



United States Department of Agriculture

Food Safety and
Inspection Service

JAN 31 2017

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Dear Dr. Gómez Meza,

The USDA Food Safety and Inspection Service (FSIS) onsite audit conducted from June 6 through June 24, 2016, supports that Chile's inspection system continues to remain equivalent to that of the United States. Enclosed is a copy of the final audit report. The comments received from the Government of Chile are included as an attachment to the report.

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

Sincerely,

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

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

CHILE

JUNE 6 - 24, 2016

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT AND POULTRY

EXPORTED TO THE UNITED STATES OF AMERICA

January 31, 2017

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from June 6 - 24, 2016. The purpose of the audit was to determine whether Chile's food safety system governing meat and poultry products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and accurately labeled and packaged. Chile currently exports the following categories of products: raw and processed poultry, beef, lamb and mutton, and pork products.

The audit focused on six system equivalence components: Government Oversight (Organization and Administration), Government Statutory Authority, Food Safety, and Other Consumer Protection Regulations (Inspection System Operation, Product Standards and Labeling, and Humane Handling), Government Sanitation, Government Hazard Analysis and Critical Control Points (HACCP) System, Government Chemical Residues Testing Programs, and Government Microbiological Testing Programs.

The following findings were identified:

Government Oversight: The practices in use to evaluate the competence of in-plant personnel do not follow standardized procedures to objectively assess and document the skills and abilities of individual inspectors. In addition, instructions and guidance from the Central Competent Authority (CCA) provided to inspection personnel and establishments on the re-inspection of broilers in accordance with Finished Product Standards (FPS) do not describe the respective responsibilities of inspection personnel and the establishments.

Government Statutory Authority, Food Safety, and Other Consumer Protection Regulations: The post-mortem inspection (PMI) procedures for broilers do not include an observation of the surfaces of the tibio-tarsal joints, which is a deviation from FSIS equivalence criteria. The CCA has not requested FSIS to conduct a new equivalence determination for the modified PMI procedures for broilers.

Government HACCP System: The corrective actions described in the Slaughter HACCP plan prepared by poultry establishments are incomplete. Visual examination of carcasses for the absence of visible fecal contamination is not included as part of the corrective actions. However, inspection officials had not detected this flaw during routine HACCP verification activities.

An analysis of the findings within each component did not identify significant deficiencies that posed an immediate threat to public health. During the audit exit meeting, the CCA presented evidence of the completion of corrective actions implemented to address minor concerns identified at the establishments, and committed to addressing the audit findings as presented. FSIS will evaluate the adequacy of the CCA's proposed corrective actions once received.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Chile's food safety system from June 6 - 24, 2016. The audit began with an entrance meeting held on June 6, 2016, in Santiago, Chile, with the participation of representatives from the Central Competent Authority (CCA), the Servicio Agrícola y Ganadero (SAG), and the FSIS auditor.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure the food safety system governing meat and poultry in Chile maintains equivalence to that of the United States, with the ability to export products which are safe, wholesome, unadulterated, and correctly labeled and packaged.

FSIS applied a risk-based procedure which included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included an analysis of data collected by FSIS over a three-year timeframe, in addition to information obtained directly from the CCA, through a self-reporting process.

The FSIS auditor was accompanied throughout the entire audit by representatives from the CCA headquarters, and regional and local inspection offices. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (Organization and Administration), (2) Government Statutory Authority, Food Safety, and Other Consumer Protection Regulations (Inspection System Operation, Product Standards and Labeling, and Humane Handling), (3) Government Sanitation, (4) Government Hazard Analysis and Critical Control Points (HACCP) System, (5) Government Chemical Residues Testing Programs, and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at CCA headquarters, two regional offices, and six local inspection offices, during which the FSIS auditor evaluated the implementation of control systems in place that ensure that the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of six establishments was selected from 23 establishments certified to export meat and poultry products to the United States. During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety. The FSIS auditor examined the CCA's ability to provide oversight through supervisory reviews conducted in accordance with Title 9 of the United States Code of Federal Regulations (CFR) § 327.2, the FSIS regulations addressing eligibility of foreign countries for importation of meat products into the United States, and § 381.196, the FSIS regulations addressing eligibility of foreign countries for importation of poultry products into the United States. No ovine slaughter establishments were operating during the audit.

Additionally, the National Reference Laboratories for microbiology and chemical residue analysis were audited to verify their ability to provide adequate technical support to the inspection system and to assess the oversight that the CCA maintains over their functions.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	Servicio Agrícola y Ganadero/ Santiago
	Regional Offices	2	Los Lagos Regional Office/ Osorno O'Higgins Regional Office/ Rancagua
Laboratories		2	Microbiological and Chemical Residue analytical government laboratories/ Lo Aguirre
Establishments		6	Est. 9-12 / Temuco (beef) Est. 10-26 / Osorno (beef) Est. 6-08 / San Vicente (poultry) Est. 5-09 / La Calera (poultry) Est. 13-07 / El Monte (poultry) Est. 6-06 / Rengo (pork)

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

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601, et seq.);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, et seq.);
- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.);
- FSIS Regulations for Imported Meat (9 CFR Part 327); and
- FSIS Regulations for Imported Poultry (9 CFR Part 381, Subpart T).

The audit standards applied during the review of Chile's inspection system for meat and poultry included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the Sanitary/Phytosanitary Agreement.

Currently, Chile has equivalence determinations in place for the following:

- For generic *Escherichia coli* (*E. coli*): four sampling sites for cattle and swine
- For *Salmonella*:
 - Year-round, on-going testing;
 - Immediate corrective actions required by establishments that display positive result; followed by additional sampling by the SAG to verify the effectiveness of the establishment's corrective actions;
 - Four sampling sites for cattle and swine;
 - 400 cm² are sampled, 100 cm² from each sampling site; and
 - Sample analysis by private laboratories.
 - For *Listeria monocytogenes* (*Lm*):
 - The *Lm* control program;
 - Screening method for ready-to-eat (RTE) in meat and poultry VIDAS Lm Xpress (03/09/11); and
 - Detection and confirmation method VIDAS LMO2 (07/06/09).

- For *E. coli* O157:H7:
 - The National Program for *E. coli* O157:H7;
 - Screening method VIDAS ECO (07/08/09);
 - Confirmatory method VIDAS ICE (07/08/09);
 - Screening method in RTE meat VIDAS ECPT (03/09/11); and
 - Non-O157:H7 Shiga toxin producing *E. coli* (STEC) Verification Testing Program.

III. BACKGROUND

Chile is eligible to export raw and processed meat and poultry products to the United States. However, the bulk of imports received at the United States POE are raw intact and non-intact meat and poultry products. Currently, Chile does not export thermally processed/commercially sterile products.

From October 1, 2013, through September 30, 2015, FSIS import inspectors performed 100% re-inspection on 132,659,543 pounds of meat and poultry products exported by Chile to the United States. From that volume, FSIS rejected a total of 491,550 pounds of product due to violations that included inadequate labeling and certification of products, and violations of the United States food safety requirements involving lamb meat.

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

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

The first of six equivalence components of Chile's meat and poultry inspection system that the FSIS auditor reviewed was Government Oversight. FSIS import regulations require that an equivalent foreign inspection system be organized by the national government in a manner that provides ultimate control and supervision over all official inspection activities; ensures the uniform enforcement of requisite laws; provides sufficient administrative technical support; and assigns competent qualified inspection personnel at establishments where products are prepared for export to the United States.

The meat and poultry inspection system of Chile is organized and managed by the national government as mandated by national statutes. The SAG, an agency of the Ministry of Agriculture (MOA) of the Chilean government serves as the CCA to administer the meat and poultry inspection system. The CCA issues regulatory standards based on national laws that apply to the production of meat and poultry products for human consumption. In addition, the CCA provides regulatory oversight to certified establishments, uniformly enforcing the United States requirements. The FSIS auditor verified that the CCA maintains regulatory oversight of production practices conducted at certified meat and poultry establishments. The analytical laboratories that serve the system also continue to operate under the oversight of the CCA and provide adequate technical support to the sectors of the system that utilize their services.

The CCA has legal authority to certify and de-certify establishments that seek to export their products to the United States. Documents reviewed and interviews conducted during this audit demonstrate that the CCA has administrative and regulatory mechanisms to grant, suspend, and withdraw authorization for meat and poultry establishments to export their products to the United States. Furthermore, when regulatory non-compliance is identified at certified establishments, the CCA requires corrective actions, and takes additional enforcement steps when warranted. A review of documents reporting the corrective actions implemented by the CCA to address POE violations of FSIS food safety standards that occurred in March and April 2015, demonstrated that in each reported event, inspection personnel followed uniform procedures to effectively enforce equivalent regulatory requirements.

Regulatory actions taken by the CCA at the two certified establishments with POE violations resulted in temporary suspension of their eligibility to export to the United States, as first step in the enforcement process; followed by an assessment of the establishments' food safety programs in operation and implementation of needed corrective actions. Verification of the adequacy of the corrective actions was followed by lifting the suspension to one establishment while delisting the other one that was found unable to meet the CCA standards. The regulatory measures implemented by the CCA are effective. FSIS has not detected any violations of the United States food safety standards involving Chilean meat and poultry products at POE since April 2015.

The FSIS auditor verified the adequacy of implementation of the corrective actions proffered by the CCA to address the last audit's findings and reported observations related to shortcomings in regulatory oversight of establishments. The FSIS auditor confirmed that the CCA implements protocols to maintain adequate staffing levels at all certified establishments, in particular, at poultry slaughter establishments that operate under equivalent post-mortem inspection systems. At the slaughter establishments, the speed of slaughter lines remains under the control of on-line slaughter inspectors and Lead Veterinary Medical Officers (LVMOs). Furthermore, supervisory officials have developed improved approaches to evaluate the performance of establishments and inspection personnel when they conduct periodic supervisory reviews.

The FSIS auditor verified that certification of product for export to the United States takes place under the oversight of the CCA. Certified establishments are required to control and segregate product destined for the United States market and to maintain identity of products. Prior to the issuance of export certificates, in-plant inspection personnel verify that the products are accompanied by information that provides enough data for traceability of all products included in the load. Only products obtained from certified establishments are eligible for certification for export to the United States. The inspection system maintains strict control over all official documents that are generated during the processing of export certificates that accompany exported products. Automated data management tools are utilized by the CCA to facilitate the management and transmission of information to officials that oversee the export programs.

The CCA reports that the central government funds its meat and poultry inspection system. FSIS verified that this arrangement has not changed since the last audit conducted by FSIS in 2014. Government inspectors receive payment for services rendered directly from the government of

Chile. Inspection personnel are retained as contracted officials whose contracts are renewed in accordance with contractual terms and national statutes that apply to the hiring of civil servants.

