

To Whom it May Concern:

### STATEMENT OF COMPLIANCE

- 1 Frigorífico Canelones S.A. is approved by the US Food Safety and Inspection Service (FSIS) to produce for export bovine meat.
- 2 In the Federal Register, Vol. 61, N° 144, 25 July 1996 FSIS released the PR/HACCP Rule (also referred to as the MegaRegs). The Pathogen Reduction (PR) component mandated a program of bacteriological testing of bovine carcasses for the presence of *Escherichia coli*, *Salmonella* spp bacteria to verify the effectiveness of process controls for hygiene and sanitation under the plant's HACCP program.
- 3 In the Federal Register, Vol. 76, N° 226, 23 November 2011 FSIS released a proposed rule containing information regarding contamination of beef products with non-O157 Shiga toxin-producing *Escherichia coli* (STEC) (*E. coli* O26, *E. coli* O45, *E. coli* O103, *E. coli* O111, *E. coli* O121 y *E. coli* O145). As per this new proposed rule these contaminants must be considered as adulterants.
- 4 The company has in place a fully documented HACCP- based quality assurance system which has been established in accordance with the Uruguayan Veterinary Inspection Service (DIA, Dirección de Industria Animal). The program:
  - complies with DIA guidelines for meeting FSIS Pathogen Reduction/HACCP requirements; and
  - is audited by on-plant supervisors;
  - is audited at least each month by external DIA officers; and
  - has been subjected to a detailed verification audit external DIA auditors and found to meet DIA and FSIS requirements; and
  - was most recently audited by USDA officers in 2018 and accepted as satisfactory.
- 5 In relation to *E. coli* 0157:H7, establishment 8 confirms that its HACCP Plan has been reassessed in accordance with "Federal Register Notice 9 CFR Part 417 Docket Number 00-022N dated 7 October 2002 and titled *E. coli* 0157:H7 Contamination of Beef Products. The HACCP Team concluded, and the Senior Management Team agrees, that *E. coli* 0157:H7 is a hazard reasonably likely to occur in its products without the implementation of a HACCP Plan. The DIA/USDA has audited and approved the establishment's HACCP Plan.

- 6 In relation to non-O157 Shiga toxin-producing *Escherichia coli* (STEC): *E. coli* O26, *E. coli* O45, *E. coli* O103, *E. coli* O111, *E. coli* O121 y *E. coli* O145), establishment 8 confirms that its HACCP Plan has been reassessed in accordance with "Circular 3/2012 Dirección General de Servicios Ganaderos División Industrial Animal, MGAP dated 2 April 2012 and titled "Revisión de planes HACCP en referencia a la nueva reglamentación de USDA/FSIS sobre programas de control de *Escherichia coli* no-O157 productoras de toxina shiga (STEC)s". The HACCP Team concluded, and the Senior Management Team agrees, that *E. coli* O26, *E. coli* O45, *E. coli* O103, *E. coli* O111, *E. coli* O121 y *E. coli* O145 are a hazard reasonably likely to occur in its products without the implementation of a HACCP Plan. The DIA/USDA has audited and approved the establishment's HACCP Plan.
- 7 The reassessed HACCP Plan includes the following interventions and other measures:
- washing or rejection of cattle with heavy hide faecal contamination (verified by inspection of hide-on carcasses by Quality Assurance Assessors);
  - occlusion of the oesophagus during the slaughtering operation (verified by observation by Quality Assurance Assessors or nominated Operatives carrying out their work procedures);
  - use of a rubber ring for tying and sealing the bung to prevent spillage;
  - use of 2 knives for hide removal procedures (verified by observation by Quality Assurance Assessors of hide removal Operatives carrying out their work procedures);
  - sanitizing hands and tools between carcasses;
  - identification, using tags, of carcasses where faecal/ingesta leakage is suspected or occurs during dressing procedures which prepare for removal of the gastrointestinal tract (verified by observation by Quality Assurance Assessors or nominated Operatives carrying out their work procedures);
  - tagged carcasses subjected to intensified inspection and, where necessary, intensified trim and operational sanitation procedures prior to chilling (verified by observation by Quality Assurance Assessors of the nominated Trimmer carrying out his/her work procedures);
  - CCP on the slaughter floor monitoring carcasses;
  - steam vacuuming of fore and hindquarters.
  - application of lactic acid to carcasses (lactic acid spray cabinet)
  - carcasses are rapidly dry chilled to reduce, eliminate or control *E. coli* O157:H7 and non-O157 Shiga toxin-producing *Escherichia coli* (STEC).

