USDA

United States Department of Agriculture

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Food Safety and
Inspection Service

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Washington, D.C.
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Ing. Ricardo Paz Mejía, Director
Servicio Nacional de Sanidad Agropecuaria (SENASA)
Secretaría de Agricultura y Ganadería (SAG)
Tegucigalpa, M.D.C.
Honduras

Dear Ing. Paz Mejía,

The Food Safety and Inspection Service (FSIS) conducted an ongoing on-site equivalence verification audit of Honduras' inspection system governing raw beef products from April 16 through April 20, 2018. Enclosed is a copy of the final audit report. The comments received from the Government of Honduras are included as an attachment to the report.

FSIS acknowledges that SENASA has provided documentation to address the findings noted during the on-site audit. FSIS is in the process of evaluating your response, and once complete, FSIS will notify you.

For any questions regarding the FSIS audit report, please contact the Office of International Coordination, by electronic mail at InternationalCoordination@fsis.usda.gov.

Sincerely,

Sharon McMurtrey

for Janell Kause
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

HONDURAS

APRIL 16-20, 2018

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

RAW BEEF PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

September 10, 2018

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from April 16-20, 2018. The purpose of the audit was to determine whether Honduras' food safety inspection system governing raw beef products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Honduras currently exports the following subcategories of raw-intact and raw non-intact beef to the United States: boneless manufacturing trimmings; edible offal; primals and subprimals.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., 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 Residue Testing Programs; and (6) Government Microbiological Testing Programs.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditor identified the following findings:

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- The FSIS auditor identified inconsistent official verification procedures related to the control of specified risk materials (SRM) in cattle. At one of the two audited slaughter establishments, the official post-mortem head inspector performed removal of the lingual tonsils (rather than establishment personnel, as required by Honduras' official written inspection procedures). In addition, the establishment was not maintaining records to demonstrate the removal of the brain, skull, eyes, trigeminal ganglia, tonsils, vertebral column, dorsal root ganglia, and distal ileum during implementation of its SRM control program; only the removal of the spinal cord was recorded. This is a significant finding. However, this was a recently certified establishment that had not yet exported to the United States.

Government Hazard Analysis and Critical Control Points (HACCP) System

- At one of the two audited slaughter establishments, the operating parameters associated with the application of an antimicrobial rinse was not consistent with the documentation maintained by the facility to support decisions within its HACCP system. The validation study maintained by the establishment referenced a lactic acid concentration of 2.5%, while the production records indicated that the acid concentration applied was typically below this value.
- At one of the two audited slaughter establishments, the critical limit associated with the critical control point for carcass chilling addressed only internal temperature without a reference to time. Review of the establishment's hazard analysis determined that this critical control point was established to control the growth of microbial pathogens. From a scientific standpoint, the parameters of both time and temperature should be applied when addressing the growth-curve of microorganisms.

During the audit exit meeting, the Central Competent Authority (CCA) committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Honduras' food safety system from April 16-20, 2018. The audit began with an entrance meeting held on April 16, 2018, in Tegucigalpa, Honduras, during which the FSIS auditor discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – the National Plant and Animal Health Service (*Servicio Nacional de Sanidad e Inocuidad Agroalimentaria* [SENASA]).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety system governing raw beef products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged.

Honduras is eligible to export raw-intact and raw non-intact beef products to the United States. The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Honduras as free from foot and mouth disease and rinderpest. APHIS restricts export of raw pork because of classical swine fever (hog cholera). Honduras currently exports the following subcategories of raw intact beef to the United States: boneless manufacturing trimmings; edible offal; primals and subprimals.

FSIS applied a risk-based procedure that 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, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the self-reporting tool (SRT).

Representatives from the CCA accompanied the FSIS auditor throughout the entire audit. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., 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 Residue Testing Programs; and (6) Government Microbiological Testing Programs.

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

The FSIS auditor visited all (two) cattle slaughter establishments certified as eligible to export raw beef to the United States. There are currently no other processing establishments in Honduras which are certified as eligible to export in the United States. During the establishment

visits, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditor examined the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2.

Additionally, FSIS audited the microbiological and chemical residue testing departments of the Honduras' National Laboratory (Laboratorio Nacional de Análisis de Residuos [LANAR]) to verify its ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits	#	Locations
Competent Authority	1	• SENASA headquarters, Tegucigalpa
Laboratories	2	• LANAR (government laboratory) microbiological testing division, Tegucigalpa • LANAR (government laboratory), chemical residue testing division, Tegucigalpa
Cattle slaughter establishments	2	• Establishment 4, Empresa Ganadera de Honduras S.A. de C.V., Catacamas • Establishment 20M, Agroindustrias Del Corral, Siguatepeque

FSIS performed the audit to verify the food safety inspection system met requirements equivalent to those under the specific provisions of 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. 1901-1906); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of Honduras' inspection system for raw beef products 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 World Trade Organization's *Agreement on the Application of Sanitary and Phytosanitary Measures*.

III. BACKGROUND

From January 1, 2015 to October 31, 2017, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 3,523,120 pounds of raw beef exported by Honduras to the United States. FSIS also performed reinspection on 507,481 pounds at POE for additional verification activities, including visual inspection, chemical residue analysis, and testing for microbiological pathogens: Shiga toxin-producing *Escherichia coli* (STEC) O157:H7, O26, O45, O103, O111, 0121, and O145. As a result of these additional inspection activities, FSIS rejected one lot of raw beef product (42,000 pounds) for the presence of fecal contamination.

The current audit (i.e., that reflected in this report) included a visit to the establishment implicated in the above-referenced POE violation, for which FSIS concluded that SENASA had satisfactorily worked with the food business operator to identify the root causes of the problem and institute appropriate corrective actions. This included a) verification of the establishment's traceability program to properly identify slaughter dates and other implicated product; b) review of sanitary slaughter and HACCP records for the specific dates; c) follow-up review of sanitary dressing procedures on the day of the investigation; and d) review of microbiological (establishment) and chemical (government) testing records, for which no violative results were identified.

