

Frigorífico San Jacinto - Nirea S.A. Ruta 7 Km 59.500 - C.P. 91.300 Peatonal Sarandí 675 Of.: 502 - C.P. 11.000

Peatonal Sarandi 675 Of.: 502 – C.P. 11.000 Montevideo – Uruguay T: (+598) 2916 2052 – F: (+598) 2916 2102 www.nirea.com



URUGUAY

STATEMENT OF COMPLIANCE 2016 FOR THE U.S.A.

I. Exporting beef products to the United States of America

San Jacinto - Canelones - Uruguay

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- The Establishment is approved by the Ministry of Livestock, Agriculture and Fisheries (MGAP) of Uruguay
 to produce for export bovine and ovine meat and offals fit for human consumption. It has the Register
 Number 344 issued by the Official Competent Authority Animal Industry Department (DIA) of the
 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 (USDA, Eligible Foreign Establishments: Uruguay, dated June 1st of 2015).
- 3. The FSIS has determined that Uruguay has an equivalent *E. coli* O157 and Non O157 shiga- toxin-producing *Escherichia coli* (STEC O26, O45, O103, O111, O121 and O145) control Program.

II. The Establishment Pathogen Reduction Program

- The Establishment has an operative and documented HACCP-based food safety assurance system, verified 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 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 November 2015, 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. All testing results are available before the container is released for shipping.



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10. The Establishment control procedure for *E. coli* Q157: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.

- 11. All the current records from the above information are available at the Establishment.
- 12. The Establishment HACCP System Reassessments done by the HACCP Team includes:
 - a. The HACCP Plan which has been initially validated on June 1999 (CFR Part 304, §417.4(a) (1).
 - b. 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 October 1st, 2015 and it was registered on file Nº R181.
- 13. The Establishment HACCP Reassessment for E.coli O157:H7 and for E.coli non O157 (STEC).
 - a. The Hazard Analysis Reassessment for E. coli O157:H7 done on 2015 concluded that this hazard –as an unforeseen hazard- is not reasonable likely to occur in the Establishment products.
 - b. The Hazard Analysis Reassessment for Shiga toxin producing E. coli (STEC) concluded that this hazard—as an unforeseen hazard—is not reasonable likely to occur in the Establishment products.
 - c. 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).
 - d. If a deviation occurs, the Establishment changes from routine sampling to follow up sampling and microbiological control of beef under the Official Competent Authority (MGAP) supervision.
 - e. Training additional activities are performed with the Establishment personnel on hygiene practices, daily sanitary standard operations (SSOP) and related good manufacturing practices (GMP), during slaughtering, chilling, deboning, packaging, cold storage and loading.

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).
- 3. 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.
- 4. The Official Veterinary Inspection performs a daily ante mortem inspection procedure, condemning every cattle dead, dying, disabled or diseased and determining their proper disposition.



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- 5. 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.
- 6. 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.
- 7. The final disposition of the SRM includes an inactivation process: incineration at more than 800°C and appropriate disposition of the ashes.
- 8. 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.
- 9. 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 both internal and third party audits on them. The records are available at the Quality Assurance Department.
- 3. Since November 2015, the establishment is certified under the Animal Welfare Protocol, issued by the National Meat Institute (INAC).

V. Food Defense Plan

- The Establishment has in place a written voluntary Food Defense Plan for policies and procedures in all areas of the Plant to strengthen their protection against any potential and deliberate practices that could violate the products, the consumers, the human resources or the property of the Company.
- 2. The Food Defense Plan is internal and annually audited and the records are available at the Q.A. Department.

December 18th, 2015

Paola Souto

Quality Assurance Chief