



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, DC  
20250

NOV 01 2012

Dr. Janusz Zwiazek  
Chief Veterinary Officer  
Veterinary Inspection  
General Veterinary Inspectorate  
Republic of Poland  
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Warsaw, Poland

Dear Dr. Zwiazek:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Poland's meat inspection system May 10 through June 1, 2011. Your comments to the audit report have been included in the report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile at (202) 720-7990, or electronic mail at [internationalequivalence@fsis.usda.gov](mailto:internationalequivalence@fsis.usda.gov).

Respectfully,

A handwritten signature in blue ink, appearing to read "Keller".

Dr. Andreas Keller  
Director  
International Equivalence Staff  
Office of International Affairs

Enclosure

NOV 0 1 2012

FINAL REPORT OF AN INITIAL EQUIVALENCE ON-SITE AUDIT

CONDUCTED IN

POLAND

May 10 – June 1, 2011

EVALUATING THE FOOD SAFETY SYSTEMS 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 audit report describes the outcome of an initial on-site audit of Poland's poultry inspection system conducted by the Food Safety and Inspection Service (FSIS) from May 10 - June 1, 2011. The audit objective was to verify that Poland has a poultry inspection system equivalent to the United States' with capacity to produce safe, unadulterated, and properly labeled product.

FSIS auditors were not able to assess the status of the poultry slaughter activity. This was due to withdrawal of the lone poultry slaughter establishment scheduled for the FSIS review during the audit. Therefore, FSIS can not move forward with the recommendation of equivalence. At this point, the only evaluation completed is the administrative functions of the government oversight.

The FSIS auditors determined that the Central Competent Authority (CCA) met the FSIS equivalence requirements for component: (5) Chemical Residue Testing Programs. The FSIS auditors, however, identified systemic findings within components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems, and (6) Microbiological Testing Programs, as described below.

There was inconsistency in the enforcement of corrective action requirements in response to non-compliances. In some instances, the administrative decisions issued according to the established procedure were not closed out accordingly. The administrative decisions ought to be close out to indicate that corrective actions were complete, verified and deemed acceptable by inspection.

The inspection system relies on familiarity of the supervisors with the inspection personnel's knowledge of relevant requirements when staffing establishments that produce poultry products destined for the United States. The inspection system was not able to produce records documenting completion of ongoing training at all levels of the inspection system. The periodic supervisory reviews, as conducted, do not assess, identify or document the knowledge or training needs of inspection personnel with respect to specific inspection program requirements.

The inspection system was conducting daily activities to ensure the execution of HACCP and SSOP. The CCA, however, was lacking current policy or regulations that specifically require establishments to develop and implement written SSOP and describe how to implement HACCP plans as condition for gaining certification for export of poultry products to the United States.

Poland did not inform the FSIS or request equivalence determination for its current use of private laboratories to analyze official microbiological samples of product destined for the United States.

The CCA addressed the FSIS audit by initiating or taking immediate corrective action. The CCA is still expected to submit a comprehensive corrective action plan addressing the audit findings for each component. FSIS will evaluate the extent to which the proffered corrective actions sufficiently address the systemic findings and make determination regarding the equivalence of Poland's poultry inspection. FSIS, however, may conclude that an additional on-site audit is necessary to verify the adequacy of the corrective actions. Upon determination that an equivalent inspection system is maintained, FSIS may make recommendation to move forward with the rulemaking making process.

FSIS has received Poland's proposed corrective actions for the audit findings on September 5 and October 10, 2012. Initial FSIS's review and analysis of the corrective actions indicated that additional information is needed before making a final conclusion about the adequacy of Poland's response to the audit findings.

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## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

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>
FSIS	Food Safety and Inspection Service
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
IES	International Equivalence Staff
PR/HACCP	Pathogen Reduction/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
VI	Veterinary Inspector

## **1. INTRODUCTION**

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of the Poland's poultry inspection system in the period from May 10 - June 1, 2011. This audit occurred simultaneously with FSIS's on-site audit of Poland's meat inspection system, for which the observed findings are documented in a separate report.

The audit entrance meeting was held on May 10, 2011, in Warsaw with participation of representatives from the Central Competent Authority (CCA) – the General Veterinary inspectorate (GVI) of the Ministry of Agriculture and Rural Development (MARD) of Poland, representatives from the United States Embassy in Poland. The FSIS auditors were accompanied throughout the entire audit by representatives from the GVI, the provincial veterinary inspectorate (PVI) or the district veterinary inspectorate (DVI).

## **2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY**

The objective of the initial equivalence audit that was verify that Poland's food safety system governing poultry inspection is equivalent to that of the United States (U.S.), with the capability to produce and export products that are safe, wholesome, unadulterated, and properly labeled.

In pursuit of this objective and prior to the on-site audit, FSIS conducted a review of the information provided by the CCA in the *Self-Assessment Tool (SAT) for Initial Equivalence* and accompanying references. These documents provide a comprehensive overview of all the relevant legislation and procedures supporting the poultry slaughter inspection system.

FSIS determinations concerning program effectiveness of the Polish poultry inspection program focused on performance within the following six components upon which system equivalence is based: (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 administrative functions were reviewed at the CCA headquarters in Warsaw; three provincial offices; and three district offices. During the review, the FSIS auditors evaluated the implementation of the management control systems put in place to ensure that the national system of inspection, verification, and enforcement was being implemented as intended. The review of the administrative functions of the local inspection offices was conducted as part of the establishment review. The outcome of the two reviews was used to determine the existence of an effective coordination between the different levels of the CCA.

In order to verify the CCA's ability to provide consistent government oversight, the inspection operations at two processing and one cold storage establishments were reviewed. The three subject establishments are located in three different provinces. The selected establishments were identified by the CCA as establishments intended to be certified to export poultry products to the United States, thereby providing a representative sample of Poland's poultry inspection system. 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 conducted in accordance with 9 CFR 381.196. Additionally, four laboratories conducting microbiological and chemical residue testing were audited to verify the CCA's ability to provide adequate technical support to the inspection system.

### Audit Scope Summary

Competent Authority Visits		No.	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> <li>• General Veterinary Inspectorate - CCA Headquarters office (Warsaw).</li> </ul>
	Provincial offices	3	Provisional Veterinary Inspectorate offices in <ul style="list-style-type: none"> <li>• Gdansk</li> <li>• Poznan</li> <li>• Katowice</li> </ul>
	District offices	3	District Veterinary Inspectorate offices in <ul style="list-style-type: none"> <li>• Gdynia</li> <li>• Ostrzeszow</li> <li>• Pszczyna</li> </ul>
	Local offices	3	Reviews of local offices were conducted as part of the establishment review, at Gdynia, Grabow and Pszczyna.
Government Laboratories (microbiological and residue testing)		4	<ul style="list-style-type: none"> <li>• National Reference Laboratory (Pulawy)</li> <li>• Regional Veterinary Laboratory (Warsaw)</li> <li>• Regional Veterinary Laboratory (Kielce)</li> <li>• Regional Veterinary Laboratory (Gdansk)</li> </ul>
Establishments			
• Cold Storage Facility		1	<ul style="list-style-type: none"> <li>• Est. # 22621102, Poland Services Cold Store - Gdynia (ID warehouse/cold storage)</li> </ul>
• Poultry Processing		2	<ul style="list-style-type: none"> <li>• Est. # 30184103, Greater Food Label, Ltd -Grabow (processing)</li> </ul>
• Poultry Slaughter		0	
		Total 3	<ul style="list-style-type: none"> <li>• Est. # 24100302, Henryk Kania Meat Processing S.A. Pszczyna (processing)</li> </ul>

### 3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

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

- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.)
- The Poultry Products Inspection Regulations (9 CFR 381.196)
- Sanitation Regulations (9 CFR Part 416 et seq.)
- HACCP Regulations (9 CFR Part 417 et seq.)
- Generic *E. coli* Testing and *Salmonella* Performance Standard (9 CFR 381.94)
- *Listeria monocytogenes* (*Lm*) control programs (9 CFR Part 430 et seq.)
- Canning and canned products (9 CFR 381.300 - 311)

The audit standards included all applicable legislation 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 legislation included:

- EC legislation concerning food safety (Regulation (EC) 852;853;854;882;178;20723; and Council Directive 96-22 and 96-23);
- Poland's national legislation concerning food safety (Act on Products of Animal Origin; Act on Veterinary Inspection; Act on Civil Service; Act on Safety of Food and Nutrition; Act on Animal Protection; Ordinances; Guidelines and Instructions of the General Veterinary Inspectorate); and
- FSIS regulations adopted by Poland (Sanitation Standard Operating Procedures (SSOP) requirements; HACCP requirements; generic *E. coli* requirements; *Salmonella* Performance Standard requirements; and *Listeria monocytogenes* control programs in accordance with FSIS regulations)

Currently, Poland has equivalence determinations in place for:

- 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)

#### **4. BACKGROUND**

Poland is currently listed in the 9 CFR 327.2 as one of the countries eligible to export meat products to the United States. The USDA's Animal and Plant Health Inspection Service (APHIS) has affirmed that Poland is not affected with Highly Pathogenic Avian Influenza subtype H5N1 (9 CFR 94.6). However, Poland is affected by Exotic Newcastle Disease (END). Therefore, once determined equivalent, Poland will be eligible to export only fully-cooked poultry to the United States, i.e. poultry products processed with a (heat) lethality treatment into (74 °C) which is consistent with the updated requirements described in Title 9, Parts 93 and 94 of APHIS' regulations related to the importation of fresh and processed poultry products into the United States.

