

December 6, 2017

Ms. Carmen Rottenberg
Acting Deputy Under Secretary
Office of Food Safety
United States Department of Agriculture
331-E Jamie L. Whitten Building
12th Street and Jefferson Drive SW
Washington, DC 20250-3700

Transmitted electronically

RE: Petition to remove Brazil from 9 CFR 327.2 (b), Eligibility of foreign countries for importation of meat products into the United States

Dear Ms. Rottenberg,

On behalf of the advocacy group Food & Water Watch, I am respectfully filing this petition, in accordance with 9 CFR 392, to USDA's Food Safety and Inspection Service (FSIS) to remove Brazil as a country that is eligible to export meat products to the United States under 9 CFR 327.2 (b). We are taking this action because it has become obvious, through the agency's own audits of Brazil's meat inspection system over the past sixteen years and because Brazil's own law enforcement authorities recently exposed corruption of the inspection system, that Brazil no longer meets the criteria for equivalency with USDA's meat inspection system. To allow Brazil to continue to be eligible to export meat products to the United States would make a mockery of the equivalency determination process and lead to a diminishment of our food safety standards for imported products from other countries.

Legal Underpinnings of the FSIS Equivalency Determination Process

To remind the agency, 9 CFR 327.2 (a) (2) sets out the following criteria for evaluating a foreign country's meat inspection system to determine whether its system is equivalent to that of USDA:

- "(i) The system shall have a program organized and administered by the national government of the foreign country. The system as implemented must provide standards equivalent to those of the Federal system of meat inspection in the United States with respect to:
- (A) Organizational structure and staffing, so as to insure uniform enforcement of the requisite laws and regulations in all establishments throughout the system at which products are prepared for export to the United States;

- (B) Ultimate control and supervision by the national government over the official activities of all employees or licensees of the system;
 - (C) The assignment of competent, qualified inspectors;
- (D) Authority and responsibility of national inspection officials to enforce the requisite laws and regulations governing meat inspection and to certify or refuse to certify products intended for export;
 - (E) Adequate administrative and technical support;
- (F) The inspection, sanitation, quality, species verification, and residue standards applied to products produced in the United States.
- (G) Other requirements of adequate inspection service as required by the regulations in this subchapter.
- (ii) The legal authority for the system and the regulations thereunder shall impose requirements equivalent to those governing the system of meat inspection organized and maintained in the United States with respect to:
- (A) Ante-mortem inspection of animals for slaughter and inspection of methods of slaughtering and handling in connection with slaughtering which shall be performed by veterinarians or by other employees or licensees of the system under the direct supervision of the veterinarians;
- (B) Post-mortem inspection of carcasses and parts thereof at time of slaughter, performed by veterinarians or other employees or licensees of the system under the direct supervision of veterinarians;
- (C) Official controls by the national government over establishment construction, facilities, and equipment;
- (D) Direct and continuous official supervision of slaughtering and preparation of product, by the assignment of inspectors to establishments certified under paragraph (a)(3) of this section, to assure that adulterated or misbranded product is not prepared for export to the United States;
- (E) Complete separation of establishments certified under subparagraph (3) of this paragraph from establishments not certified and the maintenance of a single standard of inspection and sanitation throughout all certified establishments;
- (F) Requirements for sanitation at certified establishments and for sanitary handling of product;
- (G) Official controls over condemned material until destroyed or removed and thereafter excluded from the establishment;
- (H) A Hazard Analysis and Critical Control Point (HACCP) system, as set forth in part 417 of this chapter.
- (I) Other matters for which requirements are contained in the Act or regulations in this subchapter.
- (iii) Countries desiring to establish eligibility for importation of product into the United States may request a determination of eligibility by presenting copies of the laws and regulations on which the foreign meat inspection system is based

and such other information as the Administrator may require with respect to matters enumerated in paragraphs (a)(2) (i) and (ii) of this section.

Determination of eligibility is based on a study of the documents and other information presented and an initial review of the system in operation by a representative of the Department using the criteria listed in paragraphs (a)(2) (i) and (ii) of this section. Maintenance of eligibility of a country for importation of products into the United States depends on the results of periodic reviews of the foreign meat inspection system in operation by a representative of the Department, and the timely submission of such documents and other information related to the conduct of the foreign inspection system, including information required by paragraph (e) of section 20 of the Act, as the Administrator may find pertinent to and necessary for the determinations required by this section of the regulations.

- (iv) The foreign inspection system must maintain a program to assure that the requirements referred to in this section, equivalent to those of the Federal system of meat inspection in the United States, are being met. The program as implemented must provide for the following:
- (A) Periodic supervisory visits by a representative of the foreign inspection system to each establishment certified in accordance with paragraph (a)(3) of this section to ensure that requirements referred to in paragraphs (a)(2)(ii)(A) through (H) of this section are being met: Provided, That such visits are not required with respect to any establishment during a period when the establishment is not operating or is not engaged in producing products for exportation to the United States;
- (B) Written reports prepared by the representative of the foreign inspection system who has conducted a supervisory visit, documenting his or her findings with respect to the requirements referred to in (A) through (H) of paragraph (a)(2)(ii) of this section, copies of which shall be made available to the representative of the Department at the time of that representative's review upon request by that representative to a responsible foreign meat inspection official: Provided, That such reports are not required with respect to any establishment during a period when the establishment is not operating or is not engaged in producing products for exportation to the United States; and
- (C) Random sampling of internal organs and fat of carcasses at the point of slaughter and the testing of such organs and fat, for such residues having been identified by the exporting country's meat inspection authorities or by this Agency as potential contaminants, in accordance with sampling and analytical techniques approved by the Administrator: Provided, That such testing is required only on samples taken from carcasses from which meat or meat food products intended for importation into the United States are produced.
- (3) Only those establishments that are determined and certified to the Department by a responsible official of the foreign meat inspection system as

fully meeting the requirements of paragraphs (a)(2) (i) and (ii) of this section are eligible to have their products imported into the United States. Eligibility of certified establishments is subject to review by the Department (including observations of the establishments by Program representatives at times prearranged with the officials of the foreign meat inspection system)."

