboratory and reviewed the records associated with the testing programs for egg products. The auditor focused on the verification of analysts' qualifications, sample receiving and handling, timely analysis, analytical methodologies, analytical controls, and recording and reporting of results. FSIS' review of the laboratory operations found that the sampling plans for microbiological analysis were in place, and the analyses were performed using equivalent methods that had been validated. There were no issues of concern identified related to the sampling and testing programs. The review of past audit reports of the laboratory reveals that all internal and external audit findings were promptly corrected and verified by a supervisor or through follow-up audits.

The FSIS auditor verified that all of the establishments that are intended to export egg products to the U.S. conduct microbiological testing in accordance with the regulatory requirements. The auditor's reviews of the establishments' written programs and official inspection records did not identify any issues of concern, and confirmed that all audited establishments complied with the CCA regulatory requirements. COKZ/NCAE supervisory reviews include a special emphasis on verifying establishments' control measures for relevant microbiological pathogens (*Salmonella* and *Listeria*). The inspection system provides appropriate enforcement action whenever applicable pathogen tolerances are exceeded. The enforcement strategy ensures proper disposition of product and requires negative *Salmonella* results for samples intended for export to the United States. The CCA defines a production lot as it relates to government testing of product as a group of similar product characteristics, produced under the same conditions, during a limited period of time (EU Directive 2011/91).

The audit demonstrated that the Netherlands' egg products inspection system has a microbiological testing program, organized and administered by the national government. The inspection system implements certain sampling and testing programs to ensure that egg products produced for export to the U.S. are safe and wholesome. The microbiological control program is carried out in accordance with Regulation (EC) No 178/2002–Article 17; Regulation (EC) No 2073/2005; and Regulation (EC) No 2160/2003 on the control of *Salmonella* and other specified food-borne bacteria. FSIS' document analysis and audit verification activities cumulatively indicated that the CCA meets the equivalence requirements for the Microbiological Testing Programs component.

IX. CONCLUSIONS AND NEXT STEPS

The audit results establish that the Netherlands' egg products inspection system meets the equivalence requirements. Only one finding was identified in equivalence Component 3, Sanitation, and that finding does not change the overall determination of equivalence because of the nature of the finding and the immediate actions taken in response to the finding by the competent authority and verified by the auditor. The audit finding is related to the fact that the inspection personnel did not consistently ensure that egg products processing establishments implement sanitation programs that ensure that eggs loaded to the breaking machines are free from contamination with foreign materials, and that the egg product is free of shell particles

immediately after breaking. Batches of eggs, ready to be loaded to the breaking machine, contained several eggs with adhering egg yolk or dark brown material.

The CCA addressed this finding by adopting and implementing new sanitation program requirements. The new sanitation procedures require that establishments seeking export certification for egg products to the U.S. take appropriate measures to ensure that only clean and dry eggs are loaded onto the breaking machine and take measures to control, and eliminate the presence of shell particles in the liquid egg products. The inspection program personnel will verify compliance with this requirement and document the outcome of the verification activity.

The FSIS auditor documented one observation, at the establishment level that was related to candling. The egg products processing establishments do not conduct on-site candling to detect eggs with cracked shells and interior defects. The candling is conducted and verified by COKZ/NCAE official inspection personnel at egg packers as part of primary production specified in Article 3(17) of Regulation 178/2002, and Annex I, Part A, point I (1) of Regulation 852/2004. This verification falls outside the activities of primary production of egg products processors and should be reviewed and verified as part of the overall inspection verification activities conducted at the establishment level.

COKZ/NCAE adopted specific procedures to ensure that there is verification and documentation of the candling results at the packing station and included that requirement as part of the supply chain information accompanying each batch of product. This information will be provided to the egg products processing establishment and will be used as part of the processing procedure verified by COKZ/NCAE inspection personnel and documented for all incoming eggs intended for processing and export to the United States.

During the closing meeting, held in Utrecht on June 26, 2014, the FSIS auditor presented the main findings and preliminary conclusions of the audit to the CCA. The CCA understood and accepted the findings. All findings were addressed by the CCA and verified by the auditor. The CCA provided documents during and after the exit meeting to support actions taken to address the FSIS finding and observation identified during the audit. The auditor verified that CCA adequately implemented its corrective actions and addressed all the audit findings. FSIS' evaluation of the Netherlands' egg processing and food safety program, verification of the corrective actions implemented in response to the audit finding, and observations establish that the Netherlands' food safety system governing egg products inspection is equivalent to that of the U.S. with the capability to produce and export products that are safe, wholesome, and properly labeled. Therefore, FSIS will reinstate the Netherlands' equivalence for egg products and consequently allow the country to resume export of egg products to the United States.

X. ATTACHMENT TO THE AUDIT REPORT

The Netherlands' response to the audit report

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Bouwhuis Enthoven B.V. Aakstraat 14, 8102 HH Raalte *(Egg product processing)*	6/18/2014	Est. NL EP6063 EG	The Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faiz Agarib, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. 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	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

NL EP6063 EG, Bouwhuis Enthoven B.V. (*Egg product processing*), Raalte

The establishment applies HACCP principles in accordance with Article 5 of Regulation (EC) No 852/2004 which requires food business operators to put in place, implement and maintain a permanent procedure based on Hazard Analysis and Critical Control Point (HACCP) principles.