The previous FSIS audit conducted in 2015 included visits to the central headquarters, two laboratories, and one cattle slaughter establishment. The onsite verification audit identified only isolated findings within the Government Sanitation and Government HACCP System components, which the CCA promptly and adequately corrected. None of the audit findings impacted Honduras' ongoing equivalence.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Honduras' SRT responses and supporting documentation. During the audit, the FSIS auditor conducted interviews, reviewed records, and made observations to determine whether Honduras' food safety inspection system governing raw intact beef is being implemented as documented in the country's SRT responses and supporting documentation.

The FSIS final audit reports for Honduras' food inspection safety system are available on the FSIS Web site 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 (E.G., ORGANIZATION AND ADMINISTRATION)

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

The FSIS auditor verified that SENASA continues to maintain the overall responsibility for policy, legislation, and implementation of official controls in relation to food safety in accordance with *Phytosanitary Law-157-94* and *Executive Decree 344-2005*. These laws establish SENASA as the CCA for Honduras. Specifically, the Sub-Directorate General for Agrifood Safety (SGIA) is the staff within SENASA that is responsible for the inspection of meat products that are exported to the United States.

Within Section X of its *Guidelines for the Inspection of Meat Products* (*GIPC-05*), SENASA has developed a procedure for the certification of establishments. While onsite, the FSIS auditor reviewed documents specifically for the approval process for one cattle slaughter establishment that was newly certified to export to the United States since the last audit (Establishment 20M). This review indicated that the above-referenced approval process was implemented as intended.

SENASA controls the processing of animal products and by-products in all of their establishments through the Official Veterinary Inspector (OVI), Official Auxiliary Inspectors (OAIs), and Supervisory Official Veterinarians (SOV). While onsite, FSIS verified that inspection personnel possessed the appropriate educational credentials, training, and experience to carry out their inspection tasks. All OVIs must have a Doctor of Veterinary Medicine or equivalent degree, and the OAIs have specialized experience or education that allows them to perform their assigned duties. The FSIS auditor also verified through monthly payroll documents (*SENASA Planilla Mensual de Salarios*) and employment contracts (*Contrato de Servicios Personales No.71/3*) that personnel assigned to establishments certified to export meat products to the United States are SENASA employees paid directly by the Honduran government.

The FSIS auditor verified that inspectors had successfully completed the induction-training program outlined in Section II of *GIPC-05*. All new employees complete supplemental training on meat inspection regulations, inspection and verification activities, and country-specific export requirements. Successful completion of training is the fundamental requirement for personnel to be assigned to perform inspection and verification procedures. Veterinary and non-veterinary personnel receive on-the-job training when they are first assigned to establishments certified to export to the United States. SENASA also provides ongoing specialized-training on FSIS requirements to inspectors at least once a year. The FSIS auditor noted that recent training included a course for Food Safety Practices and Animal Welfare in Cattle (Texas Tech University), as well as attendance at the 2017 FSIS Equivalence Seminar (Bogota, Colombia).

SENASA has the authority and responsibility to ensure that adulterated product is not eligible for United States export. Article 8 of *Agreement No. 552-05* defines an adulterated food product to be any food product that does not match its chemical composition and organoleptic characteristics, nomenclature, legal name, and established regulations. Section IX of *GIPC-05* requires that establishments certified as eligible to export to the United States develop product recall procedures. The FSIS auditor noted that each audited certified establishment maintained comprehensive recall procedures and maintained records sufficient to conduct trace-back activities if adulterated product were exported to the United States. No product recalls have occurred in recent history regarding product from Honduras.

The FSIS auditor reviewed documents maintained at the government offices and verified that SENASA's regulatory directives and procedures are designed to enforce Honduras' laws that apply to the safe production of beef products for human consumption destined for domestic and international markets. SENASA supplements core regulatory issuances with updates to export requirements and administrative notifications distributed electronically to officials in the field. FSIS interviewed inspection personnel and verified that they were knowledgeable of work instructions, operational procedures, and regulatory guidance provided to them by SENASA to

conduct inspection activities and verify that food safety controls at the establishments certified to export raw beef products to the United States were adequate.

The FSIS auditor verified that laboratories conducting analyses of raw beef exported to the United States comply with *International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 17025*. The primary laboratory used in conjunction with export to the United States is LANAR, with the exception of a private laboratory in Costa Rica ("LAMBDA") which is contracted by SENASA to confirm the presence of antibiotic residues. All methods of analysis used by both laboratories are scientifically validated. SENASA performs onsite audits of the LANAR laboratory at a minimum of once per year, with the purpose of ensuring adherence to ISO 17025 standards as well as the use of approved methods of analysis. SENASA also verifies maintenance of the ISO 17025 accreditation for the contracted laboratory in Costa Rica.

During the visit to LANAR, the FSIS auditor verified SENASA's ability to coordinate evaluations of laboratory performance, including proficiency testing schemes for analysts and evaluations of the quality controls maintained by laboratory managers. FSIS also verified that laboratory managers possess relevant academic credentials and experience as analysts in their specialty areas.

The FSIS auditor concluded that SENASA continues to organize and administer its food safety inspection system in a manner that meets the core requirements for this component.

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

The second of six equivalence components that the FSIS auditor reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; inspection on the line during all slaughter operations; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

During visits to two cattle slaughter establishments, the FSIS auditor verified that the OVI conducts ante-mortem inspection in accordance with the *Regulation for the Inspection of Meat and Meat Products (No. 078-00)*. The FSIS auditor verified that this was being conducted as prescribed on the day of slaughter through observation of ante-mortem inspection and a review of ante-mortem condemnation records. In accordance with procedures and requirements, the OVI observed all animals at rest and in motion to determine whether they are fit for slaughter. Each establishment presented a designated observation pen for further examination of suspect animals. The FSIS auditor observed and verified that all animals have access to water in all holding pens (including the pens used for suspect animals); and that if animals are held

overnight, feed is provided. Within Section VIII of *GIPC-05,* SENASA has adopted a zero tolerance policy against the slaughter of non-ambulatory disabled cattle.