Poland requested initial equivalence of its poultry product in October 2004. A thorough review of documentation submitted by Poland, in March 2007, July 2008 and August 2009, in support of its application has been conducted by the FSIS. The review was intended to determine the eligibility for Poland to export poultry products to the United States in accordance with 9 CFR 381.196. In October 2009, the FSIS completed the document review and analysis of Poland's responses and determined that Poland's poultry inspection system meet the basic equivalence requirements. Before proceeding with the on-site audit, the FSIS requested that Poland provide updated information on regulations and procedures applied to the poultry inspection system by

completing SAT. The completed SAT was used to convert Poland's previous responses to the newly adopted technical evaluation approach that replaced the review of five risk areas with six components that is currently used to assess the equivalence of the foreign countries' inspection system. This document review was conducted in light of the progress on the review of 2004 EC legislation and the equivalence determinations made. The review of the SAT showed that Poland's laws, regulations, control programs and other issuances cumulatively provide the same level of public health protection attained by the United States. Therefore, FSIS decided to proceed with the on-site audit of Poland's poultry inspection system to verify that CCA has satisfactorily implemented all the laws, regulations, and other issuances that FSIS found to be equivalent during the document review and analysis.

## **5. GOVERNMENT OVERSIGHT**

The first of the six components reviewed by the FSIS auditors was the Government Oversight. The FSIS auditors verified through interviews of government officials and review of inspection records such as daily inspection reports, periodic control reports, sampling and oversight reports that, the inspection system is organized and administered by the national government and that it provides standards equivalent to those of the federal system of poultry inspection in the United States. The evaluation included review and verification of documentation submitted by the CCA as part of Poland's response to the SAT.

The GVI in Warsaw represents the CCA that is responsible for the transposition of the regulations relating to the poultry inspection. The GVI is headed by the Chief Veterinary Officer (CVO) who is appointed by the Prime Minister while taking into consideration the recommendation of the Minister of Agriculture and Rural Development. The GVI represents the first level of the inspection system and has a direct authority over the subsequent two inspection levels. The PVI represents the second inspection level and is headed by the Provincial Veterinary Officer (PVO). Each of Poland's sixteen PVIs oversees the inspection activities carried out by 15 to 32 DVIs. The DVI represents the third level of the inspection system. The DVI which is headed by the District Veterinary Officer (DVO), oversees all direct inspection activities. The FSIS auditors verified that the GVI receives copies of the periodic reviews conducted by DVI and PVI as well as summary of noncompliance records issued. The FSIS auditors verified that the CCA operations are funded by the government budget and supplemented by assessed fees on exported products.

The FSIS' review of the activities carried out at all three levels of the inspection system indicated that the CCA has single set of rules and legal authority and responsibility to enforce inspection laws and to ensure that adulterated or misbranded products are not exported to the United States. The European Community regulations are the primary overarching laws for regulating poultry inspection. In addition, Poland issues national legislation to address the implementation of the inspection activities. The national legislation include; *the Act on Veterinary Inspection; the Act on Safety of Food and Nutrition; the Act on Safety of Food and Nutrition; and the Act on the health conditions of food and nutrition*. As authorized by applicable legislation, the GVI issues guidelines, checklists and instructions that deal with the frequency of supervisory review; procedures for registration, approval, conditional approval or suspension and withdrawal of

approval of regulated establishments; the verification of the microbiological sampling; the performance of official inspection tasks; and the scope and method of carrying out the National Residue Control Plan. The CCA disseminates information related to the regulatory and administrative affairs by mail, e-mail, or electronically through the GVI website.

The inspection personnel assigned at the establishments certified to export poultry products to the U.S. are employees of the national government. They perform inspection activities under direct supervision of the DVIs. The certification of establishments for export to the United States is conducted according to the procedure delineated in the *Act on Products of Animal Origin of 16 December 2005*. The procedure starts with a review conducted at DVI level. The DVI reports the result of each review approval to the PVI which verifies the DVI decision through document review and an on-site visit by PVI staff. The list of approved establishments is posted on the GVI website. The FSIS auditors verified that the CCA follows the prescribed procedure for certification of poultry establishments and it has the authority to list or delist any establishment.

The CCA is responsible for hiring and assigning qualified inspection personnel to perform inspection and enforcement activities at the regulated establishments. All official veterinarians are graduated from an accredited college of veterinary medicine with a Doctor of Veterinary Medicine degree, have an internship with the CCA, specialty or a graduate degree in food science or related area, and possess a national board certification. Appointed veterinarians are certified private veterinarians who are appointed by the DVI to carry out inspection activities on an interim basis provided that the appointed individual has no conflict of interest when they perform assigned duties. Non-veterinarian inspectors (VI) possess a college degree, have an internship with the CCA and hands-on experience prior to their assignment at regulated establishments. Every inspector is assigned a program badge. All official inspection personnel are paid monthly by direct deposit to their bank accounts. The FSIS auditors did not encounter any situation that could likely result in a conflict of interest.

The FSIS auditors verified that the CCA provides an initial and ongoing training program that is intended to ensure that inspection officials are aware of specific inspection requirements that pertain to Poland export to the United States. Poland's ongoing training program depends on cascade training. As a general rule, a select number of inspection officials is trained at the GVI office and then convey the knowledge gained to other colleagues. The FSIS review of the ongoing training program revealed that:

- Evidence of staff participation in training was available at first level but no evidence of training or training records were presented for the subsequent training levels.
- The ongoing training program lacks a mechanism that assesses the effectiveness of the training. The inspection personnel involved in the daily enforcement of the regulatory requirements affecting export to the U.S. are more likely to be the second or third recipients of the ongoing training. This may have been the root cause of misunderstanding of information related to the implementation of HACCP, SSOP and standard sampling procedures as evident by some of the FSIS's audit findings.

- The CCA did not have official training records to indicate the subject of the training or the attendee of the training at the PVO and DVO levels. This practice may hinder the effectiveness of the CCA's ongoing plan to continuously analyze and implement the staffing requirements at certified establishments due to the lack of accurate information and tracked records at all levels of the CCA.

The enforcement strategies in place are similar to those outlined in 9 CFR 500, Rules of Practice, and are based on *Regulation (EC) 882/2004* and the *instructions of the CVO* issued on the basis of the *Act on Veterinary Inspection*. The FSIS auditors verified that the CCA issuances related to the inspection procedures are implemented in accordance with Poland's standards as well as the standards imposed by importing countries. The Polish inspection system has an established procedure where the inspection personnel must verify the implementation and effectiveness of the corrective action. The procedure starts by issuing an administrative decision in response to each noncompliance. The administrative decision includes a deadline for the rectification of the identified deficiency and may include a fine for the establishment's failure to meet the specified deadline. Each issued administrative decision must be closed out when the inspection personnel verify the completion of the corrective action taken by the establishment. The FSIS auditor's review of the inspection composite noncompliance reports and periodic oversight reports revealed that:

- There was inconsistency in the enforcement of the laws and regulations governing poultry inspection in official establishments at which products are prepared for export to the United States. In some instances, the inspection personnel failed to follow the established procedure by closing the administrative decisions within the specified timeframe. Noncompliance with the sanitation and the microbiological follow-up testing requirements due for closure were still open during the FSIS review. The inspection program personnel indicated that the establishments' corrective actions were completed with the specified time frame but there were no documented evidence to confirm that claim. The PVI routine audits of the DVI did not identify any of the FSIS findings during their routine audit and did not take action to ensure that the corrective actions were properly taken and documented and the law and regulations were consistently enforced throughout the inspection system. In response to FSIS findings, the PVI/DVI decided to initiate an immediate corrective action that intended to ensure that all administrative decisions are closeout and documented within the specified timeframe.

The issuance of export certificates is based on *the GVI Instruction # 0801-24/11 of December 23, 2010*. The FSIS auditors verified that Poland has controls in place to prevent fraud or misuse of export certificates. Export certificates, seals and stamps are secured at the official inspection office. The inspection system is capable of tacking export certificates issued for a specific country. The paper tracking system relies on the issuance of unique identification number for each certificate and the maintenance of records that include signature card for each authorize veterinarian as well as copies of all issued certificates at the PVO and DVO. Therefore, the FSIS auditors determined that Poland maintains the security and integrity of poultry products during transportation between establishments and port facilities.

