FINAL REPORT OF AN AUDIT CONDUCTED IN BRAZIL

JUNE 10 - 28, 2019

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING RAW AND PROCESSED MEAT PRODUCTS EXPORTED TO THE UNITED STATES OF AMERICA

December 13, 2019

Food Safety and Inspection Service
United States Department of Agriculture

APPENDIX A

Responses and additional comments from the Brazilian competent authority regarding the audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from June 10 through 28, 2019

N°	***FSIS findings***	***Corrective actions proposed by the CCA and additional comments***
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)		
01	*The implemented post-mortem inspection procedures were inadequate to ensure that only wholesome carcasses, free of contamination and defects, receive the mark of inspection at three of the seven audited beef slaughter and processing establishments.*	These were sporadic flaws that also characterize a failure to comply with current Brazilian legislation in force. During the on-site verification audit all the findings were transmitted to the Federal Inspection teams in the Establishments for the appropriate corrections; some findings were addressed and adjusted immediately. After *Appendix A: Individual Foreign Establishment Audit Checklist* was received, the individual reports were forwarded to the audited establishments and SIPOAs for additional measures to be taken. The actions were assessed and deemed satisfactory by the SIPOA and DIPOA. The findings will also be included in guidance for auditors of the Division for Audits in Establishments (DAE) so as to maintain continuous verification, both in the establishments at which the findings were observed, and in others. Furthermore, we state that the Federal Agricultural Inspectors/Auditors (AFFAs) in the audited units have been trained in regard to the findings contained in the report and its appendices, in a face-to-face setting, during the training entitled Standardization of Ante-mortem and Post-mortem Oversight and Inspection Procedures for Slaughter Animals ("*Padronização de procedimentos de fiscalização e inspeção ante e post mortem de animais de abate*") which was held at ENAGRO - Brasília/DF, as given in SEI Case File No. 21000.013547/2019-63. The certificates and course contents of the training initiative are attached to this document as Appendix 1.

02	*The Central Competent Authority (CCA) does not maintain written guidelines that prescribe the body temperature at which livestock (i.e., beef cattle and swine) are to be condemned during ante-mortem inspection*	A consolidated protocol containing all the specific requirements for the US market has been prepared. In this document (CIRCULAR OFFICIAL LETTER Nº 112/2019/DIPOA/SDA/MAPA – Appendix 2) we defined the reference temperatures for the thermometry of animals for slaughter, during examinations that are supplementary to the Ante-mortem inspection activities, so as to meet the specific requirement of 9 CFR 309.3. In items 6.1.1.3 and 7.1.2, the document stipulates that if pigs or bovines are detected during ante-mortem inspection showing temperatures equal to or above 41ºC in the case of pigs, and 40.5ºC in the case of bovines, these animals must be condemned.
03	*The FSIS auditors identified deficiencies at five of the seven audited beef slaughter and processing establishments related to the control of specified risk material (SRM). These included the potential for contamination of head or cheek meat by brain tissue from cattle 30 months or older during head washing, inadequate trimming of lingual tonsils, and failure to document the removal of dorsal root ganglia and vertebral column at deboning*	Reports of the FSIS auditors state that cross- (or direct) contamination was not observed during the washing process for heads, and subsequent processes for obtaining raw materials from them (head and cheek meat). However, based upon the audit findings, DIPOA determined in timely fashion, by publishing Official Circular Letter no. 62/2019/DIPOA/SDA/MAPA dated 27/06/2019 7716197, to ban the use of head meat as raw material for heat-processed production of any nature intended for export to the United States. Furthermore, in response to the emphasis given by the FSIS auditors during the Exit Meeting held on 28/06/2019, where the possible use of head meat (including cheek meat) as raw material for making products for export to the United States of America was questioned, a letter dated 20/09/19 was sent to FSIS, the explanations contained in which were considered to be sufficient, and may be the subject of verification in a future audit. We stress that all the measures were defined and fully implemented after the document was published, and are verified on a daily basis during the oversight exercised by the Federal Inspection Service in the Establishments, and during DAE audits on establishments approved for export to the USA. Additionally, the ban is part of the protocol of compliance with US requirements (Appendix 2 - items 6.1.1.7; 6.2.1.1 and 8). Regarding the removal of the lingual tonsils and the spinal column, as cited in the body of the certificate *"(...) Furthermore, the FSIS auditors identified deficiencies related to the removal of lingual tonsils (one establishment) and* *documentation of removal of dorsal root ganglia and vertebral column (one*

