



United States Department of Agriculture

Food Safety and
Inspection Service

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Dr. Marek Pirsztuk
Chief Veterinary Officer
Veterinary Inspection
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Republic of Poland
30 Wspolna Street
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Dear Dr. Pirsztuk:

Enclosed is a copy of the final audit report that describes the outcome of two initial equivalence on-site audits of Poland's poultry inspection system conducted by the Food Safety and Inspection Service (FSIS) from May 10 to June 1, 2011, and July 14 to 25, 2014. FSIS appreciates the comments provided by Poland on the draft audit report and has made the appropriate technical changes in the final audit report. In addition, your comments will be attached to the Final Audit Report.

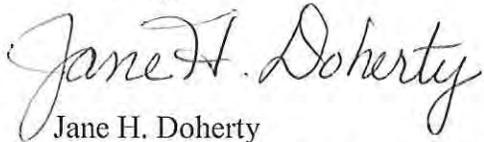
Following the FSIS audit of Poland's poultry inspection system, on August 21, 2014, FSIS published a final rule to modernize poultry slaughter inspection (79 Federal Register 49566, copy attached). The rule implemented new U.S. regulatory requirements including (1) the New Poultry Inspection System (NPIS), an optional post-mortem inspection system, and (2) regulatory changes that apply to all poultry slaughter establishments. A copy of the FSIS letter to equivalent countries announcing these changes is attached for your reference. FSIS expects Poland to submit sufficient evidence to demonstrate how the Polish poultry inspection system achieves an equivalent outcome as the revised U.S. regulations.

FSIS intends to proceed with rulemaking to determine whether Poland may be added to the list of equivalent poultry inspection systems in U.S. Title 9, Code of Federal Regulations, section 381.196. However, before issuing a final rule to add Poland to the list of equivalent countries, and before any product is shipped to the U.S., FSIS must verify that the Polish poultry inspection system is equivalent with the new U.S. regulatory requirements announced in the August 21, 2014, final rule.

Dr. Marek Pirsztuk
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If you have any questions, please contact Dr. Linda Chittum by telephone at (202) 720-6240 or by electronic email at linda.chittum@fsis.usda.gov or internationalequivalence@fsis.usda.gov.

Sincerely,

A handwritten signature in cursive script that reads "Jane H. Doherty".

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosures

FINAL REPORT OF AN INITIAL EQUIVALENCE FOLLOW-UP AUDIT

CONDUCTED IN

POLAND

July 14 - 25, 2014

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING
THE PRODUCTION OF POULTRY 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 an initial equivalence audit of Poland's poultry inspection system conducted by the Food Safety and Inspection Service (FSIS) from July 14-25, 2014. The audit objective was to verify whether Poland employs inspection measures equivalent to that of the United States (U.S.), with the ability to produce poultry products that are safe, wholesome, and properly labeled. This audit was necessary to assess the effectiveness of the corrective action plan proffered and implemented by Poland in response to the findings of an initial equivalence on-site audit that FSIS conducted from May 10 - June 1, 2011.

This follow-up audit focused on the ability of the General Veterinary Inspectorate (GVI), the Central Competent Authority (CCA) in Poland, to implement effective inspection and control programs related to the production and export of poultry products to the U.S. The auditor focused the following six equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems, (5) Chemical Residue Programs, and (6) Microbiological Testing Programs. The auditor also verified the adequacy and effectiveness of the corrective action plan implemented by the CCA to address the findings of the previous audit.

The CCA addressed all the findings made by FSIS in its previous audit by developing and implementing a comprehensive corrective action plan. FSIS evaluated Poland's results from this plan and concluded that the corrective actions, as documented, satisfactorily addressed the previous initial equivalence audit findings. The auditor verified that the GVI had effectively implemented the proffered corrective action plan, and that Poland met the equivalence criteria for all six components. The current audit identified three non-systemic findings. These audit findings are addressed in their respective sections of the report.

Based on the analysis of the corrective actions taken by the GVI in response to the 2011 audit findings and the results of the current follow-up audit, FSIS concluded that the CCA has adequately addressed all previously identified issues of concern and was able to meet FSIS requirements and equivalence criteria related to all six components. There is no need to conduct another follow-up audit. The evaluation of all data collected prior to, during, and after the on-site audit indicates that Poland's poultry products regulatory system cumulatively provides the level of protection achieved by the U.S.'s inspection system. Therefore, FSIS will move forward with proposing regulation to list Poland as a country eligible to export poultry product to the U.S.

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

APHIS	Animal and Plant Health Inspection Service
CCA	Central Competent Authority
CFR	Code of Federal Regulations
CVO	Chief Veterinary Officer
DVI	District Veterinary Inspectorate
DVO	District Veterinary Officer
<i>E. coli</i>	<i>Escherichia coli</i>
EC	European Commission
EU	European Union
EU-RLs	European Union Reference Laboratories
FSIS	Food Safety and Inspection Service
ISO/IES	International Organization for Standardization/International Electrotechnical Commission
GVI	General Veterinary Inspectorate
<i>Lm</i>	<i>Listeria monocytogenes</i>
MARD	Ministry of Agriculture and Rural Development
NRL	National Reference Laboratory
NVRI	National Veterinary Research Institute
HACCP	Hazard Analysis and Critical Control Point System
PVI	Provincial Veterinary Inspectorate
PVO	Provincial Veterinary Officer
RVL	Regional Veterinary Laboratories
RTE	Ready-to-Eat
<i>Salmonella</i>	<i>Salmonella</i> species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
USDA	United States Department of Agriculture
VI	Veterinary Inspector

1. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an initial equivalence on-site follow-up audit of Poland's poultry inspection system in the period from July 14-25, 2014. This follow-up audit was conducted to verify that the country effectively implemented the corrective actions in response to the deficiencies identified during the initial equivalence audit conducted from May 10-June 1, 2011. The follow-up audit began with an entrance meeting on July 14, 2014, in Warsaw, Poland, with participation of representatives from the Central Competent Authority (CCA), the General Veterinary Inspectorate (GVI) of the Ministry of Agriculture and Rural Development (MARD), and the Embassy of the United States in Poland. The FSIS auditor was accompanied throughout the audit by representatives from the GVI, the provincial veterinary inspectorate (PVI) or the district veterinary inspectorate (DVI).

This initial equivalence follow-up audit was conducted to verify whether the system maintained regulations consistent with specific provisions of the U.S. laws and regulations:

- The Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*).
- The Poultry Products Inspection Regulations (9 CFR 381.196 *et seq.* and other relevant regulations including HACCP and SSOP (9 CFR 416 and 417).

The audit standards included all applicable legislations and procedures originally determined by FSIS as equivalent during the initial document review process and any subsequent equivalence determinations that have been made by FSIS under provisions of the Sanitary/Phytosanitary Agreement (SPS). The legislations included:

- European Commission (EC) Regulations 999/2001 *as amended*, 178/2002; 852/2004; 853/2004; 854/2004; 882/2004; 41/2004; 396/2005; 2073/2005; 1881/2006; 1883/2006; 333/2007; 470/2009; 1069/2009; 1099/2009; 1774/2002; 726/2004; and 37/2010; and Council Directives found equivalent under the Veterinary Equivalence Agreement (VEA), 96-22 and 96-23;
- Poland's national legislation concerning food safety (Products of Animal Origin Act; Veterinary Inspection Act; Civil Service Act; Safety of Food and Nutrition Act; Animal Protection Act; Polish Ordinances; Instructions of the General Veterinary Inspectorate); and
- U.S. regulations and control measures adopted by Poland through the Instructions of the Chief Veterinary Officer consistent with the standards addressing the lethality and stabilization requirements for cooked products as described in 9 CFR 381.150; the control programs for *Lm* in Ready-to-Eat (RTE) products as described in 9 CFR 430; Canning and canned products (9 CFR 381.300 - 311); the Sanitation Standard Operating Procedures (Sanitation SOPs) requirements as described in 9 CFR 416; HACCP requirements as described in 9 CFR 417; Generic *E. coli* testing requirements as described in 9 CFR 381.94; and *Salmonella* and *Campylobacter* verification program for raw poultry products as described in 9 CFR 9 CFR 381.170(a).

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

- The use of ISO 11290-1, microbiology testing method for testing *Listeria monocytogenes* (*Lm*) in ready-to-eat (RTE) products.
- The use of ISO 11290-2, microbiology testing method for *Lm* in RTE products as confirmatory and enumeration method only when used in conjunction with ISO 11290-1.
- The use of ISO 6579:2002 microbiology testing for *Salmonella* in RTE products (325 g).

2. AUDIT OBJECTIVES, SCOPE, AND METHODOLOGY

The objective of the initial equivalence follow-up audit was to verify whether the corrective action plan proffered in response to the findings of FSIS audit conducted from May 10-June 1, 2011, was adequate. The audit also was designed to determine whether the food safety system governing poultry products inspection is equivalent to that of the United States' inspection system. Prior to conducting this audit, the auditor reviewed the proffered corrective action plan and supporting documents provided by the CCA in response to the previous audit findings. These documents included descriptions of the new control measures and procedures adopted by Poland's poultry products inspection system.

The audit focused on the CCA's performance in all six equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems (HACCP), (5) Chemical Residue Programs, and (6) Microbiological Testing Programs. The FSIS auditor paid particular attention to the inspection performance in the areas linked to the FSIS findings made during the previous audit conducted in 2011. The previous audit findings and related corrective actions are addressed in this report under their respective equivalence components.

The auditor reviewed the administrative functions at the CCA headquarters in Warsaw; three provincial offices; and three district offices. During the review, the FSIS auditor evaluated the implementation of the management control systems put in place to ensure that the national system of inspection, verification, and enforcement are being implemented as intended. The auditor conducted review of the administrative functions of the local inspection offices as part of the establishment review. The FSIS auditor assessed the administrative functions of sampling and testing through a review of records at the CCA's headquarters office and provincial offices. The auditor further assessed sampling and testing through document review and observations at the central laboratory and one regional laboratory.

In order to verify the CCA's ability to provide consistent government oversight, the FSIS auditor reviewed the inspection operations at two poultry slaughter and three poultry processing establishments. The selected establishments are located within three different provinces and intend to export poultry products to the United States (U.S.). The establishments involved poultry slaughter and processing that includes raw - intact, and raw non-intact products, ready-to-eat (RTE) products, and thermally processed commercially sterile (canned) products. During the establishments' review, particular attention was paid to the extent to which industry and government interact to control hazards, and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews.

Furthermore, the FSIS auditor conducted a review of two official laboratories that perform residue and microbiological testing of poultry product intended for U.S. export. The review was intended to verify that the laboratory testing programs are equivalent to FSIS's. The auditor reviewed the National Veterinary Research Institute (NVRI)/National Reference Laboratory (Pulawy) and one of the Regional Veterinary Laboratory (Warsaw).

Audit Scope Summary

Competent Authority Visits		No	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> General Veterinary Inspectorate - CCA Headquarters office (Warsaw).
	Provincial offices	3	Provisional Veterinary Inspectorate offices in <ul style="list-style-type: none"> Siedlce Poznan Krakow
	District offices	3	District Veterinary Inspectorate offices in <ul style="list-style-type: none"> Mława Ostrzeszow Chrzanów
	Local offices	5	Reviews of local offices were conducted as part of the establishment review, at Chrzanów, Sącz, Mława, Słupca, and Ostrzeszów.
Government Laboratories (microbiological and residue testing)		2	<ul style="list-style-type: none"> National Veterinary Research Institute (NVRI)/National Reference Laboratory (Pulawy) Regional Veterinary Laboratory (Warsaw)
Establishments			
Poultry Slaughter/processing		2	<ul style="list-style-type: none"> Est. 14130502, WIPASZ S.A. Zakład Drobiarski w Mławie; Est. 30230501, PPHU "Konspol-Bis" Sp. z o.o.
Poultry Processing (Raw/RTE)		2	<ul style="list-style-type: none"> Est. 12030323, Zakary Miens "UNIMIĘS" SP. Z O.O Est. 12620602, Konspol-Holding Spółka z o.o.
Poultry Processing (Canned)		1	<ul style="list-style-type: none"> Est. 30184103, Wielkopolska Wytwórnia Żywności Profi Spółka Z Ograniczoną Odpowiedzialnością- Kolejowa
Total Number of Establishments		5	

3. BACKGROUND

Poland is a member of the European Union (EU) and consequently conforms to the European Commission (EC) legislation and issues national regulations and procedures to address aspects of the regulations, programs or export requirements that need to be implemented and verified by the CCAs of each Member State. Poland is currently eligible to export raw and processed pork products, to the U.S.

USDA’s Animal and Plant Health Inspection Service (APHIS) considers Poland as one of the countries not affected with Highly Pathogenic Avian Influenza subtype H5N1 and free of Exotic Newcastle Disease (END). Once determined equivalent, Poland needs to address APHIS’s special restrictions defined under 9 CFR 94.28 in relation to the importation of poultry from the APHIS-defined EU Poultry Trade Region, in addition to the certification requirements described in 9 CFR 381.197. Since Poland’s disease status may change during the equivalence process, FSIS will follow-up with APHIS and take into consideration how changes in the animal disease status may impact the country’s eligibility to export certain types of poultry products to the U.S.

Prior to proceeding with the initial equivalence on-site audit, FSIS requested that Poland provide updated information related to its poultry inspection system regulations by completing the Self-Assessment Tool (SAT). Based on the document review conducted based on FSIS’s current equivalence

criteria covering the six equivalence components, FSIS's concluded that Poland's laws, regulations, control programs, instructions, and procedures cumulatively provide the same level of public health protection attained by the FSIS.