The FSIS audit included assessment of the oversight provided by the CCA to ensure that procedures for the country's official laboratories were established and implemented as intended. The government laboratories are responsible for conducting chemical and microbiological testing of product destined for the United States. The laboratory system consists of the National Veterinary Research Institute (NVRI) and 16 Regional Veterinary Laboratories (RVLs). The NVRI has been identified as the National Reference Laboratory (NRL) that is responsible for the harmonization of standards and diagnostic methods and the coordination of the routine activities of the regional laboratories. The Director of the NRL coordinates with the CVO and reports to the MARD. The CCA has recently created a position of Laboratories Policy Office to coordinate the administrative functions between the GVI and the NRL. The RVLs are technically under NRL and administratively under the PVO. The FSIS auditors verified that NRL performs supervisory role over the RVLs through supervisory visits and administration of proficiency tests. There was evidence available that these supervisory visits took place, usually, 3-4 visits per year. The RVLs visited regularly participates, with satisfactory results, in proficiency tests organized by the NRL. RVLs staff is adequately trained and internal audit procedures are in place as evident by reviewed documents. Periodic internal audits were conducted at the RVLs by the NRL and copies of the audit reports were sent to audited laboratory, the PVO and the GVO. The PVI presented document that demonstrate actions taken to ensure that RVLs take appropriate corrective action in response to internal audit findings. The CCA has the legal authority under the *Act on Veterinary Inspection* and the responsibility to approve and disapprove laboratories conducting analytical testing on products for export to the United States. The CCA ensures that, laboratories analyzing product destined for the U.S., participate in appropriate proficiency testing schemes for food analysis. 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).

The FSIS auditors verified that official laboratories testing RTE product destined for the U.S. were using ISO 6579-2002 and 11290.1 for detection of *Salmonella* and *Listeria monocytogenes* respectively. The FSIS has previously determined these two methods as equivalent analysis methods. There was an electronic database system identified as (CELAB) that was available for the CCA to collect and manage data concerning the results of laboratory analyses carried out in the NRL and in the RVLs.

This audit indicated that the CCA has administrative controls in place to support the inspection system. There was inconsistency in the enforcement of the regulations. The CCA has initial and ongoing training program. The ongoing training, as implemented, did not ensure proper dissemination of information, assessment or maintenance of accurate records at all training levels. The FSIS concluded that the Polish poultry inspection system meets the basic requirements for this equivalence component. The CCA needs to properly address all the audit findings to fully meet the requirements of this component.

## **6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS**

The second of the six equivalence components that the FSIS auditors reviewed was Statutory Authority and Food Safety Regulations. This component pertains to the legal authority and the

regulatory framework utilized by the CCA to impose requirements equivalent to those governing the system of poultry inspection organized and maintained in the United States. These requirements include ante-mortem inspection of birds, postmortem inspection of carcasses and parts, controls over condemned materials, controls over establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits to official establishments.

The headquarters in Warsaw, three PVI offices and three DVI offices were audited in order to review the legislation associated with the requirements of this component. The FSIS auditors assessed the CCA's ability to effectively communicate these requirements throughout the inspection system as well as the country ability to ensure proper implementation of the requirements. The evaluation of this component included an analysis of information provided by the CCA in the SAT, interview of government officials, observations and evidence gathered during the on-site audit of the inspection system. The FSIS auditors, however, were not able to review Poland's poultry slaughter process since the single poultry slaughter establishment presented for FSIS auditor's review withdrew during the entrance meeting with the CCA. Poland was not able to present a substitute poultry slaughter establishment, the FSIS audit team was only able to review the poultry processing establishments.

Two processing and one cold storage establishments intending to export poultry products to the U.S. were reviewed by FSIS to assess the CCA's ability to properly implement the requirements of this component. The FSIS auditors verified on-site the adequacy of the functions of the government offices, laboratories, and establishments of the system against the standards promulgated by the CCA. The FSIS auditor's observations and review of the periodic control audit reports and documentation of oversight reports revealed that the CCA provided direct and continuous inspection to the poultry processing establishments, ensured separation of domestic and exported products, and verified that the inspection system has procedure in place to verify that the end product met the requirement of the importing countries.

The FSIS auditors verified that Poland, as European Union Member State, participates in the European Commission (EC) *Salmonella* eradication program. The program requires *Salmonella*-free flock certification for all flocks intended to be presented for slaughter. Ante-mortem is conducted by official or appointed veterinarian and documented in paper records. Since the CCA did not present any slaughter establishment for review during the on-site audit of the poultry inspection system, FSIS auditors were not able to verify how the CCA carries out ante-mortem inspection of birds, humane handling-Good Commercial Practice of live birds and postmortem inspection of carcasses. During the audit, the FSIS auditors reviewed relevant procedures and periodic inspection reports maintained by the DVI offices on the inspection procedure carried out by inspection personnel as part of their responsibilities of routine inspection, verification and enforcement.

The observations of the condition at the visited poultry processing establishments, interviews conducted with government inspection officials, and the examination of the documentation of the periodic supervisory reviews provided objective evidence to the FSIS auditors that the CCA maintains official oversight over design and maintenance of the regulated processing facilities. The FSIS auditors did not visit any poultry slaughter establishment during the audit of Polish poultry inspection system.

The FSIS auditors verified that the CCA maintains ultimate control and supervision for establishments intended to be certified to export poultry products to the United States. Direct supervision of the inspection personnel is performed by the DVI. The DVIs are under direct supervision of the PVI. Evidence was provided for periodic supervisory reviews conducted by the PVIs and DVIs at the visited establishments. The supervisory reviews were conducted in accordance with *the CVO Instruction GIWhig-500-11/07 of August 14, 2007 defining, 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 regulated establishments into risk categories. The frequency of the review could be once every two years; once a year; once every six months, or once every three months depends on the risk category designated as very low, low, medium and high. The determination of the level of risk of individual establishment takes into account the type of establishments, production system, products, production hygiene, establishment compliance records and commitment of the plant management. The CCA reserve the right to conduct *ad hoc* review in response to issues of concerns. The supervisory reviews included 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, and look into the sanitation and HACCP records generated and maintained by the establishment, and examine the official the inspection records. The supervisory reviews were conducted using a uniform detailed checklist. Though the supervisor may choose to address the performance of the inspection program personnel in response to a noted failure to identify obvious structural deficiencies, the supervisory checklist lacks elements that independently focus on the assessment of the performance and knowledge of the in-plant inspection program personnel; this would be useful in determining if the training was adequate. The interviews conducted at the PVI and the DVI revealed that:

- The supervisory reviews were not conducted on all official and appointed veterinarian according to the scheduled frequency of one annual supervisory review for each veterinarian. The supervisory reviews of inspection employees, when conducted, do not usually include observation or assessment of the VI abilities to execute the standard sampling procedures or respond to actual or potential noncompliance. The assessment of the VI's technical knowledge and performance is necessary for addressing inadequate performance as well as the development of assigned inspection personnel. Proactive supervisory intervention would protect the public health, prevent recurrence of performance deficiency, and ensure consistently and homogeneous application of the CCA instructions.

The FSIS auditors review of the sampling and periodic oversight reports, and interviews with the inspection officials resulted in the identification of several findings affecting this component. The following finding were more likely related to the lack of an effective ongoing training program at all levels of inspection, and to the absence of routine supervisory assessment of the inspection program personnel's knowledge about inspection duties related to their assignments:

- The official veterinarian assigned at one of the visited establishments and one of DVI veterinarian was not able to describe or refer to an existing reference guide for information related to the official microbiological testing scheme and standard sampling procedures for products destined for the United States.

The FSIS was not able to assess how the CCA conducts the inspection tasks of poultry slaughter since the FSIS auditors have not had a chance to review the operation of any poultry slaughter establishment during the audit. The assessment of Poland's poultry slaughter inspection is crucial factor in the determination whether or not Poland has a sound poultry inspection program. The assessment of the slaughter process provides imperative information about the ability of the inspection system to properly implement daily slaughter operations that include; ante mortem inspection procedure that ensure acceptance of only birds that are healthful, safe from harmful chemical and drug residues, and capable of being converted into wholesome product for the consumer, verify the implementation of the Good Commercial Practices applicable to humane handling of birds at the receiving, through bleeding and entry to the pre-scalding areas; and to verify post mortem inspection that protect the public health by ensuring that the carcasses and parts that enter commerce are wholesome, not adulterated, and properly marked, labeled, and packaged; and finished product standards subsequent to the postmortem inspection. The review of the slaughter process is essential for assessing the inspection personnel ability to make regulatory decisions, documenting findings, and take enforcement actions when appropriate, as guided by Poland's statutes, regulations, instructions and policies.

In conclusion, 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 United States. One of the fundamental components needed for the successful execution of this regulatory authority, is the full awareness of the requirements of the importing country. The interviews conducted with the inspection personnel, at the establishments seeking certification for export to the United States, indicated that some VI were not fully aware of the Poland's export requirements for microbiological sampling or did not fully understand the CCA's microbiological testing scheme for product destined for the United States.

In the absence of supportable evidence of poultry slaughter process, the FSIS was not able to determine whether or not Poland's poultry inspection fully meet the equivalence requirements for this component. Poland must present poultry slaughter establishments for FSIS to audit in order to enable the FSIS to make its final equivalence determination on this component.