The FSIS auditor verified that government inspection personnel were performing continuous on-line post-mortem inspection of each and every carcass at the two audited cattle slaughter establishments, in accordance with the *Regulation for the Inspection of Meat and Meat Products (No. 078-00),* Chapter IX, Articles 288 and 289. The FSIS auditor observed the performance of the inspection personnel examining the heads, viscera, and carcasses in which the proper incision, observation, palpation of required organs, and lymph nodes were made. Line synchronization between carcasses and viscera was properly maintained. Inspection stations were staffed with the appropriate number of on-line inspectors identified in *GIPC-05,* in a manner consistent with 9 CFR 310.1 (the FSIS regulation for post-mortem staffing standards used domestically). Observed line speeds ranged from 35-40 carcasses/hour.

The FSIS auditor also reviewed OVI documentation to support that inspection verification activities occurred during each processing shift that product was prepared for export to the United States. Documented verification activities included direct observation and review of establishment records, including HACCP, sanitation standard operating procedures (sanitation SOPs), sanitation performance standards (SPS), and microbiological sampling programs.

SENASA maintains adequate official control over condemned materials. Articles 120 and 144 of *Agreement No. 552-05* stipulate that receptacles used for storing inedible material must not be used for storing any edible product and bear conspicuous and distinctive marking to identify permitted uses. Article 120 also requires inedible materials be denatured or destroyed under direct supervision of the official inspector. Lastly, Article 290 of the *Regulation for the Inspection of Meat and Meat Products (No. 078-00)* requires the denaturing of carcasses and parts condemned at post-mortem. During the audit, FSIS verified that the relevant portions of these requirements were applied, including: (1) appropriate identification in accordance with the categories described therein; (2) segregation in specially-marked or otherwise secure containers; and (3) final documented disposal of these materials at nearby rendering facilities.

Requirements for complete separation of establishments certified from those that are not certified are outlined in the *Regulation for the Inspection of Meat and Meat Products (No. 078-00),* Article 156. According to this regulation, all meat slaughter establishments must be enclosed by a perimeter fence, with a minimum separation distance of 50 meters. Only construction approved by SENASA is allowed within this perimeter. The FSIS auditor noted that the audited establishments processed only meat from cattle that were slaughtered on-premises and did not receive any raw materials from outside sources.

SENASA ensures that its meat exports are not subject to animal health restrictions by regularly consulting the relevant sections of the APHIS website in addition to FSIS' product eligibility chart for individual countries, which also considers current APHIS restrictions. Pre-printed export certificates issued by SENASA for a given country are species and commodity specific. Consequently, only those products previously identified by SENASA as meeting both FSIS and APHIS requirements can be certified for export to the United States.

Procedures for the supervisory visits are described in *GIPC-05*, Section V, instructing the SOV to conduct reviews at a frequency of at least once per month. The scope of these reviews includes ante-mortem and post-mortem inspection; official controls over good manufacturing practices and sanitation; HACCP; control of export certificates; chemical and microbiological testing programs and results; and control over condemned materials. The results of periodic supervisory visits are documented on form *FIMEC-01*. During the onsite audit of the two establishments certified to export to the United States, the FSIS auditor determined that official SOVs conducted these reviews at the intended frequencies. However, the systemic findings discussed in the following paragraphs of this component and the Government HACCP Systems component indicate procedural weakness in the manner that these reviews are conducted.

Within Section VIII of *GIPC-05*, SENASA maintains a definition of specified risk materials (SRM) which is consistent with that outlined in 9 CFR 310.22. This document also includes requirements for official verification that slaughterhouses and beef processing plants to implement and maintain documented procedures for the removal, segregation, and disposal of SRM within the scope of their HACCP system. The FSIS auditor identified the following finding:

- The FSIS auditor identified inconsistent official verification procedures related to implementation of *GIPC-05*. As previously mentioned, Section VII of *GIPC-05* states that removal, segregation, and disposal of SRM is the responsibility of the establishment. This document also limits the role of government inspection to strictly verification activities. At one of the two audited cattle slaughter establishments, the FSIS auditor noted that removal of the lingual tonsils was performed by the official post-mortem head inspector. In addition, the establishment was not maintaining records to demonstrate the removal of the brain, skull, eyes, trigeminal ganglia, tonsils, vertebral column, dorsal root ganglia, and distal ileum during implementation of its SRM control, for which only the removal of the spinal cord was recorded. This was a recently certified establishment that had not yet exported to the United States.

FSIS concludes that while Honduras' food safety inspection system maintains the legal authority and a regulatory framework that is consistent with criteria established for this component, the finding related to the control of SRM represents a need for increased coordination on the part of SENASA to provide for a single standard of inspection at establishments certified to export to the United States.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditor reviewed was Government Sanitation. The FSIS auditor verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation SOPs to prevent direct product contamination or insanitary conditions.

Within Honduras' food safety inspection system, the principal documents outlining the sanitation requirements for establishments certified to export to the United States include:

1. *Agreement No. 552-05*, Articles 58-75: provide requirements for establishment construction.

2. *GIPC-05*, Section VI, Part II: requires that establishments conduct necessary cleaning and disinfecting of the areas of the establishment. Equipment and utensils used for processing must be designed in such a manner as to prevent the creation of insanitary conditions on food contact surfaces. Establishments must facilitate sanitary practices to prevent cross contamination of equipment, tools, food, and personnel, water, and raw materials.
3. *GIPC-05*, Section VI, Part III: requires that each official establishment develop, implement, and maintain written sanitation SOPs. Sanitation SOPs are to be implemented daily (per shift where applicable) and verified by the government inspector. These procedures include pre-operational and operational procedures.

In accordance with these requirements, SENASA has developed a checklist (*Cronograma Mensual de Actividad de Verificación Oficial*) of controls to verify and document that establishments certified to export to the United States are complying with sanitation requirements on a daily basis. This form includes the name and number of the establishment and the date that the inspection activity was performed.