The FSIS conducted an initial equivalence on-site audit of Poland's poultry products inspection system to verify whether the CCA's effectively implemented the laws, regulations, and control programs that FSIS found to be equivalent during the document review and analysis. The FSIS audit conducted in the period from May 10-June 1, 2011 identified several systemic findings related to the implementation of the inspection programs. The [previous report of FSIS's on-site audit of Poland's poultry products inspection system](#), posted on FSIS website on November 14, 2012, identified systemic findings within components: (1) Government Oversight, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems, and (6) Microbiological Testing Programs. For example, FSIS found that the GVI did not have current legislative commitment that authorizes the CCA to require establishments that intend to export product to the U.S. to develop, implement, and maintain Sanitation SOPs and HACCP systems as conditions for meeting the certification requirements. In addition, FSIS was not able to make a determination on whether or not the equivalence requirements for component (2) Statutory Authority and Food Safety Regulations, were met because the CCA did not present poultry slaughter establishments for FSIS review during the audit.

Poland addressed the FSIS audit findings through corrective action plans presented on September 5, and October 11, 2012, and presented a comprehensive corrective action plan on March 20, 2013 that addressed all the audit findings identified in 2011. FSIS evaluated the corrective action plan provided in response to the FSIS previous audit findings. Additionally, Poland presented two poultry slaughter establishment for FSIS review during its next audit. Consequently, FSIS decided to conduct a follow-up initial equivalence audit to assess the effectiveness of the implemented corrective actions, to assess the slaughter operation that was not presented during the 2011 initial equivalence audit, and to verify the implementation of additional FSIS requirements related to thermally treated commercially sterile products, as described in Self Reporting Tool (SRT).

4. COMPONENT ONE: GOVERNMENT OVERSIGHT

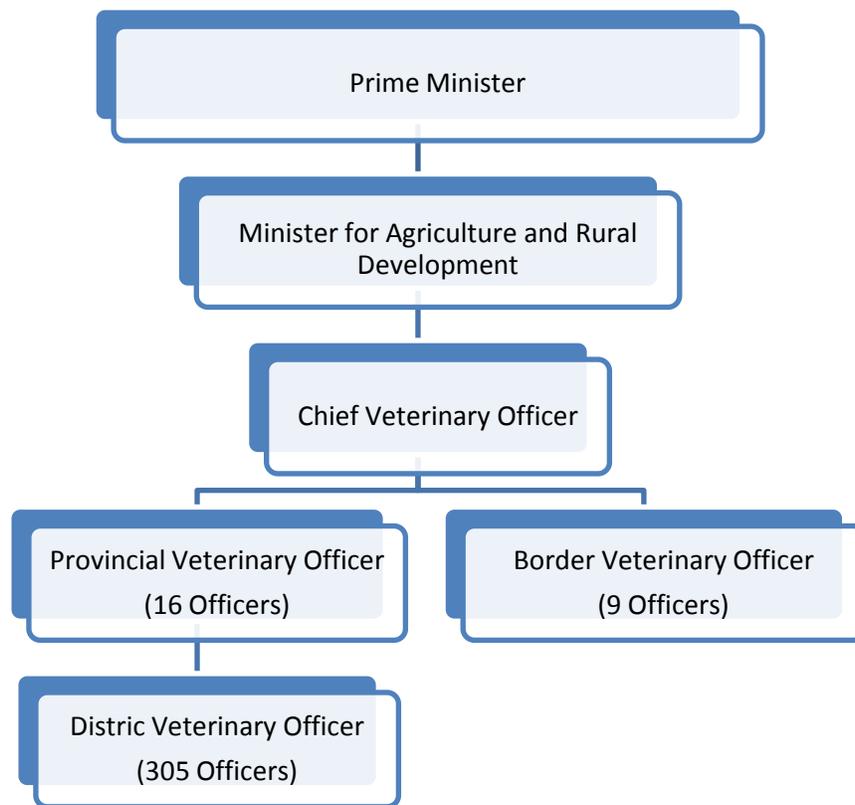
The first of the six components that the FSIS auditor reviewed was Government Oversight. FSIS' import eligibility requirements state that the foreign inspection system must be designed and administered by the national government of the foreign country, with standards equivalent to those of the poultry products inspection system in the U.S., as described in 9 CFR 381.196. 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.

The FSIS auditor assessed how Poland's poultry products inspection system is organized and administered to promulgate and enforce inspection regulations, ensure food safety, and certify poultry products when they meet the requirements for export to the U.S., as described in 9 CFR 381.196-Eligibility of foreign countries for importation of poultry products into the United States.

The GVI is headed by the Chief Veterinary Officer (CVO) who is appointed by the Prime Minister based on recommendation of the Minister of Agriculture and Rural Development. The GVI is the first level of the inspection system and has direct authority over the subsequent two inspection levels. The

PVI is the second inspection level and is headed by the Provincial Veterinary Officer (PVO). Each of Poland's 16 PVIs oversees the inspection activities carried out by 12 to 42 DVIs. The DVI is the third level of the inspection system and is headed by the District Veterinary Officer (DVO). The DVI oversees all direct inspection activities in the establishments that intend to export poultry products to the U.S. The FSIS auditor verified that the CCA operations are funded by the government budget and supplemented by fees assessed on plants by the GVI on exported products. The Polish Veterinary Inspection System (GVI, PVI and DVI and the Border Veterinary Inspectorates) is funded by the government. For the official controls carried out in plants, the District Veterinary Officer collects fees from establishments which are then discharged into the government budget.

ORGANIZATIONAL CHART OF THE VETERINARY INSPECTION



The FSIS auditor verified that inspection program personnel assigned to establishments, proposed for certification for poultry product exports, are full-time employees of the national government and perform activities under administration of the DVI and the PVI. The GVI receives copies of the periodic reviews conducted by DVI and PVI and summary reports of noncompliance records issued for official establishments.

The FSIS auditor verified that the DVO has the authority, and responsibility to hire and assign competent, qualified inspectors to official establishments that would export products to the U.S. The CCA employs an effective ongoing plan to analyze and meet staffing requirements at establishments that intend to export product to the U.S. Every inspector is assigned a program badge and receives a monthly salary payment by direct deposit from government funds. The auditor's review did not encounter any situation that could result in a conflict of interest.

The FSIS' review of the activities carried out at all three levels of the inspection system demonstrated that the CCA has a single set of rules, legal authority, and responsibility to enforce inspection laws and to ensure that adulterated or misbranded products are not exported to the U.S. The EC regulations, the primary overarching laws for regulating poultry inspection, are supplemented with national legislation to address the implementation of the inspection activities. Vested by Poland's legislation, the GVI issues guidelines and instructions that address performance of official inspection tasks, supervisory review, establishment registration procedure comparable to FSIS grant of inspection (i.e., approval, conditional approval, suspension, and withdrawal of approval of regulated establishments), how to verify microbiological sampling and testing; and how to carry out the National Residue Control Plan. The CCA disseminates information related to regulatory and administrative affairs to all levels of the inspection system by mail and e-mail and by posting it on the GVI website.

The auditor's review of inspection personnel training records, at the CCA headquarters and provincial offices, demonstrated the CCA takes control measures to ensure that its personnel, including official veterinarians and non-veterinarian inspectors, have appropriate educational credentials and receive training to enable them to carry out their assigned inspection tasks.

During the previous FSIS audit, FSIS determined that the GVI did not possess evidence of staff participation in training or maintain tracked records at all levels of the CCA, and that the GVI was lacking a mechanism that assesses the effectiveness of the training programs. In response to the previous audit finding, the CCA developed and implemented a procedure for documenting its on-going training program at all levels of the CCA (training materials, objectives, attendees, and results of final assessment). The auditor verified that the CCA had effectively implemented these training programs. Furthermore, the FSIS auditor verified that the CCA improved the procedure used to conduct the periodic supervisory reviews to ensure assessment of its inspection personnel's competency, with respect to specific inspection program requirements and U.S. export requirements. Similarly, the FSIS auditor verified that the supervisors use the training records to ensure that inspection personnel, assigned to certified establishments, possess the necessary knowledge to carry out their assigned responsibilities.

The certification of establishments for export to the U.S is carried out in accordance with the Products of Animal Origin Act. The certification procedure starts with a review conducted at DVI level in response to a request from an interested establishment. The DVI reports the results, of each review, to the PVO who verifies the DVI's decision through document review and an on-site visit by PVI staff if needed; the resulting recommendation is forwarded to the GVI. The list of approved establishments is posted on the GVI website. The FSIS auditor verified that the CCA follows the prescribed procedure for certification of poultry establishments, and that it has the authority to list or delist establishment based on their ability to comply with all of the requirements applied to official establishments in the U.S. and otherwise to meet the requirements of 9 CFR 381.196.

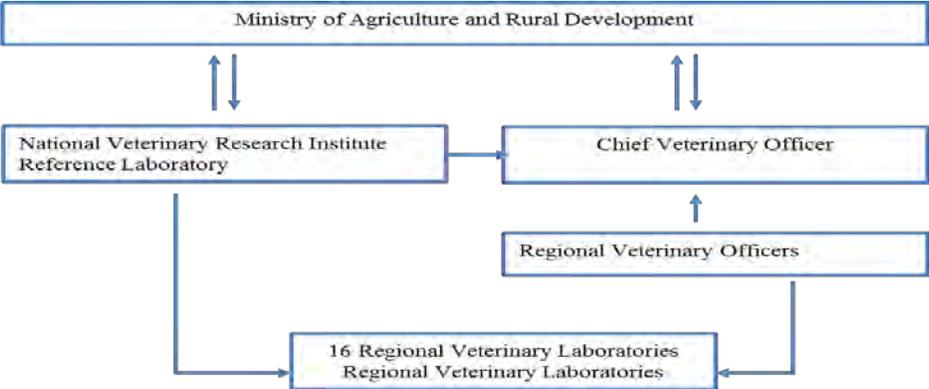
The issuance of inspection certificates for exporting goods to third countries, outside the EU, is based on the GVI Instruction No GIWue 0201-2/11 of 19 May 2011.. The FSIS auditor verified that Poland has controls in place to prevent fraud or misuse of export certificates. Export certificates, seals, and stamps are secured in the official inspection office. The inspection system tracks export certificates using a unique certificate identification number, signature cards for each authorized veterinarian, and archives copies of all issued certificates in the PVO and DVO. These measures demonstrate the inspection

system’s ability to maintain the security and integrity of poultry products during transportation between establishments and port facilities and to ensure that adulterated or misbranded product is not exported to the U.S.

The CCA has enforcement procedures based on Regulation (EC) 882/2004 and the CVO’s instructions as authorized by the Veterinary Inspection Act. These enforcement procedures are comparable to those outlined in 9 CFR Part 500, Rules of Practice. The inspection personnel follow these enforcement procedures and verify the effectiveness of the establishments’ corrective actions by issuing administrative decisions in response to noncompliance (Code of Administration Procedure- Art 104, the Instruction of the Chief Veterinary Officer, No GIWhig-500-2/13). The administrative decision includes a deadline for the rectification of the identified deficiency and a monetary fine to be imposed when the establishment fails to meet the specified deadline.

During the previous audit, FSIS found that some of the inspection personnel failed to follow the established procedure for closing the administrative decisions within the specified timeframe and for documenting the outcome of official verification activities. In response to the previous audit finding, the CCA implemented a procedure to ensure that inspection personnel effectively close administrative decisions, as part of periodic supervisory reviews. The CCA also made changes so that the supervisors are now required to verify the adequacy of the corrective action accepted by the inspection program personnel. During this audit, the FSIS auditor reviewed the inspection program’s records related to closure of administrative decisions. Through review of the composite noncompliance reports, records of periodic supervisory reviews, and documented enforcement actions, the auditor verified that the CCA has measures that ensure consistent enforcement of regulatory requirements.

FSIS’s audit of Poland’s poultry inspection system demonstrated that the CCA has adequate administrative and technical support for its inspection system. The GVI uses an official laboratory system that consists of the National Veterinary Research Institute (NVRI) and 16 Regional Veterinary Laboratories (RVLs) to conduct chemical and microbiological testing of product destined for the U.S. The NVRI serves as the National Reference Laboratory (NRL) responsible for setting the standards and harmonizing activities among the RVLs. The RVLs are technically under the supervision of the NRL and administratively under the PVO. The GVI’s Laboratories Policy Office coordinates activities between the GVI, the NRL and regional labs, as well as coordinates some of the activities of regional laboratories. The NRL is under financial and substantial supervision exercised by MARD.



The FSIS auditor verified that NRL has a supervisory role over the RVLs through supervisory reviews and administration of proficiency tests. The FSIS auditor's review of the NRL records indicated that these supervisory visits took place, usually, 3-4 times per year. All RVLs regularly participate in proficiency tests organized by the NRL and score satisfactory points. The review of the RVL indicated that the technical staff is adequately trained to perform their assigned functions, and that internal audit procedures were in place, as evidenced by the audit findings and corrective actions records. The periodic external audits were conducted at the RVLs by the NRL, and copies of the audit reports are sent to the audited laboratory, the PVO, and the CVO. During previous and current FSIS audits, the PVI provided documents to demonstrate that audits were conducted as scheduled to ensure that RVLs take appropriate corrective action in response to external audit findings and continue to meet the certification requisites.