## **7. SANITATION**

The third of the six equivalence components that the FSIS auditors reviewed was Sanitation. The inspection system must provide requirements for sanitation, for sanitary handling of products, and for the development and implementation of sanitation standard operating procedures.

The headquarters in Warsaw, three PVI offices and three DVI offices were audited in order to review the legislation, regulation and instructions associated with this component, as well as assessing the CCA's ability to effectively communicate these requirements throughout the inspection system and the country ability to ensure proper implementation of the requirements

The FSIS auditors verified that the CCA requires that each official establishment operates in a manner to prevent insanitary conditions and take measure similar to those outlined in 9 CFR 416.1-416.7. The measures taken by the inspection system are supported by *Regulation (EC) No. 178/2002, Articles 6, 7, 53, 54, 55, 56, 57, 58, and 60; Regulations (EC) No. 852/2004 (Article 4 and Annex II, Chapter V); Regulation (EC) No 853/2004 (Annex III, Section I, Section VI); and Regulation (EC) No 854/2004(Article 4)* delineating specific hygiene rules for food of animal origin as well as domestic legislation. *Regulation (EC) No. 882/2004, Title II, Chapter II, Article 10* discusses general food hygiene. Article 4, 'General and Specific Hygiene Requirements' 3, (b) discusses hygiene procedures. The regulation also illustrates official controls performed to verify and ensure compliance with feed and food law.

The FSIS document review indicated that the CCA has adopted the FSIS regulatory requirements for SSOP (9 CFR Part 416.11-16) and incorporated the requirements into its regulatory design through the *Guidelines for Managing the Sanitation of Plants and Plan Operations; the Instruction of the Chief Veterinary Officer Number GIWhig 500/2/05 of May 2, 2005; and the Act of May 11, 2001 on the health conditions of food and nutrition* as amended. In Response to the SAT, Poland indicated that the inspection system has adopted FSIS Directive 5000.1 as guidance for the inspection personnel on how they are to verify the establishment's compliance with the SSOP regulations. However, the FSIS's review of documents and interview conducted at the CCA revealed that the CCA has no current regulation, policy or instruction in place to support the enforcement of the adopted FSIS measure. The CCA explained the lack of regulatory measures as the consequence of a recent amendment of the *act on the health conditions of food and nutrition*. The amendment resulted in the removal of articles that provide for the issuance of the GVO instruction and guidelines that specifically require establishments seeking certification to meet the export requirements to the United States; specifically the requirements related to the development of a written SSOP plan, implementation the written procedure and documenting the findings in accordance with 9 CFR Part 416.11-16.

- Although the inspection system was implementing SSOP requirements at establishments intended to be certified to export product to the United States, the Polish inspection system lacked current regulation or policy that authorize the CCA to require these establishments to develop and maintain SSOP's. The CCA acknowledged this finding and made a commitment to reinstate the amended articles and reissue the GVO instruction. The CCA's initial respond, however, did not specifically link the conduction of measures that are intimately tied to 9 CFR 416 with any relevant legislation. The CCA should demonstrate legislative commitment to the specific inspection measures through the issuance and dissemination of regulation, policy, written guidance, or any other form of legislation to the inspection personnel and the regulated industry.

Three establishments were visited to assess the CCA's ability to implement the inspection system's requirements for sanitation. The review included review of the establishment's sanitation monitoring records, documented corrective actions, training program for employees, and assessments of the actual sanitation conditions in the production areas. In addition, the FSIS auditors reviewed the instructions for conducting official verification as well as the records generated to document the inspection's findings. The FSIS review indicated that

inspection system continued to require each official establishment develop, implement and maintain written SSOP. This review resulted in the following finding:

- At one of the visited establishments, the sanitation records used generalized terms to describe the status of the establishment's sanitary conditions and findings. This lack of accurate descriptions of the sanitation findings may hinder the inspection personnel ability to verify the establishment's corrective actions and ensure appropriate disposition of product that may be contaminated, restoration of sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product. The inspection personnel at the visited establishment have failed to identify such findings as noncompliance. These findings have not been identified during the periodic supervisory review. This may serve as additional evidence for the need to improve the ongoing training program of the inspection personnel and the need to include an assessment of the inspection personnel knowledge during the supervisory review.

In accordance with the above findings, the FSIS concluded that Poland's inspection system did not fully meet the equivalence requirements for this component. The CCA must take measures to ensure the possession of current legislation, policy, instructions or any other appropriate measure that supports the CCA decision to adopt the FSIS's sanitary measures for SSOP. The adopted measures mandate the development and implementation of a written SSOP program in accordance with 9 CFR 416.11-16 at all establishments intended to be certified to export poultry products to the United States. Additionally, the CCA must take measures to ensure effective implementation of the requirements for sanitation and sanitary handling of poultry products destined for the United States.

## **8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS**

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

The CCA headquarters in Warsaw, three PVI offices and three DVI offices were audited in order to review the legislation associated with this component, as well as assessing the CCA's ability to effectively communicate these requirements throughout the inspection system and the country ability to ensure proper implementation of the requirements for HACCP.

The FSIS document review indicated that CCA has adopted FSIS's regulatory requirements for the implementation of HACCP according to 9 CFR Part 417 et seq. and incorporated the requirements into the country regulatory design through the *Guidelines for Managing the Sanitation of Plants and plant Operations*; the *Instruction of the Chief Veterinary Officer Number GIWhig 500/2/05 of May 2, 2005*; and the *Act of May 11, 2001 on the health conditions of food and nutrition* as amended. In Response to the SAT, Poland indicated that the inspection system has adopted FSIS Directive 5000.1 as guidance for the inspection personnel on how they are to verify the establishment's compliance with the HACCP regulations. However, the FSIS's review of documents and interview conducted at the CCA revealed that the CCA lacked current regulation, policy or instruction in place to support the current enforcement of the adopted

FSIS's measures. The CCA explained the lack of regulatory measures as a consequence of a recent amendment of the *Act on the health conditions of food and nutrition*. The amendment resulted in the removal of articles that provide for the issuance of the GVO instruction and guidelines that specifically requires establishment seeking certification for exporting product to the United States to implement HACCP requirements in accordance with 9 CFR Part 417.

- Although the inspection system personnel were enforcing HACCP requirements at establishments intended to be certified to export product to the United States., the Polish inspection system did not possess current regulation or policy that authorize the CCA to require these establishments to implement the adopted HACCP measures as described in 9 CFR 417. The equivalence criteria of this component call for the inspection system to have HACCP requirements grounded in the country's requisite laws and regulations. The CCA acknowledged this finding and made a commitment to reinstate the amended articles and reissue the GVO instruction. The CCA's initial response, however, did not provide a precise link between the conduction of inspection measures that are intimately tied to 9 CFR 417 and any relevant legislation. The CCA should demonstrate legislative commitment to the specific inspection measures through the issuance and dissemination of regulation, policy, written guidance, or any other form of legislation to the inspection personnel and the regulated industry.

Three establishments intending to export poultry products to the United States were visited to assess the CCA's ability to implement the inspection system's HACCP requirements. The FSIS auditors reviewed the establishment's HACCP records as well as the official inspection records maintained by local inspection offices having regulatory oversight of the visited establishments. The official documents included but not limited to, records of daily verification of the inspections tasks, official microbiological sampling programs and results, routine assessment of the establishment operation and supervisory reviews. In addition, the FSIS auditors observed how inspection personnel applied 9 CFR 417 and other official instructions to verify establishment compliance with the HACCP requirements. This review resulted in the identification of the following finding:

- At one of the poultry processing establishments, the HACCP plan as designed was missing the ongoing verification activity for direct observation of the monitoring and any required corrective actions. The inspection personnel at the establishment have failed to identify this noncompliance. There was no observation regarding this finding in the prior supervisory reviews conducted at the establishment. This may serve as evidence for the need to improve the ongoing training program of the inspection personnel to ensure better understanding of the HACCP system requirement and the importance of including an assessment of the inspection personnel as part of the supervisory review. The assessment of the inspection personnel's knowledge would provide the CCA with the opportunity of address the inspection personnel's needs for training before training gaps have a negative impact on public health.

In accordance with the above findings, the FSIS concluded that Poland's inspection system did not fully meet the equivalence requirements for this component. The CCA must take measures to ensure that the adopted HACCP requirements are grounded in the country's requisite laws and

regulations through the issuance of legislation, policy, instructions or any other appropriate measure. Additionally, Poland must demonstrate effective implementation of the requirements for HACCP at all establishments seeking certification to export poultry products to the United States.

## **9. CHEMICAL RESIDUES PROGRAMS**

The fifth of the six equivalence components the FSIS auditors reviewed was Chemical Residues. The inspection system must have a chemical residue control program that is organized and administered by the national government. The residue control program should include random sampling of internal organs and fat of carcasses for chemical residues identified by either the exporting country's poultry inspection authorities or by the FSIS as potential contaminants.