The FSIS auditor observed in-plant inspection verification of sanitation procedures at both audited establishments. Additional audit evidence was gathered through direct observation of establishment operations, and a review of establishment and government records. The FSIS auditor noted that the government and establishment records generally mirrored the actual sanitary conditions of the establishment, although isolated findings were identified at both establishments. These isolated findings are noted on the individual establishment checklists attached to this report (Appendix A).

The FSIS auditor concluded that SENASA requires establishments certified to export to the United States to develop, implement, and maintain sanitation programs consistent with 9 CFR Part 416 to ensure that establishment construction, facilities, and equipment prevent the contamination or adulteration of meat products destined for United States export.

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

The fourth of six equivalence components that the FSIS auditor reviewed was Government HACCP System. The food safety inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

Section VI, Part IV of *GIPC-05* requires that each establishment implement and maintain a HACCP system. The HACCP system is to identify all possible hazards identified by the establishment as being likely to occur and include all decision-making documents related to the development of the HACCP system. This document also requires that the HACCP system be revised annually, or whenever there is a change to the slaughter process.

The above guidelines also describe specific verification activities to be conducted by inspection personnel. This document instructs the OVI to verify the establishment's record-keeping system, monitoring procedures, validation of critical limits, and adequacy of corrective actions taken in response to a deviation from a critical control point (CCP). Before any product is exported to the

United States, a pre-shipment review is conducted which includes a review of records associated with the production of the product to ensure that all critical limits have been met and any necessary corrective actions were taken. These guidelines further state that establishments with inadequate HACCP systems are to be removed from the list of establishments certified to export to the United States. While onsite, the FSIS auditor visited two cattle slaughter establishments to determine whether SENASA maintained adequate government oversight for the implementation of HACCP requirements.

Within Section VII of *GIPC-05*, SENASA has established procedures for controlling fecal matter, ingesta, and milk (i.e., "zero tolerance") during cattle slaughter. In addition to 100 percent monitoring of the zero tolerance CCP, additional documented control points employed by establishments included: bung tying, weasand (esophagus) rodding, and evisceration. Inspection verification activities include review of establishment records, direct observation of monitoring (of establishment employees), and hands-on verification. Inspection personnel document daily verification of zero tolerance and sanitary dressing procedures on form *FCVT-01*. The FSIS auditor conducted an onsite observation and review of establishment and government records generated over the past 12 months, for which no concerns were identified. The FSIS auditor also verified the physical CCP location by observing official inspection personnel conducting HACCP hands-on verification activities.

The FSIS auditor verified that establishments certified to export to the United States had addressed contamination of carcasses with STEC (O157:H7, O26, O45, O103, O111, O121, and O145) within the context of their HACCP system. This included the use of an organic acid spray, as well as additional controls to ensure that carcasses were chilled in a manner sufficient to prevent the outgrowth of microbial pathogens. However, deficiencies related to official verification of HACCP system design were identified at both audited cattle slaughter establishments. The FSIS auditor identified the following findings:

- At one establishment, the operating parameters associated with the application of an antimicrobial rinse were not consistent with the documentation maintained by the facility to support decisions within its HACCP program. This establishment implemented a control point (prerequisite program) for the application of a lactic acid rinse on beef carcasses prior to entering the chiller. The operational limit for the concentration of lactic acid, as described in the establishment's written program, was 2-2.5% (i.e., a lower control limit or minimum of 2%). The establishment also maintained a validation study which is based on a lactic acid concentration of 2.5%. Consequently, there was a discrepancy between the lower control limit (minimum of 2%) and the validation study (2.5%). A review of production records indicated that the acid concentration applied was typically below the value referenced by the validation study.
- At the other establishment, the critical limit associated with the CCP for carcass chilling addressed only internal temperature (7^{o} C) without a reference to time. Review of the establishment's hazard analysis determined that this CCP was established to control the growth of microbial pathogens. From a scientific standpoint, the parameters of both time and temperature should be applied when addressing the growth-curve of microorganisms, for which the current design of this CCP cannot assure that pathogen growth is controlled. No further documentation was provided by the establishment to support the omission of the time parameter from this critical limit.

SENASA requires that establishments certified to export to the United States design a written program for implementing verification testing for *E. coli* O157:H7 and non-O157 STECs. The FSIS auditor reviewed the following specific government verification activities related to implementation of the establishments' program, for which no concerns were identified. On a routine basis, official inspection personnel conduct direct observation of the establishment's sample collection procedures and review prior testing results. OVIs record these verification activities on form *SGIA-CMAI-17*. On a monthly basis, SOVs review the verification activities of the OVI and record the results on form *FIMEC-01*. The SOV also performs direct observation of the establishment's procedures for sample collection and reviews the results of the sampling performed by the establishment. The results of this review are recorded on form *FIMEC-01*. On a yearly basis, the official government laboratory (LANAR) performs audits of the private laboratories used in conjunction with establishment testing.

The FSIS auditor determined that SENASA requires establishments certified to export to the United States to develop, implement, and maintain HACCP programs. However, the audit identified instances where the food safety inspection system did not always effectively verify the adequacy of the design of these HACCP systems. During the exit meeting, SENASA presented evidence that it had taken immediate measures to resolve the noncompliances identified at the above-referenced locations, including issuance of noncompliance reports and verification that food business operators had modified their HACCP programs accordingly.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditor reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue testing 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 inspection authorities or by FSIS as potential contaminants.

Prior to the onsite visit, FSIS' residue experts thoroughly reviewed Honduras' *National Residue Program* (NRP) for 2017 (and 2016 results), associated methods of analysis, and additional SRT responses outlining the structure of Honduras' chemical residue testing program. Methods of analysis are consistent with those outlined in the *FSIS Chemistry Laboratory Guidebook* or other internationally recognized organization.

The FSIS auditor verified that personnel from SENASA, in cooperation with LANAR, develop and implement the annual residue monitoring plan. SENASA prepares the sampling schedules and instructions for random collection of samples of specific matrices within a defined period. The onsite inspection officials collect meat samples at the slaughter facility as prescribed by sampling protocols. The NRP delegates to LANAR the responsibility to analyze tissues to detect chemical residues and to issue a food safety alert that prohibits export of involved meat products to the United States when chemical residues are detected above tolerance levels. The NRP establishes tolerance levels for the compounds of interest according to the Honduran regulations; Codex Alimentarius Commission standards; regulations of the United States Food and Drug

Administration and the United States Environmental Protection Agency; and the Directorate General for Health and Consumers of the European Commission requirements.