Individuals assigned to the inspection service meet academic and technical requirements stipulated by the CCA that qualify them to conduct regulatory inspection and verification activities at the certified establishments. Entry-level Veterinary Medical Officers (VMOs) must possess an academic degree from an accredited university and one year of professional experience, or have completed a course on meat inspection offered by an accredited center of learning. Non-veterinary personnel must have experience in animal production. Once hired, inspection personnel receive on-the-job training for their specific positions under the direct supervision of LVMOs.

The LVMOs and the VMOs must complete additional training on inspection and verification activities. Their skills and abilities are evaluated prior to being assigned to conduct inspection and/or verification duties at a designated duty station. Ongoing training of inspection personnel and evaluation of their general knowledge of food safety and inspection is coordinated by the Chief of Inspection (COI) in cooperation with LVMOs in the different regions, where certified establishments are located. In addition, the COI, during periodic supervisory reviews, evaluates the overall performance of all in-plant personnel and addresses identified performance shortcomings.

Daily monitoring of the performance of in-plant inspectors is one of the functions of the LVMOs, who regularly correlate inspection standards and procedures with their subordinates to ensure consistency and accuracy of their regulatory decisions. However, the current approach used to evaluate the skills and abilities of in-plant inspection personnel, does not include standardized procedures to objectively assess the competence of each individual inspector. In addition, evaluators do not document the results of the evaluations, or the remedial actions taken when performance shortcomings are detected.

There are a variety of ways to train inspection personnel on United States food safety standards, such as self-taught courses, short training sessions imparted by inspection personnel that participate in FSIS foreign officials training programs, and training provided by USDA trainers. Information obtained by the FSIS auditor through reviews of training records and interviews of inspection personnel demonstrate that inspection personnel stationed at certified establishments possess knowledge of the United States food safety standards.

In response to findings reported during the last FSIS audit, the CCA has implemented controls to ensure that poultry slaughter establishments operate under systems of PMI, that consistently adhere to equivalent production line rates. As required by the CCA, establishments slaughtering broilers and turkeys are to follow procedures and requirements contained in 9 CFR §381.76 and inspection personnel are to evaluate their compliance with the requirements by following F-PP-IT-058, *Evaluation of U.S. Exporting Poultry Slaughter Establishments*. The establishments that slaughter broilers under the Streamlined Inspection System (SIS) are required to verify that the product being produced is consistently wholesome and unadulterated by re-inspecting carcasses before and after chilling, using for that purpose the methods and finished product standards provided by the FSIS regulations.

The COI and LVMOs regularly evaluate the implementation of the establishments' finished product standards evaluation of processed birds. However, the instructions and guidance provided by the CCA to inspection officials and establishments, do not describe the specific responsibilities that belong to an establishment and inspection personnel. As a result, inspection officials do not collect carcasses from each production line to assess the product for compliance with the finished product standards. Conversely, establishments evaluate processing non-conformances, but disregard the presence of long shanks (the tibio-tarsal joint not exposed) and the presence of uropygial glands (oil glands) as defects, even though FSIS considers both of those defects as processing non-conformances.

The inspection system has the legal authority and responsibility to approve and disapprove laboratories conducting analyses of product and tissue samples collected as part of the official verification testing programs managed by the CCA. The CCA coordinates audits of the laboratories in accordance with International Organization for Standardization (ISO) 17025 guidelines and requirements. The CCA and accrediting bodies audit the laboratories to ensure adequacy of their work products and to verify the scope of their accreditation. FSIS conducted interviews and reviewed documents at the government laboratories included in this audit and verified that they remain in compliance with the requirements of ISO 17025. Audit reports demonstrate that the laboratories are being managed in a manner that is consistent with international standards. Analysts and managers meet professional qualifications required for their field of analysis. All analysts have successfully completed periodic evaluations of their competence. Handling of samples is done under the guidance provided by the laboratories and instructions issued by the CCA to ensure prompt delivery, analysis of samples, and delivery of results to stakeholders.

The meat and poultry inspection system of Chile is structured in a manner in which the CCA provides oversight to certified establishments, laboratories, and government offices. Regulatory controls are implemented following uniform instructions and guidance that ensures compliance of producers with the United States importing requirements. However, there are aspects of this component that require the attention of the CCA to improve its current performance.

The evaluation of the competence of in-plant personnel does not follow standardized procedures to assess the skills and abilities of individual inspectors and to document the results of the evaluations. In addition, the CCA instructions and guidance provided to inspection personnel and establishments on the evaluation of broilers in accordance with FPS do not provide the necessary description of responsibilities that belong to inspection personnel and the establishments. Although, the above listed concerns do not have a direct impact on food safety, it is necessary that the CCA implement adjustments to the reported concerns of this component of the system to achieve a greater alignment with FSIS requirements.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY, FOOD SAFETY, AND OTHER CONSUMER PROTECTION REGULATIONS (INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

The second of the six equivalence components of Chile's meat and poultry inspection system that the FSIS auditor reviewed was Government Statutory Authority, Food Safety, and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection (AMI) of animals; PMI of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; and periodic supervisory visits to establishments certified to export their products to the United States.

On August 21, 2014, FSIS published a final rule to modernize poultry slaughter inspection (79 FR 49566). The rule includes (1) a new regulatory program that affects all poultry slaughter establishments that involves sampling for Salmonella and Campylobacter to demonstrate process control at two points on the line and treating enteric pathogens as hazards reasonably likely to occur; and (2) an optional post-mortem inspection system known as the New Poultry Inspection System (NPIS). Implementation of these new provisions was not assessed by FSIS in the 2015 audit. The specific regulatory changes that were made by this final rule can be found in 9 Code of Federal Regulations (CFR) 381.65 and 9 CFR 381.66. As it pertains to the implementation of the newly introduced regulatory changes, the CCA has issued instructions for establishments to implement the newly required changes that affect all poultry slaughter establishments, as described in FSIS regulations. In addition, in-plant inspection personnel monitor implementation of poultry slaughter activities to ensure that establishments maintain compliance with the new regulatory requirements. Establishment documents reviewed by the FSIS auditor showed that results of microbial testing and carcass evaluations being conducted by the establishments are in line with FSIS requirements and indicate that the establishments maintain adequate control of sanitary dressing practices.

As it pertains to the implementation of newly introduced changes to FSIS poultry slaughter inspection regulations, the CCA received FSIS' notification of the implemented changes and has since issued instructions for establishments to implement the required changes, as described in FSIS regulations. The in-plant inspection personnel monitor implementation of poultry slaughter activities to ensure that establishments maintain compliance with the new regulatory requirements. Establishment documents reviewed by the FSIS auditor showed that results of microbial testing and carcass evaluations conducted by the establishment indicate adequate control of sanitary dressing practices.

FSIS verified that in-plant inspection personnel work under the coordination and direct supervision of LVMOs who direct and coordinate the verification activities of the establishments' food safety programs and the delivery of AMI and PMI conducted by subordinate inspection personnel. Government inspectors verify that establishments comply with regulatory requirements that apply to humane handling and slaughter of livestock; good commercial practices for poultry slaughter; and safe production of meat and poultry products.

Government inspectors conduct PMI of broilers following the regulations of the system and CCA instructions that are aligned with requirements specified in FSIS regulations. However, during this audit, the FSIS auditor observed that broiler slaughter establishments presented for inspection, birds with the tibio-tarsal joint (hock joint) not exposed. That practice prevents slaughter line inspectors from observing the surfaces of the hock joints to determine degrees of inflammation of the synovial membranes and surrounding structures, as required by the regulations. Although the other aspects of the PMI procedure are being conducted in accordance with the regulations, the variation described above is not consistent with FSIS PMI protocols for poultry. It is therefore necessary that the CCA either revise its current PMI procedures for broilers to bring them in alignment with FSIS protocols, or submit a request for FSIS to conduct an equivalence determination for a PMI procedure that does not include observation of the surfaces of the tibio-tarsal joint of broilers.

Additional verification activities conducted by the FSIS auditor confirm that the meat and poultry inspection system of Chile maintains official controls over establishment construction, facilities, and equipment. Official slaughter inspection is continuously maintained. Processing activities for meat and poultry take place under daily inspection conducted by government inspectors. Supervisory officials visit certified establishments to assess the adequacy of the design and implementation of the food safety programs maintained by the certified establishments, and evaluate delivery of AMI and PMI activities, establishments' construction, facilities, and equipment, production processes, and control over condemned materials. Records of supervisory visits reviewed by the FSIS auditor document the results of these activities and demonstrate that this activity is conducted in accordance with instructions issued by the CCA that are consistent with FSIS expectations.

The CCA has required implementation of changes at poultry slaughter operations in accordance with newly introduced FSIS regulatory requirements. However, in order for all aspects of PMI to align with FSIS procedures, the CCA should either revise its current PMI procedures and broiler processing practices, or submit a request for FSIS to conduct an equivalence determination for a PMI procedure for broilers that does not include observation of the surfaces of the tibio-tarsal joints.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Government Sanitation. To be considered equivalent to FSIS' program, the CCA is to provide general requirements for sanitation, sanitary handling of products, and development and implementation of sanitation standard operating procedures (SSOPs).

The FSIS auditor verified that the CCA requires that establishments develop and adhere to written programs that prevent direct product contamination and operate in a manner that prevents the creation of insanitary conditions. The CCA also requires that establishments' monitor the adequacy of the construction of their facilities, and develop maintenance programs for equipment and structures. Government officials verify the compliance of certified establishments with sanitation requirements on a daily basis by reviewing establishment records and verifying the adequacy of the establishments monitoring and implementation of the sanitation programs.

Inspection personnel also review the written sanitation programs prepared by the establishments to verify that they describe the procedures they will follow to prevent direct product contamination by cleaning and sanitizing surfaces prior to the start of operations and monitoring production practices during operations.

The FSIS auditor verified the adequacy of official verification and inspection activities related to sanitation programs at certified establishments by observing government inspectors as they assessed the implementation of the establishments' sanitation procedures for pre-operational and operational sanitation. The FSIS auditor also reviewed inspection records and assessed the overall sanitary conditions of production areas and storage rooms, and observed the production processes conducted in slaughter and cut/up areas of the establishments.

During the assessment, the FSIS auditor identified several minor sanitary deficiencies that were promptly corrected by the establishments under the oversight of inspection personnel in accordance with established procedures. The results of the verification demonstrated that official establishments maintain adequate compliance with the CCA requirements and follow their written SSOPs in an effective manner.