To assess Poland's ability to meet the equivalence requirement for this component, the FSIS audit team conducted a review of the CCA headquarters in Warsaw, the NRL in Pulawy and three RVLs in Warsaw, Gdansk and Kielce. The FSIS auditors interviewed the CCA officials and reviewed the NRL and the regional laboratories testing methods, enforcement strategies, and communication tools. The FSIS auditors verified that Poland's residue control program is designed and conducted as coordinated efforts of the GVI and NRL. The NRL supervises the quality of analyses made in the regional laboratories, organizing proficiency tests, trainings and analytical seminars and participates in such proficiency tests organized by the NRL or the EU reference laboratory. The *CVO's instruction No. GIWhig-500-3/06 of March 21, 2006* described the scope and methods of execution of the national program for control tests on illegal substances, chemical and biological residues, medical products and radioactive contamination of animals and in their secretions and excretions, tissues or organs, products of animal origin, water intended for animals and animal nutrition products. The review indicated that Poland's residue plan was properly designed to include all compounds of concern to both Poland and the United States.

Factors considered when determining the annual monitoring residue program include registered use of a particular chemical, likely occurrence of residues, extent and pattern of use, incentives for misuse, persistence of the compound in the environment, past monitoring results, availability of suitable analytical methods, testing capacity and laboratory proficiency, testing arrangements, and perceptions of the residue as a possible public health hazard. The CCA manages national random and targeted testing programs for chemical residues. The design of the testing programs and operational processes that include sample collection, shipping to laboratories, management and analysis of data and initiation of trace-back activities are also managed by the CCA.

At the government laboratories, the FSIS auditors reviewed the sample handling, sampling frequency, timely analysis, date reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, percent recoveries, intra-laboratories check samples, and quality assurance programs, including standards books and corrective actions. The laboratory conditions, records generated, and results of past audits were evaluated and found to be acceptable.

The FSIS auditors verified that the GVI has maintained monitoring and surveillance of animals and animal products to detect evidence of chemical residues in edible tissues. Poland's residue testing laboratories are ISO 17025 accredited and are equipped to provide technical support to the poultry inspection system. The management and the staff of the visited laboratories were familiar with the Poland's testing requirements for products destined for the United States. The FSIS auditors received copies of the scopes of accreditation for chemical testing for the NRL as well as the regional laboratories of Kielce, Gdansk, and Warsaw by the PCA. The FSIS auditors concluded that laboratory personnel were qualified, adequately trained, and capable of conducting analytical methods, and the residue laboratories demonstrated the ability to produce timely and accurate data.

There is an electronic database (CELAB) available for the CCA to collect and manage of data concerning the results of laboratory analyses carried out in the NRL and in the RVLs. Samples are usually sent to the RVLs. In the case of a complicated analysis, samples are sent to the NRL. GVI officials have the legal authority to condemn food products when laboratory analysis indicates the presence of chemical residues at a level that exceeds Polish and EU standards of acceptable limits. When results of the analyses exceed regulatory limits, the CCA responds by implementing measures to stop contaminated product from entering the market and to determine the source of the contamination. Upon detection of a noncompliant sample by the government laboratories the information is immediately transmitted to the PVI, which in turn forwards it to the pertinent government offices and establishment to preclude distribution of food or initiate a recall of meat and poultry products and deal with the problem at its source. Poland uses the EU's Rapid Alert System for Food and Feed (RASFF) which was put in place to provide food and feed control authorities with an effective tool to exchange information about measures taken responding to serious risks detected in relation to food or feed. Action taken 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 of 23 March 2011*. The action to taken by the CCA takes into account the nature of the violation and that establishment's compliance history. The CCA action includes investigations in the farm of origin that may result in restriction in the animal movement, additional and intensified sampling at the farm and the slaughter establishment for 6-12 months, hold of slaughter of animal form suspect source for the entire withdrawal period of subject drug, and in the case of a repeated violations, the CCA may permanently withdrawn the slaughter establishment from the approved establishment list.

The FSIS analysis of all the audit observation, records and findings indicated that the CCA effectively implemented a national residue control program for its poultry inspection system. Therefore, the FSIS concluded that Poland's poultry inspection system meets the equivalence requirements for this component.

## **10. MICROBIOLOGICAL TESTING PROGRAMS**

The sixth of the six equivalence components that the FSIS auditors reviewed was the Microbiological Testing Program used by the CCA. This component pertains to regulatory requirements for the inspection system to have a microbiological testing program, organized and

administered by the national government. The sampling and testing program is intended to ensure that poultry products produced for export to the U.S. are safe, wholesome and unadulterated. The criteria the FSIS used to assess microbiological testing programs included:

- The inspection system provides for a sampling and testing program for generic *E. coli* in raw poultry product, and the CCA uses the test results to verify establishment slaughter processing and dressing controls for fecal contamination.
- The inspection system provides control measures to prevent adulteration of both; non post-lethality exposed ready-to-eat (RTE) products and post-lethality exposed RTE products by *Listeria monocytogenes (Lm)* and *Salmonella spp.* Furthermore, the CCA is to conduct verification sampling and testing for *Lm*, *Listeria spp.* or Listeria-like organisms in the post-lethality exposed RTE products, product contact and environmental surface samples, and *Salmonella* in the ready-to-eat (RTE) products, at a frequency that ensures that the establishments' control measures are effective in controlling these pathogens.
- The inspection system provides for a sampling and testing program for *Salmonella* in raw product, and includes performance standards for *Salmonella*. The inspection system achieves pathogen reduction by ensuring that all slaughter and ground product establishments meet the *Salmonella* Performance Standards.

The review of the laboratory and the CCA's microbiological testing records indicated that Poland has applied criteria reflect the performance standards for raw poultry at the time of the audit. The FSIS has since revised the standards for *Salmonella* and developed new standards for *Campylobacter*, as reflected in a Federal Register Notice issued on March 21, 2011. The CCA was informed of the revised FSIS's standards and the intent to begin implementing these standards in July of 2011.

There are no requirements for routine microbiological testing for thermally processed commercially sterile (canned) products. However, the inspection system is expected to demonstrate 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 when there is suspicion of process deviations, underprocessing, or when inspection personnel observe abnormal containers that need to be submitted for laboratory analysis. The CCA oversees the performance of establishment verification activities, ensuring the problems were identified, corrected and preventive measures are implemented.

At the three CCA levels, the FSIS auditors reviewed the microbiological sampling regulatory requirements and procedures, testing reports, and internal audit reports of government's laboratories. This review was intended to determine whether the CCA was capable of designing and coordinating the conduction and reporting of the microbiological testing results, applying microbiological performance standards, and taking appropriate enforcement actions in response to nonconforming product.

The FSIS auditors verified that the NRL participated regularly in proficiency tests organized by the Community Reference Laboratories with satisfactory results. The NRL executes its supervisory role over the RVLs through periodic supervisory visits and proficiency tests. The provided evidence demonstrated that supervisory visits took place, usually, 3-4 visits per year to randomly selected laboratories. Proficiency tests are regularly organized by the NRL for the RVLs covering different microbiological criteria including *Salmonella* and *Listeria*, and uses different matrices, including poultry products.

Poland participates in the EC's *Salmonella* eradication program. The program required 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. The CCA conducts *Salmonella* testing 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 institute sanitation and hygienic procedures deemed acceptable by the CCA to prevent recurrence. In response to recurring unsatisfactory result, the establishment must reassess its HACCP plan, take appropriate corrective action and start sampling for the third time. Failure by the establishment to meet that standard for the third consecutive time is deemed by the Polish authorities 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 frameworks of the Polish poultry inspection system and exclude such an operator from the exports program.

Even though export to the U.S. has not occurred yet, the FSIS auditors 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 United States. To achieve this goal, the FSIS auditors interviewed laboratory personnel and supervisors, reviewed relevant records including analyst qualifications, sampling protocols, testing methods, test reporting, enforcement strategies, and communication tools. The review indicated that the visited laboratories had qualified staff as evident by staff credential and regularly participation in professional training. The electronic database CELAB has been used to manage data and report results of laboratory analyses carried out in the NRL and in the RVLs. The FSIS auditors 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. Additionally, the FSIS auditors verified that Poland's microbiological testing laboratories are ISO 17025 accredited and well equipped to provide technical support to the poultry inspection system, and that laboratory management is familiar with Poland's export requirements for the United States 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.

- During the interviews conducted with the GVI and PVI officials, FSIS auditors learned that the CCA uses certified private laboratories to analyze official samples in limited and exceptional cases. These laboratories are certified by the CVO and are included in the list of accredited laboratories. Poland did not inform the FSIS or request equivalence determination for the use of private laboratories to analyze official samples of product intended for export

to the United States. If Poland is intended to continue using private laboratories to conduct official samples, The CCA must inform the FSIS and request an equivalence determination.