The number of scheduled samplings in establishments is based on the production numbers of the preceding year. Supplemental factors taken into consideration include: the registered use of a chemical compound of interest; the likelihood of a residue occurring in animal tissues; the extent and pattern of use of the compound; incentives for misuse; known persistence of the compound in the environment; past monitoring results; and requirements of importing countries (in accordance with the Codex Alimentarius Commission *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with the Use of Veterinary Drugs in Food Producing Animals).* In addition to routine sampling, sample collections may be generated by the inspectors whenever they have a reason to suspect that a sample is needed. If a screening test returns a positive detection for antibiotics, LANAR will prepare and send the sample to the LAMBDA laboratory in Costa Rica for confirmation and quantification.

While there have been no residue violations in recent history, the FSIS auditor verified that SENASA has developed the necessary enforcement procedures should a violative result be reported. Section 8 of the NRP states that LANAR is to convey violative results directly to SENASA headquarters, the SOV, and local OVI assigned to the establishment. The OVI will then submit a demand for corrective action to the establishment and will request a root-cause analysis, a reassessment of the HACCP plan, and determine appropriate corrective actions and preventive measures in response to this violation. The establishment must submit the results of the reassessment of the HACCP plan, as well as the corrective actions and preventive measures to the OVI. SENASA may modify the schedule and perform intensified sampling from that supplier for analyses of the chemical compound identified in the violation. The establishment may return to the normal sampling after obtaining 16 consecutive negative results. Honduras' *Accord No. 330 (2013)* grants SENASA the authority to impose sanctions on any individuals presenting animals for slaughter with levels above the maximum residue limit (MRL). The specific sanctions are outlined in *Decree No. 344 (2005),* Article 39, and range from financial fines to permanent closure of the offending business.

A review of the sampling records maintained at the local inspection office of the audited slaughter establishments indicated that the 2018 sampling program was being adhered to as scheduled. Monitoring residue samples are collected by the OVI and are shipped under inspection seal. Samples are shipped to the laboratory in accordance with protocols issued by LANAR. LANAR tracks the samples and provides feedback to the in-plant OVI concerning adequacy of sample shipping and results of analysis. SENASA has adopted a hold and test procedure within its NRP to ensure product is not exported to the United States until acceptable results are obtained, for which the FSIS auditor was presented with sufficient audit evidence while onsite (e.g., review of inspection records, presence of "veterinary retained" cages) to demonstrate that this policy was being effectively implemented.

During the evaluation of ante-mortem inspection at the two cattle slaughter establishments, the FSIS auditor observed that the OVIs verify that all lots of animals are accompanied by

documentation that discloses their origin and includes a signed declaration that attests that owners have adhered to veterinary pharmaceutical withdrawal periods.

The FSIS auditor conducted an onsite audit of LANAR, the principal laboratory providing technical support to Honduras' food safety inspection system. The audit reports reviewed at the laboratory demonstrated that the technical and organizational aspects of the functions of the laboratory were periodically evaluated by the laboratory quality control manager, SENASA, and by a third-party accrediting institution. Findings reported during laboratory audits were promptly addressed and documented as required by the ISO 17025 standard. The FSIS auditor verified that analysts assigned to the chemical residue laboratory have completed academic work and specialized training that qualify them to conduct the analytical methods for detection and quantification of chemical residues in their scope of accreditation.

There have not been any violations related to chemical residue testing conducted by FSIS at POE in recent history. The result of the onsite audit activities indicate that Honduras continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in meat products destined for human consumption.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last of six equivalence components that the FSIS auditor reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat products prepared for export to the United States are safe and wholesome.

SENASA has established process control criteria that are consistent with those listed in 9 CFR Part 310.25(a) in order to verify process control for generic *Escherichia coli* (*E. coli*) in raw products. The FSIS auditor verified the microbiological sampling and testing program through document reviews at the branch office and in one audited slaughter establishment. The FSIS auditor reviewed the establishment's written program and confirmed that the OVIs and SOVs (during monthly supervisory reviews) verify that slaughter establishments comply with SENASA's regulatory requirements regarding generic *E. coli*, including sampling frequency, technique, and methodology; maintaining records of analytical results; and sampling requirements. The FSIS auditor's review of the establishment program and inspection records identified no concerns.

The FSIS auditor reviewed the CCA's *Salmonella* sampling and testing program which is consistent with those listed in 9 CFR Part 310.25(b). The FSIS auditor verified that the implementation of the program in the audited cattle slaughter establishments met the CCA's requirements outlined in the *Regulation for the Inspection of Meat and Meat Products (No. 078-00)*. Inspection personnel use swabs or sponges to collect a 100-cm^2 surface area from the flank, rump, and brisket at a frequency of once per every 300 carcasses. Performance standards consist of a moving window of 58 consecutive carcass samples, for which the maximum number of positive samples is two. SENASA uses the *FSIS Microbiology Laboratory Guidebook* (MLG)

method 4.09 for official analysis of *Salmonella* in beef.

Within its *Program for the Control of E. coli O157:H7 and Non-O157 Shiga Toxin-Producing E. coli (2017)*, SENASA stipulates a zero tolerance policy for *E. coli* O157:H7, O26, O45, O103, O111, O121, and O145 in raw beef products intended for grinding or other non-intact product exported to the United States. This document includes instructions for government sample collection (sixty pieces, i.e., N-60) and submission procedures, interpretation of results, and outlines an enforcement strategy that includes immediate corrective actions, HACCP reassessment, and follow-up testing. The program specifically designates LANAR as the only laboratory that performs screening and confirmation analyses of official samples.