The CCA has the legal authority, under the Veterinary Inspection Act, and the responsibility to approve and appoint laboratories conducting analytical testing on products for export to the U.S. (Regulation (EC) No 882/2004- Article 12). The CCA ensures that laboratories analyzing product destined for the U.S. participate in proficiency testing schemes for food analysis. Analyses of official samples are carried out by official laboratories constituting the organizational units of the RVI, and are accredited in accordance with ISO17025 by the Polish Centre for Accreditation (PCA). The FSIS auditor verified that official laboratories, testing raw and RTE product destined for the U.S., use methods determined to be equivalent by FSIS (ISO 6579-2002 and 11290.1 for detection of *Salmonella* and *Listeria monocytogenes* respectively).

Poland's poultry products inspection system adopted, through the Instructions of the Chief Veterinary Officer, a legislative commitment consistent with FSIS regulations addressing the control programs for *Lm* in Ready-to-Eat (RTE) products (9 CFR 430) and require that each establishment that intends to export poultry products to the U.S. implement control measures that prevent adulteration of both non post-lethality exposed RTE products and post-lethality exposed RTE products by *Listeria monocytogenes* (*Lm*) and *Salmonella spp.* The inspection verification activities are developed based on those in FSIS Directives 5000.1 and 10,240.4 and are incorporated into the Polish inspection procedure.

Poland's poultry inspection system classifies thermally processed commercially sterile product (canned) as products that have received a full thermal process, as defined in regulations consistent with 9 CFR 381.300(d), with a water activity above 0.85 that receives a thermal process either before or after being packed into a hermetically sealed container (rigid and semi-rigid containers, flexible pouches, glass jars). The Polish inspection system has issued CVO instructions setting out required verification and enforcement provisions equivalent to 9 CFR 381- subpart X (canning regulations). The instructions to inspectors specify the rules for managing the inspection activities. The rules include requirements and procedures to address operations (e.g., posting of processes, retort traffic control, initial temperature) in thermal processing areas and verification procedure for canning process. The FSIS auditor verified that official establishments proposed to export poultry products address microbiological hazard associated with canning through their HACCP plans. In such cases, the canning regulations serve a role similar to a prerequisite programs supporting documentation for the establishment's decision (9 CFR 417.5 (a)(1)). The CCA maintains written requirements and procedures for official establishments to recall product when there has been process deviations, and for inspection personnel to verify the effectiveness of the establishments recalls in accordance with Regulation (EC) No 178/2002.

FSIS auditor's observations of inspection program and reviews of official inspection records during the audit verified that the CCA has administrative controls to support its inspection system, and that the CCA was consistently enforcing applicable export regulations and that it had properly addressed the previous FSIS audit findings. Therefore, FSIS determined that the GVI meets the equivalence criteria for the Government Oversight component.

5. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. For an inspection system to be equivalent, it must provide an appropriate regulatory framework to demonstrate equivalence with FSIS' inspection system, including but not limited to HACCP; sanitation; chemical residue and microbiological sampling; good commercial practices for poultry slaughter; animal welfare, antemortem inspection of birds, postmortem inspection of carcasses and parts; establishment construction, facilities, and equipment, daily inspections at slaughter establishments (continuous during slaughter) and inspection at food processing establishments (at least once per day per shift), and periodic supervisory visits to official establishments.

FSIS has determined that the European Commission's (EC) 2004 legislation is equivalent as overarching legislation, given that CCAs of the EU Member States address the implementation of the legislation and other U.S. import requirements through their national laws, regulations, and policies. The FSIS's assessment of the inspection and control programs employed by the CCAs of EU Member States includes review of the country's national food hygiene control plan. The development of a National control plan is required by the EC, and it is used as a measure of the effectiveness of the food control regulations employed by the CCA. The national plan is updated every five years, and evaluated annually. The FSIS auditor verified that the GVI manages Poland's poultry products inspection program in accordance with the National Control Plan for the period from 2012 to 2016. The review of the national plan is used to determine whether the official controls employed by the CCA are organized in conformity with the set criteria and the overarching EC legislation.

Poland complemented the EC 2004 food hygiene legislation with a series of statutory instruments that organize the national framework of control programs related to inspection of poultry products including both slaughter and processing. The framework of the inspection and control programs includes: the Products of Animal Origin Act; the Veterinary Inspection Act, as amended; the Instruction of the Chief Veterinary Officer, No GIWhig-500-2/2013 on the conduct of the Veterinary Inspection bodies; the Code of Administrative Procedure; the Instruction of the Chief Veterinary Officer, No GIWbż-500-2/11 on using risk analysis to determine the frequency of controls in food sector operators; the Guidelines of Chief Veterinary No GIWbż-500-2 /12 (1) concerning the inspection of slaughterhouses in good hygiene practices (GHP) and animal welfare; the Instructions for the Veterinary Inspection Authorities, setting out the methods for the verification and enforcement of the homologous provisions to title 9 of the Code of Federal Regulations (CFR) of the U.S; the Ordinance of MARD on the scope of activities and qualifications of personnel; the Instruction of the Chief Veterinary Officer, No GIWbż-500-7a/09 on procedures for the implementation of the supervision of production processes; and the NRL Manual-Sampling of poultry carcasses and test for the presence of *Salmonella* and *Campylobacter* according FSIS Directive [10,250.1- Salmonella and Campylobacter Verification Program for Raw Meat and Poultry Products](#) and MLG 41.03-[Isolation and Identification of Campylobacter jejuni/coli/lari from Poultry Rinse, Sponge and Raw Product Samples](#). These statutory instruments form the basis for

regulatory oversight of the poultry products inspection system and are applied in conjunction with the EC *Salmonella* control programs intended to reduce the prevalence of *Salmonella* in poultry, particularly serotypes most responsible for human infections (*S. enteritidis*), as one of the measures used to bring down the number of human illnesses across the EU.

FSIS's evaluation of this component included the review and analysis of documents submitted by the CCA in the SRT, interviews with inspection officials, and observations made by the FSIS auditor during the onsite audit. The FSIS auditor verified that the CCA carried out official inspections and verification activities as outlined in the official instructions, including enforcement of animal welfare good commercial practices for poultry slaughter requirements, antemortem inspection, postmortem inspection, and verification that establishments have necessary construction, facilities and equipment, and control over inedible and condemned materials.

The FSIS auditor verified through records review and observations that the CCA takes measures to ensure that poultry products are safe to consume by carrying out daily inspection of slaughter establishments the whole time that slaughter is going on, and by conducting direct continuous inspections in processing establishments, at least once per day per shift, when producing product for export to the U.S.

The FSIS auditor further verified that Polish official veterinarians conducted antemortem inspection of birds on the day of slaughter, by examining individual birds, and by reviewing the incoming registration, food chain information, including results of *Salmonella* tests of the flocks, and identification documents that enable traceability of bird to their source. (The EC has a *Salmonella* eradication program that requires *Salmonella* testing of flocks intended to be presented for slaughter.) In accordance with the regulatory requirements and other established inspection procedures (Regulation (EC) No 854/2004 and Instruction of the Chief Veterinary Officer, No GIWbż-500-4/12), birds that show clinical symptoms of disease may not be slaughtered for human consumption. However, suspect birds may be slaughtered at the end of the normal slaughter process, and precautions must be taken to avoid the risk of spreading pathogenic organisms. Furthermore, measures are to be taken to clean and disinfect facilities right after killing.

The FSIS auditor verified that the inspection program personnel documents ante-mortem inspection activities in all visited poultry slaughter establishments. During ante-mortem inspection activities, Polish official veterinarians verified and documented that the establishments follow the requirements of animal welfare (good commercial practices) when handling birds presented for slaughter and meet the requirements specified in the Animal Protection Act- Article 5- 6 and Instruction of the Chief Veterinary Officer, No GIWbż-500-4/12.

The FSIS auditor verified through record review, interviews, and observations that Polish official veterinarians perform post-mortem inspection activities by observing viscera, outer and inner surfaces, and body cavities of every carcass in accordance with the regulatory requirements. The design of the postmortem inspection stations included sufficient lighting and the appropriate number of inspection program personnel (Veterinary Inspection Act- item 287 as amended, article 21). Although postmortem inspection activities were performed and documented in accordance with regulatory requirements (point 6, Chapter IV of Section II of Annex III to Regulation (EC) No 853/2004 and Part B 1. Chapter V Section IV of Annex I to Regulation (EC) No 854/2004 and the Instruction of the Chief Veterinary

Officer, No GIWbž-500-1/2013 on the supervision of slaughter), the following deficiency was identified in one of the poultry slaughter establishments:

- One of three designated veterinary inspectors at one of the poultry slaughter establishments was observed omitting postmortem inspection verification activities on some carcasses. Further examination of omitted carcasses did not identify any public health concerns. The other two in-line veterinary inspectors were found to be performing postmortem inspection activities in accordance with the inspection program instructions.

This finding was deemed to be an isolated incident that is not likely to affect the inspection system ability to product safe poultry products. This determination was based on the FSIS auditor's further observations of the postmortem activities in the same slaughter establishment, and in the second slaughter establishment, that indicated proper implementation of the postmortem inspection verification activities by all assigned veterinary inspectors.

In response to this finding, the CCA ordered immediate corrective actions to address deficiencies related to postmortem inspection by one of the assigned veterinary inspectors in this slaughter establishment. Evidence of these corrective actions was provided later during the course of the audit. The DVO instructed the designated veterinarian who omitted carcasses to undergo training on postmortem inspection activities and to successfully pass an exam before being allowed to resume performing inspection tasks. Additional preventive measures included correlation sessions to ensure that postmortem verification activities are carried out consistently in accordance with the regulatory requirements and GVI instructions. The FSIS auditor was able to verify the adequacy of the corrective action implemented in response to this audit finding.

The FSIS auditor verified that, for all products intended for export to the U.S., the portions of the carcass that are naturally inedible by humans or rendered unfit for human food by reason of adulteration are identified as "inedible parts" and include the comb and the ears, the wattles, and caruncles of birds. The GVI takes measures to ensure that carcasses that are found to be unfit for human consumption because of systemic diseases or violative drug residues are condemned in accordance with Regulation (EC) 854/2004- Annex III, Section I and Chapter IV, 16, Council Directive 96/23/EC, and the Instruction of the Chief Veterinary Officer, No GIWbž-500-1/2013 on the supervision of slaughter. The CCA ensures that condemned carcasses are separated from inspected and passed carcasses and products, and that they are properly denatured and disposed. The FSIS auditor also verified that the CCA ensures complete separation of establishments that intend to export product to the U.S. from other establishments. Moreover, the CCA uses traceability to ensure that processing establishments that intend to export product to the U.S. only use products originating from an approved source.

The FSIS auditor verified that the CCA maintains effective control to ensure disposal of condemned material in accordance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules regarding animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal By-Products Regulation). The condemned materials and inedible animal parts are divided into three categories, based on the risks they pose to public health. (Category I include the highest risk materials, such as parts condemned for zoonotic diseases; category II includes other risky materials, such as carcasses and parts condemned for infectious animal diseases; category III includes materials of low risk, such as feathers, peaks, and condemned part that had no signs of infectious disease.) Condemned materials are transferred from the establishment to entities authorized to collect, store, and process

category I, II and III animal by-products not intended for human consumption. These entities are supervised by district veterinarians to ensure compliance with the requirements described in Regulation (EC) No 1069/2009. This Regulation prescribes strict public health rules for the storage, handling, processing, and use or disposal of animal byproducts.

The FSIS auditor assessed the CCA's ability to exercise effective coordination between the different elements of the CCA and to provide oversight through supervisory reviews in accordance with the requirements described in 9 CFR 381.196. The FSIS auditor found that Poland's poultry products inspection system provides for periodic supervisory visits by a representative of the inspection system to each establishment that intends to export product to the U.S. The FSIS auditor verified that supervision of inspection personnel is performed by the DVO, who in turn falls under the direct supervision of the PVO. The FSIS auditor found that the PVIs and the DVIs conduct periodic supervisory reviews at the visited establishments. The supervisory reviews of official establishments were conducted in accordance with the Instruction of the Chief Veterinary Officer, No GIWbż-500-2/11 of 1 September 2011 determining, on the basis of risk analysis, the frequency of assessment of operators in the food sector under official supervision of the Veterinary Inspectorate. The CCA uses a risk assessment system to classify official establishments into risk categories. The frequency of the review is once every two years; once a year; once every six months; or once every three months depending on the risk category designated as very low, low, medium, and high. The determination of the level of risk of an individual establishment takes into account the type of establishment, production system, products, production hygiene, establishment compliance records, and commitment of the plant management. The CCA reserves the right to conduct an *ad hoc* review in response to issues of concerns (consumer complaints, foodborne illnesses, or product recall). The supervisory reviews include an assessment of the establishment's operation and its compliance with the regulatory requirements. During the review, the supervisors tour the establishment, review the establishment operations, look into the sanitation and HACCP records generated and maintained by the establishment, and examine official inspection records. The supervisory reviews were conducted using a uniform detailed checklist.

The FSIS 2011 audit identified that the inspection system failed to conduct supervisory reviews of all official and appointed veterinarians according to the scheduled frequency, failed to assess their competency related to assigned tasks, and did not emphasize the control of biological pathogens such as *Salmonella* and *Campylobacter* in raw poultry products and *Listeria monocytogenes* and *Salmonella* in RTE product. In response to these findings, the CCA amended the GVI instructions and the checklist used to document supervisory reviews. The amendment requires PVI and DVI to conduct and document annual supervisory reviews of all veterinary inspectors, with emphasis on control of biological pathogens, and report results of the reviews to the GVI. The auditor's review, during this audit, included observing the performance of pathogen control programs by the inspection personnel and their ability to implement inspection activities including specific U.S. requirements. Furthermore, the FSIS auditor interviewed supervisors and reviewed supervisory records and concluded that periodic supervisory reviews are being conducted according to the specified frequency, of all inspection personnel. The FSIS auditor verified that supervisory reviews placed emphasis on the competency of the inspection program personnel, and that it identified their training needs. The supervisory review results were found to be consistent with the knowledge of inspection personnel.

