



*Embassy of Uruguay
Washington, D.C.*

Note 042/2004
HIF/RN/AGA

The Embassy of Uruguay presents its compliments to the Department of Agriculture of the United States of America –Food Safety and Inspection Services, Docket Clerk- and has the pleasure to inform that the Uruguayan Ministry of Livestock, Agriculture and Fisheries expressed its intention of submitting by this mean the attached comments to Dockets N° 03-025IF, 01-033IF and 03-038IF.

The Embassy of Uruguay avails itself of this opportunity to renew to the Department of Agriculture of the United States of America – Food Safety and Inspection Services, Docket Clerk - the assurances of its highest consideration.

Washington DC, May 3rd, 2004



To the Department of Agriculture of the United States of America
Food Safety and Inspection Services
Docket Clerk
WASHINGTON, D.C



*Embassy of Uruguay
Washington, D.C.*

April 14, 2004

**FSIS Docket Clerk,
Room 102, Cotton Annex,
300 12th and C Street, S.W.,
Washington, DC 20250-3700.**

RE: Docket No. 03-025IF, Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle, Interim final rule and request for comments
Docket No. 01-033IF, Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter, Interim final rule and request for comments.
Docket No. 03-038IF, Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems, Interim final rule and request for comments

**Comments of the Government of Uruguay
Ministry of Livestock, Agriculture and Fisheries**

Foreword and Background

Uruguay thanks the Food Safety and Inspection Service (FSIS) of the United States of America Department of Agriculture (USDA) for the opportunity to comment on the Interim Final Rules published in the Federal Register, Vol. 69, No. 7, Monday, January 12, 2004.

FSIS is taking this action in response to the diagnosis, made on December 23, 2003 by the USDA, of a positive case of bovine spongiform encephalopathy (BSE) in an adult Holstein cow in the State of Washington.

The Agency has determined that immediate action must be taken to ensure that materials that could present a significant risk to human health are excluded from the human food supply.

Among other measures FSIS is amending the Federal Meat Inspection Regulations to designate the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (DRG) of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle, as "specified risk materials" (SRMs).

FSIS is declaring that SRMs are inedible, prohibiting their use for human food and is requiring that federally-inspected establishments that slaughter cattle and process the carcasses of cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs.

Establishments must incorporate these procedures into their HACCP plans or in their Sanitation SOPs or other prerequisite program.

Comments

1.) Emergency Response and Cooperation between FSIS-USDA and Uruguay.

The underlying rationale of this action is to minimize human exposure to materials that scientific studies have demonstrated as containing the BSE agent in cattle infected with the disease.

The Interim Final Rules, published in the Federal Register, Vol. 69, No. 7, Monday, January 12, 2004, do not exclude nor expressly mention any requirements or obligations for establishments exporting to the US from foreign countries that could claim BSE free status for their cattle population.

Nevertheless, the FSIS Office of International Affairs on January 8, 2004 requested in written form, from Competent Authorities and Veterinary Administrations of trade partner countries, the implementation of equal or equivalent measures in foreign countries, regardless of their BSE status, and stated that implementation and compliance with the regulations, by US-listed foreign establishments, will be subject to audit and verification by FSIS-Missions to trade partners scheduled for the year 2004.

Despite Uruguay's international recognized BSE free country status, it was assumed that FSIS rulemaking was necessary on an interim and emergency basis and, under this circumstance, Uruguay agreed to comply with the new BSE rules and consequently the Uruguayan US-listed establishments were timely notified on January 2004.

Officers of the Government of Uruguay, request and held a meeting, on February 5, 2004, in Washington DC, with Staff Officers of the Office of International Affairs of FSIS-USDA in order to clarify the way that the Animal Industry Division of the Livestock Services of the Ministry of Agriculture of Uruguay (DIA-DGSG/MGAP) will be ensuring, due to the implementation of equivalent measures, that all Uruguayan beef and beef product establishments, that are listed as eligible to export products to the United States, are in compliance with the new BSE regulations published in the Federal Register on 12 January 2004. It is worth noting here that the FSIS-Mission Team that visited Uruguay, from February 11 to March 20, 2004 had the opportunity to audit and assess the compliance of the Uruguayan US-listed establishments with the FSIS Interim Final Rules.

2.) FSIS Interim Final Rules and International Standard Setting Role of OIE.

We are concerned that FSIS is not taking into account the existing international standard of the International Office of Epizootics (OIE) regarding the sanitary measures required by the BSE Interim Final Rules to be implemented by trade partner countries with BSE free status.

The OIE International Health Code in the Chapter 2.3.13 addresses BSE and requires, that the BSE status of the cattle population of a country or zone, be determined on the basis of the five (5) criteria described in the Article 2.3.13.2.

3.) Risk Assessments and BSE Status of the Cattle Population of Uruguay.