LANAR uses the FSIS methods for official analysis of *E. coli* O157:H7 (MLG 5A.04) and Non-O157 (MLG 5B.05) in raw beef. The number of verification samples collected is proportional to production volume, with a minimum frequency of 12 samples per month (increased to 14 times per month during the rainy season). In the interest of complete transparency, Chapter VII of this document states that all official positive results associated with product processed in establishments certified to export to the United States will be immediately communicated to FSIS. The onsite visit to two beef establishments indicated that inspection personnel were adhering to the sampling plans established by the CCA and implemented hold and test protocols for each lot of product destined for export to the United States.

During the audit of LANAR, the FSIS auditor reviewed official reports of laboratory audits conducted by SENASA and the Costa Rican Accreditation Entity, documentation of analysts' proficiency evaluations, inter-laboratory proficiency testing results, and records of evaluations of corrective actions taken in response to audit findings. The FSIS auditor also verified that the laboratory maintained appropriate discard criteria to ensure the integrity of the sample and testing results. This included written standard operating procedures to ensure that samples arrive under government seal within specified timeframes and required temperatures, as well as outlining specific follow-up activities to be undertaken when these requirements are not met. Follow-up procedures are in place to notify the OVI and the SENASA headquarters. SENASA receives laboratory results directly from LANAR. The FSIS auditor's review of *Salmonella* and STEC testing procedures indicated that the appropriate MLG methods were implemented as prescribed.

There have not been any violations related to microbiological testing conducted by FSIS at POE in recent history. The result of the onsite audit activities indicate that Honduras continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system aimed at controlling the presence of microbiological pathogens in beef products exported to the United States.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on April 20, 2018, in Tegucigalpa, Honduras, with SENASA. At this meeting, the FSIS auditor presented the preliminary findings from the audit.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditor identified the following findings:

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- The FSIS auditor identified inconsistent official verification procedures related to the control of SRM in cattle. At one of the two audited slaughter establishments, the official post-mortem head inspector performed removal of the lingual tonsils (rather than establishment personnel, as required by Honduras' official written inspection procedures). In addition, the establishment was not maintaining records to demonstrate the removal of the brain, skull, eyes, trigeminal ganglia, tonsils, vertebral column, dorsal root ganglia, and distal ileum during implementation of its SRM control program, for which only the removal of the spinal cord was recorded. This was a recently certified establishment that had not yet exported to the United States.

Government Hazard Analysis and Critical Control Points (HACCP) System

- At one of the two audited slaughter establishments, the operating parameters associated with the application of an antimicrobial rinse was not consistent with the documentation maintained by the facility to support decisions within its HACCP system. The validation study maintained by the establishment referenced a lactic acid concentration of 2.5%, while the production records indicated that the acid concentration applied was typically below this value.
- At one of the two audited slaughter establishments, the critical limit associated with the critical control point for carcass chilling addressed only internal temperature without a reference to time. Review of the establishment's hazard analysis determined that this critical control point was established to control the growth of microbial pathogens. From a scientific standpoint, the parameters of both time and temperature should be applied when addressing the growth-curve of microorganisms.

During the audit exit meeting, the CCA committed to address the preliminary findings as presented. Once FSIS receives the documented proposed corrective actions, FSIS will evaluate the adequacy of the information to determine the scope of future equivalence verification activities.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Empresa Ganadera de Honduras S.A. de C.V. Catacamas, Oloncho	04/18/2018	4	Honduras
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by the Honduran inspection officials during the establishment review:

15/51. The operating parameters associated with the application of an antimicrobial rinse was not consistent with the documentation maintained by the facility to support decisions within its HACCP program. The establishment implements a control point (prerequisite program) for the application of a lactic acid rinse on bovine carcasses prior to entering the chiller. The operational limit for the concentration of lactic acid, as described in the establishment's written program, is 2-2.5% (i.e., a lower control limit or minimum of 2%). The establishment also maintains a validation study which is based on a lactic acid concentration of 2.5%. Consequently, there is a discrepancy between the lower control limit (minimum of 2%) and the validation study (2.5%).

41/51. Inadequate ventilation was identified in the carcass chiller. The body heat from recently slaughtered bovine carcasses produced excessive water vapor which was condensing on surrounding structures, thereby creating insanitary conditions which could result in the contamination of product (no direct product contamination observed at time of the audit).

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	04/18/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Agroindustrias Del Corral Siguatepeque	04/17/2018	20M	Honduras
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Honduran inspection officials during the establishment review:

15/51. The critical limit (CL) associated with the CCP for carcass chilling addressed only internal temperature (7º C) without a reference to time. Review of the establishment's hazard analysis determined that this CCP was established to control the growth of microbial pathogens. From a scientific standpoint, the parameters of both time and temperature should be utilized to describe the growth-curve of microorganisms, for which the current design of this CCP cannot assure that pathogen growth is controlled. No further documentation was provided by the establishment to support the omission of the time parameter from this CL.

58/51. The establishment was not maintaining records to demonstrate the removal of brain, skull, eyes, trigeminal ganglia, tonsils, vertebral column, and distal ileum during implementation of its program to control specified risk materials (SRM) in cattle (all cattle were being treated as 30 month of age or older). Only removal of the spinal cord was documented.

In addition, FSIS identified the following findings related to the implementation of Honduras' inspection system:

51/55. The viscera pans were not being sanitized between carcasses during post-mortem inspection.

51/58. The FSIS auditor noted that the official post-mortem inspector (heads) was assigned the responsibility of removing lingual tonsils. However, Honduras' self-reporting tool (SRT) submission states that removal, segregation, and disposal of SRM is the responsibility of the establishment. The SRT submission also limits the role of government inspection to strictly verification activities (i.e., does not assign a responsibility for SRM removal).

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	04/17/2018

Appendix B: Foreign Country Response to the Draft Final Audit Report

SAG-SENASA
SERVICIO NACIONAL
DE SANIDAD E INOCUIDAD
AGROALIMENTARIA

NOTA.DGS.SGIA.953.2018

Tegucigalpa, M.D.C.,
September 06, 2018

Ms
JANELL CAUSE
Office of International Coordination
Food Safety and Inspection Service
US Department Agriculture
Washington, D.C., USA

Dear Ms Cause:

I am pleased to address you, with the purpose of providing corrective actions and comments to the Draft Final Report of an Audit Conducted in Honduras April 16-20, 2018. Evaluating the Food Safety Systems Governing Raw Beef Products Exported to the United States of América.