In addition, an FSIS document entitled, "Equivalence Process Overview" defines the equivalence determination process as follows:

"Equivalence is the process of determining whether a country's food safety inspection system achieves the Food Safety and Inspection Service's (FSIS) appropriate level of public health protection as applied domestically in the United States (US). Additionally, the foreign food safety inspection system is to provide standards equivalent to the FSIS to ensure other non-food safety requirements (such as humane handling, accurate labeling, and assurance that meat, poultry, or egg products are not economically adulterated) are met. This means that the country is not required to develop and implement the same procedures that the US does, but rather the country must objectively demonstrate how its procedures meets the US level of protection. Countries wishing to become eligible to export meat, poultry, or egg products to the US must demonstrate that they have a regulatory food safety inspection system that is equivalent to that of the US." 1

The Brazilian Track Record – It's A Broken Record

FSIS has posted on its website written audit reports for the Brazilian meat inspection system dating back to 2001, even though there are references to a 2000 audit in the 2001 audit report. What they reveal are systemic shortcomings in the Brazilian meat inspection system that surface and resurface regularly – it's like listening to a broken record.

The 2001 Audit

At that time, Brazil was restricted to export canned corned beef, canned beef, frozen processed beef and cured beef products because of animal diseases present in Brazil's animal herds (e.g., Hog Cholera, Swine Vesicular Disease, and Food and Mouth Disease). The restrictions on fresh meat imports were eventually lifted in 2010 for pork² and 2015 for beef³ (it should be noted that Food & Water Watch opposed both rules lifting these restrictions).

¹ See https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/Equivalence/equivalence-process-overview

²See 75 FR 69851–69857 and 76 FR 15211-15212

³ See 80 FR 37923 - 37934

Nine of the 28 establishments eligible to export to the United States were audited. While the Brazilian inspection system was found to meet U.S. meat inspection standards, the audit revealed deficiencies in eight of the nine establishments audited. Among the issues raised were: Hazard Analysis Critical Control Point (HACCP) implementation was found to be inadequate; sanitation was found to be lacking in one establishment; recordkeeping was inadequate for Sanitation Standard Operating Procedures (SSOP) in one establishment; there were cross-contamination issues identified in five of the establishments; humane slaughter violation in one establishment; Brazil did not ban felons who had violated Brazilian meat inspection laws from continuing to own and operate meat processing plants; differences were identified in the Salmonella testing program from that used in the United States; supervisory monthly reviews of the certified establishments were not conducted; pre-shipment reviews were not always conducted before products were exported to the United States.⁴

The 2002 Audits

Two audits were conducted in 2002 and they began to identify major problems in the Brazilian meat inspection system.

The first audit was conducted from January 9 through February 6, 2002. Thirteen establishments were visited and the FSIS auditor found the following deficiencies:

- continuing problems with periodic supervisory reviews of certified establishments (this
 is a repeat deficiency in all the establishments from 2001 audit);
- in eight establishments, the final review of all documentation associated with the production of the product prior to shipping was not done (**this is a repeat deficiency** in two establishments from 2001 audit);
- in seven establishments, the critical limits that were set were not measurable (this is a repeat deficiency in all the establishments from last audit except corrected in one establishment);
- in two establishments, the HACCP plan did not adequately address the corrective actions to be followed in response to deviations from critical limits (this is a repeat deficiency in one establishment from 2001 audit);
- in one establishment, the HACCP plan was not validated to determine that it was functioning as intended (repeat deficiency from 2001 audit);
- in one establishment, the HACCP plan's record-keeping system was not adequately documenting the monitoring of critical control points and/or was not including records with actual values and observations (this is a repeat deficiency from 2001 audit);
- convicted felons were not prohibited from owning/operating meat establishment (**this is a repeat issue** from 2001 audit); instances of actual product contamination and

⁴ See https://www.fsis.usda.gov/wps/wcm/connect/c5fa9ea4-e076-456e-ac93-d16ac2e9d561/Brazil2001.pdf?MOD=AJPERES

- instances of the potential for direct product contamination (this is a repeat issue from 2001 audit);
- the continuing problems with the implementation and maintenance of SSOPs in certified establishments (this is a repeat deficiency from 2001 audit); the continuing problems with implementation and maintenance of HACCP systems in all certified establishments (this is a repeat deficiency from 2001 audit);
- deficiencies in the approved private laboratories for the testing of Salmonella concerning the laboratories' quality assurance programs;
- deficiencies in the residue Laboratorio Regional de Apoio Animal (LARA/MG) in Porto Alegre concerning the laboratory's quality assurance programs. In the other residue Laboratorio Regional de Apoio Animal (LARA/MG) in Pedro Leopoldo, mercury testing was not included in the trace element testing program;
- lack of inspectional control of devices (brands and including signature verification seals) requiring security and maintenance of inventory records;
- inadequate pest control prevention programs; government meat inspectors were reconditioning the dropped meat instead of inspecting and verifying the adequacy and effectiveness of handling and reconditioning of dropped meat in a sanitary manner by the establishment personnel.⁵

The second audit was conducted between October 16 and November 18, 2002. The auditor visited 20 establishments. The audit found that the Brazilian food safety authorities had addressed most of the deficiencies found in the January-February 2002 audit with the following exceptions: There were still deficiencies in the implementation of SSOPs. For example, there was inadequate recordkeeping to document when preventive actions were taken for deficiencies; five establishments did not have preventive actions addressed in the SSOP plan; one establishment did not specify activities being verified on their records; an incomplete SSOP plan; one establishment had a written SSOP plan, but no operational SSOP plan; one establishment did not have verification or validation included in its SSOP, but daily records indicated that they were being carried out; one establishment only documented production runs for the United States and did not record preventive actions. There were visible sanitation issues in four of the plants visited (e.g., product surfaces were not free of product residues from previous day's production.)

The 2003 Audits

There were two audits conducted in 2003. Many old problems and new issues surfaced that raised concerns for FSIS auditors.

