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May 7, 2004

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

Dear Sir or Madam

On behalf of the government of Argentina I am enclosing comments on docket number 03-025IF and request for an amendment final rule.

Sincerely,

José Domingo Molina
Minister
Agricultural affairs

**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.

**COMMENTS FROM THE GOVERNMENT OF THE
REPUBLIC OF ARGENTINA
SENASA**

Introduction:

The Republic of Argentina is grateful to the Food Safety and Inspection Service (FSIS) of the United States of America for the opportunity given to submit comments to the Interim Final Rules published in the Federal Register, Vol. 69, N°7, dated January 12, 2004.

The Republic of Argentina is aware that FSIS is imposing these measures in response to the diagnosis of December 23, 2003 by USDA to a positive BSE case diagnosed in an adult Holstein cow in the State of Washington and understands the importance of implementing new regulations in your country.

Backgrounds of the situation in the Republic of Argentina: The comments to the regulations are mainly focused in the situation of the Republic of Argentina as "BSE free". This is mainly based on international recognition and the actions taken for the prevention of the disease, which is constantly adapted according to evolution of scientific and technical knowledge.

International Recognition

- On March 12, 2004, a document stating that the Scientific Commission has accepted the recommendation made by the Ad Hoc group on BSE, appointed to make an assessment of BSE reports, was submitted to the OIE delegates. It also proposes the International Committee to recognize **Argentina as BSE provisionally free** -the best categorization to the moment- according to Article 2.3.13.4 of the O.I.E. International Animal Health Code.
- The Geographical Risk Analysis (GBR) carried out by the European Union to the Republic of Argentina in 1999, and updated in April, 2003, states that the current BSE geographical risk level is I. This means that "it is highly improbable that domestic cattle is (clinically or preclinically) infected by the BSE agent". According to EU Regulation 999/01 and amendments, countries within this category do not have specific risk materials. Therefore their removal in slaughtering processes is not necessary and there are no restrictions to exports of products of animal origin to the European Union member countries.
- After the pertinent assessment process, Argentina was recognized by Australia, during the year 2003, as **category A country** "offers optimum conditions for export of meat for human consumption with regards to BSE risk".
- Since January 29, 2004, the government of Canada allows the entrance of meat products coming from the Republic of Argentina and processed or in transit through the United States.

Actions carried out to prevent BSE

The actions implemented as from the beginning of 1990 to maintain the Republic of Argentina as BSE free country consist, mainly, in:

- Development of several risk analysis, with the first one made in 1991. In addition, a risk analysis on Scrapie was carried out in 1997, establishing also the conditions of Free Country for this disease.
- Prohibition of entrance of live cattle and products of animal origin from TSE susceptible species, with potential risk of transmission of the disease from affected countries. The first prohibitions, established in 1990, have been updated through time and according to the knowledge of the disease and the changing situation of the countries sanitary status. The current standards establish the methodology for the assessment of live animal imports, their reproductive material, products and by-products of animal origin and merchandises containing these materials, with regards to the risk of BSE introduction to the country. They are established according to a triple entry form considering the risk of the country of origin, the risk of the product and the risk of the merchandise to be imported final use destination. It may be applied to all interested countries.
- Active and passive epidemiological surveillance based on brain samples not only from bovines, but from ovine and other TSE susceptible species collected in field or coldstore plants, according to the criteria requested by the International Animal Health Code and the diagnosis methods validated by the OIE. More than 20.000 samples from bovines, ovine and other TSE susceptible species have been analysed since 1992 with negative results.
- As from 1995 the prohibition of feeding ruminants with Meat and Bone Meals (MBM) from ruminants is in force and it was broaden in 2002 to mammal proteins. The Ruminants Feed Sampling Programme, developed to verify the compliance of the prohibition, which consists of inspections with collection of samples at manufacturing plants and field establishments, was established and enforced. Likewise, supervisions and auditories of all Animal Feed System (manufacturing plants) are being carried out to verify and supervise compliance of standards.
- There is a training and promotion programme to keep all involved parts aware and in alert.

In the Republic of Argentina, all the above mentioned actions are framed within a National Programme of Transmissible Spongiform Encephalopathies (TSE) Prevention and Surveillance. This programme depends from the Health and Quality Agri-Food National Service (SENASA), which is in charge of the strategies and actions to be developed and works jointly with official and private sectors.

General Comments

Compliance of Final Interim Rules in the Republic of Argentina:

Based on FSIS regulations, countries exporting to the United States shall adopt these measures or their equivalent when manufacturing meat products in establishments approved to export to the United States.

The Republic of Argentina declares that, in spite of its international recognition and in complete disagreement, has adopted, by means of Circular Note N° 3580, the new BSE regulations published in the Federal Register on January 12, 2004, in particular in Docket N° 03-0251F. Compliance of these regulations is carried out through procedures which can be written, registered and audited by the Official Inspection Service in each one of the plants approved to export to the United States. It is understood that these new regulations are additional guarantees to the measures that had been already put in force with regards to BSE prevention in the United States. Nevertheless, it is considered that to generalize such regulations to countries which are internationally recognized as "Free Country", does not have any scientific foundation nor can they be justified in any way.

Conclusion:

According to what was mentioned in this regulation: "This action will minimize human exposure to materials that scientific studies have demonstrated as containing the BSE agent in cattle infected with the disease" it should be pointed out that there is no specific risk material in cattle in the Republic of Argentina. Therefore, its consumption does not mean any risk for human health.

Due to all the actions developed in the country since 1990 and detailed to maintain the current level, it is considered that products to be exported have a Protection Level at least equivalent for human health than the level that the United States is looking for through new measures. Therefore, there is no need to adopt them in the Republic of Argentina.

Due to what was previously mentioned, we request the recognition of the Republic of Argentina sanitary status as "BSE free country" as equivalent to the need of implementing risk mitigation measures arisen from the United States regulations, and, therefore it is requested that unjustified restrictions to import of products from our countries be withdrawn. Likewise and with the purpose of assessing the international recognition of BSE free countries, it is considered that the inclusion of the following text: ... except for animals born and raised in a country internationally recognised as "FREE" has been left out in the definition of Specified risk materials.

Particular Comments to Interim Final Rules published in the Federal Register on January 12, 2004 – They are attached to this document as appendixes.

Appendix I: Docket No. 03-0251F: Prohibition of the Use of Specified Risk Materials for Human Food.

- Since October 1, 2000 it is mandatory for all the countries belonging to the European Union to remove specified risk materials such as spinal cord, brain, eyes, tonsils, part of the intestines from bovines from the human and animals food chain. Despite what was mentioned, and according to our Risk Level I category, the European Community accepts all the small intestine coming from the Republic of Argentina, as stated in circular note dated Brussels, October 9, 2003 E3D(03) 532459/jfp.
- In the Republic of Argentina, bovine brain, spinal cord and small intestine are usually used for human consumption and are an important part of the gastronomic culture of the country.
- It should be pointed out that small intestine (inside of which is the distal ileum) was exported by our country to the United States as Salted. The implementation of the new interim rules has left local producers and their products (small intestine, commonly known as tripes) out of the commercialisation market with the United States, creating an unjustified obstacle for trade between both countries.