Mechanically Separated Poultry (MSP) is produced by removing remaining meat from flesh-bearing bones after the deboning or from poultry carcasses. In accordance with the requirements of Regulation

(EC) No 852/2004; Regulation (EC) No 882/2004; and Regulation (EC) No 853/2004-Annex III, Section V, Chapter III point 1, Poland requires official establishments to follow specific hygiene requirements during and after production to address the potential hazard to these products from microbiological contamination during production and further handling. The inspection program personnel verification activities include, among others, the verification of the correct labeling for final consumers of MSP products (Regulation of MARD on the labelling of foodstuffs implements Directive 2000/13/EC) and verification of the use of mechanically separated product in a product that has to undergo a heat treatment, e.g. frankfurter sausages. In response to concerns that undeclared MSM is used in a poultry product, samples of the product are tested in one of the laboratories accredited Polish Accreditation Centre (PCA) using a reference method that assesses the content and the presence of bone elements. Regulation (EC) No. 2074/2005 set the maximum calcium content in mechanically separated product as referred to in Regulation (EC) No 853/2004 at 0.1% (=100 mg/100 g or 1000 ppm) of fresh product and is determined using a standardized international method.

In conclusion, the FSIS auditor's observations and reviews of inspection program records found that the CCA has legal authority and a regulatory framework to impose requirements equivalent to those governing the system of poultry inspection organized and maintained by the U.S. The FSIS auditor verified that the CCA carried out official inspections and verification activities as outlined in the official instructions. The review and analysis of all relevant regulations and procedures resulted in concluding that the GVI meets the requirements for this component.

6. COMPONENT THREE: SANITATION

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

The FSIS auditor's review of regulations, official instructions, and guidelines demonstrates that Poland's poultry products inspection system adopted sanitation requirements equivalent to FSIS's requirements. The CCA requires each establishment that intends to export poultry products to the U.S to develop, implement, and maintain written Sanitation SOPs to prevent direct product contamination or the creation of insanitary conditions. The CCA's regulatory oversight of establishment compliance is conducted in accordance with Regulation (EC) No 852/2004; Regulation (EC) No 853/2004; Regulation (EC) No 882/2004; and the instruction for the veterinary inspection authorities setting out the method for the verification and enforcement of the relevant and homologous provisions to the standards addressing regulatory requirements for Sanitation SOPs (9 CFR Part 416) through the Food Safety and Nutrition Act as amended and the Instruction of the Chief Veterinary Officer, Letter of CVO - No GIWbż-52-452/2013(1)US, to all PVOs implementing "*Requirements for establishments approved for export of meat and poultry and their products to the market of the United States of America - Recommendations for the Veterinary Inspection authorities setting out the method for the verification and enforcement of the provisions of the Federal Meat Inspection of the United States Department of Agriculture 9 CFR and specifying the rules for managing the knowledge imparted to the Veterinary*

Inspection employees within the framework of cascade training and continuous training on the US requirements”.

During the 2011 audit, FSIS found that the CCA had erroneously dropped a legislative article (Food Safety and Nutrition Act) that authorizes the CCA to require establishments that intend to export to the U.S. to develop and maintain Sanitation SOPs. In response to the previous audit finding, the CCA reinstated the amended articles and issued the Instruction of the Chief Veterinary Officer, No GIWhig-500-2/2013, which reestablished the regulatory requirement and describe verification and enforcement methodology of the regulations.

The FSIS auditor verified, during the follow-up audit, that the GVI has communicated these regulatory requirements to all inspection program personnel, took measures to ensure continuous compliance with the regulatory requirements, and instituted measures to ensure that the veterinary supervisors have added this requirement to the checklist of verification activities that they need to perform at establishments that intend to export poultry products to the U.S. The auditor verified that the inspection system has established official procedures to verify that each establishment seeking certification for U.S. export has an effective sanitation program that meets the regulatory requirements. The inspection program personnel follow the Guidelines for official veterinarians on checks in slaughterhouses on good hygiene practices (GHP) and animal welfare, Instruction of the Chief Veterinary Officer, No GIWbž-500-2/12 (1), to verify whether establishments maintain effective sanitation programs. The guidelines were developed based on FSIS Directive 5000.1, verifying an Establishment’s Food Safety System. The inspection program personnel perform daily inspection and verification of the establishments’ Sanitation Performance Standards (SPS) programs and Sanitation SOPs and document the outcome of their verification activities using Form 5000.1-6.

The FSIS auditor assessed the CCA’s ability to verify and enforce the regulatory requirements for sanitation at the establishment level. The assessment included review of the official inspection records, review of the establishment’s sanitation monitoring records, review of the documentation of corrective actions, and assessment of the actual sanitary conditions in the production areas. The FSIS auditor verified that each establishment maintains a written Sanitation SOP to prevent direct product contamination and adulteration. The programs include processes for maintenance and improvement of sanitary conditions through routine assessment of the establishment’s hygienic practices and the condition of the premises. The FSIS auditor observed that the inspection program personnel conduct daily verification procedures on the establishments’ sanitation programs. The official verification activities consist of a combination of document review and organoleptic inspection. These verification activities are described in the Guidelines for official veterinarians on checks in slaughterhouses in good hygiene practices (GHP), Instruction of the Chief Veterinary Officer, No GIWbž-500-2/12 (1).

Although the FSIS auditor verified that sanitation verification activities were performed in accordance with regulatory requirements, the audit did identify the following deficiencies in two poultry slaughter and processing establishments proposed for certification for U.S. export.

- In one poultry slaughter establishment, blood was accumulating in the bleeding tray and the floor of the bleeding room, creating insanitary conditions. The establishment procedure for cleaning the kill area, during the break between different flocks, or as needed, was not followed.
- In one processing establishment, exposed product (chicken wieners) was observed touching the floor and the sides of a cart used to transport food to and within the processing room.

These two findings were not documented by the establishment or official inspection program personnel. Article 5 of Regulation (EC) 852/2004 delineated the general and specific hygiene requirements for each establishment to operate in a manner to prevent insanitary conditions, and the Instruction of the Chief Veterinary Officer, No GIWbż-500-2/12 (1), provided instructions for the inspection personnel on how they verify the establishments' compliance with the regulatory requirements. These two sanitation findings were deemed as isolated incidents. This determination was based on the FSIS auditor's observations of the sanitation program as implemented at the two establishments and the auditor's review of the establishments' sanitation records that revealed that they consistently complied with the sanitary requirements.

In response to the two above findings, the CCA implemented immediate corrective actions, including measures to restore the sanitary conditions and proper disposition of the affected products. The CCA's preventive measures included further review of the establishments' sanitation SOPs, resulting in adjustments to the design and implementation of the sanitation programs at the two establishments. The FSIS auditor verified that inspection program personnel reviewed the adequacy and effectiveness of the establishment's corrective actions as implemented. The GVI addressed the two findings during the correlation sessions convened for the inspection program personnel as a mean to establish consistency in conducting official inspection and verification activities.

In conclusion, the FSIS auditor verified that the CCA had implemented corrective action plan related to previous audit findings and the two findings identified during this audit for this component. The CCA has taken measures to ensure that certified establishments implement effective Sanitation SOPs and other sanitary measures that prevent direct contamination and adulteration of poultry products destined for the U.S. The measures employed by the GVI were found to be equivalent to those governing the U.S. inspection system. Therefore, it was determined that Poland's poultry products inspection system meets the equivalence criteria for the Sanitation component.

7. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEMS

The fourth of the six equivalence components that the FSIS auditor reviewed was Hazard Analysis and Critical Control Point (HACCP). To be equivalent to the U.S. inspection system, a foreign system must require that each official establishment develop, implement, and maintain a HACCP system. The FSIS auditor's review of the regulations, official instructions, and guidelines demonstrates that Poland's poultry inspection system has HACCP requirements equivalent to FSIS's. The CCA requires each establishment that intends to export poultry products to the U.S. to develop and implement an effective HACCP plan. The CCA continuously evaluates the effectiveness of its regulatory oversight and performs daily and periodic verification activities to ensure establishments' compliance with the regulatory requirements described in: Regulations (EC) No 852/2004; 853/2004; and 882/2004; and the Instruction of the Chief Veterinary Officer, No GIWbż-52-452/2013(1).

Poland has statutory requirements consistent with FSIS HACCP requirements (9 CFR Part 417) through the Safety of Food and Nutrition Act as amended and the Instruction of the Chief Veterinary Officer. During the 2011 audit, FSIS determined that the CCA has erroneously dropped a legislative article (Food Safety and Nutrition Act) that authorizes the CCA to require establishments that intend to export

product to the U.S. to develop, implement, and maintain HACCP systems as one of the conditions for meeting the certification requirements.

In response to the previous audit finding, the CCA reinstated the amended articles and issued the Instruction of the Chief Veterinary Officer, No GIWhig-500-2/2013 that re-establish the regulatory requirement and describe verification methodology of the homologous regulations for HACCP (9 CFR Part 417). The FSIS auditor verified that the GVI has communicated these regulatory requirements to the inspection program personnel, took effective measures to ensure continuous compliance with the regulatory requirements, and instituted measures to ensure that the veterinary supervisors added this requirement to the checklist of verification activities for establishments that intend to export poultry products to the U.S. Furthermore, FSIS verified that the inspection system has official procedures to verify that each establishment has an effective HACCP system that meets the regulatory requirements as set out in Regulation (EC) No 852/2004, Chapter I, Article 1; Regulation (EC) No 853/2004 Article 4; and “The Guidelines for official veterinarians on checks in slaughterhouses in good hygiene practices (GHP) and animal welfare”, Instruction of the Chief Veterinary Officer, No GIWbż-500-2/12 (inspectors follow the verification methods similar to those in FSIS Directive 5000.1, and the official veterinarian performs daily and periodic supervision over the HACCP verification procedures carried out at the establishment and documents them using Form 5000.1-6 (daily), and Form 5000-6, and Form 5000.1-1 (monthly)).

To determine whether equivalence was maintained for this component, the FSIS auditor assessed the design and verified the implementation of HACCP programs in poultry establishments that intend to export to the U.S. The assessment included review of the establishments’ HACCP plans, establishments’ records, and the official records maintained by official inspection personnel. Additionally, the FSIS auditor observed the establishments’ operations and assessed their ability to produce safe product. The FSIS auditor verified that all visited establishments had developed, implemented, and maintained HACCP system for products intended for U.S. export. The establishments’ HACCP systems are subject to daily verification by in plant inspection personnel and annual audits performed by GVI auditors (comparable to Food Safety Assessment conducted by EIAOs).

During this audit, the FSIS auditor verified that the in-plant inspection personnel stationed in slaughter and processing establishments conducted and documented official daily verification activities related to HACCP in accordance with regulatory requirements. Additionally, the inspection personnel’s verification procedures encompass evaluation of written HACCP programs and verification of HACCP pre-requisites, of plan monitoring, of corrective actions, and of recordkeeping in accordance with Regulations (EC) No 852/2004 and Regulations (EC) No 882/2004. Furthermore, supervisory reviews (supervisory veterinary inspector and lead auditor) of HACCP verification activities by inspection personnel were conducted and well documented.

Although the FSIS auditor verified that HACCP verification activities were executed in accordance with Poland’s regulatory requirements, the auditor did find, related to the verification procedures in one of the poultry slaughter and processing establishments, that:

- The establishment’s verification records for one of the critical control points (CCPs), designed to ensure that poultry products meet the stabilization requirements following heat treatment, did not document the type of the verification procedures (record review or direct observation), the results of the verification, or the time and date the verification was conducted. The missing information is

required by the establishment's HACCP plan, Article 5 of Regulation (EC) 852 as described in EC Guidance Document Implementation of procedures based on the HACCP Principles, and described in the Instruction of the Chief Veterinary Officer for establishments and official veterinarians related to the implementation of HACCP (consistent with requirements in 9 CFR part 417.5- Records and 417.8- Inspection verification). The establishment's monitoring records demonstrated that the critical limits for this CCP were met.

There no indication that the problem is systemic. This finding was corrected by the establishment, and the inspection program personnel verified the corrective action was adequate. The CCA corrective actions to address the establishment's failure to meet the record keeping requirements included a re-assessment of the establishment's HACCP plan. The re-assessment resulted in adjustment to the HACCP plan to include clarification of the verification procedure and modification of the establishment's records to ensure performance of the verification activities, in accordance to the defined frequency, and to ensure proper documentation of the verification activities. The FSIS auditor verified that the inspection program personnel reviewed the establishment's corrective action and found it to be effective and adequately met the regulatory requirements.

The GVI implements instructions that contain provisions for traceability. The system requires that each establishment identify its suppliers, the intended consumer, and the actual recipients of each batch of product and develop and maintain an establishment recall plan. The official veterinarian assesses the effectiveness of the establishment's traceability system daily and the GVI annually. The FSIS auditor verified the effectiveness of the traceability by following random product samples back to their origin and forward to the distribution. The daily verification of the product traceability is conducted as part of completing a HACCP checklist, while the annual assessment of the traceability system is conducted as part of the annual audit of the HACCP system. The CCA has a system in place to verify and enforce regulatory requirements related to HACCP as described in the Instruction of the Chief Veterinary Officer, No GIWbż-500-1 /10 on the organization of official controls on the traceability of products of animal origin and labeling.