At the establishment level, FSIS reviews were conducted to determine inspection personnel's ability to enforce the requirements of the Microbiological Testing Programs' equivalence component. The FSIS auditors reviewed Poland's legislation, inspection instructions, and inspection records maintained at local inspection offices. The CCA has regulatory requirements including sampling and enforcement strategies for testing programs related to generic *E. coli*, *Salmonella* and *Lm* that mirror the FSIS testing requirements. The inspection personnel at almost all visited establishments were following the inspection system's sampling protocol, which includes testing frequency, sample collection, and the delivery of samples to laboratories. However, the FSIS auditors found out that:

- At one of the visited establishments, the designated veterinarian directed the establishment's management to use sampling protocol and testing portions used to collect official verification samples of for RTE products, when they collect *Salmonella* samples for the establishment's routine verification sampling. The VI professed this mandate as an enforcement of the Poland's export requirements for microbiological sampling for RTE product destined to the United States. The sampling protocol for *Salmonella* in RTE products apply the official verification sampling not to the establishment's testing for *Salmonella* in RTE products

Based on CVO instruction, an individual annual microbiological sampling plan for each establishment is developed by the DVI. The plan is based on risk and aim to verify operators' own sampling and testing for food safety and process hygiene criteria, in accordance with Regulation (EC) No 2073/2005. The number of samples collected and tested by the DVI for verification purposes constitute up to 10% of samples tested by the food business operator annually. The FSIS auditors verified that each visited establishment had an annual sampling program for laboratory analyses including products, product contact surface and environment.

Poland requires establishments intending to export poultry products to the U.S. to meet the export requirements for *Lm* and *Salmonella* for both post-lethality and non post-lethality exposed ready-to-eat (RTE) poultry products, and to implement an establishment's testing programs that is based on the risk associated with the produced product. The RTE programs include specific provisions for government sampling of product, government oversight of establishment sampling, and the verification of control measures in every establishment certified for export to the United States. Certified establishments may collect a companion sample with each official sample. The companion sample is analyzed at an accredited private laboratory. The FSIS auditors determined that Poland's RTE program meets the testing requirements for products destined to the United States.

The FSIS auditors determined that the CCA's *Lm* testing program as executed is compliant with the requirements adopted by Poland's inspection system. The FSIS was not able to review and verify the implementation of generic *E. coli* testing for poultry products as well as *Salmonella* performance standard testing in raw poultry carcasses since there was no poultry slaughter establishments presented for review during the audit. The microbiological testing program for

*Salmonella* in raw poultry carcasses and testing for generic *E. coli* would be verified when Poland present poultry slaughter establishments for FSIS review. Poland must inform FSIS of the inspection system's use of private laboratories to analyze official samples and request equivalence determination. In conclusion, the FSIS determined that the Polish inspection system meets the basic equivalence requirements of this component. This determination was based on the portions of the program that were verified during the audit.

## **11. EXIT MEETING**

An exit meeting was held on June 1, 2011 in Warsaw with the CCA and representatives of the American Embassy in Warsaw. At this meeting, the preliminary findings from the audit were presented by the FSIS auditors. The CCA understood and accepted the audit findings.

## **12. CONCLUSIONS AND NEED FOR FURTHER ACTIONS**

The FSIS was not able to accurately conclude whether or not the CCA meet the equivalence requirements of component (2) Statutory Authority and Food Safety Regulations. The FSIS auditors were not able to assess the system capability to conduct the poultry slaughter activity as well as other activities associated with the slaughter such as humane handling-Good Commercial Practice and verification of generic *E. coli* testing. This was due to withdrawal of the lone poultry slaughter establishment scheduled for the FSIS review during the audit.

The FSIS concluded that the CCA was able to meet the equivalence requirements of component (5) Chemical Residue Testing as well as the principal equivalence requirements for components: (1) Government Oversight, Programs and (6) Microbiological Testing Programs. However, the following findings were also made:

- The FSIS was not able to access the status of the microbiological testing conducted at slaughter establishments such as generic *E. coli* testing and *Salmonella* Performance Standard for poultry.
- The CCA did not request an equivalence determination for its use of certified private laboratories to conduct analysis of official samples.
- The CCA did not consistently enforce corrective action requirements for the sanitation program and in some instances did not ensure the adequacy of the HACCP verification activities by direct observation and documentation of the monitoring activities.
- The CCA has not implement a mechanism to ensure the effectiveness of the ongoing training program of the inspection personnel assigned to certified establishments. In particular, these requirements associated with Poland's export requirements to the United States, such as HACCP, sanitation requirements and microbiological testing programs.

- The direct supervision of inspection personnel, at establishments seeking certification for export to the United States, did not ensure uniform knowledge of the export requirements through periodic assessments and follow up supervisory reviews that address deficiencies related to the performance of the inspection personnel.
- The CCA practice of appointing veterinarian depended on acquaintance of the DVO of the appointed veterinarians' knowledge and past training rather than official records that track the status of completed training programs. This practice may not ensure effective ongoing plan to analyze and implement the staffing requirements at certified establishments due to the lack of accurate information at all inspection levels.

Findings of greater systemic impact were identified within the equivalence components for (3) Sanitation and (4) Hazard Analysis and Critical Control Point Systems.

- Poland has adopted FSIS's Sanitation Standard Operating Procedures (SSOP) requirements as per 9 CFR 416.11-16 as well as HACCP implementation requirements according to 9 CFR 417. This adoption was grounded in the country's requisite laws and regulations through the CVO instruction. The inspection system conducted its verification activities in accordance with the requirements of 9 CFR 146 and 417. However, FSIS' review of documents and interview conducted at the CCA revealed that the CCA lacked current policy or regulation in place to support the enforcement of the adopted FSIS measures. The CCA acknowledged these findings and decided to initiate corrective action to reinstate the CCA's authority to enforce adopted regulations.

The CCA's response to the above findings, received after the conclusion of the audit, did not form a specific link between the conduction of inspection measures that are intimately tied to 9 CFR 416 and 417 and any relevant legislation. To demonstrate its legislative commitment to the implementation of the specific adopted inspection measures, the CCA should issue and disseminate regulation, policy, written guidance, or any other form of legislation to the inspection personnel and the regulated industry.

In order for the FSIS to demonstrate that Poland's poultry inspection system meets the FSIS import requirements, the CCA is to submit a comprehensive corrective action plan addressing the specific audit findings outlined in the report for each component. The FSIS will evaluate the extent to which the proffered corrective actions sufficiently address the systemic findings identified. Provided the corrective actions are sufficient, the FSIS will make the recommendation to move forward with the rulemaking process for system equivalence. However, the FSIS may conclude that an additional on-site audit is necessary to verify the adequacy of the corrective actions provided. Poland needs to present at least one poultry slaughter establishment for FSIS review or take measures to ensure that certified establishments obtains poultry product from an approved for processing of poultry product destined for the United States.

FSIS has received Poland's proposed corrective actions for the audit findings on September 5 and October 10, 2012. Initial FSIS's review and analysis of the corrective actions indicated that

additional information is needed before making a final conclusion about the adequacy of Poland's response to the audit findings.

Faiz Agarib, DVM, Senior Equivalence Officer (OIA)



Oto Urban, DVM, Senior Program Auditor (OIA)

Myra Gardner, Microbiologist, Office of Public Health Science (OPHS)

Margaret O'Keefe, Chemist, Office of Public Health Science (OPHS)

### **13. ATTACHMENTS TO THE AUDIT REPORT**

Foreign Country Response to Draft Final Audit Report sent on September 5 and October 10, 2012

Warsaw, 05 September 2012



## VETERINARY INSPECTION

DEPUTY CHIEF VETERINARY OFFICER

**Jarosław Naze**

### **According to the distribution list**

GIWue.080-USA-50/12(7)

Dear Sirs,

With reference to the routine audit of Polish pork establishments, combined with the preliminary audit of the Polish system of supervision over production of poultry meat, which were conducted by the FSIS from 10 May to 1 June 2011, I would like to kindly inform you that the General Veterinary Inspectorate asked the local bodies of the Veterinary Inspection, which were covered by the above-mentioned audits, to take a position on the irregularities indicated in the draft reports on both audits as well as in the 5000-6 forms assigned to the visited establishments.

According to the above, I would like to present the information provided to the General Veterinary Inspectorate by the competent regional and district veterinary officers and by 3 establishments where the irregularities had been observed.

1. The District Veterinary Officer in Łuków, through the Regional Veterinary Officer in Lublin, provided the following information concerning the corrective actions taken with respect to the irregularity [9 CFR § 310.25 (b)] found at Zakłady Mięsne "Łmeat-Łuków" S.A. (veterinary approval number **06110266**):

In the year 2011, after the audit conducted by the FSIS services, testing of monitoring samples for *Salmonella* in swine carcasses was transferred to the official Regional Veterinary Laboratory in Warsaw. Samples are taken by official veterinarians on a basis of the requirements of the procedure developed by the National Veterinary Research Institute in Puławy, entitled "*Rules of testing for the presence of Salmonella in the process of verification control in pig slaughterhouses*", recognised by the FSIS services as equivalent to the requirements of the United States.

In the year 2012, monitoring for *Salmonella* in swine carcasses was started on 24.05.2012 and the planned date for the completion of testing is 29.08.2012. Samples are sent for testing to the official Regional Veterinary Laboratory in Warsaw.