The first audit was conducted between August 29 and September 24, 2003. Five laboratories and 11 establishments were visited. The issues raised during this audit included the following:

⁵ See https://www.fsis.usda.gov/wps/wcm/connect/60a2ce45-48ed-430a-91bd-fa6a80161787/Brazil2002.pdf?MOD=AJPERES

- two of the establishments visited were delisted by Brazilian authorities due to poor sanitation, ineffective implementation of SSOP and HAACP programs, and monthly supervisory reviews with documented deficiencies that had not been addressed;
- one establishment received a Notice of Intent to Delist from the Brazilian Inspection Service due to the lack of SSOP and HACCP implementation documentation;
- during the exit meeting, the FSIS auditor learned that it was possible for "the Brazilian Inspection Service to use the services of establishment-paid inspection personnel (auxiliaries) in the "extreme" situation. The "extreme" situation was defined as not having enough government inspectors. This is provided for in Brazilian law. The unacceptability of this practice for the U.S. exporting establishments has been previously pointed out to Brazilian inspection officials by FSIS officials"⁶;
- in three establishments, the following deficiencies were observed: pre-operational deficiencies were observed in the boning area in one establishment. Pieces of fat and meat were found on the conveyor belt and skinning equipment. This area was released for operation after corrective action was completed by the cleaning crew;
- in one establishment, many cartons had been damaged by fork lifts, exposing product that was likely contaminated. A product re-inspection table was dusty. (This is a repeat finding);
- in one establishment, the hindquarters of beef carcasses were contacting employees'
 platforms in the boning room. In one establishment, dripping condensate from
 overhead refrigeration units, rails and ceilings that were not cleaned sanitized daily, was
 falling onto beef carcasses in three coolers. This deficiency was not recorded in the daily
 sanitation report and was not described as a deficiency in the SSOP program. (This is a
 repeat deficiency);
- non-dripping condensation from the ceiling and at the entrance to the offal processing room in the viscera cooler in one establishment;
- in the slaughter area in one establishment. an employee was observed contaminating a carcass by removing a hoof and not washing his hands before touching the carcass with his contaminated hand:
- in one establishment, maxilla and mandibula separating equipment was contacting the wall and there was no sanitizing equipment in the room;
- in one establishment, a bucket used for edible product purposes was set directly on the floor in the beef extract area;
- in one establishment, the facility corridors were in total disarray, creating the potential for rodent harborage. (This is a repeat finding);
- in two establishments, the doors to the outside were not sealed properly to prevent rodent or other pest entry. (**This is a repeat finding**);
- in two establishments, extensive structural damage was noted throughout the facilities and many of the ceiling areas were wet due to roof damage. in one establishment, the

⁶ See https://www.fsis.usda.gov/wps/wcm/connect/afbb134f-f9bb-4d3c-ad33-de89c141e663/Brazil2003.pdf?MOD=AJPERES, p. 7.

- chlorination system for the water used for cleanup of the dock and reinspection areas was broken;
- in one establishment, the employee dressing room was in complete disarray. Street clothes and personal items were stored with clean work clothes;
- numerous insects and spiders were observed;
- hand-washing equipment in the restroom was hand operated;
- not all cartons were covered or protected;
- the rodent/insect control program was not clearly described and the corrective actions taken were not sufficient in one establishment;
- numerous flies were observed in the slaughter room in one establishment;
- Washing of dirty containers was observed to be deficient in the offal processing area in one establishment;
- no liquid soap was found at the hand washing area in the canned beef area in one establishment;
- sanitizers were not maintained at the required temperature in the offal processing room and mincing room in two establishments. (**This is a repeat finding)**;
- Additional problems were found in other establishments audited: HAACP plan implementation was inadequate in four establishments (This was a repeat finding); generic E. coli testing was inadequate in two establishments; residue testing was found to be deficient. (This is a repeat finding); Salmonella sampling program was not consistent with FSIS protocols. (This is a repeat finding).

A special follow-up audit was conducted from November 10 through 20, 2003. That audit revealed the fact that 185 company-paid inspectors—not government inspectors—were performing inspection functions for meat products in establishments that exported to the United States in violation of 9 CFR 327.2.⁷

The 2004 Audit

FSIS visited 13 establishments and four laboratories during the audit that took place between August 26 and September 28, 2004. While many of the issues raised during the 2003 audits were corrected, the FSIS auditor still found sanitation problems in several of the plants visited. One plant was delisted when numerous sanitation problems were identified by the FSIS auditor, there were issues identified in the government laboratories with the residue testing protocols and there were still deviations with the Salmonella testing program.⁸

⁷ See https://www.fsis.usda.gov/wps/wcm/connect/2fb8320b-aca5-4ac4-807c-8b069a0229fa/BrazilNov2003.pdf?MOD=AJPERES

⁸ See https://www.fsis.usda.gov/wps/wcm/connect/4cdfe384-5ea5-4eea-bff1-fc8fa7d777ce/Brazil2004.pdf?MOD=AJPERES

The **FOUR** 2005 Audits

FSIS conducted four audits in 2005 due to another series of major lapses in the Brazilian food safety inspection program.

- 1. FSIS conducted an on-site enforcement audit between March 10 and April 14, 2005. The purpose of the audit "was to determine whether Brazil was maintaining an equivalent meat inspection system and may continue to export meat products to the United States (U.S.)." The audit covered 11 establishments for the payment of inspectors, 15 establishments for meeting U.S. food safety standards, seven residue testing and ten microbiological testing laboratories. The issues identified in the audit included the following:
- the organizational structure of the meat inspection system did not provide for effective oversight of inspection system at the establishment level;
- the inspection system did not have direct oversight of the laboratories;
- the inspection authority did not have systems in place to address deficiencies in the inspection system;
- there was no consistent training program for inspectors;
- 14 of the establishments audited did not adequately enforce U.S. standards over products exported. In fact, the Brazilian meat inspection authorities relied on the FSIS auditor to show them how U.S. food safety standards were not being met;
- the Brazilian inspection authorities could not demonstrate that they had control over how non-federal inspectors who are loaned to the federal government to perform inspections in certified establishments were being paid by the government. The FSIS auditor found that there were no systems in place to ensure uniform hiring practices and how salaries were paid to contracted inspection personnel. In addition, the auditor found that both contracted and permanent inspectors were permitted to eat free or at a reduced rate in establishment cafeterias. Some inspectors received free or reduced fee transportation and free housing or subsidized housing provided by the establishments they inspected. All inspectors were receiving free medical check-ups from establishment medical personnel. Establishment medical personnel were permitted to put government inspectors on sick leave. These findings raised serious conflict-of-interest concerns;
- as was found in previous audits, HACCP requirements were not effectively implemented in 14 establishments that were visited;
- as was found in previous audits, the Brazilian meat inspection authorities did not have adequate controls over sanitation in plants;
- both residue and microbiological testing programs were found to be deficient and issues raised in previous audits conducted by FSIS still had not been addressed;