In conclusion, FSIS verified that the meat and poultry inspection system of Chile requires that all certified establishments implement sanitation programs to prevent the creation of insanitary conditions and to prevent direct product contamination. Inspection personnel conducting verification on the implementation adequacy of sanitation programs assess the risks posed by conditions that could cause direct product contamination, and when a non-compliance is identified, they require the establishment to implement adequate corrective actions. The inspection system has an effective enforcement program that includes suspension and withdrawal of inspection, for those establishments that fail to prevent product contamination or fail to take corrective actions.

VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM

The fourth of the six equivalence components of Chile's meat and poultry inspection system that the FSIS auditor reviewed was Government HACCP System. The CCA is to require that each official establishment develop, implement, and maintain a HACCP program.

The FSIS auditor conducted reviews of records maintained by inspection personnel and the establishment, and interviewed in-plant officials to assess the adequacy of the design and implementation of the HACCP programs used by the establishments. The evaluation demonstrated that the CCA has issued regulations that require that certified establishments develop, implement, and maintain HACCP programs that identify and evaluate food safety hazards that can affect the safety of their products.

The HACCP programs must also implement necessary controls to prevent, or keep within acceptable limits the identified hazards and develop procedures to monitor and document the performance of the implemented controls. Consistent with the CCA regulatory requirements, the establishments have developed flow charts for each process and conducted hazard analyses for

each step of the processes. For identified hazards that are reasonably likely to occur, the establishments have instituted critical control points (CCPs) that are monitored at validated frequencies to ensure that critical limits are not exceeded.

The regulations of the meat and poultry inspection system of Chile also require that establishments implement corrective actions when deviations from established critical limits occur that result in food safety hazards. Establishments prepare HACCP plans that identify the CCPs, the critical limits to be monitored, the monitoring frequency, the corrective actions to be implemented when a deviation occurs, and verification actions to be implemented. In-plant inspectors in turn, are to verify compliance of the establishments with the HACCP regulations to ensure adequacy of the establishments' food safety controls.

The FSIS auditor reviewed the HACCP plans prepared for poultry slaughter establishments and verified that they included a CCP for visible fecal contamination. In addition, the plans describe the monitoring procedures and monitoring frequency that would be implemented to prevent carcasses with visible fecal contamination from entering the chilling tanks. In addition, the plans describe the corrective actions that would be taken when a deviation from that CCP occurs, that is, actions to be taken when presence of visible fecal contamination is detected. As described in the HACCP plans, the affected carcasses will be retained to undergo an antimicrobial treatment application without being visually examined to verify the absence of visible fecal contamination.

However, the fact that the establishment was not examining the retained carcasses to verify the absence of visible fecal contamination had not been identified during the verification activities conducted by in-plant officials. Furthermore, supervisory reviews had not detected that the establishments did not include in the planned corrective actions the visual examination of carcasses affected by a deviation of the critical limit that is defined as absence of visible fecal contamination.

The FSIS auditor verified that the CCA requires regulated establishments to implement HACCP programs that meet equivalent regulatory requirements. The establishments in turn have developed programs that adequately identify known food hazards and have established controls for the identified hazards as required by equivalent regulations issued by the CCA. However, as discussed above, inspection officials had not identified a flaw in the planned corrective actions to be implemented by poultry slaughter establishments, when deviations from the limit for visible fecal contamination would occur. Although, the finding does not have a direct impact on food safety, the CCA is required to ensure that this flaw in the planned corrective actions is adequately and promptly corrected by the poultry slaughter establishments and that inspection personnel develop greater proficiency in the performance of HACCP verification activities to improve the performance of this component of the system.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components of the meat and poultry inspection system of Chile that the FSIS auditor reviewed was Government Chemical Residue Testing Programs. The Chile inspection system is to present a chemical residue control program, organized and administered

by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat and poultry inspection authorities or by FSIS as potential contaminants.

The FSIS auditor verified that the CCA coordinates and oversees the implementation of a national residue control program to prevent contamination of food products with chemical residues. FSIS reviewed the residue control program submitted by the CCA and verified that it includes protocols for the detection of chemical compounds that include veterinary drugs, pesticides, and environmental contaminants. The program is designed to meet the requirements of all countries that import meat and poultry products from Chile and provides data that the CCA analyzes to identify developing trends and any need for corrective actions.

National laws, regulations, and decrees issued by the different agencies of the Chilean government provide the legal framework for the operations of the program. Establishments that process livestock and poultry for the manufacturing of products for the United States market and suppliers of animals destined for slaughter are required to comply with government regulations that apply to the use, manufacturing, importing, and selling of veterinary drugs prohibited for use in animals destined for human consumption. For other compounds that are permitted for use in primary production, the program has established maximum tolerance levels, analytical methodology and sampling protocols to be implemented throughout the year at ranches and establishments to verify compliance with equivalent requirements.

The CCA provides to FSIS its annual residue control plan that describes the approaches that will be implemented to collect tissue samples. In-plant personnel follow instructions issued by the CCA and the analytical laboratories to ensure adequate collection of samples for the annual monitoring program. In addition to the monitoring plan sampling, inspectors also collect tissue samples to verify the adequacy of control of targeted violators that present animals for slaughter. Unscheduled sampling is also performed when veterinary inspectors detect suspect animals during AMI and PMI.

The preparation of the annual monitoring plan takes into consideration the assessment of sampling results obtained from past sampling programs, types of drugs, their method of administration, and animal species for which those drugs are permitted, including regulated extra-label use of veterinary drugs. The plan specifies the analytes to be detected, the method of analysis to be used, the matrix to be collected, the tolerance, and the total number of samples to be collected for each species.

Analysis of the samples is conducted at the National Reference Laboratory (NRL) and at approved laboratories. The CCA ensures that only approved analytical methods are used for analysis of samples for the United States exports. In both situations, an accrediting organization conducts yearly audits of the functions of the laboratories in accordance with the ISO 17025 standard. The FSIS auditor verified that accrediting organizations regularly audit the chemical residue laboratory and when non-conformities to the standard are identified; corrective actions are implemented and verified for acceptability by the auditors from the accrediting institutions.

The results of the tissue analyses are promptly communicated to in-plant officials and CCA supervisors to ensure that only products that comply with FSIS food safety standards are certified for export to the United States. In addition, sampling results that found to be in violation of CCA standards are subject to follow up in accordance with established procedures that are designed to educate the producers, monitor their compliance, and penalize them if they fail to comply with the laws and regulations of the system.

The FSIS auditor conducted an evaluation of Chile's national chemical residue control program and determined that it meets established criteria. The re-inspection conducted by FSIS at POE has not identified any residue control violations. The CCA has ensured that collection and analyses of tissue samples are conducted in accordance with standard protocols that meet FSIS criteria.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of the six equivalence components of Chile's meat and poultry inspection system that the FSIS auditor reviewed was Government Microbiological Testing Programs. This component pertains to the microbiological analysis programs organized and administered by the CCA to verify that meat and poultry products destined for export to the United States are safe and wholesome.

The FSIS auditor reviewed the programs implemented by the CCA as part of its pathogen reduction programs that include generic *E. coli*, *Campylobacter* and *Salmonella* sampling, as well as Chile's *E. coli* O157:H7 and non-O157 STEC and *Lm* control programs.

Collection and handling of samples is conducted by government inspectors in accordance with the instructions provided in the Manual for Official Microbiological Sampling, issued by the CCA. The samples are analyzed at CCA-approved, NRL-accredited laboratories that are required to use approved methods of analysis and to report the results of the analyses to CCA officials and establishments at the same time.

The FSIS auditor confirmed that the meat and poultry inspection system is supported by a network of microbiology laboratories to handle the bulk of samples collected for *Salmonella* and generic *E. coli*. Laboratories are closely overseen by the CCA to ensure that they operate in accordance with official procedures, and adequately handle samples, using approved analytical methods and ensure prompt release of results to stakeholders. The CCA has delegated to the NRL the responsibility of assessing the adequacy of the performance of all laboratories.

FSIS audited the NRL during the on-site verification portion of this audit and reviewed official documents including reports and records containing the results of past accreditation audits, proficiency tests results, and verification of implemented corrective actions. The FSIS auditor verified that the Instituto de Normalización Nacional serves as the accrediting institution for the NRL. The NRL participates in inter-laboratory proficiency tests organized by private analytical institutions and government sponsored evaluations. The proficiency evaluations are regularly conducted and documented. Records reviewed by FSIS at the NRL show that when discrepant

results have been obtained, the root cause for the variations was first identified, followed by actions that adequately corrected the analytical discrepancy.

The NRL assesses the performance of laboratories approved by the CCA to be part of the technical support of the system. Approval of laboratories is granted to private laboratories that meet the CCA's acceptability criteria and required analytical scope. To retain approved status, they must be audited by NRL on a yearly basis to assess the adequacy of their quality control, management and technical competence of their analysts in accordance with the ISO 17025 standard.

In reference to the analytical method for the detection of STECs, the CCA submitted its program and FSIS has determined that it is equivalent. However, the CCA has elected to refrain from authorizing the export of ground beef to the United States, because the validation of an acceptable method of detection of STECs in ground beef has not been finalized.

Audit findings reported by FSIS in 2014, indicated that the CCA verification sampling program for control and prevention of *Lm* where RTE products are exposed to the post lethality environment did not include sampling and testing of food contact surfaces and environmental surfaces. This finding has been adequately addressed by the CCA and instructions have been issued to establishments and inspection personnel to revise sampling protocols to include food contact surfaces in addition to testing of product.

Government officials at certified slaughter establishments collect samples for detection of generic *E. coli* and *Salmonella* in raw products. In addition, at poultry slaughter establishments, inspection personnel collect samples for the detection of *Campylobacter*.

The microbiological testing programs component of the meat and poultry inspection system of Chile is organized and administered by the national government to verify that meat and poultry products destined for export to the United States are unadulterated, safe, and wholesome in accordance with United States requirements. Document analyses and on-site audit verification activities demonstrate that this component of the system continues to meet core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on June 24, in Santiago, Chile, with CCA representatives. At this meeting, the FSIS presented the preliminary findings from the audit. The CCA understood and accepted the findings.

FSIS assessed the performance of the six components of Chile's meat and poultry inspection system. Information was collected during visits of government offices, laboratories, and establishments, where the FSIS auditor reviewed documents, interviewed inspection officials, and conducted on-site evaluations of operations and facilities at the sites visited. During this audit, FSIS concluded that the meat and poultry inspection of Chile meets core requirements for each one of its components. However, the findings described below, although of limited impact

on food safety, could undermine the overall effectiveness of the administration of the inspection program if left unaddressed.