2. The District Veterinary Officer in Starachowice, through the Regional Veterinary Officer in Kielce, provided the following information concerning the corrective actions taken with respect to the irregularities found at the plant of the ANIMEX S.A. Group in Starachowice (veterinary approval number **26 11 02 01**):

- a) The irregularity concerning the lack of drinking troughs for suspected animals (suspect pens) [9 CFR § 413.2 (e)] has been removed by equipping the pens with drinking troughs, in order to provide animals with access to water;
- b) The irregularity concerning the insufficiently described results of SSOP monitoring [9 CFR § 416.13 (c)] has been removed in the following way:

The head of the Quality Control Department reviewed the records of the establishment's sanitary state and conducted a training for the Quality Control Department employees in terms of keeping the records – **Annex No 1**. The records currently kept contain a detailed description of the type of contamination – **Annex No 2**.

Removal of the above-mentioned irregularities was also confirmed during the audits conducted from the district and regional level i.e. the review of the records of the establishment's sanitary state (records of pre-operational actions of the sanitary state audit and records of corrective actions for the irregularities concerning the sanitary state) showed that the records kept contain a detailed description of the type of contamination. Inspection of the lairage confirmed that the pen is equipped with drinking troughs.

### 3. TRAINING

Referring to the records on page 3 and page 13 of the report for pork, i.e.:

- „*The inspection system was not able to produce records documenting completion of ongoing training at all levels of the inspection system*”.
- „*The CCA did not have official training records to indicate the subject of the training or the attendee of the training at the PVO and DVO levels*”

According to the above-mentioned records in the content of the report, enclosed please find the documentation of recent training for respective levels of the Veterinary Inspection, which were conducted on a basis of training organised by the GVI with participation of the American company HACCP Consulting Group in the years 2009 and 2011.

***Annex No 3 – training conducted from the district level***

***Annex No 4 – training conducted from the regional level***

***Annex No 5 – training conducted from the GVI level***

In view of the above, it should be stressed that the parts of the reports on the lack of the documentation of training with regard to its subject-matter and participants at individual levels of the Veterinary Inspection are inaccurate, because:

- such the documentation existed both prior to and during the audit and is maintained until now after each training conducted;
- after each training conducted with participation of the HCG company, the GVI, in writing, reminds its participants about the obligation to conduct training for official veterinarians and the need to provide the GVI with the documentation confirming the fact of conducted cascade training.

In addition, with reference to the text on page 25 of the draft report, i.e. *“Evidence of staff participation in training was available at first level but no evidence of training or training records were presented for the subsequent training levels. The ongoing training program lacks a mechanism to ensure accurate flow of information from the trainer to the trainee at subsequent levels.”*

It should be stressed that training conducted with participation of the HCG company is not limited only to the employees of the General Veterinary Inspectorate and regional veterinary inspectorates but it is also participated in by the employees of district veterinary inspectorates who exercise direct supervision over establishments approved for export to the US market. Therefore, it is not possible for the official veterinarian participating in cascade training to be a third-tier recipient. In each district where the establishment approved for export to the USA is located, there is the DVI employee holding a certificate of the completed training, so this employee is a first-tier recipient and has an obligation to train official veterinarians. In addition, the rotation of people from the level of regions and districts participating in further training organised by the GVI is always maintained i.e. each subsequent training is participated in by different people. This is due to the necessity of training as many Veterinary Inspection employees as possible. In addition, the training participants receive in Polish all American requirements and presentations which form the starting material to conduct cascade training. On the GVI website, the FSIS regulatory requirements are also placed to be used by official veterinarians exercising daily supervision at establishments approved for export to the US market.

However, in case of any doubts from the part of the VI field bodies with respect to the interpretation of the FSIS requirements, consultations with the FSIS experts are conducted through the GVI employees.

Also, it should be stressed that for financial and logistic reasons there is no possibility of organising training which would concurrently cover all official veterinarians exercising permanent supervision at establishments exporting to the USA market.

However, taking into account the objection of the FSIS services, the Polish party shall develop and deliver to the Veterinary Inspection field bodies relevant instructions laying down the conditions to be met by conducted cascade training, including, *inter alia*, the requirement to train newly appointed official veterinarians in terms of supervision at establishments approved for export to the US market.

#### 4. MICROBIOLOGY

##### a) *Salmonella*

As it was mentioned in section 1 of this paper, the irregularity found at Meat Plant "Łmeat-Łuków" S.A. (06110266) concerning testing of monitoring samples for *Salmonella* in swine carcasses at a private laboratory was corrected after the audit of the FSIS services in 2011.

The above results from the fact that from the GVI level, the letter ref. GVibż-52-US-34 (1)/11 of 5 October 2011 (constitutes **Annex No 6**) was sent to the competent VI bodies, containing instructions on the need of taking official samples for *Salmonella* from swine carcasses by official veterinarians and testing of these samples at official Regional Veterinary Laboratories, in accordance with the entry on page 4 of the procedure developed by the National Veterinary Research Institute in Puławy entitled "*Rules of testing for the presence of Salmonella in the process of verification control in pig slaughterhouses*", recognised by the FSIS services as equivalent to the requirements of the United States.

However, in view of the fact that Meat Plant "Łmeat-Łuków" S.A. (06110266) sent to the GVI a request for a possibility of performing the above-mentioned testing at the private laboratory "Biochemik", the Polish party asks the FSIS services if there is a possibility of recognising private laboratories accredited according to the ISO 17025 standard as competent to perform official tests.

It should be stressed that the private laboratory "Biochemik" has the status of a laboratory approved by the Chief Veterinary Officer and is included in the list placed on the General Veterinary Inspectorate website. The link to the list is as follows: [http://www.wetGVI.gov.pl/index.php?action=art&a\\_id=2059](http://www.wetGVI.gov.pl/index.php?action=art&a_id=2059)

Pursuant to art. 25a of the Act on Veterinary Inspection, private laboratories may apply for the status of the official laboratory approved to perform laboratory tests of given types. The conditions for approval by means of an administrative decision issued by the Chief Veterinary Officer are:

- possession of accreditation by the laboratory according to the ISO 17025 standard (accreditation range consistent with the test type specified in the application)
- positive opinion by the competent national reference laboratory (or the EU reference laboratory or other national reference laboratory situated in other Member State where there is no national reference laboratory in Poland) with regard to:
  - qualifications of persons performing tests,

- fulfilment of the conditions necessary to perform tests,
  - research methods applied by the laboratory;
- report on proficiency testing organised by the national reference laboratory (or the EU reference laboratory or other national reference laboratory situated in other Member State)

In connection with the above, taking into account the requirements and conditions to be met by laboratories in order to obtain approval, as well as taking into account the irregularity specified in the report, please analyse whether the American party allows a possibility of testing samples from carcass surfaces for *Salmonella* at private laboratories approved by the Chief Veterinary Officer. In the case of the acceptance of this solution, the procedure developed by the National Veterinary Research Institute in Puławy, entitled "*Rules of testing for the presence of Salmonella in the process of verification control in pig slaughterhouses*" (constitutes **Annex No. 7**) shall be amended.

b) *Clostridium botulinum*

According to the objection of the FSIS services mentioned in point 10 on page 23 of the draft report concerning the need to perform tests of thermally processed commercially sterile (canned) products for *Clostridium botulinum*, at the beginning, I would like to inform you that, as it was rightly stressed by the US party, there is no requirement for routine microbiological testing for thermally processed commercially sterile (canned) products "*There are no requirements for routine microbiological testing for thermally processed commercially sterile (canned) products.*"

Among 11 Polish establishments currently approved for export to the US market, only 4 establishments export thermally processed commercially sterile (canned) products to the designated market. Please find these establishments below:

- 1) „Łmeat- Łuków” S.A. (06110266)
- 2) Wielkopolska Wytwórnia Żywności „PROFI” (30 18 41 03)
- 3) „SOKOŁÓW” S.A. Oddział w Jarosławiu (WNI 18 04 02 01)
- 4) Animex Oddział w Szczecinie (WNI 32 62 02 01)

All these establishments have procedures in place regarding:

- method of performing the thermostat test, taking into account the criteria for the evaluation of this test,
- microbiological testing of thermally processed commercially sterile (canned) products in the event of a positive result of the thermostat test (bulging, leakage) and method of procedure in the event of positive results (investigation of the cause) and;
- method of dealing with a lot of thermally processed commercially sterile (canned) products for which a positive microbiological result was obtained.

Microbiological testing of thermally processed commercially sterile (canned) products includes sulfite-reducing anaerobic bacteria (*inter alia*, *Clostridia* group). However, individual species of bacteria of the genus *Clostridium* are not actually identified. In the case of obtaining positive results of microbiological testing, a non-compliant

lot of thermally processed commercially sterile (canned) products is detained and an investigation of the cause is conducted. Also, in-house procedures of establishments determine the method of dealing with a non-compliant product in the case of positive results for anaerobes, i.e. the entire lot of thermally processed commercially sterile (canned) products in which the presence of anaerobes was detected is not placed on the market but is detained and managed as waste to be rendered.