⁹ https://www.fsis.usda.gov/wps/wcm/connect/a744c7f7-f13e-4b5f-a0c5-f2e4c8af8792/Brazil2005.pdf?MOD=AJPERES, p. 4

- inspections for bovine spongiform encephalopathy were not being done properly.
- most of the plants audited were either delisted or served with a Notice with the Intent to Delist as a result of the audit. As a result, Brazil was suspended as being eligible to export to the United States.
- 2) A second enforcement audit was conducted between June 2 and 23, 2005. Three laboratories and six meat establishments were visited. The six establishments visited were among those that had serious sanitation issues identified in the March/April 2005 audit. This audit showed that those deficiencies had been corrected. In addition, the conflict of interest concerns for Brazilian inspection personnel raised in the earlier audit were being addressed by the Brazilian meat inspection authorities.

However, the deficiencies found in this audit included: FSIS was unable to verify even though the central Brazilian meat inspection authority's claim that new monthly review procedures of establishment inspections had been put in place; the meat inspection agency still had no direct oversight of the laboratory system; methods to detect and confirming Listeria monocytogenes and Salmonella still did not meet FSIS requirements; and while the inspection system had received additional funding to provide training to inspectors, there was no way to assess the effectiveness of the new training program.¹⁰

- 3) A third enforcement audit was conducted between July 7 and July 27, 2005. Eleven laboratories and eight meat establishments were visited. While some of the deficiencies identified during the June 2005 audit had been addressed, the issues that surfaced in this audit included: The new training program for inspectors and laboratory personnel was not effective; the methodologies used in some of the microbiological testing laboratories were found to be deficient; the Sanitation Standard Operating Procedures in two meat establishments were found to be deficient; and four meat establishments did not meet sanitation performance standards. One of these plants received a Notice of Intent to Delist; one establishment did not meet HACCP recordkeeping requirements; inspection personnel did not take enforcement actions when an establishment failed to implement corrective actions as scheduled; the supervisory monthly review of inspections had still not been implemented; and the conflict-of-interest mitigation measures were still being implemented by the Brazilian meat inspection authorities. 11
- 4) A fourth enforcement audit was conducted between October 19 and November 7, 2005. Six laboratories and 8 meat establishments were audited during this visit. While many of the deficiencies identified in the previous three enforcement audits had been addressed, there were still several outstanding issues that had not been corrected to FSIS' satisfaction. Among those issues: the supervisory monthly review system could cause

¹⁰ See https://www.fsis.usda.gov/wps/wcm/connect/9457b17e-cfc6-43d6-9463-61e61cd4789f/BrazilJun2005.pdf?MOD=AJPERES

 $^{^{11}}$ See https://www.fsis.usda.gov/wps/wcm/connect/ee105053-5e38-4e14-a7af-8b7ed896f8a7/BrazilJul2005.pdf?MOD=AJPERES

conflicts-of interest problems to arise; one plant received a Notice with the Intent to Delist because of sanitation violations even though Brazilian inspection authorities had selected the plant to audit because they were confident that it would meet U.S. standards; two of the microbiological testing laboratories were found to have deficient methodological procedures. One of them was eventually removed as being eligible to test meat products destined for the United States; two of the meat establishments still had inadequate HACCP recordkeeping procedures; the Brazilian meat inspection authority was still in the process of implementing safeguards against conflict of interest issues involving the payment of inspectors.¹²

The 2006 Audit

This audit was conducted between August 16 and September 12, 2006. One microbiological laboratory and eight meat establishments were visited. While some of the issues raised in the October/November 2005 enforcement audit had been addressed, the following deficiencies were identified in the 2006 audit: One meat establishment had an inadequate HACCP plan and as a consequence was found not to be able to maintain process control over products destined for the United States. That plant received a Notice with the Intent to Delist because of that issue; several plants were found to have had inadequate HAACP plans; two establishments had inadequate HAACP recordkeeping; one establishment had an inadequate SSOP, SOP or prerequisite program to deal with the reconditioning of meat that had dropped to the floor; and one establishment had insanitary conditions where meat was being processed.

The method of payment to Brazilian meat inspectors had met FSIS requirements, although not all inspectors were employed directly by the Brazilian Ministry of Agriculture.¹³

The 2007 audit

FSIS conducted an audit between August 14 and September 13, 2007. Three laboratories and eight meat establishments were visited. The following deficiencies were found during the audit: In one establishment, inspection officials were not conducting verification of monitoring activities for zero tolerance for milk, ingesta, and fecal material on beef carcasses; in three establishments, pre-shipment review records were initialed, but were not signed; in one establishment, corrective actions for measures to prevent recurrence of fecal contamination identified in the HACCP plan and in the records documenting actions taken in response to a deviation from a critical limit were not effective; in one establishment, a grinder did not have a protective shield to prevent contamination.¹⁴

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¹² See https://www.fsis.usda.gov/wps/wcm/connect/cf3de5b8-aa8a-4f33-8431-cdabdda0ab80/BrazilOct2005.pdf?MOD=AJPERES

¹³ See https://www.fsis.usda.gov/wps/wcm/connect/05db2d15-2244-409a-b3df-763b772975ed/Brazil2006.pdf?MOD=AJPERES

¹⁴ See https://www.fsis.usda.gov/wps/wcm/connect/152dc3ff-849d-4fdf-8e93-65654ab89899/Brazil2007.pdf?MOD=AJPERES

The *Two* 2008 Audits

There were two audits conducted in 2008 because there was a relapse in the Brazilian meat inspection system.