Government Oversight: The practices in use to evaluate the competence of in-plant personnel do not follow standardized procedures to objectively assess and document the skills and abilities of individual inspectors. In addition, instructions and guidance from the CCA provided to inspection personnel and establishments on the re-inspection of broilers in accordance with FPS do not describe the respective responsibilities of inspection personnel and the establishments.

Government Statutory Authority, Food Safety, and Other Consumer Protection Regulations: The PMI procedures for broilers do not include an observation of the surfaces of the tibio-tarsal joints, which is a deviation from FSIS equivalence criteria. The CCA has not requested FSIS to conduct a new equivalence determination for the modified PMI procedures for broilers.

Government HACCP System: The corrective actions described in the slaughter HACCP plan prepared by poultry establishments are incomplete. Visual examination of carcasses for the absence of visible fecal contamination is not included as part of the corrective actions. However, inspection officials had not detected this flaw during routine HACCP verification activities.

An analysis of the findings within each component did not identify significant deficiencies that posed an immediate threat to public health. During the audit exit meeting, the CCA presented evidence of the completion of corrective actions implemented to address minor concerns identified at the establishments, and committed to continue addressing the audit findings as presented. FSIS will evaluate the adequacy of the CCA's proposed corrective actions once received.

|

APENDICES

Appendix A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorifico de Osorno S. A Francisco del Campo No.200 Osorno Region de Los Lagos, Chile	2. AUDIT DATE 06/16/2016	3. ESTABLISHMENT NO. 10-26	4. NAME OF COUNTRY Chile
	5. NAME OF AUDITOR(S) International Audit Staff		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

This establishment slaughters bovine and export beef products to United States (US).

10/51. The outer surfaces of the metal pans used to transport viscera from evisceration to the inspection stations were not being cleaned properly. Although the product contact surfaces were being cleaned and sanitized, ingesta and fecal contamination remained on the outer surfaces of the pans, as they continued being used. This sanitary deficiency had not been noted by in-plant personnel.

Observed deficiencies were corrected under the oversight of CCA representatives.

61. NAME OF AUDITOR
International Audit Staff

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorifico Temuco S. A. Avenida Altamira No. 01825 Temuco Araucania, Chile	2. AUDIT DATE 06/15/2016	3. ESTABLISHMENT NO. 09-12	4. NAME OF COUNTRY Chile
	5. NAME OF AUDITOR(S) International Audit Staff		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

This establishment slaughters bovine and export beef products to United States (US).

10/51. During pre-operational verification of the sanitation program the auditor observed that Sanitation Performance Standards were not being met. The food contact surfaces of the conveyor used to transport major carcass portions had become discolored. The food contact surfaces also had multiple deep scratches that made it difficult to clean. Fat and meat was observed to be lodged between the belt and its metal frame. Additional frames found in the room, also had broken surfaces that made them difficult to clean. This deficiency had not been identified by in-plant personnel.

Observed deficiencies were corrected under the oversight of CCA representatives.

61. NAME OF AUDITOR

International Audit Staff

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Faenadora San Vicente Ltda. Carretera H66G, Km 19.2 San Vicente de Tagua Region del Libertador Gral. Bernardo O'Higgins Chile	2. AUDIT DATE 06/09/2016	3. ESTABLISHMENT NO. 6-08	4. NAME OF COUNTRY Chile
	5. NAME OF AUDITOR(S) International Audit Staff		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

This establishment slaughters chickens and exports boneless breast, wings, thighs and breaded and fried, formed products to United States (US).

20/51 The slaughter HACCP plan being implemented by the establishment, does not does not include in the corrective actions, visual inspection of product involved in a deviation at the critical control point for zero tolerance for visual fecal matter.

26/51. The establishment evaluates the finished product standards (FPS) for broilers using a set of non-conformances that differs from FSIS approach. In-plant inspection does not conduct a daily assessment of the FPS, but only observe the establishment technicians as they perform the tests.

51. Review of records maintained by inspection personnel show that sanitary verification results do not specify the details of observed non-compliances but the entries are limited to report that the result of the verification was not in compliance.

Observed deficiencies were corrected under the oversight of CCA representatives.

61. NAME OF AUDITOR

International Audit Staff

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Procesadora de Alimentos del Sur Limitada Ruta H-50, Km. 0.304. Camino Quinta de Tilcoco Rengo O'Higgins, Chile	2. AUDIT DATE 06/22/2016	3. ESTABLISHMENT NO. 06-06	4. NAME OF COUNTRY Chile
	5. NAME OF AUDITOR(S) Francisco Gonzalez, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

This establishment slaughters young hogs and exports raw-frozen pork products to United States (US).

10/51. Old dry meat and fat fragments had accumulated along the base of one of the walls of the carcass chilling coolers. Inspection officials assessed the sanitary conditions of that cooler in accordance with a prepared schedule. However, the chosen verification frequency for that task seems to be inadequate.

Observed deficiencies were corrected under the oversight of CCA representatives.

61. NAME OF AUDITOR

Francisco Gonzalez, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Sopraval S.A. Panamericana Norte, Km 112 La Calera Region de Valparaiso, Chile	2. AUDIT DATE 06/10/2016	3. ESTABLISHMENT NO. 05-09	4. NAME OF COUNTRY Chile
	5. NAME OF AUDITOR(S) International Audit Staff		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

60. Observation of the Establishment

This establishment slaughters turkeys and exports boneless breast, wings, and thighs to United States (US).

20/51 The slaughter HACCP plan being implemented by the establishment, does not does not include in the corrective actions, visual inspection of product involved in a deviation at the critical control point for zero tolerance for visual fecal matter.

10/51. Dry meat and fat fragments adhered on overhead structures in one production area that had been found acceptable by the establishment sanitation monitors.

Observed deficiencies were corrected under the oversight of CCA representatives.

61. NAME OF AUDITOR

International Audit Staff

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Agroindustrial el Paico S. A. Avenida Libertadores No. 1714 El Monte Region Metropolitana, Chile	2. AUDIT DATE 06/13/2016	3. ESTABLISHMENT NO. 13-07	4. NAME OF COUNTRY Chile
	5. NAME OF AUDITOR(S) International Audit Staff		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

60. Observation of the Establishment

This establishment slaughters chickens and exports boneless breast, wings, thighs and breaded and fried, formed products to United States (US).

20/51 The slaughter HACCP plan being implemented by the establishment, does not does not include in the corrective actions, visual inspection of product involved in a deviation at the critical control point for zero tolerance for visual fecal matter.

26/51. The establishment evaluates the finished product standards (FPS) for broilers using a set of non-conformances that differs from FSIS approach. In-plant inspection does not conduct a daily assessment of the FPS, but only observe the establishment technicians as they perform the tests.

10/51. Dry meat and fat fragments adhered to large areas of the walls in one production area that had been found acceptable by the establishment sanitation monitors.

46/51. The establishment was conducting salvaging and reconditioning of carcasses in an insanitary manner. The capacity of the reconditioning station was exceeded and cleaned, sanitized and trimmed carcasses remained in the line contacting contaminated, untrimmed carcasses that had not been removed from the line to be reprocessed. Responding to the situation, slaughter line inspection officials condemned all carcasses that could not be salvaged or reconditioned and the establishment adjusted flow of product. Inspection officials indicated that a corrective action for this type of deficiency was previously presented to the establishment, which had proffered a long term corrective action that is scheduled to be fully implemented by September 2016. However, inspection personnel need to exert greater control on the slaughter line speed when less than optimum conditions result in insanitary dressing.

Observed deficiencies were corrected under the oversight of CCA representatives.

61. NAME OF AUDITOR

International Audit Staff

62. AUDITOR SIGNATURE AND DATE

Appendix B: Foreign Country Response to Draft Final Audit Report



CARTA N° 7770/2016

SANTIAGO, 28/12/2016

**MRS. JANE DOHERTY
INTERNATIONAL COORDINATION EXECUTIVE
FOOD SAFETY AND INSPECTION SERVICE OFFICE OF INTERNATIONAL COORDINATION
WASHINGTON, D.C 20250-3700,**

Junto con saludar cordialmente, me permito enviar a usted los comentarios y acciones tomadas por el Servicio Agrícola y Ganadero a los hallazgos indicados en el borrador de informe final de auditoría realizada en Chile, entre Junio 06 y Junio 24 de 2016, donde se evaluó el sistema de inocuidad alimentaria que rige sobre la producción de productos de carne y aves de corral para su exportación a Estados Unidos.

Quedo atento a cualquier duda y/o consulta que requiera aclaración.

Saluda atentamente a usted,

**JOSÉ IGNACIO GÓMEZ MEZA
JEFE DIVISIÓN PROTECCIÓN PECUARIA**

Incl.: Documento Digital: COURTESY TRASLATION
Documento Digital: Comentarios SAG
Documento Digital: COMMENTS SAG COURTESY TRASLATION

Adjuntos

Documento	Fecha Publicación
833/2016 Circular	26/12/2016

DGM/ECS/OVP

c.c.: Eduardo Enrique Concha Sepulveda Jefe Unidad de Producción Primaria Or.OC
Jorge Carvajal Vasquez Colaborador (Correspondencia Internacional) Unidad Acceso a Mercados Or.OC
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Carlos Orellana Vaquero Coordinador Unidad de Productos Elaborados Or.OC
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División Protección Pecuaria - Paseo Bulnes N° 140



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COMENTARIOS DEL SERVICIO AGRICOLA Y GANADERO (SAG) AL INFORME DE AUDITORIA DEL FSIS REALIZADO ENTRE EL 06 Y 24 DE JUNIO DE 2016

I. COMPONENTE UNO: SUPERVISIÓN DEL GOBIERNO (ORGANIZACIÓN Y ADMINISTRACIÓN)

Alcance referente a:

“No se cuenta con procedimientos estandarizados para evaluar objetivamente la competencia de cada inspector oficial y el Registro y documentación de las medidas correctivas cuando se detectan deficiencias en el rendimiento del equipo de inspección oficial. Las instrucciones y guías de la CCA proporcionadas al personal de inspección y de los establecimientos sobre la reinspección de pollos de engorde de acuerdo con el control de Estándares de Producto Final (FPS por sus siglas en inglés), no describen las responsabilidades respectivas del personal de inspección y los establecimientos. Como resultado, los funcionarios de inspección no recogen carcasas de cada línea de producción para evaluar el producto para el cumplimiento de los estándares del producto terminado. Por el contrario, los establecimientos evalúan las no conformidades de procesamiento, pero no incluyen la presencia de restos de la articulación tibio-tarsal (articulación tibio-tarsal no expuesta) y la presencia de glándulas uropígeas (glándulas oleosas) como defectos, aunque el FSIS considera ambos defectos como no-conformidades de procesamiento.”