The FSIS auditor's review and observations during this audit show that Poland's poultry inspection system had implemented a corrective action plan related to all previous audit findings and the finding identified during this audit for this component. The FSIS auditor verified that the GVI requires operators of official establishments to develop, implement, and maintain HACCP programs for each operation, as set forth in accordance with U.S. regulatory requirements and relevant CCA requirements. The CCA has applied these standards across the poultry products inspection system intended for export to U.S. The auditor found that the measures employed by the GVI are equivalent to those governing the U.S. inspection system. Therefore, FSIS found that Poland's poultry products inspection system meets the equivalence criteria for the HACCP component.

8. COMPONENT FIVE: CHEMICAL RESIDUES CONTROL PROGRAMS

The fifth of the six equivalence components that the FSIS auditor reviewed was Chemical Residue Control Programs. To be equivalent to FSIS's inspection system, the inspection system must have a chemical residue control program designed and administered by the national government that functions to prevent chemical residue contamination of food products. In addition, to be considered equivalent to the FSIS program, the program must include random sampling of internal organs, muscle, and fat of carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants.

The CCA must provide a description of its residue sampling and testing plan and the process used to design the plan. The CCA must maintain oversight of laboratories to ensure the validity and reliability of test data.

Poland's National Residue Plan is designed and conducted as coordinated efforts of the GVI and NRL. The residue plan includes a description of the various sampling schemes, lists the selected matrices for each compound, and includes a rationale and process for adding and removing chemical compounds. The GVI provides direction, coordination, and oversight of the residue control program in accordance with Council Directive 96/23/EC and Commission Decision 97/747/EC. The Instruction of the Chief Veterinary Officer, No GIWlab-830-9/13 describes the scope and method of the implementation of the national residue control plan for unauthorized substances, chemical, biological, medicinal residues in animals, products of animal origin, water intended for animals, and animal nutrition products. The FSIS auditor verified that the operation of the residue plan has resulted in measures being in place that ensure segregation of domestic product from product that would be destined for export to the U.S. when domestic residue tolerances are higher. The separation ensures that product that does not meet U.S. standards is not commingled with product destined for export to the U.S.

The GVI manages random and targeted testing programs for chemical residues. The testing programs and operational processes, which include sample collection, shipping to laboratories, management and analysis of data, and initiation of trace-back activities, are also managed by the CCA. The FSIS auditor reviewed, at government laboratories, records related to the sample handling, sampling frequency, timely analysis, date reporting, analytical methodologies and matrices, equipment operation and detection levels, intra-laboratories check samples, and quality assurance programs, including standards books and corrective actions. The review indicated that the laboratory conditions, records generated, and results of past audits met EN ISO/IEC 17025:2005 standard. The FSIS auditor did not identify any deficiencies or areas of concern during the audit of the official laboratories (NVRI/ NRL and the RVL-Warsaw). The staff and management of visited laboratories are knowledgeable about and apprised of Poland's testing requirements for products destined for the U.S. The FSIS auditor received copies of the scopes of accreditation for chemical testing for the NRL as well as the regional laboratory in Warsaw by the PCA. The FSIS auditor concluded that laboratory personnel are qualified, adequately trained, and capable of conducting analytical methods, and the residue laboratories demonstrated the ability to produce timely and accurate data.

The CCA uses an electronic database (CELAB) to collect and manage data concerning the results of laboratory analyses conducted primarily in RVLs. However, samples requiring complex analysis are sent to the NRL. The DVO has legal authority to condemn food products when laboratory analysis indicates the presence of chemical residues at a level that exceeds Poland's and EU standards of acceptable limits. In response to detection of violative levels of residue in food products, the CCA takes measures to prevent contaminated product from entering into commerce and initiates investigation to determine the source of the contamination. Poland uses the EU's Rapid Alert System for Food and Feed (RASFF) as a tool to exchange information about measures taken responding to serious risks detected in food or feed. The enforcement action taken by the GVI in response to recurring violative residue findings are based on the guidelines described in article 16, 22-28 of Council Directive 96/23/EC and the Instruction of the Chief Veterinary Officer, No GIWlab 830-9/13. These enforcement actions include investigations in the farm of origin that may result in restriction of animal movement, intensified sampling at the farm and the slaughter establishment for 6-12 months, discontinuation of slaughter from

suspect source for the entire withdrawal period of subject drug, and, in the case of a repeated violations, permanent withdrawal of the slaughter establishment from the official establishment list.

The CCA has mechanisms to ensure that product exported to the U.S. is below the established tolerance in the U.S. or has non-detectable levels for those compounds for which tolerances have not been established in the U.S. The DVI veterinary officers are required to ensure that poultry products shipments meet all the export requirements, including microbiological and residue limits, before signing the export certificates for product destined for the U.S.

The FSIS analysis and review of records and observations made during previous and current audit indicated that the CCA effectively implemented a national residue control program for its poultry inspection system. The laboratory used to support the inspection system conducts analysis in accordance with the SOP and follows the standards of ISO/IEC17025:2005 related to general requirements for the competence of testing and calibration laboratories. The CCA ensures that designated laboratories use validated methods and uses effective enforcement strategies and communication tools. Therefore, FSIS concluded that Poland's poultry inspection system meets the equivalence requirements for the Chemical Residue Programs component.

9. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS

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

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

Poland's poultry inspection system requires slaughter establishments seeking certification for export of poultry products to the U.S. to conduct sampling and testing program for generic *E. coli* in raw poultry product (broiler carcasses), as one of the means used to assess the effectiveness of sanitation and process control in slaughter facilities. GVI requirements are carried out in accordance with the CVO Instructions for the verification and enforcement of the provisions of consistent with relevant FSIS standards described in 9 CFR 381.65 and 381.94. The inspection program personnel are to review the establishment records to verify that they accurately document the generic *E. coli* results (CFU/ml of rinse fluid for whole-bird rinse) and record the results on a process control chart or table that shows at least the most recent 13 test results. The DVI verification activities (once a month) are to be documented using Form 5000.1-3-Checklist of Meeting the Basic Requirements of *E. coli* Testing Program. Furthermore, some establishments were conducting additional testing (e.g. *Enterobacteriaceae* or Aerobic Plate Count "APC"). The purpose of these testing programs is to verify the effectiveness of sanitation and process control and as indicator for fecal contamination in slaughter establishments. *Enterobacteriaceae* and *E. coli* are common in the intestinal tract which functions as the primary pathway for contamination of poultry with pathogens such as *Salmonella* and *Campylobacter*. Ongoing testing for indicator organisms by slaughter establishments helps them to determine whether the slaughter process is under control, or whether carcasses are being contaminated with feces. The auditor's

reviews of the establishments' written programs and the official inspection records did not identify any concerns.

Poland, as an EU Member State, participates in the EC's *Salmonella* reduction program in slaughter and processing establishments. The program requires testing of poultry flocks at the farm and the issuance of *Salmonella*-free flock certification. Under this program, only flocks that are nearly free of *Salmonella* are to be presented for slaughter. Additionally, the inspection program follows the Guideline of the Chief Veterinary Officer for the bodies of the Veterinary Inspection of 10.09.2014 on the rules for the procedure for the implementation of oversight of research performed by entities producing foodstuffs of animal origin in terms of their safety and hygiene control of production processes. . This Guideline was developed based on [FSIS Directive 10,250.1](#), *Salmonella* and *Campylobacter* Verification Program for Raw Meat and Poultry Products, and is used by the in plant inspection personnel to conduct official verification activities at the establishments seeking certification for export to the U.S. and to ensure that these establishments are able to meet the performance standards for *Salmonella* and *Campylobacter*. This requirement is employed in conjunction with the EC *Salmonella* control programs. The table below illustrates the testing program employed to meet the EC microbiological hazard control programs requirements as well as U.S. export requirements.

Food category	Micro-organisms/their toxins, metabolites	Sampling plan ⁽¹⁾		Limits	Analytical reference method ⁽²⁾
		n	c		
Poultry carcasses of Broilers	<i>Salmonella</i> spp. ⁽³⁾ <i>Campylobacter</i> (for U.S. export)	51 ⁽⁴⁾ 51	5 ⁽⁵⁾ 8 ⁽⁵⁾	Absence in 30 ml of total bird rinsate (<i>U.S. export</i>)	MLG 41.03-(U.S. export) 1 ml direct plating method
	<i>Salmonella</i> spp. ⁽³⁾	50	7 ⁽⁵⁾	Absence in 25 g of a pooled sample of neck skin (<i>Domestic</i>)	EN/ISO 6579 (for detection)
Minced meat and meat preparations made from poultry meat	<i>Salmonella</i>	5	0	Absence in 25 g	EN/ISO 6579
Mechanically separated meat (MSM)	<i>Salmonella</i>	5	0	Absence in 10 g	EN/ISO 6579
Fresh poultry meat ⁽⁶⁾	<i>Salmonella typhimurium</i> ⁽⁷⁾ <i>Salmonella enteritidis</i>	5	0	Absence in 25 g (<i>Domestic</i>)	EN/ISO 6579 (for detection) White-Kaufmann-Le Minor scheme (for serotyping)

- (1) n = number of units comprising the sample; c = number of sample units. (2) The most recent edition of the standard shall be used.
(3) Where *Salmonella* spp. is found, the isolates shall be further serotyped for *Salmonella typhimurium* and *Salmonella enteritidis* in order to verify compliance with the microbiological criterion set out in Regulation (EC) 2071.
(4) The 50 samples shall be derived from 10 consecutive sampling sessions in accordance with the sampling rules and frequencies illustrated in this Regulation.
(5) The number of samples where the presence of salmonella is detected. The c value is subject to review in order to take into account the progress made in reducing the *Salmonella* prevalence. Member States or regions having low *Salmonella* prevalence may use lower c values.
(6) This criterion shall apply to fresh meat from breeding flocks of *Gallus gallus*, laying hens, broilers and breeding and fattening flocks of turkeys.
(7) As regards monophasic *Salmonella typhimurium* only is included.

Interpretation of the test:

- satisfactory, if all the values observed indicate the absence of the bacterium,
 - unsatisfactory, if the presence of the bacterium is detected in any of the sample units.
- Action in case of unsatisfactory results includes improvement in slaughter hygiene and review of process controls, origin of animals and biosecurity measures in the farms of origin.

The CCA conducts *Salmonella* testing of poultry carcasses at regulated establishments. If the *Salmonella* testing finds a positive result, the operator has to immediately commence daily sampling until satisfactory results are obtained and to institute sanitation and hygienic procedures deemed acceptable by the CCA to prevent recurrence. In response to recurring unsatisfactory results, the establishment must reassess its HACCP plan, take appropriate corrective action, and start sampling for the third time. Failure by the plant to meet the established standard for the third consecutive time is deemed by the GVI as a failure to maintain the minimum standard for slaughter hygiene and sanitation,

and consequently would bring into question the adequacy of the HACCP plan of the establishment. Accordingly, the CCA would impose regulatory sanctions consistent with the statutory framework of Poland poultry inspection system and exclude the establishment from the export program.

Commensurate with FSIS's decision to combine *Salmonella* and *Campylobacter* verification activities for raw poultry products (broilers), the GVI issued the Instruction of the Chief Veterinary Officer, No GIWhig-500-2/2013 that adopted a policy homologous to the FSIS testing and verification requirements described in FSIS Directive 10,250.1- *Salmonella* and *Campylobacter* Verification Program for Raw Meat and Poultry Products. The GVI plans to incorporate, as part of the GVO Instructions, any new FSIS testing requirements.

Poland's poultry inspection system requires each slaughter establishment proposed for certification for poultry export to the U.S. to conduct, as part of the validation of its HACCP system, a microbiological sampling and testing program for raw poultry products. The testing program includes performance standards for *Salmonella* developed in accordance with Regulation (EC) No 2073/2005- Annex 1- Chapter 1- Clause 1.5 and 1.6 and the Protection of Animal Health Act Article 52b and Article 57a (eradication of animal infectious diseases) as well as *Campylobacter* in official establishments seeking certification for export of poultry products to the U.S. The CCA verifies the effectiveness of the establishments' testing program by taking companion samples of 10% of the total number samples collected by the establishments and comparing results.

The FSIS auditor verified through review and observations that official inspection program personnel received training and are able to conduct official sampling and verification procedures following the instructions described in the manual developed by the National Veterinary Research Institute (sampling of poultry carcasses and test for the presence of *Salmonella* and *Campylobacter* according to FSIS guidelines). The inspection personnel collect representative samples from the young chicken product class for *Salmonella* and *Campylobacter* as part of completing the full set and send samples to NRL and RVLs. CCA does not allow the use of private labs for official testing. The inspection system assesses the effectiveness of the establishment's process controls in reducing or controlling microorganisms on or in raw products. The manual discusses measures to be taken by the inspection program to verify the effectiveness of the measure taken by the establishment in response to unsatisfactory test results that do not meet the standards as defined in the establishment's HACCP-based procedures. The establishment's required corrective measures in response to not meeting the standards include efforts to find the cause of the unacceptable results in order to prevent the recurrence of the unacceptable test results. These measures may include reassessment of the HACCP plan or other applicable control measures or prerequisite programs. The FSIS auditor's reviews of inspection records indicated that there have not been any set failures for the past six months. The auditor's reviews of the establishments' and inspection records did not identify any concerns.