		establishment). " We acknowledge these findings, which were sporadic flaws showing a failure to comply with the legislation in force. Many corrective actions were adopted during the on-site audit, while after *Appendix A: Individual Foreign Establishment Audit Checklist* was received, it was forwarded to the SIFs and SIPOAs for additional measures to be taken. The actions were assessed and deemed satisfactory by the SIPOA and DIPOA. The findings will also be included in guidance for auditors of the Division for Audits in Establishments (DAE) so as to maintain continuous verification, both in the establishments at which the findings were observed, and in others. Furthermore, we state that the Federal Agricultural Inspectors/Auditors (AFFAs) in the audited units have been trained in regard to the findings contained in the report and its appendices, in a face-to-face setting, during the training entitled Standardization of Ante-mortem and Post-mortem Oversight and Inspection Procedures for Slaughter Animals ("*Padronização de procedimentos de fiscalização e inspeção ante e post mortem de animais de abate*") which was held at ENAGRO - Brasília/DF, as given in SEI Case File No. 21000.013547/2019-63. The certificates and course contents of this training initiative can be found as an attachment to this document (Appendix 1).
04	*The FSIS auditors identified concerns in meeting the APHIS requirements outlined in 9 CFR 94.29 regarding carcass maturation. This included the use of a set of inaccurate pH meters at one establishment, as well as the inability for all audited establishments to demonstrate that the carcasses had reached a pH of 6.0 or below within 48 hours of entering the maturation chamber as required by 9 CFR 94.29(i).*	Regarding the calibration of the pH meters, the findings were based on the note: *(...). The first concern relates to observation of the use of a set of inaccurate pH meters at one establishment, as the auditors observed that the pH meters did not measure the accurate pH of the calibration solutions after being calibrated*." A Protocol of Compliance with US Sanitary Requirements has been drafted (Appendix 2) and in item 6.3.1 this gives the routine cleaning of the equipment's bulb, and calibration of the device in accordance with manufacturer's specifications, as an obligation of the establishments. It also lays down that the Official Service must include the evaluation of these devices in its inspection plan so that they will be officially verified at the frequency determined by Internal Standard (*Norma Interna*) 01/2017. Regarding the point quoted in the body of the report: "(...)*The second concern derived from discussions held with the government officials and inspection personnel, reflects a country-wide practice, where it was indicated that carcasses enter the maturation chamber on Friday, the pH would not be measured until Monday. This practice does not permit the establishments to demonstrate that the carcasses had reached a pH of 6.0 or below within 48 hours of entering the maturation* *chamber as required by 9 CFR 94.29(i). FSIS has communicated these findings to APHIS,*

		who has committed to following up on these issues. At this time, there are no establishments in Brazil eligible to export raw beef to the United States." It is our understanding that what is set forth in 9 CFR 94.29(i) is clear when it cites the need to reach a pH less than 6.0 after 48h: "*Any carcass in which the pH does not reach less than 6.0 may be allowed to maturate an additional 24 hours and be retested, and, if the carcass still has not reached a pH of less than 6.0* ***after 48 hours****, the meat from the carcass may not be exported to the United States."* [emphasis added] We believe that the procedure in force does not pose risks of being a vehicle for the foot-and-mouth disease virus; nonetheless, we deem this issue to be a certification requirement and have included in the Protocol of Requirements a specific and clearer mention of the measurement of the pH in carcasses after 48 hours of maturation, as set down in the preliminary report (item 6.3.1 c of the protocol): *"Those carcasses that did not reach pH less than 6.0 may be additionally maturated for another 24 hours, after which the pH must be taken again. After this second pH measurement, if the pH is not less than 6.0, the carcass cannot be exported to the US as fresh beef."*
COMPONENT SIX: **GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS**		