Summing up, microbiological testing of thermally processed commercially sterile (canned) products (including testing for anaerobes) is performed and each time when a positive test result for anaerobes is obtained, the cause is determined and appropriate actions in relation to a non-compliant product are taken.

In view of the above and of the fact that the US requirements do not specify the need to perform testing for *Clostridium botulinum* with respect to thermally processed commercially sterile (canned) products, the Polish party requests the FSIS services to accept the measures adopted in relation to testing of anaerobes in thermally processed commercially sterile (canned) products, without further distinction between individual species of bacteria of the genus *Clostridium*.

## **5. ADMINISTRATIVE DECISIONS**

With regard to the objection of the FSIS services mentioned in point 5 on page 11 and in point 12 on pages 24 and 25 of the draft report for pork, concerning a failure to close an administrative decision within the anticipated time frame:

- *"(...) In some instances, the inspection personnel failed to follow the established procedure by closing the administrative decisions within the specified timeframe.(...)"*,
- *"(...) However, FSIS observed that there was a failure of some PVI/DVI offices to enforce the close out of the corrective action by issuing administrative decision in response to non-compliance with the sanitation and the microbial follow-up testing requirements within specified deadlines."*
- *"In some instances, the administrative decisions were not closed within the specified deadline to indicate that identified deficiencies were properly corrected."*

It is necessary to stress the rightness of the US party's comment as in the light of the existing legal regulations there is an obligation to verify and document corrective actions carried out by the establishment within the time limits set by an administrative decision.

In connection with that, the GVI, in the near future, will remind and provide to the Veterinary Inspection field bodies relevant instructions (they will be provided to the FSIS services for inspection) determining the absolute necessity to carry out follow-up inspection, in the case of issuance of an administrative decision, which specifies the date of removing irregularities, in order to document that identified irregularities have been corrected within the time limit specified by the decision.

## **6. COMMENTS ON THE AUDIT WITH REGARD TO THE FUNCTIONING AND ACTIVITY OF LABORATORIES AND RESIDUE MONITORING PLAN**

With respect to the entries concerning the supervision over Regional Veterinary Laboratories and their functioning under the quality management system in accordance with the ISO 17025 standard, included on page 14 of the report for pork, it should be clarified that Regional Veterinary Laboratories (provincial/regional labs) are part of Regional Veterinary Inspectorates managed by regional veterinary officers who are responsible for development of test types performed at RVLs subordinated to them. The entire process takes place in agreement with the CVO as well as with reference laboratories. The latter, pursuant to art. 33 of the Regulation 882/2004 exercise content-related supervision over the functioning of official laboratories and for the majority of test types are situated in NVRI in Puławy. Representatives of reference laboratories, as part of the above-mentioned supervision, shall inspect official laboratories, also by means of on-the-spot inspection visits. In addition, under the quality management system, audits from the part of the PCA (Polish Accreditation Body) are carried out in accredited laboratories. Moreover, as part of quality management, internal audits are also carried out in laboratories.

A similar observation refers to the entry contained in point 9 concerning the residue control plan (page 20 of the report), where the US party mentions the frequency of supervisions of the central competent authority in laboratories participating in the plan. Representatives of the General Veterinary Inspectorate do not carry out audits in laboratories. Supervision and administrative actions are taken on a basis of information obtained from the reference laboratory (which carries out inspection visits).

With regard to the instructions for proficiency testing organised for official and private laboratories, referred to on page 21 of the report, the Chief Veterinary Officer does not draw up such documents. Detailed instructions on performing proficiency testing are prepared from time to time by the testing organiser, which for official laboratories is the national reference laboratory.

In addition, with reference to the penultimate paragraph on the same page, it should be corrected that the decision on further dealing with a product in which maximum residue levels were exceeded, is within the competence of the district veterinary officer competent for the place of sampling and not, as stated in the report, of the GVI representatives.

## **7. HACCP AND SSOP**

With regard to the objections of the FSIS services mentioned in points 7 and 8 of the draft report for pork and concerning the lack of equivalence with regard to SSOP and HACCP, I would like to remind you that the Polish party, at the meeting closing the audit in question, informed the FSIS services that incorporation of the entries regarding the above-mentioned components into national regulations was a long-term process and was not within the competence of the GVI. In connection with that, it was agreed that those components would be regulated by way of issuance of the appropriate instructions or guidelines of the Chief Veterinary Officer for establishments approved

for export to the US market, based on the provisions of 9 CFR. After developing the guidelines in question (together with the instructions on training), they will be provided at a later date to the FSIS services to review and accept the entries.

#### **8. POULTRY DRAFT REPORT**

Replies to the recommendations contained on pages 23 and 24 of the report concerning poultry meat are to be found in points 4, 5, 6 and 8 of this letter. Simultaneously, I would like to stress that at present there is no slaughterhouse in Poland interested in obtaining approval for export to the USA and one of the inspected poultry plants, i.e. Zakłady Przetwórstwa Mięsnego Henryk Kania S.A. (veterinary approval number **24 10 03 02**) resigned from applying for approval for export to the specified market.

Sincerely yours,

  
DEPUTY  
CHIEF VETERINARY OFFICER  
*Jarostaw Naze*

#### Recipients:

- 1) Dr. Andreas Keller, Director, International Equivalence Staff, Food Safety and Inspection Service, United States Department of Agriculture, 1400 Independence Avenue, SW, Washington, DC 20250-3700, USA
- 2) Dr. Shauket H. Syed, Director, International Audit Staff, Food Safety and Inspection Service, United States Department of Agriculture, 1400 Independence Avenue, SW, Washington, DC 20250-3700, USA
- 3) Michael Henney, Agriculture Attaché, U.S. Embassy Warsaw, Al. Ujazdowskie 29/31, 00-540 Warsaw
- 4) Robert Kupiecki, Ambassador, Embassy of the Republic of Poland, 2640 16th Street, N.W., 20009, Washington, USA

Warsaw, 10 October 2012



## VETERINARY INSPECTION

DEPUTY CHIEF VETERINARY OFFICER

*Krzysztof Jazdzewski*

### **According to the distribution list**

GIWue.080-USA-50/12(10)

Dear Sirs,

With reference to the letter GIWue.080-USA-50/12(7) of 5 September 2012 containing the remarks of the Polish side to draft reports on audits conducted by the FSIS from 10 May to 1 June 2011, I would like provide you with the description of follow-up measures, which were indicated in the a/m letter and kindly ask you for their approval.

Point 1 and 2 of the letter GIWue.080-USA-50/12(7) of 5 September 2012 contained the description of corrective actions, taken by the establishments. This information was prepared on the basis of documentation provided by the regional and district bodies of the Veterinary Inspection. The documentation confirms the information provided to the US side in the a/m letter and constitutes a proof that the corrective actions had been verified by the relevant Regional Veterinary Officers. The documentation is included in the Annex 1 and Annex 2.

Point 3 of the letter GIWue.080-USA-50/12(7) of 5 September 2012 contained the self-obligation to develop at the central level the guidelines on conducting training at regional and district levels and in point 5 it was proposed to develop the guidelines on closing out administrative decisions by District Veterinary Officers in the specified time-frame. To address both issues, in the attachment you will find the letter of Deputy CVO GIWbż-52-US-20/12(5) of 26 September 2012 along with its attachments in Annex 3, which were sent to the field bodies of the Veterinary Inspection for the implementation.

Point 4 of the letter GIWue.080-USA-50/12(7) of 5 September 2012 contained the question by Polish side whether there is a possibility of recognizing private laboratories accredited according to the ISO 17025 standard as competent to perform tests as well as a request to accept the measures adopted in relation to testing of anaerobes in thermally processed commercially sterile (canned) products, without further distinction between

individual species of bacteria of the genus *Clostridium*. In the view of the above, I would like to renew our request for your reply.

Point 7 of the letter GIWue.080-USA-50/12(7) of 5 September 2012 referred to the lack of equivalence with regards to SSOP and HACCP on the grounds of the lack of the national legislation which would require the development and implementation of the SSOP and HACCP plans by establishments, as a prerequisite for approval for export to the USA. The Polish side has decided to provide the FSIS services with the standard ISO 22000 entitled: *Food safety management systems – requirements for any organization in the food chain (ISO 22000: 2005)*, so that it may be found equivalent. The standard is included in Annex 4.

If FSIS finds the standard ISO 2200 equivalent with the US legislation, the General Veterinary Inspectorate shall issue guidelines on the necessity to implement it by establishments approved for export to the US market.

Simultaneously, I would like to kindly remind you that similar procedure took place when FSIS determined equivalence of analytical methods in the case of standards ISO 11290-1, ISO 11290-2, ISO 6579:2002.

I am looking forward to your approval of the actions undertaken by the Polish Veterinary Service and closing the pork audit file.

Sincerely yours,

DEPUTY  
CHIEF VETERINARY OFFICER  
*Krzysztof Jazdzewski*

Recipients:

- 1) Dr. Andreas Keller, Director, International Equivalence Staff, Food Safety and Inspection Service, United States Department of Agriculture, 1400 Independence Avenue, SW, Washington, DC 20250-3700, USA
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