

STATEMENT OF COMPLIANCE

I. Exporting beef products to the United States of America

1. The Establishment is approved by the Ministry of Livestock, Agriculture and Fisheries (MGAP) of Uruguay to produce for export bovine and ovine meat and offal fit for human consumption. It has the Register Number 150 issued by the Official Competent Authority – Animal Industry Department (DIA) of the Ministry of Livestock, Agriculture and Fisheries (MGAP).
2. Uruguay is an active beef exporting country to the United States of America. The Establishment is approved by the USDA – FSIS to export bovine meat for human consumption to the United States of America territory.
3. The FSIS has determined that Uruguay has an equivalent E. coli O157 control Program.

II. The Establishment Pathogen Reduction Program

1. The Establishment has an operative and documented HACCP-based food safety assurance system, approved by the DIA of the MGAP. It complies with the U.S. Federal Register, 9 CFR Part 304, et al. and includes a documented SSOP Plan. The Establishment operates under Good Manufacturing Practices (GMP), mandated by the U.S. Federal Register, 21 CFR Part 110.
2. The Establishment HACCP-based food safety assurance system:
 - a) Is periodically reassessed and internally audited.
 - b) Is continuously audited by the Officers from the Official Competent Authority – DIA – MGAP.
 - c) Is periodically audited by FSIS Officers and by the Competent Authorities of other countries.
 - d) Is periodically audited by international commercial customers and certification bodies (GSFS).
3. The standard performance criteria and the testing of generic Escherichia coli bacteria to verify the effectiveness of the sanitation process control of cattle carcasses are operative.
4. The Establishment participates in the National Program for Salmonella spp. cattle carcass testing and control, issued by the MGAP.
5. The Establishment participates in the National Program for Escherichia coli O157:H7 control and testing issued in December of 2007 by the MGAP of Uruguay, which is lined up with FSIS Regulations.
6. The Establishment follows the MGAP Rule for the control and testing of Non O157 shiga- toxin-producing Escherichia coli (STEC - O26, O45, O103, O111, O121 and O145) issued in May of 2012, which is lined up with FSIS Regulations.

7. The Establishment has in place the current E. coli O157:H7 and Non O157 shiga- toxin-producing Escherichia coli (STEC) N60 sampling Methods, as defined by the MGAP and the FSIS.

8. The Establishment follows the USDA-MLG 5 Series for laboratory testing.

9. The Establishment control procedure for E. coli O157:H7 and E.coli non-O157 are based on production LOTS. LOTS are defined following FSIS and MGAP guidelines. Under these requirements, no LOT will be subdivided into more than one shipping container.

10. All the current records from the above information are available at the Establishment.

11. The Establishment HACCP System Reassessments done by the HACCP Team includes:

- 11.1. The HACCP Plan which has been initially validated on June 1999 (CFR Part 304, §417.4(a) (1).
- 11.2. Periodically or annually the Establishment develops a Verification up-date (Reassessment) to assure product safety (9 CFR Part 304, §417.4 (a) (2) and (3). The last entire reassessment was done on September 2012.
- 11.3. A specific HACCP reassessment was done on May 2012 for E.coli non-O157 (STEC) under MGAP and FSIS requirements and covers the Establishment bovine slaughters from June 4th 2012.
- 11.4. Other Competent Authorities specific importing countries requirements.

12. The Establishment HACCP Reassessment for E.coli O157:H7 and for E.coli non O157 (STEC)

12.1. The Hazard Analysis Reassessments for E. coli O157:H7 and for E.coli non-O157 (STEC) done on 2012 concluded that this hazards are not reasonable likely to occur in the Establishment products.

12.2. The justifications for not including the E. coli O157:H7 and the E.coli non-O157 (STEC) as potential hazards reasonable likely to occur in the HACCP Plan and a specific CCP, are:

- a) The HACCP Team performance of a proper and complete Hazard analysis reassessment for E. coli O157:H7 and for E.coli non-O157 (STEC - O26, O45, O103, O111, O121 and O145) assuring they are hazards not reasonable likely to occur in the Establishment.
- b) There were no positive results in the verification testing for E.coli O157:H7 and / or E.coli non-O157 (STEC) in beef finished products, both on the planned Establishment self-controls or from official (MGAP) sampling, during the last calendar year.
- c) There were no specific recalls associated with E. coli O157:H7 and / or E.coli non-O157 (STEC) in beef finished products.
- d) There were no specific recalls associated with E. coli O157:H7 and / or E.coli non-O157 (STEC) initiated as a consequence of human illness.

e) As a preventive measure, if a deviation not covered by a specified corrective action occurs, or if an unforeseen hazard arises, the Establishment: (a) Segregates and holds the affected product; (b) Takes action to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters into commerce; (c) Performs a reassessment of the Food Safety System, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan; (d) Records all corrective actions taken, which are subject to verification by the Official Competent Authority (MGAP).

f) As a preventive measure if a deviation occurs, the Establishment changes the routine sampling to follow up sampling of beef under the FSIS requirements and with the supervision of the Official Competent Authority (MGAP).

III. Bovine Spongiform Encephalopathy (BSE) preventive measures

1. The Establishment follows strict local and international rules and regulations on “Specific Risk Materials” (SRM) as preventive measures to Bovine Spongiform Encephalopathy (BSE) disease.
2. Uruguay continues having the “Negligible BSE risk Status” of the World Organization for Animal Health (OIE).
2. Under official regulations (MGAP), Uruguay does not import live animals or their products from countries having a controlled BSE risk or from countries recognized as having an undetermined BSE risk.
3. The Official Veterinary Inspection performs a daily ante mortem inspection procedure, condemning every cattle dead, dying, disabled or diseased and determining their proper disposition.
4. As required by FSIS, the Establishment does not use penetrative captive bolt stunning devices that inject air into the cranial cavity of cattle during slaughter.
5. The Establishment has a post mortem GMP procedure for handling and disposition of the bovine SRM: brain, head, eyes, trigeminal ganglia, spinal cord, dorsal root ganglia, tonsils and the distal ileum of the small intestine.
6. The final disposition of the SRM includes an inactivation process: incineration at more than 800°C and appropriate disposition of the ashes.
7. The proper records on SRM and the training activities to the personnel involved in SRM handling and disposition are available at the Quality Assurance Department.
8. The Official Competent Authority (MGAP) issued on July 2004 a Regulation forbidding the use of animal products and by-products as ruminants feeding.

IV. The Animal Welfare preventive measures

1. The Establishment follows the World Organization for Animal Health (OIE) and the U.S. A.M.I. Guidelines on Animal Welfare on livestock transport and slaughter operations.
2. The Establishment has written procedures for Animal Welfare control and makes periodical internal audits on them. The records are available at the Quality Assurance Department.



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