The documents are being enclosed for your review and consideration.

Should you require further information, please do not hesitate in contacting us via email at direccion.senasa@senasa.gob.hn and mbueno@senasa.gob.hn.

Sincerely,

SENASA
GOBIERNO DE LA REPÚBLICA DE HONDURAS
SERVICIO NACIONAL DE SANIDAD E INOCUIDAD AGROALIMENTARIA
TEGUCIGALPA, M.D.C.
DIRECCIÓN

ING. RICARDO PAZ MEJIA
General Director

cc: *Lic. Mauricio Guevara-Secretario de Estado Agricultura y Ganadería*
Dra. Mirian Bueno-Subdirectora General de Inocuidad Agroalimentaria SENASA
Dr. Manuel Soto-Jefe Departamento de Cárnicos-SENASA
Licda. Ana Gómez-Especialista Agrícola FAS-USDA
Archivo 2018

SENASA Honduras comments to the "Draft Final Report of an Audit Conducted in Honduras April 16-20, 2018 Evaluating the Food Safety Systems Governing Raw Beef Products Exported to the United States of America".

*Suggested modifications are being provided in **bold** and underlined text.*

Page 4, paragraph #3

The FSIS auditor verified that inspectors had successfully completed the induction-training program outlined in Section II of GIPC-05. All new employees complete supplemental training on meat inspection regulations, inspection and verification activities, and country-specific export requirements. Successful completion of training is the fundamental requirement for personnel to be assigned to perform inspection and verification procedures. Veterinary and non-veterinary personnel receive on-the-job training when they are first assigned to establishments certified to export to the United States. SENASA also provides ongoing specialized-training on FSIS requirements to inspectors at least once a year. The FSIS auditor noted that recent training included a course for Food Safety Practices and Animal Welfare in Cattle (Texas **Tech** ~~A & M~~ University), as well as attendance at the 2017 FSIS Equivalence Seminar (Bogota, Colombia).

Page 10, paragraph #1

SENASA requires that establishments certified to export to the United States design a written program for implementing verification testing for E. coli O157:H7 and non-O157 STECs. The FSIS auditor reviewed the following specific government verification activities related to implementation of the establishments' program, for which no concerns were identified. On a routine basis, official inspection personnel conduct direct observation of the establishment's sample collection procedures and review prior testing results. OVIs record these verification activities on form SGIA-CMAI-17. On a monthly basis, SOVs review the verification activities of the OVI and record the results on form **FIMEC-01** ~~SGIA-CMAI-17~~. The SOV also performs direct observation of the establishment's procedures for sample collection and reviews the results of the sampling performed by the establishment. The results of this review are recorded on form FIMEC-01. On a yearly basis, the official government laboratory (LANAR) performs audits of the private laboratories used in conjunction with establishment testing.

SENASA Honduras proposed corrective actions to the "Draft Final Report of an Audit Conducted in Honduras April 16-20, 2018 Evaluating the Food Safety Systems Governing Raw Beef Products Exported to the United States of America".

The following non-compliances were not identified by Honduran inspection officials during the establishment review:

US-FSIS Finding #1

The FSIS auditor identified inconsistent official verification procedures related to the control of SRM in cattle. At one of the two audited slaughter establishments, the official postmortem head inspector performed removal of the lingual tonsils (rather than establishment personnel, as required by Honduras' official written inspection procedures). In addition, the establishment was not maintaining records to demonstrate the removal of the brain, skull, eyes, trigeminal ganglia, tonsils, vertebral column, dorsal root ganglia, and distal ileum during implementation of its SRM control program, for which only the removal of the spinal cord was recorded. This was a recently certified establishment that had not yet exported to the United States

SENASA Honduras Corrective Action #1

Cause analysis

The establishment did not have sufficient clarity over the responsibilities regarding the implementation of control procedures for SRMs.

Corrective actions implemented by the establishment

1. The establishment elaborated a procedure for the control, removal and elimination of SRMs "*Instructivo de control, retiro y eliminacion de MER I-DC-HACCP-276"* accordingly with 9 CFR 310.22, FSIS Directive 6100.4, and the Regulation for the Epidemiological Surveillance, Control and Prevention of Bovine Spongiform Encephalopathy and other Transmissible Spongiform Encephalopathies, Accord No. 322-2013 per requested by SENASA in letter NOTA.SGIA-IVO.02.2018. *See attachment #1*
2. The establishment elaborated the form *"Control de la remoción, segregación y eliminación de los productos material especifico de riesgo* F-DC-HACCP-291" to record the removal and segregation of SRMs in the slaughter area on a daily basis. *See attachment #2*

Corrective actions implemented by SENASA

1. On April 18th, 2018 the Official Veterinary Inspector (OVI) submitted a memorandum NOTA.IVO.08.2018 providing written instructions to the Official Auxiliary Inspectors to verify the establishment's procedure for the removal and segregation of SRMs. *See attachment #3*
2. The inspection program implemented the form "*Monitoreo de MER (Matanza)*" which has been standardized at the two certified establishments to record the verification activities for the removal and disposition of SRMs in the slaughter area. *See attachment #4*

SENASA official verification activities

The OVI is verifying compliance of the removal and segregation procedures of the establishment on a monthly basis and records the activities in the "*Cronograma Mensual de Actividades de Verificacion Oficial* SGIA-CMAI-17". *See attachment #5*

SENASA Honduras official veterinary supervision

The Official Veterinary Supervisor (OVS) verified compliance of the written procedure of the establishment regarding the segregation and removal of SRMs, as well as the records for controlling the removal, weight and disposition of SRMs from the slaughter area to the rendering plant. The verification activities were recorded in the FIMEC-01 form. *See attachment #6*

The form FIMEC-01 has been modified (Rev.01) to include specific items #19, 22, 25 and 77 to verify compliance of SRM control and will be implemented at the next supervisory visit scheduled for September 2018. *See attachment #7*

US-FSIS Finding #2

The operating parameters associated with the application of an antimicrobial rinse was not consistent with the documentation maintained by the facility to support decisions within its HACCP program. The establishment implements a control point (prerequisite program) for the application of a lactic acid rinse on bovine carcasses prior to entering the chiller. The operational limit for the concentration of lactic acid, as described in the establishment's written program, is 2-2.5% (i.e., a lower control limit or minimum of 2%). The establishment also maintains a validation study which is based on a lactic acid concentration of 2.5%. Consequently, there is a discrepancy between the lower control limit (minimum of 2%) and the validation study (2.5%).