- 1) The first audit was conducted between June 11 and July 22, 2008. Three laboratories and 11 meat establishments were visited. The major (and familiar) deficiencies found included:
- the federal meat inspection agency did not provide adequate oversight of inspection personnel;
- the state inspection regional offices did not provide adequate supervision over veterinarians and inspectors assigned to plants that exported to the U.S.;
- the veterinarians could not demonstrate that they provided adequate oversight of inspection personnel;
- state inspection regional offices did not demonstrate that they could enforce U.S. food safety requirements in plants that exported to the United States;
- municipal meat inspectors were still used in some establishments even though a commitment had been made to the U.S. in 2005 that only federal inspectors would staff establishments that exported to the United States;
- in one establishment, there was no inspection coverage during the first shift of plant operations;
- inspector training was inadequate;
- in newly certified plants, inspection personnel had little or no training in U.S. food safety and inspection requirements;
- two establishments were delisted for noncompliance with implementation requirements for SSOPs, Sanitation Performance Standards (SPS) and HACCP programs;
- seven establishments received a Notice of Intent to Delist for inadequate implementation of HACCP, SSOP and SPS requirements;
- in all 11 establishments visited, some SSOP requirements were not met;
- in nine of the establishments, some SPS requirements were not met;
- in ten establishments, some HACCP implementation requirements were not met;
- in all 11 establishments, the periodic supervisory reviews performed by Brazilian inspection authorities did not adequately verify the implementation of HACCP, SSOP and SPS requirements;
- in six establishments, inspection officials were not verifying the reliability and effectiveness of the SSOP adequately to ensure that the establishment met the FSIS requirements;
- in four establishments, inspection officials had conducted pre-operational and operational sanitation SSOP verifications but no deficiencies had been reported during periods ranging from two to six months;
- in six establishments, documentation of corrective actions taken in response to deficiencies identified during pre-operational and operational sanitation inspection did

- not include procedures to ensure appropriate disposition of product(s) that could be contaminated;
- in two establishments, inspection officials did not review and determine the adequacy
 of corrective actions taken when a deviation from a Critical Limit (CL) occurred.
 In one establishment, inspection officials were not verifying the adequacy of the
 establishment's HACCP plan for the first-shift operations to determine if it met FSIS
 requirements;
- in one establishment, inspection officials were not verifying the adequacy of the establishment's HACCP plan for the second-shift processing operations to determine if it met FSIS requirements for direct measurement at a critical control point;
- in two establishments, inspection officials did not remove Specified Risk Materials (SRMs) (tonsils) in a sanitary manner during the post-mortem inspection;
- in one establishment, an establishment employee was not removing SRMs (spinal cords) in a sanitary manner to ensure that there was no cross-contamination with edible product (broken pieces of spinal cords were contacting edible parts of the carcasses).
- in five establishments, inspectors at the post-mortem inspection stations were not incising and observing lymph nodes or the masticatory muscles of beef heads properly;
- laboratories were not audited on a periodic basis as was promised in 2005 by Brazilian authorities;
- there were deficiencies found in both the residue and microbiological testing laboratories visited.¹⁵

As a result of this audit, Brazil voluntarily suspended exports to the United States.

2) The second audit took place between August 28 and September 5, 2008. This was a follow-up to the highly critical audit that took place earlier in the year. Eight meat establishments were visited during this audit. No laboratories were audited. There was a reorganization of the Brazilian meat inspection system in order to make the inspection system more accountable to the national meat inspection agency. While many of the establishment deficiencies found during the June/July audit were addressed by the Brazilian meat inspection authority, the following problems were still identified: one establishment failed to verify HACCP plan requirements during the second shift of production and there was no record of inspection personnel citing the establishment for the violation; some inspection personnel and veterinarians were compensated by municipalities even though the Brazilian meat inspection authority had made a commitment to FSIS three years earlier that the federal government would employee all inspection personnel; in one establishment, SSOP requirements were not met; in two establishments, some SPS requirements were not met; in two establishments, there were deficiencies in HACCP requirements.¹⁶

¹⁵ See https://www.fsis.usda.gov/wps/wcm/connect/3490af10-c23d-4f16-b020-9404bcf36eb6/BrazilJune2008.pdf?MOD=AJPERES

 $^{^{16}}$ See https://www.fsis.usda.gov/wps/wcm/connect/dee1d3ef-434c-45a7-bf92-40702697030b/BrazilAugust2008.pdf?MOD=AJPERES

The 2009 Audit

The audit took place between July 7 and August 14, 2009. Two laboratories and 11 meat establishments were visited. The laboratory deficiencies identified during the June/July 2008 audit were corrected. However, the following deficiencies were found in the 11 meat establishments visited: in two of the establishments, some SSOP requirements were not met; in three establishments, some SPS requirements were not met; in one establishment, one or more HACCP problems were reported; in one establishment, inspection officials were not adequately reviewing and determining the adequacy of corrective actions taken when a deviation from a critical limit occurred.¹⁷

Ivermectin and the 2010 Audit

On May 14, 2010, FSIS announced that Sampco, Inc recalled 84,000 pounds of corned beef products imported from Brazil due to the presence of the excessive levels of the animal drug ivermectin in the meat. That recall was later expanded to cover another 61,000 pounds of product on June 24, 2010. It remains a mystery why those were the only two recalls since, at the time, there were millions of cans of imported corned beef products from Brazil in commerce in the United States. In March 2010, the USDA Office of Inspector General (OIG) issued an audit report in which it was critical of the FSIS National Residue Program for beef cattle. In that report, the OIG specifically identified ivermectin as an animal drug of concern to human health. The report stated that one of the potential side effects of ivermectin is that produces neurotoxicity in humans, such as "altering normal activity of the nervous system which can eventually disrupt or even kill neurons, key cells that transmit and process signals from the brain." ²⁰

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¹⁷ See https://www.fsis.usda.gov/wps/wcm/connect/4c32a003-01a7-4459-a86c-31765151d08f/Brazil2009.pdf?MOD=AJPERES