The FSIS auditor verified that GVI follows the Instruction of the Chief Veterinary Officer designed to verify that official establishments proposed for certification for export of RTE products employ control programs for *Lm* in RTE products and meet requirements consistent with FSIS standards described in 9 CFR Part 430. The inspection verifications are conducted according to the CVO instructions directing the verification of sections of 9 CFR Part 430 that relate to the control of *Lm* in post-lethality exposed RTE poultry products. The instructions are written based on FSIS verification procedures described in FSIS Directive 5000.1 and FSIS Directives 10,240 as applicable within the Polish inspection system.

The testing programs for RTE products include specific provisions for government sampling of product, government verification of establishment sampling, and government verification of control measures in every establishment that intends to export product to the U.S. The establishments are required to take corrective action in response to positive *Lm* findings in official or companion samples taken by the establishment.

The FSIS auditor verified that visited establishments have an annual sampling program that includes sampling of product and product contact surfaces, as well as environmental samples of the areas where RTE products are handled or stored. The DVO conducts verification sampling and testing for *Lm* and *Listeria spp.* in the post-lethality exposed RTE products and product contact and environmental surface samples, and *Salmonella* in the RTE products, at a frequency that ensures the effectiveness of the establishments' control measures for these pathogens of concern. Furthermore, the CCA conducts risk-based testing program that is based on FSIS Directive 10,240.5, Verification Procedures for Enforcement, Investigations And Analysis Officers (EIAOs) for the *Listeria monocytogenes (Lm)* Regulation and Routine Risk-Based *Listeria monocytogenes (RLm)* Sampling Program.

In accordance with the Instruction of the Chief Veterinary Officer, No GIWhig-500-2/2013, the GVI requires canning establishments to notify inspection personnel when they find abnormal containers as defined in provisions homologous to FSIS standards described in 9 CFR 381.300(a). There are no requirements for routine microbiological testing for thermally processed commercially sterile (canned) products. However, the inspection system demonstrates capability to maintain a microbiological program that would ensure canned poultry products produced for export to the U.S. are safe and wholesome and not contaminated with *Clostridium botulinum* spores or toxins. The establishments are required to assess the nature and cause of abnormal containers according to their HACCP plan and are to provide acceptable final disposition of the affected production, and the inspection system ensures that only safe and stable product is exported to the U.S. The FSIS auditor verified that the DVO appropriately inspects the performance of establishment verification activities, ensuring that when problems were identified, corrective and preventive measures are implemented.

Even though export of poultry products to the U.S. has not occurred, the FSIS auditor reviewed selected samples of Poland's RVLs to verify whether the laboratory system possesses the technical capacity needed to conduct accurate testing of product destined for the U.S. To achieve this goal, the FSIS auditor interviewed laboratory personnel and supervisors; reviewed relevant records including analyst qualifications, sampling protocols, testing methods, and test reporting; enforcement strategies; and communication tools. The review found that the visited laboratories have qualified staff as evidenced by staff credentials and regular participation in proficiency testing. The electronic database CELAB is being used to manage data and report results of laboratory analyses carried out in the NRL and in any of the RVLs. The FSIS auditor verified that all RVLs involved in the official microbiological analysis are accredited by PCA, approved by the GVI, and listed in the CVO list of approved laboratories. Moreover, the FSIS auditor verified that Poland's microbiological testing laboratories are ISO 17025 accredited and equipped to provide adequate technical support to the poultry inspection system. The management and staff of laboratories that the auditor visited are familiar with Poland's export requirements to the U.S. as applicable to microbiological testing. The current analytical test portions for both *Lm* and *Salmonella* meets Poland's export requirements of a minimum of 25g and 325g analytical test portions for *Lm* and *Salmonella*, respectively (ISO 11290-1 for testing *Lm* in RTE products; ISO 11290-2 as

confirmatory and enumeration method only when used in conjunction with ISO 11290-1; and ISO 6579:2002 microbiology testing for *Salmonella* in RTE products using 325 g).

The FSIS auditor verified that the NRL participated regularly in proficiency tests organized by the EU Reference Laboratories with satisfactory results. The NRL executes its supervisory role over the RVLs through periodic supervisory visits and administration of proficiency tests. These proficiency tests are regularly organized to cover different microbiological criteria including *Salmonella* and *Listeria* and uses different matrices, including poultry products.

The current and previous equivalence audit found that Poland's poultry inspection system has a microbiological testing program that is organized and administered by the national government, and that the CCA requires generic *E. coli* testing and conducts *Salmonella* and *Campylobacter* sampling and testing programs to verify the effectiveness of its system. The GVI's control measures and testing programs for *Lm* are comparable to FSIS's control and testing program. FSIS's analysis and audit verification activities of Poland's microbiological testing program found that the CCA meets the equivalence requirements for the Microbiological Testing Programs component.

10. CONCLUSIONS AND NEXT STEPS

This follow-up audit verified that Poland's CCA has appropriately implemented the corrective action plan proffered in response to the findings of FSIS audit conducted in 2011 and demonstrated that the GVI exercised adequate control over the execution of inspection programs. The audit did not identify systemic findings that would limit the ability of Poland's poultry products inspection system to meet the equivalence criteria and other FSIS import requirements.

During the closing meeting held on July 24, 2014, in Warsaw with the CCA and representatives of the American Embassy in Warsaw, the FSIS auditor presented the preliminary findings of the current audit. The CCA accepted the audit findings and provided its corrective action plan that addressed all the audit findings.

During the current audit, the FSIS auditor documented three findings at the establishment level that point to areas of desired improvement to ensure a smooth transition to meeting the eligibility requirements for export to the U.S. once equivalence status is granted. The findings are summarized as follows:

1. The FSIS auditor observed that one of the inspectors assigned to perform postmortem inspection tasks was not following the established procedures that require examination of all birds for pathology, food safety concerns, and other defects. There were two other veterinary inspectors assigned to the same line who were performing the postmortem inspection task according to the GVI instructions. The CCA addressed this finding by removing the individual from performing inspection task until successful completion of a remedial training program. Additional observations by FSIS auditor showed that postmortem procedures were properly implemented.
2. The FSIS auditor observed two incidents of insanitary conditions in two different establishments, the first was related to a slaughter establishment's failure to prevent accumulating of blood in the kill area, resulting in the creation of insanitary conditions, and the second was related to a processing

establishment's failure to protect exposed product from touching the sides of the transporting cart and the floor in the processing room. The CCA addressed the two sanitation deficiencies by documenting the noncompliance and verifying that both establishments implemented appropriate corrective actions that ensured restoration of sanitary conditions, proper disposition of affected product, and implementation of a measure to prevent recurrence of the sanitation deficiencies.

3. The inspection program personnel assigned at one of the visited establishments did not issue noncompliance in response to establishment's failure to maintain verification records that meet HACCP Recordkeeping requirements. The establishment's verification records for a CCP did not document the type of verification procedures, the results of the verification, and the time and date the verification activity was conducted. The CCA addressed this finding by verifying that the establishment modified its HACCP's verification procedure and related forms and communicated the changes to the staff to ensure proper documentation of all HACCP verification activities.

In conclusion, the CCA implemented immediate corrective action and further measures to prevent the recurrence of the same or similar findings within the inspection system. The CCA verified that the establishments made adjustments to their sanitation program, HACCP system, and complied with the regulatory requirements. The CCA provided supporting documents during and after the exit meeting. The auditor was able to verify that GVI has adequately and effectively implemented its corrective action plan and addressed the audit findings with an immediate action and preventive measures.

Furthermore, the GVI introduced policies intended to enhance performance of the food safety and verification activities by requiring correlation sessions for supervisory personnel on U.S. requirements and establishing on-going training programs for inspection program personnel.

FSIS's evaluation of Poland's proffered corrective actions and related implementation records found that all audit findings were properly addressed, and there is no need for an additional follow-up audit to pursue rulemaking. The GVI has demonstrated its ability to implement an equivalent system to that of the U.S. FSIS's document review and audit tentatively concluded that Poland's food safety system governing poultry products inspection met all FSIS equivalence criteria and has the capability to produce and export products that are safe, wholesome, unadulterated, and properly labeled.

Next Steps

Following the FSIS audit of Poland's poultry inspection system, on August 21, 2014, FSIS published a final rule to modernize poultry slaughter inspection (79 FR 49566). The rule implemented regulations including (1) the New Poultry Inspection System (NPIS), an optional post-mortem inspection system, and (2) regulatory changes impacting all poultry slaughter establishments. Therefore, FSIS expects Poland to submit sufficient evidence to demonstrate how the Polish poultry inspection system achieves an equivalent outcome as the revised U.S. regulations.

FSIS intends to proceed with rulemaking to determine whether Poland may be added to the list of equivalent poultry inspection systems in U.S. Title 9, Code of Federal Regulations, section 381.196. However, before issuing a final rule to add Poland to the list of equivalent countries, and before any product is shipped to the U.S., FSIS must verify that the Polish poultry inspection system is equivalent with the new U.S. regulatory requirements announced in the August 21, 2014, final rule. The

documentation provided by Poland to demonstrate that the new U.S. regulatory requirements are achieved will determine whether another on-site audit in Poland is necessary prior to publishing the final rule.

11. ATTACHMENTS TO THE AUDIT REPORT

Poland's response to the FSIS Draft Final Report
Establishment Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION PPHU "Konspol-Bis" Sp.z o.o. ul. Poznańska 39 62-400 Słupca	2. AUDIT DATE 7/15/14	3. ESTABLISHMENT NO. 30230501	4. NAME OF COUNTRY Poland
	5. NAME OF AUDITOR(S) Faiz Agarib DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Est. 30230501, PPHU "Konspol-Bis" Sp. z o.o. (Poultry slaughter, processing-Raw and RTE), Slupca/ Poznań**16/51 HACCP:**

Establishment's verification records for CCP 4, designed to ensure the stabilization requirements are met following heat treatment, did not document the type of the verification procedures (record review or direct observation) the results of the verification, and the time and date the verification was conducted. The missing information is required by the establishment's HACCP plan, Article 5 of Regulation (EC) 852 as described in EC Guidance Document Implementation of procedures based on the HACCP Principles, and described in the CVO instruction for establishments and official veterinarians related to the implementation of HACCP and SSOP related to the implementation of HACCP [9 CFR part 417.5 and 417.8].

This finding is to be corrected by the establishment and verified for adequacy by the inspection program personnel.

52/55 Humane Handling and Post-mortem Inspection:

During the tour of the establishment, FSIS auditor observed the inspection program personnel conducting Ante-mortem inspection, humane handling verification, and Post-Mortem inspection of birds, additionally, the auditor reviewed official inspection records and interviewed inspection program personnel on the areas of Humane Handling and Post-Mortem inspection and noticed the following two findings:

- The inspection program personnel conducting postmortem inspection of birds were looking at carcasses from both sides using mirror but they were not looking inside the birds all birds for potential pathological lesions in accordance with the requirements described in Regulation (EC) 854/2004; section IV, Chapter I, B. 8.
- The inspection program personnel verified and recorded the humane handling the poultry unloading, space and ventilation. However, they did not document the verification of the humane handling related stunning and bleeding. The DVO instructed the inspection program personnel to start immediately documenting all verification activities related to humane handling.

The CCA must take corrective action to ensure that all inspection activities are properly conducted and documented.

Observations:

- During the official verification of the establishment's pre-operational sanitation, feathers and biological residues from previous day's operations were observed on the shackles and the drainage in the evisceration and the bleeding areas of the establishment. The establishment employee and GVI assigned inspection program employee recognized the insanitary finding, took control action and documented the findings in their records. The finding was corrected by the establishment personnel and verified for adequacy by the inspection before the start of the operation. A review of the pre-operational inspection forms revealed that the GVI assigned personnel conducts the pre-operational inspection verification on a daily basis and identified, recorded, and verified non-compliances as per the CVO instruction for establishments and official veterinarians related to the implementation of HACCP and SSOP related to the implementation of HACCP SSOP [9 CFR 416.13, 9CFR 416.1]. This constitutes an *audit observation* that demonstrates the inspection system ability to perform the daily verification activities of the establishment's sanitation program.

61. NAME OF AUDITOR

Faiz Agarib, DVM

62. AUDITOR SIGNATURE AND DATE

Faiz Agarib

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Zakłady Mięsne „UNIMIĘS” SP. Z O.O. ul. Powstańców Styczniowych 9 32-500 Chrzanów	2. AUDIT DATE 7/18/14	3. ESTABLISHMENT NO. 12030323	4. NAME OF COUNTRY Poland
	5. NAME OF AUDITOR(S) Faiz Agarib DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
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 SSOPs 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	
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.		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	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Est. 12030323, Zakłady Mięsne „UNIMIES” SP. Z O.O. (Mechanically Separated Meat/RTE), Chrzanów/ Kraków**10/56 SSOP:**

During the tour of the establishment, FSIS auditor observed exposed products (Chicken wieners) touching the floor and the tan sides of a transporting cart used to transport food to and within the processing room. This findings may indicate that the establishment's sanitation program, *as designed*, is not preventing direct product contamination or the program was not properly implemented (*e.g. employees training and supervisory oversight*). Article 5 of Regulation (EC) 852 delineated the general and specific hygiene requirements for each establishment to operate in a manner to prevent insanitary conditions. This finding was not documented by the establishment or inspection program personnel.

