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FSIS Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
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RE: DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service

9 CFR Parts 301, 309, 310, 311, 313, 318, 319 and 320

Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems; Prohibition of the Use of Certain Stunning Devices Used To Immobilize Cattle During Slaughter; Bovine Spongiform Encephalopathy (BSE) Surveillance Program

Docket Number 03-025IF: Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Nonambulatory Disabled Cattle

I am writing to clarify a comment I submitted to the above mentioned docket on May 7, 2004. I had previously written that the entire length of the intestine should be excluded as SRM. I still hold this opinion and submit the same recommendation, however one of the reasons behind this opinion needs to be further clarified. I had misunderstood comments made by Dr. Danny Matthews in that immunostaining (of PrP^{bse}) was not found throughout the entire length of the intestine. There was however immunostaining in the myenteric plexus of the distal ileum in both naturally infected and experimentally challenged cattle with BSE. (Terry et al.,2003) Given that the myenteric plexus exists throughout the intestine one cannot eliminate the possibility of infectivity being in other sections. In fact this was some of the thought behind the designation of the entire intestine as SRM in the EU:

In its opinion of 7-8 December 2000 (EC 2000), the SSC concluded that the entire bovine intestine is a risk issue and Commission Regulation (EC) No.

270/2002 (14th February 2002) ANNEX II designates "the entire intestines from the duodenum to the rectum and the mesentery of bovine animals of all ages;" as SRM. Also, in the SSC opinion of 28-29 JUNE 2001, Adipose tissue associated with the digestive tract of cattle, sheep and goats: an appreciation of possibleTSE risks (EC 2001) the view was expressed that for cattle, "*due to the infectivity titre that could be theoretically reached in nervous tissues and in some parts of intestine, and due to the risk of contamination with intestine tissue….*

The International Advisory Committee appointed by Secretary Veneman also recommended that the SRM ban in the US be amended to the entire intestine from duodenum to rectum.

Although certain additional sections of the intestine were tested with no infectivity identified, not every section of the intestine was included in the bioassays. In addition, the study involving immunostaining was also extremely limited in regard to the testing of tissues other than the distal ileum. Specifically, other sections of intestinal tissues (excluding the distal ileum work) were limited to those collected from 3 calves inoculated with BSE at a timeframe of 6 months post inoculation. Instead of assuming that the untested sections are devoid of infectivity, it is my belief that we should err on the side of caution when it comes to protecting public health. Hence I maintain my opinion that the entire intestine should be considered SRM.

This clarification is also intended for my comments submitted to the FDA's ANPR.

Thank you for the opportunity to clarify my comments.

Linda A. Detwiler, DVM

REFERENCES

Terry, L. A.., Marsh, S., Ryder, S. J., Hawkins, S. A. C., Wells, G. H., and Spencer, Y. I. (2003) Detection of disease-specific PrP in the distal ileum of cattle exposed orally to the agent of bovine spongiform encephalopathy. *Vet Rec*., **152,** 387-392

Wells G.A.H., Dawson M., Hawkins, S.A.C., Green R. B., Dexter I., Francis M. E., Simmons M. M., Austin A. R., & Horigan M. W. (1994) Infectivity in the ileum of cattle challenged orally with bovine spongiform encephalopathy. *Vet. Rec*., **135**, 40-41.

Wells G.A.H., Hawkins, S.A.C., Green R. B., Austin A. R., Dexter I., Spencer, Y. I., Chaplin, M. J., Stack, M. J., & Dawson, M. (1998) Preliminary observations on the pathogenesis of experimental bovine spongiform encephalopathy (BSE): an update. *Vet. Rec*., **142**, 103-106.