En relación con la falta de procedimientos estandarizados para evaluar objetivamente las competencias técnicas de los inspectores oficiales, la División de Protección Pecuarias del SAG (CCA) emitió la Circular N° 833/2016 (adjunta), mediante la cual instruye la implementación de un sistema de evaluación de las capacidades técnicas del equipo de inspección oficial.

Del mismo modo y en referencia a las instrucciones y guías de la CCA proporcionadas al personal de inspección y de los establecimientos sobre la reinspección de pollos de engorde de acuerdo con el control de Estándares de Producto Final (FPS por sus siglas en inglés), mediante la Circular N° 833/2016 (adjunta), se ha instruido a todos los establecimientos faenadores de aves y habilitados para exportar a Estados Unidos que el Equipo de Inspección Oficial (EIO) deberá realizar diariamente una verificación, por cada turno y cada línea de faenamiento (Observación Directa o Revisión de Registros o Medición Directa), de los procedimientos de Control de Estándares de Producto Final implementado por cada empresa. En el caso de que un lote no reúna el puntaje necesario para cumplir con el estándar, este lote deberá ser rechazado para exportar a los Estados Unidos. Estas actividades serán parte de las verificaciones al Sistema de Aseguramiento de Calidad



(SAC) del establecimiento y quedaran registradas en el documento “Registro para la verificación del sistema de autocontrol del establecimiento”, F-PP-IT-032.

Finalmente y en relación a la inclusión como no conformidades de la presencia de elementos de la articulación Tibio-Tarsal y de la presencia de la Glándula Uropígia en carcasas de pollos (Broiler), la División de Protección Pecuaria está realizando un levantamiento de información técnica y regulatoria, a fin de determinar la factibilidad de solicitar al FSIS, una equivalencia en el tema.

II. COMPONENTE DOS: AUTORIDAD ESTATUTARIA ESTATAL, SEGURIDAD ALIMENTARIA, Y OTROS REGLAMENTOS DE PROTECCIÓN AL CONSUMIDOR (SISTEMA DE INSPECCIÓN, ESTÁNDARES DE PRODUCTO Y ETIQUETADO Y MANEJO HUMANO)

Alcance referente a:

“Los procedimientos de PMI para pollos de engorde no incluyen una observación de las superficies de las articulaciones tibio-tarsal, lo que es una desviación de los criterios de equivalencia del FSIS. La CCA no ha solicitado al FSIS que realice una nueva determinación de equivalencia para los procedimientos de PMI modificados para pollos de engorde.”

En relación con la no inclusión de la observación de las superficies de las articulaciones tibio-tarsal, en los procedimientos de inspección de carcasas de Pollos (Broiler), la División de Protección Pecuaria, está realizando un levantamiento de información técnica y regulatoria a fin de determinar la factibilidad de solicitar al FSIS, una equivalencia en tema.

III. COMPONENTE CUATRO: SISTEMA DE ANÁLISIS DE PELIGROS Y PUNTOS CRÍTICOS DE CONTROL (HACCP) DEL GOBIERNO:

Alcance referente a:

“El examen visual de las canales para la ausencia de contaminación fecal visible no se incluye como parte de las acciones correctivas por parte de los establecimientos.”

En la respuesta de cada establecimiento de aves se considera la modificación de las acciones correctivas y la inclusión de una verificación visual de verificación de efectividad de las acciones correctivas.

A continuación se presentan las acciones implementadas de acuerdo a los hallazgos de la auditoría en cada establecimiento visitado las cuales fueron verificadas por Servicio Agrícola y Ganadero (SAG):

➤ **Establecimiento SOPRAVAL S.A., N° de registro LEEPP: 05-09**

- **20/51:** El plan HACCP de sacrificio implementado por el establecimiento no incluye en las acciones correctivas la inspección visual del producto involucrado en una desviación en el punto de control crítico para tolerancia cero para materia fecal visual

Acción Correctiva:

- La empresa incluyó las verificaciones visuales de las carcasas de pavo posterior a las acciones correctivas definidas en plan HACCP existente frente a un descontrol del Punto de Control Crítico (PCC). El número de carcasas a verificar fue incluido en el plan HACCP.
- La verificación contempla la realización de evaluaciones visuales a las aves comprometidas entre controles de PCC, en un número de 10 carcasas de pavo. Se realiza inmediatamente una vez efectuada la acción correctiva (las 10 primeras aves). La verificación se realiza posterior al sistema de pre-enfriado de las aves (túnel de pre-frio) con el fin de detectar restos de materia fecal.
- El proceso de verificación se realiza en el punto de inspección N° 2, lugar provisto de luz (2152 lux), agua y sanitizante para corregir inmediatamente la potencial presencia de contaminación fecal visible.
- El resultado de la verificación es registrado en el registro HPF-R-00-00-001, Control de lavado final de la canal PCC N°1

Esto fue verificado por el SAG, el 22 de junio de 2016

- **10/51:** Durante el recorrido de las instalaciones, se observó que las estructuras de arriba en un área de producción tenían restos de carne seca y grasa en sus superficies. El programa de saneamiento del establecimiento incluye la limpieza de tal estructura, pero la frecuencia establecida no parece alcanzar el resultado deseado. El personal de la inspección realiza la selección aleatoria de las áreas para la verificación del saneamiento. Sin embargo, esta zona de producción en particular no se había visitado a una frecuencia apropiada.

Acción Correctiva:

- Se realizó aseo el mismo día de la auditoria al final del turno. (Verificado por SAG, Junio 22 de 2016).
 - Se ratificó programa de aseo para superficies tipo 3 para madrugada de lunes 13 de junio de 2016 y se levanta en el Sistema Integrado de Gestión de la empresa la no conformidad asociada (NCA 37). (Verificado por SAG, Junio 22 de 2016).
 - Se listaron las superficies correspondientes a cada área.(Verificado por SAG, diciembre 21 de 2016)
 - Se definió reprogramación en caso de festivo en fin de semana y producción de domingos. (Verificado por SAG, diciembre 21 de 2016)
 - Se realizó análisis de riesgo para así determinar las frecuencias de aseo correspondientes. (Verificado por SAG, diciembre 21 de 2016)
- **51:** La inspección lleva a cabo la verificación de la vigilancia al mismo tiempo que el establecimiento supervisa los puntos críticos de control con respecto a la tolerancia cero para la contaminación fecal y la temperatura de las canales. El hallazgo derivado de las actividades de monitoreo, se documenta como hallazgo identificado por el establecimiento y la inspección. Esta práctica no permite una verificación oficial independiente de la adecuación de la supervisión HACCP por parte del establecimiento.

Acción Correctiva:

- El Equipo de inspección oficial (EIO) realiza las verificaciones a los distintos puntos de control crítico (PCC) de acuerdo al programa de verificación establecido, en tiempos distintos a los ejecutados por la empresa, lo cual se registra en el documento “Registro para la verificación del sistema de autocontrol del establecimiento”, F-PP-IT-032. (Verificado por SAG, julio 02 de 2016).

- **Establecimiento Procesadora de Alimentos del SUR Ltda., N° de registro LEPP: 06-06**
 - **10/51:** Antiguos fragmentos de carne seca y grasa se habían acumulado a lo largo de la base de una de las paredes de las enfriadoras de carcasas. Los funcionarios de inspección evaluaron las condiciones sanitarias de ese enfriador de acuerdo con un programa preparado. Sin embargo, la frecuencia de verificación elegida para esa tarea parece ser insuficiente.

Acción Correctiva:

Se solicita la acción correctiva inmediata al Jefe de Calidad, verificando posteriormente que efectivamente se eliminó toda presencia de material potencialmente contaminante. (Verificado por SAG, junio 22 de 2016)

Se emite una Nota de No Conformidad al establecimiento por la falla en la implementación de los POES especificados para la sala de enfriado de carcasas. (Verificado por SAG, junio 22 de 2016)

Se realiza reunión/capacitación con el EIO (Equipo de Inspección Oficial) para indicar que la revisión de la sala de enfriado de carcasas debe ser más exhaustivo y estricto; además se cambia la frecuencia de revisión en el calendario, de 2 mensuales a 1 revisión diaria en forma pre-operacional. (Verificado por SAG, junio 24 de 2016)

➤ **Establecimiento Faenadora San Vicente Ltda., N° de registro LEEPP: 06-08.**

En el Borrador de Informe Final este establecimiento está identificado erróneamente como “Agroindustrial El Paico N° de registro LEEPP 13-07”

- **20/51:** El plan HACCP de sacrificio que está implementando el establecimiento no incluye en las acciones correctivas la inspección visual del producto involucrado en una desviación en el punto de control crítico para tolerancia cero para materia fecal visual.

Acción Correctiva:

Se modificó la descripción de la acción correctiva del punto de control crítico (PCC) Contaminación Fecal (SV-DC-HACCP-006), incorporando en el párrafo la palabra **INMEDIATAMENTE**, con un texto que señala “Para asegurarse que el sistema está bajo control, se deben efectuar **inmediatamente** 3 monitoreos sucesivos y simultáneos cada 15 minutos aproximadamente en:

- Punto de Inspección.
- Posterior a la ducha de Sanitización

(Verificado por SAG, junio 22 de 2016).

- **26/51:** El establecimiento evalúa el control de los estándares de producto terminado (FPS) para pollos de engorde utilizando un conjunto de no conformidades que difiere del enfoque del FSIS. La inspección en planta no lleva a cabo una evaluación diaria del FPS, sino que sólo observa a los técnicos del establecimiento cuando realizan la prueba.

Acción Correctiva:

Se genera una capacitación el diciembre 16 de 2016 al equipo de Inspección Oficial respecto a lo que es el FPS y como se realiza su monitoreo. Junto a lo anterior se seguirán las instrucciones de la División de Protección Pecuaria al respecto contenidas en la Circular N° 833/2016

A partir de diciembre 19 de 2016, el Equipo de Inspección Oficial (EIO) realiza diariamente una verificación, por cada turno y cada línea de faenamiento, de los procedimientos FPS.

Los lotes que no reúnan el puntaje para cumplir el estándar, son rechazados para la exportación a EE.UU.

(Verificado por SAG, diciembre 19 de 2016).



- **51:** La revisión de los registros mantenidos por el personal de inspección muestra que los resultados de la verificación sanitaria no especifican el detalle de los incumplimientos observados, pero las inscripciones se limitan a informar que el resultado de la verificación no fue conforme.

Acción Correctiva:

El día junio 15 de 2016, se realiza capacitación sobre Verificación del Sistema de Aseguramiento de Calidad, incluyendo el tema sobre la correcta descripción de los hallazgos en la planilla de registro de verificaciones (F-PP-IT-032) ante la detección de una no conformidad en las verificaciones realizadas por el Equipo Oficial.