¹⁸ See https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/recall-case-archive/recall-case-archive-

^{2010/!}ut/p/a0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOINAg3MDC2dDbz83RzdDDz9jN3CLPzcDQ38zfQLsh0VAWsFoBU !/?1dmy¤t=true&urile=wcm%3apath%3a%2Ffsis-archives-

content%2Finternet%2Fmain%2Ftopics%2Frecalls-and-public-health-alerts%2Frecall-case-archive%2Farchives%2Fct index288a

¹⁹ See https://www.fsis.usda.gov/wps/portal/fsis/newsroom/news-releases-statements-transcripts/news-release-archives-by-year/news-release-archives-by-year-

^{2010/!}ut/p/a1/jZDdCoJAEEafpQdYdlZL9Flk8ycVicz2JrbYdMFUVjHs6VO6MpKcu5k5H4cZTHGKack6kbFWVCUrxp5qF4hBl4YFXmSbNrihaid6uCOw3QzAeQIYZASSOPItC RQXZifKRP-5b0FAkUGVpBhWrM2R6K8Vzgt-

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²⁰ See https://www.usda.gov/oig/webdocs/24601-08-KC.pdf, p. 8

When the then-FSIS Administrator Alfred V. Almanza was dispatched to Brazil to investigate how widespread the residue testing deficiencies were in that country, he described the problem as being "systemic." Brazil eventually suspended all exports to the United States voluntarily.

The FSIS audit of the Brazilian meat inspection system took place between August 31 and September 22, 2010. Two residue laboratories and four meat establishments were visited. The deficiencies found included: the Brazilian meat inspection authority could not demonstrate that it had regulations or procedures in place to recall adulterated products that violated the Federal Meat Inspection Act; between March 26 and June 1, 2010, FSIS testing found 22 port-of-entry violations for ivermectin. FSIS concluded that this demonstrated a lack of process control in the Brazilian meat inspection system and a lack of oversight of the chemical residue testing system. The Brazilian meat inspection authority agreed to implement new control procedures over its laboratory testing program for chemical residues.²² It should be noted that past FSIS audits of the Brazilian meat inspection system had identified deficiencies in the Brazilian residue testing program and the lack of a testing protocol for ivermectin was specifically singled out as an issue.²³

The 2013 Audit

This audit was conducted between February 18 and March 16, 2013. Five meat establishments were visited with a special focus on swine slaughter facilities. USDA had revealed in April 2010, as part of an announcement of an agreement reached with Brazil on the settlement of a World Trade Organization ruling on U.S. cotton subsidies, that the USDA would start rulemaking to permit the export of fresh meat products from the Brazilian state of Santa Catarina. ²⁴ The two swine slaughter facilities audited were located in Santa Catarina. In addition, Brazil reported in 2012 that it had experienced its first case of bovine spongiform encephalopathy in 2010 that it had kept secret for two years which led many countries to stop beef imports from Brazil. ²⁵ The FSIS audit concentrated on the removal of specified risk removal (SRM) in the two beef slaughter facilities that were visited. One beef processing facility was also audited. The audit revealed the following deficiencies:

the Brazilian meat inspection authority did not provide a standard guideline to its
inspection personnel concerning the definition of SRM in cattle in accordance with FSIS'
requirements cited in 9 CFR 310.22, resulting in inconsistent implementation of the SRM
requirements throughout the system (this is a repeat deficiency from previous audits);

²¹ "USDA Plays Hardball over Brazilian Processed Beef," Food Chemical News, August 9, 2010.

²² See https://www.fsis.usda.gov/wps/wcm/connect/bee4f47a-b2c8-4657-809b-54364204485b/Brazil2010.pdf?MOD=AJPERES

²³ See 2004 audit, p. 7;.

²⁴ See http://www.nytimes.com/2010/04/07/business/07trade.html

²⁵ http://japandailypress.com/japan-halts-brazilian-beef-imports-after-mad-cow-discovery-1019597/

- the inspection authority's ready-to-eat verification sampling program did not include on-going verification sampling of food contact surfaces and environmental (non-food contact) surfaces in accordance with FSIS' equivalence criteria for listeria monocytogenes control in ready-to-eat products;
- the inspection authority's inspection personnel did not fully enforce its basic and ongoing HACCP requirements concerning the contents of HACCP plan and recordkeeping requirements in the five audited establishments (this is a repeat deficiency from previous audits);
- the inspection authority's inspection personnel conducted periodic supervisory reviews at a lower than intended bimonthly frequency in two swine establishments audited; and the inspection authority's inspection personnel did not fully enforce sanitation requirements to prevent cross-contamination of bovine carcasses in one slaughter establishment (this is a repeat deficiency from previous audits).²⁶

The 2014 Audit

This audit took place between September 15 and October 3, 2014. Two laboratories and five beef establishments were visited. In May 2014, Brazil discovered its second case of bovine spongiform encephalopathy in a cow. ²⁷ The 2014 audit report revealed that at the time of the 2013 audit (Feb/March 2013), there was an unusually high number of port-of-entry rejections of Brazilian beef products due to high levels of ivermectin (**this is a repeat issue**). FSIS notified Brazil that it would not permit the importation of beef products from Brazil from newly certified plants if the problem were not corrected. In June 2014, FSIS refused the importation of beef products from one Brazilian meat plant because the Brazilian meat inspection authority had failed to provide FSIS with a corrective plan to deal with the residue testing program in that plant. In December 2013, the Animal Plant Health Inspection Service (APHIS) proposed a rule to lift the ban on fresh beef imports from 14 Brazilian states because the agency had found no risk of foot and mouth disease in those states. The 2014 audit was designed to review the food safety systems in beef slaughter facilities in anticipation of the implementation of the APHIS rule.