SENASA Honduras corrective action #2:

Cause Analysis

The establishment on its 2018 HACCP reassessment did not consider the minimum limit of 2.5% concentration of lactic acid in line with the scientific validation conducted by Texas Tech University.

Corrective actions implemented by the establishment

1. The establishment adjusted the concentration of lactic acid from 2% to 2.5% for the antimicrobial intervention in the slaughter. *See attachment #8*
2. The establishment modified their HACCP plan and determined a minimum limit of 2.5% concentration of lactic acid in line with the validation study conducted by TTU and a 3% maximum limit in line with the FSIS Directive 7120.1 Rev.46. *See attachment #8*
3. The form F-HACCP No.13 was modified to include the minimum and maximum limits of lactic acid at 2.5 – 3%. *See attachment #9*
4. The establishment's HACCP team drafted a document that states their commitment in considering scientific validation studies in future reassessments and updates of the HACCP plan. *See attachment #10*

Corrective actions implemented by SENASA

1. The official inspection program modified the form "*Formato de verificación de concentración de acido láctico en la intervención y hielo en carne de cabeza*" in line with the establishment's validated limits and records these activities on a daily basis. *See attachment #11*

SENASA Honduras official verification activities

1. The OVI performs verification activities on the concentration of lactic acid and records activities in the form *"Cronograma Mensual de Actividades de Verificaion Oficial SGIA-CMAI-17". See attachment #12*

SENASA Honduras official veterinary supervision

The FIMEC-01 form has been modified (Rev.01) to include specific item #24 to verify compliance the concentration of lactic acid at 2.5% and will be implemented at the next supervisory visit scheduled for September 2018. *See attachment #7*

US-FSIS Finding #3

At one of the two audited slaughter establishments, the critical limit associated with the critical control point for carcass chilling addressed only internal temperature without a reference to time. Review of the establishment's hazard analysis determined that this critical control point was established to control the growth of microbial pathogens. From a scientific standpoint, the parameters of both time and temperature should be applied when addressing the growth-curve of microorganisms.

SENASA corrective action #3

Causes Analysis

The establishment's HACCP team did not conduct a robust technical analysis to establish the critical limit for carcass chilling based on scientific criteria for time and temperature parameters.

Corrective actions implemented by the establishment

1. The establishment reviewed scientific documents with support from Texas Tech University, specifically the *Journal of Food Protection Vol 79 N 4 2016 pages 538-543,* which establishes a maximum parameter of 24 hours to complete carcass chilling at a temperature at or below 7° C. *See attachment #13*
2. The HACCP Plan has been modified and describes that the critical limit for carcass chilling considers a maximum residence time of 24 hours at a temperature at or below 7°C monitoring the rump and brisket. *See attachment #14*
3. The forms *"Monitoreo de Temperatura de Canales Frías F-DC-HACCP 286*" and form *"Control de Ingreso de Canales en Chiller de Almacenamiento F-DC-HACCP-291"* have been modified and updated to record the time and temperature parameters of the carcasses and the residence time of the carcasses in the chiller, respectively. *See attachment #15*

Corrective actions implemented by SENASA

The FIMEC-01 form has been modified (Rev.01) to include specific item #104 to verify compliance of HACCP validation criteria and will be implemented at the next supervisory visit scheduled for September 2018. *See attachment #8*

SENASA official verification activities

The OVI is verifying compliance of the establishment's CCPs on a weekly basis and records the activities in the "*Cronograma Mensual de Actividades de Verificacion Oficial* SGIA-CMAI-17". *See attachment #5*

Other findings included in the Draft Final Audit Report

1. **Inadequate ventilation was identified in the carcass chiller. The body heat from recently slaughtered bovine carcasses produced excessive water vapor which was condensing on surrounding structures, thereby creating insanitary conditions which could result in the contamination of product (no direct product contamination observed at time of the audit).**

The establishment has implemented actions to decrease formation of condensation in the carcass chiller as follows:

1. Chiller #3 has been assigned at a pre-chill area where carcasses have a residence time of 15 minutes in order to reduce the excessive water vapor and condensation.
2. Conducted preventive maintenance of the evaporators, seals and doors
3. Installed seals to prevent entry of warm air in the chillers
4. Replaced the motors of the evaporators in the chillers to improve temperature capacity
5. An establishment employee has been assigned permanently to the area to control condensation on the structures, if needed.

To prevent the formation of condensation the establishment will be replacing all the evaporators in the chillers with larger capacity by December 2018.

The official inspection program is verifying compliance of adequate ventilation on a weekly basis and records the activities in form SGIA-CMAI-17. *See attachment #12*

2. **The FSIS auditor noted that the official post-mortem inspector (heads) was assigned the responsibility of removing lingual tonsils. However, Honduras' self-reporting tool (SRT) submission states that removal, segregation, and disposal of SRM is the responsibility of the establishment. The SRT submission also limits the role of government inspection to strictly verification activities (i.e., does not assign a responsibility for SRM removal).**

3. **The viscera pans were not being sanitized between carcasses during post-mortem inspection.**

On April 18th, 2018 the Official Veterinary Inspector (OVI) submitted a memorandum NOTA.IVO.08.2018 providing written instructions to the Official Auxiliary Inspectors to sanitize the viscera pans between carcasses and verify the adequate removal of lingual tonsils. *See attachment #3*