- 8 The efficacy of those interventions are verified by microbial testing of boned product for *E. coli* O157:H7 sampled in production lots (time zones) under a N60 program, at the rate of 5 cartons per production lot of manufacturing beef for export to the USA, Canada or any other market. Samples of approximately 180 grams are collected from 12 different places from each of the 5 cartons (composite sample of 908 grams).  
From the 908 grams composite sample, 375 are pummeled for two minutes with 1500 ml of buffered peptone water. From the incubated culture the analysis is carried out by PCR (Polymerase Chain Reaction) method, (GENEDISC by PALL Lab. in our in-house laboratory which is approved and audited to ISO 17025 standards by the Uruguayan Ministry of Agriculture (MGAP)
- 9 Since testing began in 1999 to 02/01/2019, 14168 composite samples from 70840 cartons of manufacturing meat have been tested for *E. coli* O157:H7 and one has returned a "positive" detection of *E. coli* O157:H7.
- 10 At the same time requirements for export to Canada have been met.  
The meat derived from bovine, considered as precursor material for the preparation of finished raw ground meat, is tested for the presence of *E. coli* O157:H7/NM according to procedures described in CFIA Annex O: Policy on the Control of *E. (Escherichia) coli* O157:H7/NM (non motile) Contamination in Raw Beef Products of Chapter 4 of the Meat Hygiene Manual of Procedures.
- 11 The efficacy of those interventions are also verified by microbial testing of boned product for *E. coli* O26, *E. coli* O45, *E. coli* O103, *E. coli* O111, *E. coli* O121 y *E. coli* O145 sampled in production lots (time zones) under a N60 program, at the rate of 5 cartons per production lot of manufacturing beef for export to the USA, Canada or any other market. Samples of approximately 180 grams are collected from 12 different places from each of the 5 cartons (composite sample of 908 grams).  
From the 908 grams composite sample, 375 are pummeled for two minutes with 1500 ml of buffered peptone water. From the incubated culture the analysis is carried out by PCR (Polymerase Chain Reaction) method. (GENEDISC by PALL Lab. in our in-house laboratory which is approved and audited to ISO 17025 standards by the Uruguayan Ministry of Agriculture (MGAP)

If a "positive" detection were made, procedures are in place to prevent shipment of product. Only product that is compliant with HACCP requirements and tested "negative" for *E. coli* O157:H7, *E. coli* O26, *E. coli* O45, *E. coli* O103, *E. coli* O111, *E. coli* O121 y *E. coli* O145 is shipped.

Following the reassessment of Establishment 8 HACCP Plan its continued effective operation, as detailed above, Establishment 8 has concluded that the prevalence of E. coli O157:H7, E. coli O26, E. coli O45, E. coli O103, E. coli O111, E. coli O121 y E. coli O145 has been reduced to undetectable levels.

## 12 Animal Handling and Identification Policy

Frigorífico Canelones S.A. is committed to the safe, humane treatment of animals that are received at this facility. Every effort will be made to maintain the identity and to insure proper identification and disposition according to Uruguayan Veterinary Inspection Service (DIA, Dirección de Industria Animal).

Frigorífico Canelones S.A. has incorporated the Humane and Stunning guidelines set forth by AMI in developing our animal handling procedures.

Frigorífico Canelones S.A. does not accept delivery of non-ambulatory animals. All non-ambulatory animals are condemned and disposed of in accordance with USDA FSIS 9 CFR 309.13.

Frigorífico Canelones S.A. complies with the Council Regulation (EC) N° 1099/2009 of 24 September on the protection of animals at the time of killing.

## 13 FDA ban of mammalian derived protein materials in ruminant animals.

Based on the World Health Organization (WHO) Expert Committee recommendation of April 1996, the Government of Uruguay banned the use of meat and bone meals (MBM) from ruminants in feeds for ruminants (Decree 139/96 dated April 17<sup>th</sup>, 1996)

## 14 Bovine Spongiform Encephalopathy Specified Risk Materials USDA FSIS 9 CFR Part 310.22

On January 12, 2004 USDA published new standards for Specified Risk Materials (SRM) in the federal register. All beef products produced by Frigorífico Canelones S.A. do not contain SRM's as defined by these new standards.

Frigorífico Canelones S.A. has implemented several control measures and procedures to address the removal and disposal of Specified Risk Materials (SRM's) for Bovine Spongiform Encephalopathy (BSE).

All SRM's are segregated from human food and discarded as INEDIBLE RENDERING:

- The spinal cords are removed from all carcasses.
- The distal portion of the small intestine is discarded from all carcasses.
- The skull including brains, eyes and trigeminal ganglia are discarded from all carcasses.
- The tonsils are removed from all cattle.
- In order to ensure the complete removal of the dorsal ganglia, the vertebral column of all cattle (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) will be removed during fabrication and discarded to INEDIBLE RENDERING.

15 Advanced Meat Recovery Systems USDA FSIS 9 CFR 318.24

No AMR product is used in any of Frigorífico Canelones S.A. products. Furthermore Frigorífico Canelones S.A. does not have AMR Systems.

16 Ban on the use of Air Injection Stunning Method USDA FSIS 9 CFR Part 315.15 (b)(2)(ii)

Frigorífico Canelones S.A. does not utilize air injection stunning.

Yours sincerely,



Chem. Robert Welters  
Quality Assurance Manager