El día julio 25 de 2016, se reitera instrucción sobre el correcto llenado de registros.

(Verificado por SAG, junio 25 de 2016).

➤ **Establecimiento Frigorífico Temuco S.A., N° de registro LEEPP: 09-12.**

- **10/51:** Durante la verificación pre-operacional del programa de saneamiento, el auditor observó que las Normas de Desempeño del Saneamiento no estaban siendo cumplidas. La superficie de contacto con los alimentos del transportador utilizada para transportar las partes principales de la carcasa se había decolorado. Las superficies de contacto con los alimentos también tenían múltiples rasguños profundos que hacían que fuera difícil de limpiar. Se observó que la grasa y la carne estaban alojadas entre la correa y su armazón metálico. Marcos adicionales encontrados en la habitación, también tenía roto las superficies que hacían difícil de limpiar. Esta deficiencia no había sido identificada por el personal dentro de la planta.

Acciones Correctivas:

- Acción Correctiva Inmediata: Limpieza Inmediata de Superficies de contacto. Esto fue verificado por el Monitor de calidad (Verificado por SAG, junio 13 de 2016)
- Desarme y limpieza quincenal de las superficies de contacto (Verificado por SAG, junio 23 de 2016)
- Aseo Diario de Superficies de contacto directo con una acción mecánica mediante uso de escobillas (Verificado por SAG, junio 23 de 2016)
- Inclusión de estas superficies de contacto directo en programa de monitoreo microbiológico. (Verificado por SAG, julio 01 de 2016).
- Cambio de cintas transportadoras por equipos nuevos. (Verificado por SAG, octubre 03 de 2016).

➤ **Establecimiento Frigorífico de Osorno S.A., N° de registro LEPP: 10-26.**

En el Borrador de Informe Final este establecimiento está identificado erróneamente como “Frigorífico Temuco S.A., N° de registro LEPP: 09-12”

- **10/51:** Las superficies exteriores de las bandejas metálicas utilizadas para transportar las vísceras desde la evisceración hasta las estaciones de inspección no se estaban limpiando adecuadamente. Aunque las superficies de contacto del producto estaban siendo limpiadas y desinfectadas, la ingesta y la contaminación fecal permanecieron en las superficies externas de las cacerolas, ya que continuaron siendo utilizadas. Esta deficiencia sanitaria no había sido anotada por el personal interno.

Acción Correctiva:

Causa: Contaminación externa durante el flujo de circulación en línea debido a las operaciones propias de la Etapa de Evisceración.

- Acción Correctiva: Se implementó una línea de agua a 85°C , que realiza barrido húmedo operacional en superficie externa de bandejas, en momentos de detención de la línea.(Verificado por SAG, Agosto 10 de 2016)
- Acción preventiva: Se incorporó en el SSOP del ítem noria de bandejas de vísceras, la acción descrita en la Acción correctiva. (Verificado por SAG, Agosto 10 de 2016)

➤ **Establecimiento Agro Industrial El Paico S.A., N° de registro LEEPP: 13-07.**

- **20/51:** El plan HACCP de sacrificio que está implementando el establecimiento no incluye en las acciones correctivas la inspección visual del producto involucrado en una desviación en el punto de control crítico (PCC) para tolerancia cero para materia fecal visual.

Acción Correctiva: La empresa frente a la ocurrencia de una desviación en los puntos críticos de control (PCC) 1.1, 1.3, ha establecido como nueva acción correctiva el control visual de un número representativo de las carcasas afectadas durante el tiempo de desvío.

La verificación contempla la realización de dos controles visuales a 100 carcasas en el caso de pollos. En control se hará posterior a la salida de las canales desde el Enfriador (chiller) de agua con el fin de detectar restos de fecas o restos de tracto intestinal.

Para efectuar la verificación, la empresa ha implementado un puesto de inspección en la sala de Pre enfriado de canales (Enfriador (Chiller) de Agua).

Se realizará un primer monitoreo al momento de la pérdida de control del PCC y se volverá a realizar una segunda verificación una hora después de terminada la desviación.

La acción correctiva será registrada en la Planilla de Registro de Acciones Correctivas SAC RAC 01.1.

La empresa realizará la reevaluación del PCC 3 e incluirá los controles visuales de las carcasas de pavo como acción correctiva. El número de carcasas a inspeccionar, la reevaluación y modificaciones al PCC 3 serán incorporados al HACCP durante el transcurso de la semana 27.

Con Fecha 18-06-2016 el equipo de Inspección Oficial:

Realiza una revisión documental de los procedimientos HACCP de la empresa referente al punto crítico de control de cero tolerancia de fecas.

Realiza la inclusión, como medida correctiva al producto frente a una desviación, del control visual de las carcasas a la salida del enfriado por agua.

Se comprueba la implementación de una estación de inspección en la sala.

Realiza supervisión de las acciones correctivas implementadas por la planta cada vez que ocurre una desviación de PCC.

Realiza supervisión presencial al momento que los monitores de calidad de la empresa realizan el control visual de las carcasas a la salida del enfriador (chiller) de agua.

- **26/51:** El establecimiento evalúa los estándares de producto terminado (FPS) para pollos de engorde utilizando un conjunto de no conformidades que difiere del enfoque del FSIS. La inspección en planta no lleva a cabo una evaluación diaria del FPS, sino que sólo observa a los técnicos del establecimiento cuando realizan la prueba

Acción Correctiva:

- El equipo SAG realiza supervisión diaria del procedimiento de monitoreo que realiza la empresa respecto al control de estándares de producto terminado. Junto a lo anterior se seguirán las instrucciones de la División de Protección Pecuaria al respecto contenidas en la Circular N° 833/2016
 - En relación con la inclusión como no conformidad de la presencia de elementos de la articulación tibio-tarsal y de la Glándula Uropígia en carcasas de Pollos (Broiler), la División de protección Pecuaria, está realizando un levantamiento de información técnica y regulatoria a fin de determinar la factibilidad de solicitar al FSIS, una equivalencia en tema.
- **10/51:** La carne seca y los fragmentos de grasa adheridos a grandes áreas de paredes en un área de producción que habían sido considerados aceptables por los monitores de saneamiento del establecimiento.

Acción Correctiva: Posterior al término de la producción del día 13 se realiza durante el aseo pre operacional de las salas afectadas acciones correctivas para corregir las deficiencias encontradas.

La empresa realiza una evaluación de la frecuencia del programa de altura de la planta y se modifica la periodicidad de realización de aseo en las salas donde se detectaron los problemas. Se cambia la frecuencia anterior de 12 días a 7 días de manera inmediata.

A su vez se programa la realización de la una reevaluación de la frecuencia de aseo de alturas de todas las salas de la planta el cual será presentado la semana 26 y su puesta en marcha se llevará a cabo a partir de la semana 27 del presente año.

Con Fecha 14-06-2016 por parte del equipo de Inspección Oficial:

- Se realiza Verificación del aseo pre operacional de la sala IQF 2 y Deshuesado de Pechugas de Pollo donde fueron detectaron problemas en las estructuras aéreas.
 - Se comprueba la realización de las acciones correctivas pertinentes antes del comienzo de los procesos productivos.
 - Se verifica la modificación del programa de limpieza de altura de la planta, comprobando el acortamiento de los tiempos de realización a las salas implicadas a un intervalo de 7 días.
- 46/51: El Establecimiento estaba realizando la recuperación y reacondicionamiento de las canales de manera antihigiénica. Se superó la capacidad de la estación de reacondicionamiento y las canales limpias, desinfectadas y recortadas permanecían en la línea que entraba en contacto con las canales contaminadas no recortadas que no habían sido retiradas de la línea a ser reprocesada. En respuesta a la situación, los funcionarios de inspección de la línea de sacrificio condenaron todas las canales que no pudieron ser recuperadas o reacondicionadas y el establecimiento ajustó el flujo del producto. Los funcionarios de inspección indicaron que la medida correctiva para este tipo de deficiencia fue notificada previamente al establecimiento, que había ofrecido una acción correctiva a largo plazo que está programada para ser implementada completamente antes de septiembre de 2016. Sin embargo, el personal de inspección necesita ejercer un mayor control sobre la velocidad de la línea de sacrificio cuando las condiciones son menos que óptimas y resultan en un en un proceso no higiénico.

Acciones Correctivas:

- Se Cursa la Notificación de No Cumplimiento N° 028 por Incumplimiento al Sistema de Aseguramiento de Calidad de la Empresa, por Deficiencias en el manejo Sanitarios de Carcasas de Aves en estación de Reproceso :
- Respuesta Frente a NNC 028:
 - La empresa genera producto de la NNC cursada, un cronograma de trabajo que aborda de manera integral el sistema de reproceso actual y define modificaciones a realizar tanto en lo estructural como en la forma de trabajo del personal.
 - Se realizó un alargamiento de la línea de reproceso en 3 metros, para incorporar nuevos puestos de trabajos.



- Cambio de ganchos de colgado y aumento en el espaciado de éstos, con el fin de evitar la sobre posición de carcasas y eliminar la contaminación cruzada por contacto
- Modificación de las líneas de lavado de carcasas para asegurar mejor volumen y presión de agua
- Instalación de lavamanos y esterilizados por cada estación de trabajo de reproceso (corte de cogote y buche, expurgo y aspirado)
- Modificación de la ducha de lavado y sanitizado de carcasas
Incorporación de una línea directa hacia Chiller de agua que transporte las canales reprocesadas de la sala de eviscerado.

Con Fecha 12-09-2016 por parte del equipo de Inspección Oficial se verifica:

- Que Se aumentó la dotación de trabajadores y se realiza capacitación técnica por parte de la planta a sus operarios.



ALCANCES AL INFORME DE AUDITORÍA.

A continuación, la División de Protección Pecuaria se permite realizar algunos comentarios referentes a lo indicado en el informe de Auditoria los cuales se señalan a continuación.

En los “APENDICES” en el “Appendix A: Individual Foreign Establishment Audit Checklist”, se adjuntan dos reportes del Establecimiento El Paico (13-07), y dos reportes del Establecimiento Frigorífico Temuco (09-12).

- En el caso de los reportes del Establecimiento El Paico el Primer reporte corresponde al establecimiento San Vicente (06-08).
- En el caso del Establecimiento Frigorífico Temuco, el Segundo Reporte corresponde al establecimiento frigorífico Osorno (10-26).