Observation

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

61. NAME OF AUDITOR

Faiz Agarib, DVM

62. AUDITOR SIGNATURE AND DATE

Faiz Agarib

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Konspol-Holding Spółka z o.o. ul. Grottgera 40 33-300 Nowy Sączul. Kolejowa 3	2. AUDIT DATE 7/17/14	3. ESTABLISHMENT NO. 12620602	4. NAME OF COUNTRY Poland
	5. NAME OF AUDITOR(S) Faiz Agarib DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

60. Observation of the Establishment

Est. 12620602, Konspol-Holding Spółka z o.o. (Processing -RTE), Sącz/ Kraków

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

61. NAME OF AUDITOR
Faiz Agarib, DVM

62. AUDITOR SIGNATURE AND DATE

Faiz Agarib

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION WIELKOPOLSKA WYTWÓRNIĄ ŻYWNÓŚCI PROFI SPÓŁKA Z OGRANICZONĄ ODPOWIEDZIALNOŚCIĄ SPÓŁKA KOMANDYTOWA 63-520 Grabów nad Prosną ul. Kolejowa 3	2. AUDIT DATE 7/16/14	3. ESTABLISHMENT NO. 30184103	4. NAME OF COUNTRY Poland
	5. NAME OF AUDITOR(S) Faiz Agarib DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
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.		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	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance	X		

60. Observation of the Establishment

Est. 30184103, WIELKOPOLSKA WYTWÓRNIA (Canning), Ostrzeszów/ Poznań

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

61. NAME OF AUDITOR
Faiz Agarib, DVM

62. AUDITOR SIGNATURE AND DATE

Faiz Agarib

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION WIPASZ S.A. Zakład Drobiarski w Mławie 06-500 Mława ul. Instalatorów 2	2. AUDIT DATE 7/21/14	3. ESTABLISHMENT NO. 14130502	4. NAME OF COUNTRY Poland
	5. NAME OF AUDITOR(S) Faiz Agarib DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
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 SSOPs 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	
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.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Est. 14130502, WIPASZ S.A. Zakład Drobiarski w Mławie (Poultry slaughter and processing) Mława/ Siedlce

10/51/56 SSOP:

During the review of the establishment process, FSIS auditor observed blood accumulating in the bleeding tray and the floor of the bleeding room which result in creating insanitary conditions. The establishment procedure for cleaning the kill area during the break between different folks or as needed was not followed.

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

The finding is to be corrected by the establishment and verified for adequacy by the inspection program personnel.

FSIS Observation:

Collection of official sample: FSIS auditor observed one of the inspection program personnel (IPP) collecting sample for *Salmonella* and *Campylobacter* analysis following the established GVI instruction for whole carcass rinse.

Ante-mortem, animal welfare and post-mortem inspection: FSIS auditor observed the inspection program personnel following the established procedure to conduct and document ante-mortem inspection, animal welfare verification, and post-mortem inspection including to check and analyze of Food Chain Information of the holding of provenance of birds intended for slaughter and taking into account of official certificates accompanying the folks, and any declarations made by veterinarians carrying out controls at the level of primary production, including official veterinarians and approved veterinarians.

61. NAME OF AUDITOR
Faiz Agarib, DVM

62. AUDITOR SIGNATURE AND DATE

Faiz Agarib



Warsaw, 23 June 2015

VETERINARY INSPECTION

CHIEF VETERINARY OFFICER

Ms. Jane H. Doherty
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
1400 Independence Avenue, SW
Washington, D.C.
20250
United States of America

Our ref. no: GIWue.0800-310/2015US

Your ref. no: -

Letter of: -

Dear Ms. Jane H. Doherty,

in relation to your letter of 6 April 2015, I would like to thank you for sending the draft poultry audit report for Polish side's consideration. Please find enclosed the Polish comments to the said document.

Please accept the assurances of my highest consideration as well as assurances that the General Veterinary Inspectorate staff members are at your disposal in case further information is needed in the above issue.

Sincerely yours,

DEPUTY
CHIEF VETERINARY OFFICER

Aleksandra Porada



Główny Inspektorat Weterynarii ul. Wspólna 30, 00-930 Warszawa

tel.: (22) 622 20 88 fax: (22) 622 14 09 e-mail: gwi@gwi.gov.pl www.gwi.gov.pl

POLISH SIDE'S COMMENTS TO THE FSIS AUDIT REPORT
(conducted in Poland from 14 July to 25 July 2014;
evaluating the food safety system governing the production
of poultry products intended for export to the USA)

3. BACKGROUND

a) **page 3, paragraph 1:**

regarding:

“Poland is currently eligible to export meat products, exclusively processed pork, to the U.S.”

proposed correction:

“Poland is currently eligible to export **fresh pork meat, pork meat by-products and processed pork meat products** to the U.S.”

4. COMPONENT ONE: GOVERNMENT OVERSIGHT

a) **page 5, graph:**

regarding:

10 BVO; 304 DVO, Regional Veterinary Officer

correction:

9 BVO; **305** DVO, **Provincial** Veterinary Officer

b) **page 5, paragraph 3:**

regarding:

“Each of Poland’s 16 PVI oversees the inspection activities carried out by 15 to 32 DVIs.”

correction:

“Each of Poland’s 16 PVI oversees the inspection activities carried out by **12 to 42** DVIs.”

and

concerning the sentence:

“The FSIS auditor verified that the CCA operations are funded by the government budget and supplemented by fees assessed on plants by the GVI on exported products.”

correction:

“The activities in Polish Veterinary Inspection (GVI, PVI and DVI and the Border Veterinary Inspectorates) are funded by the government. For the official controls carried out in plants, the District Veterinary Officer collects fees from establishments which are then discharged into the government budget.”

c) **page 5, paragraph 3:**

regarding:

“The FSIS auditor verified that the GVI has the authority, and responsibility to hire and assign competent, qualified inspectors to official establishments that would export products to the U.S.”

correction:

“The FSIS auditor verified that the **DVO** has the authority, and responsibility to hire and assign competent, qualified inspectors to official establishments that would export products to the U.S.”

d) **page 6, paragraph 4:**

regarding:

“The issuance of export certificates is based on the GVI Instruction No 0801-24/11.”

correction:

“The issuance of export certificates is based on the GVI Instruction **No GIWue 0201-2/11 of 19 May 2011 on the issuing of veterinary health certificates for goods intended for export to third countries.**”

e) **page 7, paragraph 3:**

regarding:

“The GVI’s Laboratories Policy Office coordinates activities between the GVI and the NRL, while the NRL Director and the CVO coordinate administrative functions and report to MARD”

correction:

“The GVI’s Laboratories Policy Office coordinates activities between **the GVI ,the NRL and regional labs, as well as coordinates some of the activities of regional labs. NRL is under financial and substantive supervision exercised by MARD.**”

f) **page 7, paragraph 4:**

regarding:

“The periodic internal audits were conducted at the RVLs by the NRL, and copies of the audit reports are sent to the audited laboratory, the PVO, and the CVO.”

correction:

“The periodic **external** audits were conducted at the RVLs by the NRL, and copies of the audit reports are sent to the audited laboratory, the PVO, and the CVO.”

and

regarding:

“During previous and current FSIS audits, the PVI provided documents to demonstrate that audits were conducted as scheduled to ensure that RVLs take appropriate corrective action in response to internal audit findings and continue to meet the certification requisites.”

correction:

“During previous and current FSIS audits, the PVI provided documents to demonstrate that audits were conducted as scheduled to ensure that RVLs take appropriate corrective action in response to **external** audit findings and continue to meet the certification requisites.”

g) **page 8, paragraph 1:**

regarding:

“The CCA has the legal authority, under the Veterinary Inspection Act, and the responsibility to approve and disapprove laboratories conducting analytical testing on products for export to the U.S. (Regulation (EC) No 882/2004- Article 12).”

correction:

The CCA has the legal authority, under the Veterinary Inspection Act, and the responsibility to **approve and appoint** laboratories conducting analytical testing on products for export to the U.S. (Regulation (EC) No 882/2004- Article 12).

and

regarding:

“Analyses of official samples are carried out by official laboratories constituting the organizational units of the GVI, and are accredited in accordance with ISO17025 by the Polish Centre for Accreditation (PCA).”

correction:

“Analyses of official samples are carried out by official laboratories constituting the organizational units of the **RVI**, and are accredited in accordance with ISO17025 by the Polish Centre for Accreditation (PCA).”

h) **page 8, paragraph 3:**

regarding:

“The Polish inspection system has issued GVO instructions setting out required verification and enforcement provisions equivalent to 9 CFR 381- subpart X (canning regulations).”

correction:

“The Polish inspection system has issued **CVO** instructions setting out required verification and enforcement provisions equivalent to 9 CFR 381- subpart X (canning regulations).”

5. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

a) page 10, paragraph 2:

regarding:

“The FSIS auditor further verified that GVI official veterinarians conducted antemortem inspection of birds on the day of slaughter, by examining individual birds, and by reviewing the incoming registration, food chain information, including results of *Salmonella* tests of the flocks, and identification documents that enable traceability of bird to their source.”

correction:

“The FSIS auditor further verified that **Polish official veterinarians** conducted antemortem inspection of birds on the day of slaughter, by examining individual birds, and by reviewing the incoming registration, food chain information, including results of *Salmonella* tests of the flocks, and identification documents that enable traceability of bird to their source.”

b) page 10, paragraph 3:

regarding:

During ante-mortem inspection activities, GVI official veterinarians verified and documented that the establishments follow the requirements of animal welfare (good commercial practices) when handling birds presented for slaughter and meet the requirements specified in the Animal Protection Act- Article 5- 6 and Instruction of the Chief Veterinary Officer, No GIWbż-500-4/12.

correction:

During ante-mortem inspection activities, **Polish official veterinarians** verified and documented that the establishments follow the requirements of animal welfare (good commercial practices) when handling birds presented for slaughter and meet

the requirements specified in the Animal Protection Act- Article 5- 6 and Instruction of the Chief Veterinary Officer, No GIWbż-500-4/12.

c) **page 10, paragraph 4:**

regarding:

“The FSIS auditor verified through record review, interviews, and observations that GVI veterinarians perform post-mortem inspection activities by observing viscera, outer and inner surfaces, and body cavities of every carcass in accordance with the regulatory requirements.”

correction:

“The FSIS auditor verified through record review, interviews, and observations that **Polish official veterinarians** perform post-mortem inspection activities by observing viscera, outer and inner surfaces, and body cavities of every carcass in accordance with the regulatory requirements.”

d) **page 11, paragraph 3:**

regarding:

“Regulation (EC) No 1774/2002”

correction:

Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules regarding animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation).

and

regarding:

“Condemned materials are transferred from the establishment to entities authorized to collect, store, and process category II and III wastes that are supervised by provincial veterinarians to ensure compliance with the requirements described in Regulation (EC) No 1774/2002.”

correction:

“Condemned materials are transferred from the establishment to entities authorized to collect, store, and process category **I, II and III animal by-products not intended for human consumption. Said entities** are supervised by **district** veterinarians to ensure compliance with the requirements described in Regulation (EC) No **1069/2009.**”

e) **page 12, paragraph 1:**

regarding:

“Instruction of the Chief Veterinary Officer, No GIWhig-500-11/07”

correction:

“ Instruction of the Chief Veterinary Officer **No. GIWbż-500-2/11** of 1 September 2011 determining, on the basis of risk analysis, the frequency of controls of the food sector entities subject to official supervision of the Veterinary Inspection

6. COMPONENT THREE: SANITATION

a) **page 13, paragraph 3:**

regarding:

“...regulatory requirements for Sanitation SOPs (9 CFR Part 416) through the Food Safety and Nutrition Act as amended and the Instruction of the Chief Veterinary Officer, No GIWbż-52-452/2013(1).”

correction:

“...regulatory requirements for Sanitation SOPs (9 CFR Part 416) through the Food Safety and Nutrition Act as amended and the Instruction of the Chief Veterinary Officer, **Letter of CVO – GIWbż-52-452/2013(1)US to all PVOs transferring the Recommendations for the Veterinary Inspection authorities setting out the method for the verification and enforcement of the provisions of the Federal Meat Inspection of the United States Department of Agriculture 9 CFR part 416 and 417 regarding Food Safety Systems (SPS, SSOP, HACCP) and specifying the rules for managing the knowledge imparted to the Veterinary Inspection employees within the framework of cascade training and continuous training on the US requirements.**”

b) **page 14, paragraph 3:**

regarding:

“These two findings were not documented by the establishment or GVI inspection program personnel.”

correction:

“These two findings were not documented by the establishment or **official** inspection program personnel.”

7. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEMS

a) **page 16, paragraph 1:**

regarding:

“The assessment included review of the establishments’ HACCP plans, establishments’ records, and the official records maintained by GVI inspection personnel.”

correction:

“The assessment included review of the establishments’ HACCP plans, establishments’ records, and the official records maintained by **official** inspection personnel.”

b) **page 16, paragraph 6:**

regarding:

“The GVI implements regulations that contain provisions for traceability.”

correction:

“The GVI implements **instructions** that contain provisions for traceability.”

and

regarding:

“The GVI assesses the effectiveness of the establishment’s traceability system daily and annually”.

correction:

“The **official veterinarian** assesses the effectiveness of the establishment’s traceability system **daily** and **the GVI annually**.”