The deficiencies identified in this audit included: failure by the Brazilian meat inspection authority to communicate in a timely manner to local inspection personnel port-of-entry violations involving exports to the United States; two establishments were registered to produce products they no longer had the capacity to produce; local inspection officials informed the FSIS auditor that they did not have the capacity to test suspect animals for violative levels of residues; periodic supervisory reviews were not conducted at the prescribed frequency at one establishment (this is a repeat violation); some sanitation issues were found in several of the plants, but nothing was considered major; there was an incomplete HACCP

²⁶ See https://www.fsis.usda.gov/wps/wcm/connect/597c45a9-9334-465f-aa3f-1d8b8549c573/Brazil_2013_FAR.pdf?MOD=AJPERES

²⁷ See https://www.reuters.com/article/us-brazil-madcow/brazil-confirms-second-case-of-atypical-mad-cow-disease-idUSKBN0DQ0J020140510

plan in one establishment that failed to identify a hazard likely to occur which could lead contaminated product to be exported to the United States; there was a deficient HACCP plan in one establishment that did not have proper recordkeeping requirements; the Brazilian meat inspection authority did not require intra-laboratory proficiency testing which is specifically required for meat products exported to the United States; in two establishments, outdated Salmonella testing protocols on carcasses were being used; and there was no testing program for shiga-toxin producing Escherichia coli. FSIS noted that this would need to be addressed before it would permit any fresh beef products to be exported from Brazil to the United States in the future.²⁸

The 2015 Audit

This audit took place between November 9 and 20, 2015. One laboratory, seven beef slaughter/processing facilities (including five that indicated intentions to export fresh beef to the United States), three beef processing facilities and one pork slaughter facility were visited. On July 2, 2015, APHIS published a final rule that cleared, from an animal health standpoint, fresh beef exports to the U.S. from fourteen Brazilian states.²⁹ One of the foci of the FSIS 2015 audit was to evaluate the food safety inspection system for beef slaughter.

The deficiencies found during the 2015 audit included:

- FSIS determined that the Brazilian meat inspection authority needed to revisit its
 procedure as it related to FSIS port-of-entry violation notifications. While FSIS requests a
 reply to these notifications within 30 calendar days, the auditors noted that the CCA's
 average response time is 109 calendar days (this finding is related to deficiencies
 identified during the last FSIS audit in September 2014);
- a portion of Brazil's inspection force was not familiar with procedures in the Brazilian meat inspection authority's Guidelines for Implementing the National Residue Control Plan (132/2012), which govern the targeting of animals suspected of containing violative levels of chemical residues at ante-mortem (this is a repeat finding);
- FSIS determined that the Brazilian meat inspection authority needed to improve its verification activities related to the safety of retort cooling water and retort maintenance; deficiencies regarding construction and enforcement of sanitation performance standards (SPS) were identified at five of the eleven establishments audited (this is a repeat finding);
- FSIS determined that the Brazilian meat inspection authority needed to improve its slaughter verification activities. At one of the eight slaughter establishments audited, viscera did not routinely accompany carcasses railed-out for final veterinary dispositions. At another establishment, the design of a non-mobile stand used by the government for

 $^{^{28}}$ See https://www.fsis.usda.gov/wps/wcm/connect/3ec96b2d-57a1-4688-981c-19f698fcdd99/Brazil_2014_FAR.pdf?MOD=AJPERES

²⁹ 80 FR 37923-37934

- conducting zero-tolerance verification (contamination caused by feces, milk, or ingesta) did not permit adequate observation of carcass hindquarters;
- the Brazilian meat inspection authority had not yet instituted a Shiga toxin-producing Escherichia coli (STEC) proficiency testing program at its government laboratories (this is a repeat finding from the 2014 audit);
- written STEC government laboratory testing procedures were inconsistent with actual practice;
- no official procedure existed for the handling of inconclusive STEC sample results. FSIS reiterated that until the STEC testing regime met U.S. requirements, fresh beef products would not be eligible for export to the United States.

Operation Weak Flesh and the 2017 Audit

Even though there was no official announcement from FSIS that the Brazilian STEC testing protocols met U.S. requirements, the first shipment of fresh Brazilian beef reached the United States in September 2016.³⁰ In March 2017, Brazilian federal law enforcement authorities launched raids into Brazilian meat companies that were involved in corruption which included the payment of bribes to Brazilian meat inspectors that led to adulterated meat entering commerce both domestically and in exports.³¹ The operation was called Carne Fraca, or "The Flesh is Weak," and it involved investigations into some of the largest meat processing companies in Brazil, including BRF and JBS. Many countries immediately imposed bans on Brazilian meat imports, but notably, not the United States.³² Instead, the United States instituted "100% re-inspection" of all Brazilian meat imports at our ports-of-entry.³³ FSIS conducted an audit of the Brazilian meat inspection system between May 15 and June 2, 2017. Three laboratories, five cattle slaughter/processing facilities, three meat processing facilities, and one swine slaughter/processing facilities were visited. The deficiencies identified included:

- the Brazilian meat inspection authority had not developed policies and procedures to identify potential areas where conflicts of interest could arise between inspection personnel and the regulated establishments where they work (this is a repeat finding);
- the Brazilian meat inspection authority did not verify that regulatory information provided to supervisory official veterinarians is consistently communicated to their subordinates (this a repeat finding);
- the CCA did not verify that in-plant inspectors perform their assigned duties in a manner that is consistent with the issued instructions (this a repeat finding);

³² https://www.reuters.com/article/us-brazil-corruption-food-exports/operation-weak-flesh-takes-bite-out-of-brazils-meat-exports-idUSKBN16V281

³⁰ https://www.globalmeatnews.com/Article/2016/09/28/Marfrig-celebrates-as-first-Brazilian-beef-arrives-in-US

³¹ https://www.ft.com/content/7a5df018-0b35-11e7-97d1-5e720a26771b

³³ https://www.usda.gov/media/press-releases/2017/03/22/usda-tainted-brazilian-meat-none-has-entered-us-100-percent-re