**COMMENTS FROM THE LIVESTOCK AND AGRICULTURE SERVICE (SAG) ON THE FSIS AUDIT
REPORT CONDUCTED FROM JUNE 6 THROUGH JUNE 24, 2016**

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

The scope refers to:

“The practices in use to evaluate the competence of in-plant personnel do not follow standardized procedures to objectively assess and document the skills and abilities of individual inspectors, the Record and the documentation of corrective actions when deficiencies are detected in the performance of the Official Inspection Team. In addition, instructions and guidance from the Central Competent Authority (CCA) provided to inspection personnel and establishments on the re-inspection of broilers in accordance with Finished Product Standards (FPS) do not describe the respective responsibilities of inspection personnel and the establishments. As a result, inspection officials do not collect carcasses from each production line to assess the product for compliance with the finished product standards. Conversely, establishments evaluate processing non-conformances, but disregard the presence of long shanks (the tibio-tarsal joint not exposed) and the presence of uropygial glands (oil glands) as defects, even though FSIS considers both of those defects as processing non-conformances.”

With regard to the lack of standardized procedures to objectively assess the skills and abilities of individual inspectors, the CCA (SAG Livestock Protection Division) has issued Circular N°. 833/2016 (enclosed), with instructions to implement a system to evaluate the technical skills of the Official Inspection Team.

Furthermore, and as regards instructions and guidance from the Central Competent Authority (CCA) provided to inspection personnel and establishments on the re-inspection of broilers in accordance with Finished Product Standards (FPS), we have issued Circular N°. 833/2016 (enclosed), instructing all poultry slaughter establishments eligible for export to the United States to conduct, for each shift and each slaughter line (by Direct Observation or Record Reviewing or Direct Measuring), a daily verification of the FPS Standard Control procedures for each establishment by the Official Inspection Team. In the case that a batch does not attain the required score to meet the standard, this batch will be rejected for export to the United States. These activities shall be part of the verifications of the establishment’s Quality Assurance System (QAS) and will be recorded in the document “Verification record of the establishment’s self-control system”, F-PP-IT-032.

Lastly, and with regard to the inclusion of the presence of long shanks (the tibio-tarsal joint not exposed) and the presence of uropygial glands (oil glands) in broiler carcasses as non-conformances, the CCA is gathering technical and regulatory information in order to determine the feasibility of requesting the FSIS for an equivalence on this subject.

II. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY, FOOD SAFETY, AND OTHER CONSUMER PROTECTION REGULATIONS (INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

The scope refers to:

“The PMI procedures for broilers do not include an observation of the surfaces of the tibio-tarsal joints, which is a deviation from FSIS equivalence criteria. The CCA has not requested FSIS to conduct a new equivalence determination for the modified PMI procedures for broilers.”

With regard to not including an observation of the surfaces of the tibio-tarsal joints in the inspection procedures of broiler carcasses, the CCA is gathering technical and regulatory information in order to determine the feasibility of requesting the FSIS for an equivalence on this subject.

III. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM:

The scope refers to:

“Visual examination of carcasses for the absence of visible fecal contamination is not included as part of the corrective actions of the establishments.”

The actions implemented in accordance with the audit findings in each of the visited establishments are described below, as verified by the SAG (Livestock and Agriculture Service):

- **Establishment: SOPRAVAL S.A., Establishment Registration No.: 05-09**
 - **20/51:** The slaughter HACCP plan being implemented by the establishment, does not include in the corrective actions, visual inspection of product involved in a deviation at the critical control point for zero tolerance for visual fecal matter.

Corrective Action:

- The establishment included the visual verification of turkey carcasses after corrective actions were defined in the existing HACCP plan for an out-of-control Critical Control Point (CCP). The number of carcasses to be verified was included in the HACCP plan.
- The verification entails conducting the visual examination of compromised poultry between CCP controls, at a rate of 10 turkey carcasses. This is immediately carried out once the corrective action has been implemented (the first 10 carcasses). The verification is conducted after the poultry passes through the pre-chilling system (pre-chilling tunnel) in order to detect any remaining fecal matter.
- The verification process is conducted at Inspection Point No. 2, provisioned with light (2152 lux), water and sanitizing product to immediately correct the potential presence of visible fecal contamination.
- The verification result is recorded in Record HPF-R-00-00-001, Control of final carcass wash CCP No.1

This was verified by the SAG on June 22, 2016

- **10/51:** During the tour of the facilities, overhead structures in one production area were observed to have dry meaty residue and fat on their surfaces. The establishment's sanitation program includes cleaning of such structures, but the established frequency does not appear to meet the desired outcome. Inspection personnel conduct random selection of areas for verification of sanitation. However, this particular production area had not been visited at an appropriate frequency.

Corrective Action:

- Cleanup was performed on the same day of the audit at the end of the shift. (Verified by the SAG on June 22, 2016).
 - The cleanup program was ratified for type 3 surfaces on the morning of June 13, 2016 and the associated non-conformance (NCA 37) was recorded by the establishment's Integrated Management System. (Verified by the SAG on June 22, 2016).
 - The corresponding surfaces of each area were listed. (Verified by the SAG on December 21, 2016).
 - Re-programming was defined for weekend holidays and Sunday production. (Verified by the SAG on December 21, 2016).
 - A hazard analysis was conducted to determine the frequencies of the corresponding cleanups. (Verified by the SAG on December 21, 2016).
- **51:** Inspection conducts verification of monitoring at the same time that the establishment monitors the critical control points for zero tolerance for fecal contamination and temperature of carcasses. The findings derived from the monitoring activities, are documented as findings identified by both establishment and inspection. This practice does not allow an independent official verification of the adequacy of HACCP monitoring on the part of the establishment.

Corrective Action:

- The Official Inspection Team (EIO) carries out the verification of different critical control points (CCP) in accordance with the established verification program at different times than those conducted by the establishment, which is recorded in the document "Verification record of the establishment's self-control system", F-PP-IT-032. (Verified by the SAG on July 2, 2016).

➤ **Establishment: Procesadora de Alimentos del SUR Ltda., Establishment Registration No.: 06-06**

- **10/51:** Old dry meat and fat fragments had accumulated along the base of one of the walls of the carcass chilling coolers. Inspection officials assessed the sanitary conditions of that cooler in accordance with a prepared schedule. However, the chosen verification frequency for that task seems to be inadequate.

Corrective Action:

The immediate corrective action was requested from the Quality Supervisor, who subsequently verified that all presence of potentially contaminating fecal matter had effectively been eliminated. (Verified by the SAG on June 22, 2016).

A Non-conformance Note was issued to the establishment for failure to implement the specific SSOPs for the carcass chilling room. (Verified by the SAG on June 22, 2016).

A meeting/training session was held with the EIO to inform them that the revision of the carcass chilling room must be more exhaustive and rigorous. In addition, the calendar of the revision frequency was changed from 2 monthly to 1 daily revision as a pre-operational task. (Verified by the SAG on June 24, 2016).

➤ **Establishment: Faenadora San Vicente Ltda., Establishment Registration No.: 06-08.**

The Draft Final Report erroneously identifies this establishment as “Agroindustrial El Paico N° de registro LEEPP 13-07”

- **20/51:** The slaughter HACCP plan being implemented by the establishment, does not does not include in the corrective actions, visual inspection of product involved in a deviation at the critical control point for zero tolerance for visual fecal matter.

Corrective Action:

The description was modified of the corrective action of the critical control point (CCP) Fecal Contamination (SV-DC-HACCP-006), incorporating the word IMMEDIATELY in the paragraph, as part of a text that states “In order to ensure the system is under control, 3 consecutive and simultaneous controls must be conducted immediately approximately every 15 minutes:

- at the point of inspection
- after the sanitation shower

(Verified by the SAG on June 22, 2016).

- **26/51:** The establishment evaluates the finished product standards (FPS) for broilers using a set of non-conformances that differs from FSIS approach. In-plant inspection does not conduct a daily assessment of the FPS, but only observe the establishment technicians as they perform the tests.

Corrective Action:

A training session was generated on December 16, 2016 for the Official Inspection Team as regard to what the FPS is and how to monitor it. Along with this, CCA (Livestock Protection Division) instructions will be followed to this end provided in Circular No.

As of December 19, 2016, the Official Inspection Team will conduct a daily verification, on each shift and each slaughter line, of FPS procedures.

The batches that do not score enough points to meet the standard will be rejected for export to the United States.

(Verified by the SAG on December 19, 2016).

- **51:** Review of records maintained by inspection personnel show that sanitary verification results do not specify the details of observed non-compliances but the entries are limited to report that the result of the verification was not in compliance.

Corrective Action:

On June 15, 2016, training was conducted on Verification of the Quality Assurance System, including the correct description of findings on the worksheet of the verification record (F-PP-IT-032) in case a non-conformance is detected during the verifications carried out by the Official Inspection Team.

On July 25, 2016, instruction was repeated on how to correctly fill in records.

(Verified by the SAG on June 25, 2016).

➤ **Establishment: Frigorífico Temuco S.A., Establishment Registration N° : 09-12.**

- **10/51:** During pre operational verification of the sanitation program standards, audit observed that were not being complied with. The food contacting surface of the conveyor used to transport the carcass main parts had been discolored. Food contact surfaces also had multiple deep scratches that made it difficult to clean. It was observed that the fat and meat were allocated between the belt and its metal frame. Additional frames found in the room, also had broken surfaces that made it difficult to clean. This deficiency had not been identified by the staff within the plant.

Corrective actions:

- Immediate Corrective Action: Immediate cleaning of contact surfaces. This was verified by the Quality Monitor (Verified by SAG, June 13, 2016)
- Disarm and biweekly cleaning of contact surfaces (Verified by SAG, June 23, 2016)
- Daily cleaning of surfaces of direct contact with a mechanical action through the use of brushes (Verified by SAG, June 23, 2016)
- Inclusion of these direct contact surfaces in the microbiological monitoring program. (Verified by SAG, July 01, 2016).
- Change of conveyors for new equipment. (Verified by SAG, October 03, 2016).

➤ **Establishment of Osorno Refrigerator S.A., Establishment Registration N° : 10-26.**

In the Final Report draft this establishment is erroneously identified as "Temuco Friar S.A., Registration No. LEEPP: 09-12"

- **10/51:** The outer surfaces of the metal trays used to transport the viscera from evisceration to the inspection stations were not being properly cleaned. Although the product's contact surfaces were being cleaned and disinfected, ingestion and fecal contamination remained on the outer surfaces of the pans as they continued to be used. This health deficiency had not been noted by internal staff.

Corrective action:

Cause: External contamination during in-line circulation flow due to the operations of the Evisceration Stage.