8. COMPONENT FIVE: CHEMICAL RESIDUES CONTROL PROGRAMMES

a) **page 17, paragraph 2:**

regarding:

“The GVI provides direction, coordination, and oversight of the residue control program in accordance with Council Directive 96/23/EC; Decision 97/747/EC; and Commission Decision 97/747/EC. The Instruction of the Chief Veterinary Officer, No GIWhig-500-3/06 describes the scope and methods of execution of the national program for control; tests for illegal substances; tests for chemical and biological residues; and tests for medical products and radioactive contamination of animals, their secretions and excretions, tissues or organs, products of animal origin, water intended for animals, and animal nutrition products.”

correction:

“The GVI provides direction, coordination, and oversight of the residue control program in accordance with **Council Directive 96/23/EC and Commission Decision 97/747/EC**. The Instruction of the Chief Veterinary Officer, **No GIWlab-830-9/13** describes the scope and **method of the implementation** of the **national**

residue control plan for unauthorized substances, chemical, biological, medicinal residues in animals, products of animal origin, water intended for animals, and animal nutrition products.”

b) **page 18, paragraph 2:**
regarding:

“The GVI has legal authority to condemn food products when laboratory analysis indicates the presence of chemical residues at a level that exceeds Poland’s and EU standards of acceptable limits.”

correction:

“**The DVO** has legal authority to condemn food products when laboratory analysis indicates the presence of chemical residues at a level that exceeds Poland’s and EU standards of acceptable limits.”

and

regarding:

“The enforcement action taken by the GVI in response to recurring violative residue findings are based on the guidelines described in article 16, 22-28 of Council Directive 96/23/EC and the Instruction of the Chief Veterinary Officer, No GIWlab 830-5/11.”

correction:

“The enforcement action taken by the GVI in response to recurring violative residue findings are based on the guidelines described in article 16, 22-28 of Council Directive 96/23/EC and the Instruction of the Chief Veterinary Officer, **No GIWlab 830-9/13.**”

c) **page 18, paragraph 3:**

regarding:

“The PVI and DVI veterinary officers are required to ensure that poultry products shipments meet all the export requirements, including microbiological and residue limits, before signing the export certificates for product destined for the U.S.”

correction:

“The **DVI** veterinary officers are required to ensure that poultry products shipments meet all the export requirements, including microbiological and residue limits, before signing the export certificates for product destined for the U.S.”

9. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS

a) **page 19, paragraph 3:**

regarding:

“GVI requirements are carried out in accordance with the GVO Instructions for the verification and enforcement of the provisions of consistent with relevant FSIS standards described in 9 CFR 381.65 and 381.94.”

correction:

“GVI requirements are carried out in accordance with the **CVO** Instructions for the verification and enforcement of the provisions of consistent with relevant FSIS standards described in 9 CFR 381.65 and 381.94.”

and

regarding:

“The GVI verification activities (once a month) are to be documented using Form 5000.1-3-Checklist of Meeting the Basic Requirements of *E. coli* Testing Program. Furthermore, some establishments were conducting additional testing (e.g. *Enterobacteriaceae* or Aerobic Plate Count “APC”).”

correction:

“The **DVI** verification activities (once a month) are to be documented using Form 5000.1-3-Checklist of Meeting the Basic Requirements of *E. coli* Testing Program. Furthermore, some establishments were conducting additional testing (e.g. *Enterobacteriaceae* or Aerobic Plate Count “APC”).”

b) **page 19, paragraph 4:**

regarding:

“Additionally, the inspection program follows the Instruction of the Chief Veterinary Officer, No GIWbż-500-7a/09 on the procedure for the implementation of the supervision of production processes.”

correction:

“Additionally, the inspection program follows the **Guideline of the Chief Veterinary Officer for the bodies of Veterinary Inspection of 10.09.2014 on the rules of procedure for the implementation of oversight of research performed by entities producing foodstuffs of animal origin in terms of their safety and hygiene control of production processes.**”

c) **page 21, paragraph 1:**

regarding:

“The FSIS auditor verified through review and observations that GVI inspection program personnel received training and are able to conduct official sampling and verification procedures...”

correction:

“The FSIS auditor verified through review and observations that **official** inspection program personnel received training and are able to conduct official sampling and verification procedures...”

d) **page 21, paragraph 2:**

regarding:

“The inspection verifications are conducted according to the GVO instructions directing the verification of sections of 9 CFR Part 430 that relate to the control of *Lm* in post-lethality exposed RTE poultry products.”

correction:

“The inspection verifications are conducted according to the **CVO** instructions directing the verification of sections of 9 CFR Part 430 that relate to the control of *Lm* in post-lethality exposed RTE poultry products.”

e) **page 21, paragraph 3:**

regarding:

“The CCA conducts verification sampling and testing for *Lm* and *Listeria spp.* in the post-lethality exposed RTE products”

correction:

“The **DVO** conducts verification sampling and testing for *Lm* and *Listeria spp.* in the post-lethality exposed RTE products”

f) **page 22, paragraph 1:**

regarding:

“The FSIS auditor verified that the CCA appropriately inspects the performance of establishment verification activities, ensuring that when problems were identified, corrective and preventive measures are implemented.”

correction:

“The FSIS auditor verified that the **DVO** appropriately inspects the performance of establishment verification activities, ensuring that when problems were identified, corrective and preventive measures are implemented.”



United States Department of Agriculture

Food Safety and
Inspection Service

OCT 14 2014

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

TO: SEE DISTRIBUTION
SUBJECT: New Poultry Regulations

This letter is to inform you that on August 21, 2014, FSIS published a final rule to modernize poultry slaughter inspection (79 FR 49566, available on the FSIS website at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/interim-and-final-rules>). FSIS took this action to improve food safety and the effectiveness of poultry slaughter inspection systems, remove unnecessary regulatory obstacles to innovation, and make better use of the Agency's resources.

This letter outlines the following topics:

1. The New Poultry Inspection System (NPIS)
2. Regulatory changes at all poultry slaughter establishments, except ratite slaughter establishments
3. Effect of this new rule on poultry exported to foreign countries
4. Equivalence review

The New Poultry Inspection System (NPIS): The final rule establishes the NPIS for young chicken and all turkey slaughtering establishments, but does not replace other inspection systems currently in operation, such as the Traditional Inspection System, Streamlined Inspection System (SIS), New Line Speed Inspection System (NELS), and the New Turkey Inspection System (NTIS). Young chicken and turkey slaughter establishments may choose to operate under the NPIS or instead continue operating under their current inspection systems. FSIS will continue to staff all establishments that do not choose to operate under the NPIS with their current number of online inspectors.

FSIS is currently requesting that establishments notify the applicable FSIS district office concerning whether they intend to operate under the new system and when they would like to start. FSIS will then determine the implementation schedule for the NPIS.

The NPIS will reconfigure inspector assignments in young chicken and turkey slaughter establishments. Under NPIS, in-plant inspectors will include one FSIS online Carcass Inspector (CI) and one FSIS offline Verification Inspector (VI) assigned to each slaughter inspection line per shift. Establishments that operate under the NPIS will be required to sort carcasses, dispose of condemned carcasses, and perform trimming or reprocessing tasks before carcasses are presented to the CI for inspection. The CI will conduct a carcass-by-carcass

inspection at a fixed point on the slaughter line before carcasses enter the chiller. The VI will conduct offline inspection activities that are focused on food safety, such as verifying compliance with Hazard Analysis and Critical Control Point (HACCP) and Sanitation Standard Operating Procedures (SSOPs) requirements; performing verification checks for septicemia/toxemia and visible fecal contamination; verifying sanitary dressing requirements; and collecting samples for pathogen testing.

Establishments operating under the NPIS will be required to maintain records to document that the products resulting from their slaughter operations meet the U.S. definition of Ready-To-Cook (RTC) poultry as per the 9 Code of Federal Regulations (CFR) 381.1. Establishments operating under SIS, NELS, and NTIS will continue to comply with the existing Finished Product Standards (FPS).

Establishments operating under the NPIS will be authorized to operate at a maximum line speed of 140 birds per minute (bpm) for young chickens and up to 55 bpm for turkeys, depending on their ability to demonstrate consistent process control and the CI's capability to conduct an effective online carcass-by-carcass inspection.

Regulatory Changes: In addition to establishing the NPIS, the final rule includes regulatory changes that apply to all establishments that slaughter poultry other than ratites. The new regulations are available on the FSIS website at <http://www.gpo.gov/fdsys/pkg/FR-2014-08-21/pdf/2014-18526.pdf#page=70>. The following is a synopsis of these changes:

- 9 CFR 381.65: Operations and procedures generally:
 - a) Establishments must develop, implement, and maintain written procedures to ensure that carcasses with visible fecal contamination do not enter the chiller (9 CFR 381.65(f)). Establishments must incorporate these procedures into their HACCP plans, or SSOPs, or other prerequisite programs (referred to collectively as “the HACCP system”).
 - b) Establishments must develop, implement, and maintain written procedures to prevent contamination of carcasses by enteric pathogens and fecal material throughout the slaughter and dressing operation, and they must incorporate these procedures into their HACCP systems (9 CFR 381.65(g)).
 - 1) At a minimum, these procedures must include sampling and testing for microbial organisms at the pre- and post-chill points in the process to monitor the establishment's ability to maintain process control. Very small establishments that operate under the modified traditional system must test at post-chill only. The final rule prescribes a minimum frequency with which establishments collect and analyze samples for microbial organisms (9 CFR 381.65(g)(2))

- 2) Maintain daily records sufficient to document the implementation and monitoring of these procedures (9 CFR 381.65(h))

The effective dates for these requirements are:

- In large establishments, defined as all establishments with 500 or more employees, on November 19, 2014;
- In small establishments, defined as all establishments with 10 or more employees but fewer than 500, on December 19, 2014;
- In very small establishments, defined as all establishments with fewer than 10 employees or annual sales of less than \$2.5 million, on February 17, 2015.

The final rule eliminates the requirement that establishments slaughtering poultry other than ratites test for generic *E. coli* to monitor for process control. The generic *E. coli* regulations will be replaced by the new testing requirements discussed above.

- 9 CFR 381.66: Temperature and chilling and freezing procedures:

Effective October 20, 2014, the final rule removes the existing prescriptive time and temperature parameters from the chilling requirements for RTC poultry and instead requires that poultry establishments incorporate procedures for chilling into their HACCP systems.

- a) Establishments must develop, implement, and maintain written procedures in their HACCP systems ensuring that all poultry carcasses and parts are chilled immediately after slaughter operations so that there is no growth of pathogens, unless such poultry is to be frozen or cooked immediately at the official establishment (9 CFR 381.66(b) and (b)(3)).
- b) The final rule establishes a definition for “air chilling” that provides for the use of antimicrobial interventions with water at the beginning of the chilling process, provided that its use does not result in any net pick-up of water (9 CFR 381.66(e)).

- Online and Offline Reprocessing:

Also effective October 20, 2014, establishments can use approved online reprocessing (OLR) and offline reprocessing (OFLR) antimicrobial interventions including chlorinated water containing 20 to 50 part per million available chlorine or other

antimicrobial substances (9 CFR 381.91(b)) as long as the procedures for this use have been incorporated into its HACCP system.

- Removes codified *Salmonella* performance standards for poultry:

In 2011, FSIS established new *Salmonella* and *Campylobacter* performance standards for young chickens and turkeys to address pathogen reduction in poultry establishments (76 FR 15282). FSIS will continue to collect verification samples and analyze them for *Salmonella* and *Campylobacter* and compare results to the new performance standards. FSIS is also conducting testing of comminuted chicken and turkey product to establish new performance standards for these products. Therefore, the final rule removes the outdated codified *Salmonella* pathogen reduction performance standards for poultry as per 9 CFR 381.94 (b).

Poultry Exports to Foreign Countries: As noted above, under the final rule, poultry slaughter establishments may continue to operate under the existing inspection systems.

If they choose to operate under NPIS, the online carcass inspector will conduct carcass-by-carcass inspection and determines whether product is not adulterated and eligible to receive the mark of inspection. Under NPIS, carcasses and parts exhibiting diseases or conditions will continue to be identified and retained, removed, or condemned during the inspection process. FSIS will continue to meet its own regulatory obligations to ensure that young chickens and all turkeys receive antemortem and postmortem inspection and meet food safety standards, thus satisfying importing country requirements.

NPIS was informed by the data collected under the HACCP-based Inspection Models Project (HIMP) pilot study (77 FR 4421). These data demonstrated that inspection systems, such as HIMP and NPIS, which provide increased offline inspection activities more directly related to food safety, result in greater compliance with sanitation and HACCP regulations and produce carcasses with lower levels of visible fecal contamination and the same or lower levels of *Salmonella* contamination.

Under the new system, FSIS officials will continue to certify on FSIS Form 9060-5 that poultry and poultry products came from birds that were officially subject to antemortem and postmortem inspection and passed in accordance with applicable laws and regulations of the United States Department of Agriculture, and are wholesome and fit for human consumption.

Equivalence Review: Countries exporting or intending to export poultry products to the United States are not required to adopt the NPIS to be equivalent. They can continue operating the inspection systems that were determined by FSIS to be equivalent. However, if a foreign government decides to implement a system similar to NPIS, the Central Competent Authority (CCA) of the country must submit documents to describe

how NPIS will be implemented and verified in establishments exporting products to the United States.

FSIS will request information on how the CCA is planning to implement new requirements equivalent to those discussed above at poultry (except ratites) slaughter establishments. In order to determine equivalence with these regulatory changes, FSIS will request information on the CCA's plans to implement the new requirements: for example, documented procedures to prevent carcasses with visible fecal contamination from entering the chiller, procedures to prevent contamination of carcasses by enteric pathogens, microbial testing requirements at pre-and post-chill locations, and monitoring records.

If you have any questions, please contact me at 202-708-9543, via facsimile at 202-690-3856, or by e-mail at Jane.Doherty@fsis.usda.gov.

Sincerely,



Jane Henriques Doherty
International Coordination Executive

Distribution:

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