There were no significant findings to report after consideration of the nature, extent, and degree of all observations.

FSIS Observations:

Collection of official sample: FSIS observed COKZ-NCAE inspector collected sample of powered egg product for analysis for *Salmonella* following the established procedure.

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faiz Agarib, DVM	Faiz Agarib

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
Van den Burg Eiproducten B.V. Sluisweg 20, NL-5145 PE Waalwijk *(Egg product processing)*	6/20/2014	Est. NL EP6085 EG	The Netherlands
	5. NAME OF AUDITOR(S) Faiz Agarib, DVM		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.	
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	
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46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	x
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	x
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

NL EP6085 EG, Van den Burg Eiproducten B.V. (*Egg product processing*), Waalwijk

10/51 Sanitation

FSIS auditor observed the establishment's employees loading shell egg onto the belts of the breaking machine. Some of shell eggs were dirty egg with foreign matter on the shell surface, including egg yolk, fecal materials, feathers or soil. The establishment operations did not include process for washing, drying and disinfecting dirty eggs. Furthermore, after breaking, there were egg shell particles and blood spots in the liquid egg products coming out of the breaking machine and two plant employees were removing the shell particles and blood spots with a spoon or other approved instrument. COKZ-NCAE, responsible for conducting the inspection activities, stated that, Article 26 of Regulation (EC) No 589/2008 established *tolerance for quality defects* at the packing center, just before dispatch: 5 % of eggs with quality defects. The establishment management stated that they will be able to sort out the egg at the packing station to ensure that they meet U.S. requirements and ensure that egg processing is carried out in such a way as to avoid any contamination during production, handling and storage of egg products, in particular by ensuring that Eggs are not be broken unless they are clean and dry. The establishment management provided documentation demonstrated their awareness of the shell particles in the liquid egg prior to separation and the efforts employed to reduce presence of shell particles.

Inspection Observations

During the audit, COKZ-NCAE inspector noticed and documented the following:

- The floor of the structure is broken eggs in one machine. These will need to be repaired before August 1, 2014. [Reference: LH.II.II.1.a Disclosures Hygiene Package and Animal Byproducts egg processing industry 5.1.3]
- At the bottom of the pipes of machine 3, in the crushing section there were dried drops black / gray dirt. The pipe should be cleaned immediately. [Reference: LH.II.I.1, 2 LH.II.II.1, Notes Hygiene Package and Animal Byproducts egg processing industry 5.1.1]
- A container placed outside the processing room was full of paper used to clean hand and it was not covered. This creates insanitary conditions.

FSIS Observations

Candling: The establishment does not conduct candling to detect eggs with cracked shells and interior defects. COKZ-NCAE stated that the candling is conducted and verified at egg packers as part primary production specified in Article 3(17) of Regulation 178/2002, and Annex I, Part A, point I (1) of Regulation 852/2004, primary production of eggs includes the handling of eggs, i.e. the collection and transport between buildings, and storage of eggs at the production site, provided that this does not substantially alter their nature. The packaging of eggs, either at the site of production or at a separate packing establishment falls outside the activities of primary production. These activities comply with the relevant requirements of Annex II to Regulation (EC) No 852/2004, of Annex III, Section X of Regulation (EC) No 853/2004, Article 5 of Regulation (EC) 589/2008, and of Article 116 and Annex XIV of Regulation (EC) No 1234/2007 establishing a common organization of agricultural markets and on specific provisions for certain agricultural products. COKZ-NCAE may adopt specific procedure to ensure documentation of the candlings at the packing station and include that at part of the supply chain information. This verification activity will be conducted as part Bilateral Agreement to meet requirements for export to a third country from the Community as described in Regulation (EC) No 178/2002-Article 12.

Temperature of egg products: According to Regulation (EC) 853/2004, Section X: Eggs and Egg Products, Food business operators must ensure that all operations are carried out in such a way as to avoid any contamination during production, handling and storage of egg products, if processing is not carried out immediately after breaking, liquid egg must be stored either frozen or at a temperature of not more than 4°C (*39.2 °F*). The storage period before processing at 4°C must not exceed 48 hours. However, these requirements do not apply to products to be de-sugared, if de-sugaring process is performed as soon as possible. After breaking, each particle of the egg product must undergo processing as quickly as possible to eliminate microbiological hazards or to reduce them to an acceptable level. A batch that has been insufficiently processed may immediately undergo processing again in the same establishment, if this processing renders it fit for human consumption. When a batch is found to be unfit for human consumption, it must be denatured so as to ensure that it is not used for human consumption.

To ensure that egg processing establishment meet the requirements of 9 CFR Part 590, COKZ-NCAE and NVWA made commitment to verify and document that eggs being processed is handled consistent with 9 CFR Part 590. For example§ 590.50 Temperature and labeling requirements (a) No shell egg handler shall possess any shell eggs that are packed into containers destined for the ultimate consumer unless they are stored and transported under refrigeration at an ambient temperature of no greater than 45 °F (7.2 °C). This verification activity will be conducted as part Bilateral Agreement to meet requirements for export to a third country from the Community as described in Regulation (EC) No 178/2002-Article 12.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faiz Agarib, DVM	Faiz Agarib