- the Brazilian meat inspection authority had not developed procedures to standardize the assessment of competence and performance of in-plant inspection personnel assigned to United States-certified establishments (this a repeat finding);
- the implemented post-mortem inspection procedures are inadequate to ensure that only wholesome carcasses, free of contamination and defects receive the mark of inspection;
- Brazilian thermally-processed meat products reinspected at United States point-of-entry demonstrated a trend of abnormal container violations (this is a repeat finding);
- higher-level officials did not adequately review and follow-up on periodic supervisory reports and plans of action (this is a repeat finding);
- inspection personnel do not adequately enforce sanitation regulatory requirements to prevent the creation of insanitary conditions and direct product contamination (this is a repeat finding);
- inspection personnel do not accurately assess the design and implementation of the establishments HACCP systems, and do not conduct adequate verification sampling of products (this a repeat finding);
- the official methods of chemical analysis used by the government laboratories is inconsistent with FSIS requirements (this a repeat finding);
- the Brazilian meat inspection authority has not instructed establishments and in-plant inspectors to hold livestock carcasses selected for residue sampling until acceptable results are received.³⁴

On June 22, 2017, USDA announced that it was banning the importation of fresh beef imports from Brazil due to an abnormal number of import rejections at ports-of-entry due to "public health concerns, sanitary conditions, and animal health issues." ³⁵

The European Commission's DG SANTE conducted an audit of the Brazilian meat inspection system between May 2 and May 12, 2017 and found the following deficiencies:

- the Brazilian meat inspection authority had put in place audit and supervision systems aimed at verifying the effectiveness of the official controls in establishments approved for EU exports. However, because of the shortcomings in the implementation of these systems, they were found not to be effective in detecting and acting on significant noncompliances in the performance of the inspection personnel at the state/local level;
- the inspection personnel had failed to ensure that all poultry meat slaughterhouses approved for EU exports are under the supervision of official veterinarians and/or official duties have been carried out in accordance with relevant EU rules;
- while detailed procedures existed for the de-listing of establishments intending no longer to export to the EU, the implementation of the system in place did not guarantee

³⁴ See https://www.fsis.usda.gov/wps/wcm/connect/eaf15cdd-49e1-475c-a3e1-8acb91f48645/Brazil-2017-FAR.pdf?MOD=AJPERES

³⁵ https://www.usda.gov/media/press-releases/2017/06/22/perdue-usda-halting-import-fresh-brazilian-beef

- that the list of establishments approved for EU export and communicated to the Commission is accurate and kept up-to-date;
- in some cases, the arrangements in place did not ensure that staff performing official tasks is free from conflict of interest;
- the inspection personnel were signing export certificates despite being unable to ascertain the veracity of certain statements contained therein;
- there were gaps in the disposition of rejected consignments, for which no procedures were in place to ensure that they were not subsequently re-dispatched to EU;
- products from the same batch implicated by a rejection notification for which no procedures existed to ensure that they could not be exported before proper action is taken to ensure that food safety risks had been controlled;
- while the Brazilian inspection authority was found to have reacted swiftly to the police investigations, including suspension of production and certification from the export listed establishments, there was no guarantee of preventing export of non-compliant product to the EU. However, their actions were limited to the 21 establishments under police investigation and the staff involved: they carried out no investigations of linked establishments (e.g. belonging to the same food business operator) or into official staff subject to investigation working at other locations. At the time of the DG SANTE audit, the Brazilian inspection authority had not considered any long-term actions to prevent similar situations in the future;
- most of the shortcomings detected during this audit were the subject of recommendations in previous DG SANTE audits. "The Brazilian meat inspection authority had provided written guarantees that the issues concerned by the previous recommendations had been addressed. However, the findings of this audit demonstrated that those previous guarantees were not reliable on some key EU requirements." (emphasis added)³⁶

Conclusion

FSIS has continued to permit Brazil to export pork products and thermally processed beef products to the United States although those products are subject to 100 percent re-inspection at the ports-of-entry. Essentially, FSIS still does not trust the competence of the Brazilian meat inspection system even for those products. This subverts the purpose of equivalency. FSIS is still waiting for the Brazilian meat inspection authority to address the concerns raised during the 2015 and 2017 audits before it will permit Brazil to resume fresh beef exports to the United States.³⁷ The question is why? One definition of insanity is trying the same thing over and over

³⁶ See http://ec.europa.eu/food/audits-analysis/audit reports/details.cfm?rep inspection ref=2017-6261

³⁷ From *Politico*'s "Morning Agriculture," December 1, 2017: "USDA says Brazilian beef ban stays: As Brazilian meat companies tell news outlets like Reuters that the ban on beef exports into the U.S., begun in June, will be lifted early in 2018, USDA stressed that no decisions have been made. In fact, the Brazilian government still has not provided the U.S. with answers for how it will fix the problems.

^{&#}x27;FSIS has committed to further technical discussions with the Brazilian government and will further assess equivalence of Brazil's meat inspection system once the agency receives Brazil's proposed corrective actions to

again and expecting a different result. As we have demonstrated above, FSIS has repeatedly tried to let Brazil reform its inspection system over the past sixteen and yet we find ourselves admonishing that country for the same problems over and over again. The same seems to be the experience of the DG SANTE. The time has come to stop propping up the Brazilian meat inspection system. We run the risk of endangering the lives of U.S. consumers if strong action is not taken. The USDA Office of Inspector General (OIG) recently published an audit report highly critical of the manner in which FSIS evaluates the equivalency status of countries that are eligible to export meat and/or poultry and/or egg products to the United States. We believe that FSIS would go a long way to assuage the concerns expressed by the OIG by revoking the equivalency determination of Brazil's meat inspection system now. That would also send a message to other countries that to be accorded equivalency status means that U.S. food safety inspection standards will be strictly enforced. Furthermore, USDA should not let trade considerations supplant the welfare of U.S. consumers by permitting a weak and corrupt food safety inspection system to continue to export unsafe products to the U.S.

The Brazilian meat inspection system is not equivalent to that of the United States and immediate action should be taken to remove Brazil from 9 CFR 327.2(b).

Should you have any questions regarding this petition, please feel free to contact me.

Sincerely,

WHan

Wenonah Hauter Executive Director

cc: Paul Kiecker, Acting FSIS Administrator Mary Porretta, FSIS Petitions Manager

address the reported findings in the audit,' USDA spokesman Tim Murtaugh said in an email. 'As such, no lifting of the ban has been scheduled.'"

³⁸ See https://www.usda.gov/oig/webdocs/24601-0002-21.pdf