Uruguay is free of BSE based on the criteria adopted by the OIE and has taken the appropriate measures to prevent the entry of BSE to its territory including, among others, making the disease officially notified since 1994, the adoption of a meat and bone meal (MBM) feed ban to ruminant since April 17, 1996, and since 1995 an active surveillance program, updated according to the guidelines and recommendations established in the International Animal Health Code.

The BSE free status of the cattle population of Uruguay is supported by data of epidemiological surveillance of BSE obtained from retrospective studies, covering all cases and material collected of disturbances of the central nervous system (CNS) since 1972 and up to 1993 (22 year period); from the passive epidemiological surveillance data collected from all cases investigated since the compulsory reporting regulation was enforced in 1994 and from the active epidemiological surveillance developed and updated according to the guidelines and procedures established in the OIE International Animal Health Code. All results have been negative and therefore provide sound scientific evidence of the absence of BSE in Uruguay.

Likewise Uruguay is recognized internationally as a country free of BSE.

Information derived through Uruguay's self-assessment process and risk assessments carried out by several trade partner countries are available and could be considered by FSIS.

Among others sources of information we respectfully highlight:

Uruguay is one of the few countries that Canada currently recognizes as free of BSE. This status was based on Uruguay's response to the Canadian BSE questionnaire and subsequent risk assessment (CFIA Communication on February 2001).

Uruguay's BSE free status is also recognized by the United States of America (APHIS Communication on November 26, 2001) based on the review and outcome of the risk assessment undertaken by Canada and upon the common criteria used by North America Free Trade Countries to determine BSE risk.

Uruguay was classified as a Level I Country ("Remote probability of the existence of clinically or sub-clinically cases of BSE), in 2001 according with the criteria of the Scientific Steering Committee of the European Commission (SSC-EC) on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR). The Current Opinion updated and adopted, on April 10th 2003, by the SSC-EC on the Geographical Risk of Bovine Spongiform Encephalopathy in Uruguay, remains a Level I Country (GBR I) and states: "*Due to the negligible risk that BSE infectivity entered the country (Uruguay) there was no risk that BSE infectivity was recycled or propagated. It is therefore concluded that is highly unlikely that domestic cattle (in Uruguay) are (clinically or pre-clinically) infected with BSE agent (GBR-I)*". The SSC-EC Opinion report on GBR in Uruguay can be found at: http://europa.eu.int/comm/food/fs/sc/scc/outcome_en.html.

Following the Risk Analysis undertaken by the Australian Quarantine Inspection Service (AQIS Communication on April 2003), the Australian BSE Country Categorization Committee for Human Products completed their assessment for Uruguay and has determined it to be a BSE category "A" (Negligible Risk) country. The Food Standards Australia New Zealand (FSANZ) advice to AQIS, regarding updates and changes to the BSE country categorization list, can be seen at www.foodstandards.gov.au.

Recently Uruguay submitted to the Ad hoc Group for BSE status assessment of OIE, the information required for the consideration and, further recommendation by the Scientific Commission of OIE, to the next General Meeting of the International Committee of OIE, in Paris-France on May 2004, in order to be included in the new OIE International Classification of BSE country status (Dr. B. Vallat, General Director of OIE, Communication to Uruguay, March 12, 2004).

4.) Economic Impact and Trade Disruption due FSIS Interim Final Rules

Given our freedom from BSE, and the extensive efforts we continue to undertake to ensure exclusion of this disease, Uruguay believes that any measures adopted against its exports of cattle, beef or other products because of BSE are completely unjustified.

We are concerned about potential economic impact and trade disruption resulting from the FSIS measures regarding SRMs.

Docket No. 03-025IF, declaring that SRMs are inedible, prohibiting their use for human food and requiring procedures for the removal, segregation, and disposition of SRMs by US-listed establishments regardless of the BSE free country status, is clearly inconsistent with OIE standards and would require that third countries to apply costly and unnecessary measures.

For example, in the case of Uruguay, to ensure that the distal ileum is completely removed from the carcass, the establishments shall remove the entire small intestine in order to comply with FSIS Interim Final Rule. Consequently the effect is that casings, derived from the small intestine, have lost access to the US market, despite that the said product from Uruguay is safe and no BSE infectivity could be expected.

Countries, including the United States of America, have agreed that when restrictions are placed on imports that exceed OIE recommendations a reason will be presented upon request to justify that decision.

5.) Conclusion

We respectfully suggest that FSIS rely on the international standard set by the OIE, risk assessment outcomes, conducted with internationally accepted methodology such as might be done directly by the Ad hoc BSE Group and Scientific Commission of OIE or other previously carried on by trade partners such as Canada due CFIA, United States due APHIS and or Australia due AQIS.

Accordingly, the Uruguayan Government respectfully requests that the final rule to be issued by FSIS-USDA should consider the BSE free status of Uruguay and rescind unjustified restrictions on the imports of Uruguayan products.

On behalf of the Ministry of Livestock, Agriculture & Fisheries

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