05	*The two audited government laboratories are not analyzing the entire N- 60 sample if the sample submission is greater than the size of the test portion prescribed by the screening method (325 g ±10 %)*	The body of the report states that "(...) However, the FSIS auditors noted that samples collected were typically far greater than the anticipated 325 grams and observed the collection of a government sample weighing 830 grams at one establishment. At both the Campinas and Pedro Leopoldo facilities the FSIS auditors noted that during the on- site audit that laboratory personnel may not be analyzing the entire N-60 beef trim sample as received from establishments. Laboratory personnel at both facilities reported routinely weighing and analyzing a 325-gram test portion, even if the weighed test portion did not include all 60 pieces of trim from the N-60 sample." The document entitled CIRCULAR OFFICIAL LETTER NO. 10/2019/CGAL/DTEC/SDA/MAPA (Appendix 3) ratifies the information given to the FSIS auditors in the Exit Meeting. The document informs the LFDAs (Federal Animal and Plant Health Laboratories) that: " *(...) on those occasions when they receive samples weighing over 325g+10%, such samples must be split into 2 aliquots and analyzed as two samples, such that all 60 pieces of meat that have been sent be representative of the sample sent to the laboratory. We hereby request that this adjustment be incorporated into the Standardized Operating Procedures of the respective LFDA laboratories*" As a supplement to this, DIPOA published Official Letter No. 40/2019/CRISC/CGPE/DIPOA/SDA/MAPA (Appendix 4) which contains guidance to be followed by all those individuals involved in sampling for STEC testing in bovine slaughterhouses. It was emphasized that sampling for STEC assays by Method N60 must have the suitable weight of the sample (325g +/- 10%). This document also states that the Manual of Sample-Taking for Animal Products has been revised, and guidance has been included for sample-taking to meet Normative Instruction no. 60/2018. The Manual is available on the DIPOA web page, in the Publications Area, at http://www.agricultura.gov.br/assuntos/inspecao/produtosanimal/publicacoes-dipoa.

06	*The FSIS auditors identified deficiencies related to the verification of operation and maintenance of retorts at three of the four establishments preparing thermally processed, commercially sterile products, including deficiencies related to retort temperature recording at two establishments. The FSIS auditors also noted that official verification activities at two of these facilities only included a records review and did not include a hands-on or direct observation component*	The finding was based on the following observations: (...). *The FSIS auditors identified deficiencies related to the verification of retort operations and maintenance at three of the four audited establishments, none of which were considered an immediate threat to food safety. This included incidental higher temperature readings from the time/temperature recording device than the indicating temperature device (both readings were higher than the critical limit) at two facilities; placement of bleeders (used to provide circulation of steam in the retort) in a manner where official personnel could not verify operation at one facility; and operation of retorts at partial capacity without validation of the process (which can affect the venting schedule) at one facility. During interviews held with local inspection personnel at two of the audited facilities, the FSIS auditors were informed that routine verification activities for retort operations included only records review and did not include a hands-on (in situ) verification component. This is inconsistent with the CCA's Circular Letter No. 34/2016, which requires official inspection plans to include a hands-on (in situ) verification component. DIPOA needs to take the necessary corrective actions to ensure the standardization of inspection practices throughout all establishments certified to export TPCS product to the United States.*" "*The FSIS auditors found that Brazil's meat inspection system has a microbiological testing program organized and administered by the national government, and that DIPOA has implemented the necessary sampling and testing programs to verify the effectiveness of its system. While Brazil's program includes microbiological sampling requirements that are equivalent to United States standards, the FSIS auditors identified deficiencies related to microbiological testing practices that could potentially impact the accuracy of results, as well as deficiencies related to the verification of retort maintenance and operation*." To correct this deficiency, the Protocol of Compliance with US sanitary Requirements (Appendix 2), has been prepared, and in item 6.2.1.3, cites the following obligations applying to establishments, which must be met immediately:

		During processing of the products, two measuring instruments must necessarily be used for production monitoring: one static temperature indicator, fixed to the equipment, plus one device able to record time/temperature continuously during the entire process (thermo-recorder). The difference between the two measuring systems may not be greater than 0.5°C, and the thermo-recorder must be adjusted in such a way that the temperature recorded will not be, at any moment of the process, greater than that observed for the static temperature-measuring equipment. *Regarding the number of items of packaging that were present in the retorts during the thermal processing cycles, the sterilization machines must work under the same conditions that are used during penetration and heat distribution tests - in other words, the equipment must be at its maximum capacity. In this way, if production is insufficient to fill a machine (at the end of a batch, for example) its volume must be made up using cans identical to those being processed, which must be clearly marked and filled with inert material.* The above-mentioned protocol provides detail on the procedures to be adopted by the Official Service during the verification procedures to oversee the activities carried out by the establishments in seeking to produce commercially sterile products: *"*The SIFs operating in these establishments must perform verification of the maintenance of the autoclaves/retorts with the frequency laid down in Internal Standard no. 1/2017, and this verification must necessarily include on-site evaluation of the built facilities, equipment and instruments used in the process. The working of the equipment must also be observed, especially that of the temperature-measuring instruments, the steam equipment and the vents, which must be positioned in such a way as to allow evaluation when the retorts are operating. The total filling of the equipment in accordance with the approved production process description must also be verified. The verification procedures must also take the cooling water for this equipment into consideration within the set of water supply points to be officially verified for their quality,which includes laboratory tests for facultative anaerobes, pH and free residual chlorine, on site.*"*

07	*The regional Inspection Service of Products of Animal Origin (SIPOA) offices do not have direct access to all official microbiological testing results provided by testing laboratories*	To correct this deficiency, the Protocol of Compliance with US Sanitary Requirements (Appendix 2) has been prepared, and in item 3.2 cites the following obligations applying to Federal Inspection Services (SIFs), which must be met immediately: (...). In addition to the above-mentioned controls, the SIF must create a specific case file within the Electronic Information System (SEI), and insert the reports (COAs) for the official microbiological testing for compliance with US requirements on a monthly basis. The case files and documents inserted must adopt the following standardization: • Commence 01 (one) case file per SIF/year to include all the reports • *Iniciar processo* (start case file) -> *Inspeção de Produtos de Origem Animal* (Animal Product Inspection): *Análises Laboratoriais* (Laboratory Analysis) • Specification Official Tests SIF XXXX/YEAR - Nth SIPOA • Classification by topic: 330.3 - *PRODUTOS/INSUMOS PECUÁRIOS* (LIVESTOCK PRODUCTS/INPUTS) • *Interessados* (Interested parties): SIF XXXX • *Nível de acesso* (level of access): *Público* (Target Audience) • *Incluir documento externo* (include external document) • *Tipo de documento* (document type): *Laudo Laboratorial* (Laboratory report) • *Número / Nome na Árvore* (Number/Name in Tree): COA XXX Every month, the case file containing the lab reports (COAs) received by the SIFs must be sent to the SIPOA in question for acknowledgment and management. This is a control that is supplementary to the guidance given in Circular-Memorandum no. 15/2016/CGI/DIPOA/SDA/GM/MAPA, dated 2 March, 2016.”

08	*At the single audited swine slaughter and processing establishment, the establishment personnel were using the m/M criteria to analyze the generic E. coli results from samples collected using the carcass sponge technique. However, the use of the m/M criteria are applicable to only the excision method for sample collection, not the swabbing method*	The Protocol of Compliance with US sanitary requirements was prepared (Appendix 2), and in item 7.2.4, states how the results of samples taken for *E. coli* monitoring in swine carcasses must be managed. The deadline for compliance is immediate: ***II) Management of results*** *Microbiological targets:* *a) Acceptable limit: up to 10 CFU/cm²* *b) Marginal Limit: ≥ 10 and ≤ 10,000 CFU/cm2, where 10 is the lower limit (m) and* *10,000 is the upper limit (M)* *c) Unacceptable limit: > 10,000 CFU/cm²* *It must be stressed that the above-mentioned criteria may only be taken into consideration when the sampling is by the destructive method. If the sampling method used is sponge swabbing, the results must be analyzed by statistical process control techniques.*