- Corrective Action: A water line was implemented at 85 ° C, which performs operational wet sweeping on the outer surface of trays, at times where the line has been stop. (Verified by SAG, August 10, 2016)

Preventive action: The action described in the corrective action was incorporated in the SSOP of the wash system item of trays of viscera. (Verified by SAG, August 10, 2016)

➤ **Establishment: Agro Industrial El Paico S.A., Establishment Registration N° : 13-07.**

- **20/51:** The slaughter HACCP plan that has been implementing the establishment does not include in their corrective actions the visual inspection of the product involved in a deviation at the critical control point (CCP) in zero tolerance for visual feces.

Corrective Action: the company has established, as a new corrective action, the visual control of a representative number of carcasses affected during the deviation time, in the face of the occurrence of a deviation at the critical control points (CCP) 1.1, 1.3.

The verification contemplates the realization of two visual controls to 100 carcasses for broilers. This control is carry out after the carcasses exit from the chiller in order to detect remains of feces or traces of intestinal tract.

In order to carry out the verification, the company has implemented an inspection post in the pre-cooled carcass room (chiller).

A first monitoring will be performed at the time of CCP control loss and a second verification will be made again one hour after the deviation has ended.

The corrective action will be recorded in the Corrective Action Registry Sheet SAC RAC 01.1.

The company will conduct the reassessment of CCP 3 and will include the visual controls of turkey carcasses as a corrective action. The number of carcasses to be inspected, the reassessment and modifications to CCP 3 will be incorporated into HACCP during the course of week 27.

Date 06-18-2016 the Official Inspection Team:

Performs a documentary review of the HACCP procedures of the company regarding the control critical point of zero feces tolerance.

Performs the inclusion, as a corrective measure to the product when a deviation occurs, of a carcass visual control at water cooling (chiller) exit.

The implementation of an inspection station in the room is checked.

Performs a corrective actions supervision implemented by the plant whenever a deviation from the CCP occurs.

Performs face-to-face supervision at the quality monitors of the company carry out the carcass visual inspection at the chiller exit.

- **26/51:** The establishment evaluates finished product standards (FPS) for broiler using a set of nonconformities that differs from the FSIS approach. The plant inspection does not carry out a daily evaluation of the FPS, but only observe the technicians when the test is carry out.

Corrective action:

- The SAG team performs daily supervision of the monitoring procedure performed by the company with respect to the control of the standards of the finished product. Along with the above, will be follow the instructions of the Livestock Protection Division contained in Circular N°. 833/2016

- In relation to the inclusion as a non-conformity of tibio-tarsal joint and of the gland Uropygia presence in broiler carcasses, the Livestock Protection Division is conducting a survey of technical and regulatory information to determine the feasibility to quest FSIS an equivalence in the subject.

- **10/51:** Dry meat and fat fragments adhered to large areas of walls in a production area, which were accepted by the establishment sanitation monitors.

Corrective Action: After day 13 production end, corrective actions are taken during the preoperational cleaning of the rooms related to the corrective action to correct the deficiencies found.

The company conducts a plant evaluation of the height program frequency and modifies the periodicity of the tests in the rooms where the problems were detected. The previous frequency is changed from 12 days to 7 days immediately.

At the same time, it has been planned to carry out a cleaning frequency reevaluation of heights of all plant rooms, which will be presented at week 26 and its implementation will be carried out on week 27 of this year.

Date 06/14/2016, by the Official Inspection Team:

- Verification of the preoperative cleaning of the room IQF 2 and deboning of Chicken Breasts in which problems were detected in the aerial structures.
- Proper corrective actions were checked before the beginning of the productive processes.
- The modification of the height-cleaning program of the plant is verified, checking the execution time decrease in the involved rooms at interval of 7 days.
- o **46/51:** The Facility was performing the carcass recovery and reconditioning in an unhygienic manner. The capacity of the reconditioning station was exceeded and the clean carcasses, disinfected and trimmed remained on the line having contact with the untrimmed contaminated carcasses that had not been removed from the line to be reprocessed. In response to the situation, slaughter line inspection officials condemned all carcasses that could not be recovered or reconditioned and the establishment adjusted the product flow. Inspection officials indicated that the corrective measure for this type of deficiency was previously notified to the facility, which had offered a long-term corrective action that is scheduled to be fully implemented by September 2016. However, inspection personnel requires to exercise greater control over the speed of the slaughter line when conditions are less than optimal and result in a non-hygienic process.

Corrective actions:

- Notification of non-Compliance N °028 for Failure to comply with the Company's Quality Assurance System, due to Deficiencies in the sanitary handling of Poultry carcasses, in reprocess station:
- Response to NNC 028:
 - The company generates due to the NNC, a work schedule that comprehensively addresses the current reprocessing system and defines modifications to be made both in the structural and personnel related management.
 - An extension of the reprocessing line of 3 meters was made, to include new workstations
 - Hanging hooks renewal and space increase between them, in order to avoid overcrowding and eliminate cross-contamination by contact
 - Modification of wash lines to ensure better volume and water pressure
 - Installation of lavatories and sterilized by each reprocessing workstation (cut of neck and crop, purge and aspirated)
 - Modification of the washing show and sanitizing of carcasses. Incorporation of a direct line towards water chiller that transports the reprocessed carcasses to the eviscerated room.

Date 12-09-2016 by the Official Inspection team, it is verified that:

Number of workers has increased, and the plant applied technical training to its operators.

Comments regarding the audit report

Subsequently, the Livestock Protection Division would like to make some comments regarding what the Audit report, which are as follows.

In the Appendix, specifically in Appendix A: "Individual Foreign Establishment Audit Checklist", are attached two reports of the "El Paico Establishment (13-07)", and two reports of "Temuco Refrigerator Establishment (09-12)".

- In the case of the reports of the "El Paico" establishment the first report corresponds to the "San Vicente establishment (06-08)".
- In the case of the "Temuco Refrigerator" establishment, the Second Report corresponds to the "Osorno refrigerator (10-26)".



Santiago,

COURTESY TRANSLATION

**MRS.
JANE DOHERTY
INTERNATIONAL COORDINATION EXECUTIVE
FOOD SAFETY AND INSPECTION SERVICE OFFICE OF INTERNATIONAL COORDINATION**

Dear Mrs. Doherty,

Along with my cordial greetings, I am writing you in order to send the comments and actions taken by the Agricultural and Livestock Service in front of the detected findings indicated in the draft final report of the audit conducted in Chile, between June 06th and June 24th of 2016 in which the Chilean food safety system governing the production of meat and poultry products intended for export to the United States of America was evaluated.

I will be glad to answer or clarify any doubt or concern that you may have.

Best regards,

**JOSÉ IGNACIO GÓMEZ MEZA
JEFE DIVISIÓN PROTECCIÓN PECUARIA
SERVICIO AGRÍCOLA Y GANADERO**





CIRC. Nº : 833/2016

ANT. : NO HAY

MAT. : INSTRUYE IMPLEMENTACIÓN DE MEDIDAS EN EL SISTEMA DE INSPECCIÓN OFICIAL SAG, A FIN DE ABORDAR LAS OBSERVACIONES DE LA AUDITORIA DE INSPECCIÓN REALIZADA POR EL FSIS.

SANTIAGO, 26/12/2016

DE : JEFE (S) DIVISIÓN PROTECCIÓN PECUARIA OR.OC

A : SEGÚN DISTRIBUCIÓN

En consideración con las observaciones indicadas por en el borrador del "Informe Final" de la auditoría realizada por el FSIS en Chile entre el 06 y el 24 de junio de 2016, comunico a usted, que después de realizar el análisis de este documento, la División ha determinado instruir la implementación de las siguientes acciones de forma inmediata, con el fin de elaborar en conjunto con las regiones, las acciones definitivas a implementar en el "Sistema de Inspección de carnes de Chile":

1. Evaluación de capacidades técnicas:

a) En establecimientos con inspección permanente los Médicos Veterinarios Inspectores Oficiales (MVIO), a cargo de equipos de inspección, deberán mantener, en las oficinas oficiales en el establecimiento, las evaluaciones realizadas a los "Equipos de Inspección Oficial", a fin de contar con la información que permita identificar las brechas de capacitación y tomar acciones correctivas correspondientes.

Esta debe considerar al menos: una evaluación cuatrimestral de las siguientes actividades: inspección en línea, verificación de los SAC y programas de prerrequisitos; basada en normativa nacional y requisitos de terceros países habilitados para el establecimiento. Esta evaluación deberá ser realizada por los Supervisores Regionales, de forma tal que en el año se evalúe a todo el equipo.

b) En establecimientos con inspección esporádica los Jefes de Oficina, deberán mantener las evaluaciones realizadas a los Médicos Veterinarios sectoriales que realizan labores de Inspección Oficial en establecimientos LEEPP de productos cárnicos del sector, a fin de contar con información que permita identificar las brechas de capacitación y tomar acciones correctivas correspondientes.

Esta debe considerar al menos: una evaluación anual de las siguientes actividades: verificación de los SAC y programas de prerrequisitos; basada en normativa nacional y requisitos de terceros países habilitados para el establecimiento. Esta evaluación deberá ser realizada por los Supervisores Regionales, de forma tal que en el año se evalúe a todo el equipo sectorial que realizan estas funciones.

2. En el caso de los establecimientos faenadores de aves, el Equipo de Inspección Oficial (EIO) deberá realizar diariamente una verificación, por cada turno y cada línea de faenamamiento (Observación Directa o Revisión de Registros o Medición Directa), de los procedimientos de Control de Estándares de Producto Final implementado por cada empresa. En el caso de que un lote no reúna el puntaje necesario para cumplir con el estándar, este lote deberá ser rechazado para exportar a los EE.UU. Estas actividades deberá ser parte de las verificaciones al SAC del establecimiento y deberán quedar registradas en el documento "Registro para la verificación del sistema de autocontrol del establecimiento", F-PP-IT-032.

Las acciones instruidas permitirán dar una respuesta inicial a las observaciones indicadas para los componentes uno y cuatro de la auditoría del FSIS; adicionalmente informo a Ud., que para el caso de las observaciones del componente dos y las relacionadas con el control de estándares de productos final, esta División está realizando un levantamiento para identificar la factibilidad de presentar una solicitud de equivalencia para las diferencias que se identificaron entre el sistema de Chile y la normativa de EE.UU..

Finalmente adjunto el resumen del Informe Borrador del FSIS, elaborado por esta División.

Saluda atentamente



JOSE ALFREDO HERRERA RODRIGUEZ
JEFE (S)
DIVISIÓN PROTECCIÓN PECUARIA

DGM/ECS/OVP

Incl.: Documento Digital: Resumen Informe FSIS

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División Protección Pecuaria - Paseo Bulnes N° 140



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