Owens, Julie

From:Terry S. Singeltary Sr. [flounder9@verizon.net]Sent:Monday, July 24, 2006 1:09 PMTo:FSIS RegulationsCommentsSubject:[Docket No. FSIS-2006-0011] FSIS Harvard Risk Assessment of Bovine Spongiform Encephalopathy (BSE)

Greetings FSIS,

I would kindly like to comment on the following ;

[Federal Register: July 12, 2006 (Volume 71, Number 133)] [Notices] [Page 39282-39283] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr12jy06-35]

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2006-0011]

Harvard Risk Assessment of Bovine Spongiform Encephalopathy (BSE) Update; Notice of Availability and Technical Meeting

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and announcement of technical meeting.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of an updated risk assessment model and report for BSE. The previous risk assessment, released in October 2003, was revised to incorporate information available through December 2003, including the discovery of a BSE-infected cow in Washington State. The revised risk assessment model evaluates the impact of measures implemented after the discovery of the BSE-positive cow and recommendations made by an international BSE panel. FSIS will also hold a technical meeting to discuss the updated risk assessment model and report.

DATES: The public meeting will be held on July 25, 2006, from 1 p.m. to

4 p.m. Comments on the updated Harvard Risk Assessment must be received by August 11, 2006. snip...END

http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/E6-10928.htm

MY comments/questions are as follows ;

1. SINCE the first Harvard BSE Risk Assessment was so flawed and fraught with error after the PEER REVIEW assessment assessed this fact, how do you plan on stopping this from happening again, will there be another peer review with top TSE Scientist, an impartial jury so-to-speak, to assess this new and updated Harvard BSE/TSE risk assessment and will this assessment include the Atypical TSE and SRM issues ?

*** Suppressed peer review of Harvard study October 31, 2002 ***

http://www.fsis.usda.gov/oa/topics/BSE_Peer_Review.pdf

2. WITH A RECENT NATION WIDE MAD COW FEED BAN RECALL in the past few months that consisted of some 10,878.06 TONS, then another Mad Cow feed ban warning letter in May, IT should seem prudent to ask why our feed bans continue to fail in 2006, and continue to fail today ?

RECALLS AND FIELD CORRECTIONS: VETERINARY MEDICINE -- CLASS II

PRODUCT a) PRO-LAK, bulk weight, Protein Concentrate for Lactating Dairy Animals, Recall # V-079-6; b) ProAmino II, FOR PREFRESH AND LACTATING COWS, net weight 50lb (22.6 kg), Recall # V-080-6; c) PRO-PAK, MARINE & ANIMAL PROTEIN CONCENTRATE FOR USE IN ANIMAL FEED, Recall # V-081-6; d) Feather Meal, Recall # V-082-6 CODE a) Bulk b) None c) Bulk d) Bulk **RECALLING FIRM/MANUFACTURER** H. J. Baker & Bro., Inc., Albertville, AL, by telephone on June 15, 2006 and by press release on June 16, 2006. Firm initiated recall is ongoing. REASON Possible contamination of animal feeds with ruminent derived meat and bone meal.

VOLUME OF PRODUCT IN COMMERCE 10,878.06 tons DISTRIBUTION Nationwide

END OF ENFORCEMENT REPORT FOR July 12, 2006

###

http://www.fda.gov/bbs/topics/enforce/2006/ENF00960.html

Subject: MAD COW FEED BAN WARNING LETTER ISSUED MAY 17, 2006 Date: June 27, 2006 at 7:42 am PST Public Health Service Food and Drug Administration

New Orleans District 297 Plus Park Blvd. Nashville, TN 37217

Telephone: 615-781-5380 Fax: 615-781-5391

May 17, 2006

WARNING LETTER NO. 2006-NOL-06

FEDERAL EXPRESS OVERNIGHT DELIVERY

Mr. William Shirley, Jr., Owner Louisiana.DBA Riegel By-Products 2621 State Street Dallas, Texas 75204

Dear Mr. Shirley:

On February 12, 17, 21, and 22, 2006, a U.S. Food & Drug Administration (FDA) investigator inspected your rendering plant, located at 509 Fortson Street, Shreveport, Louisiana. The inspection revealed significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 [21 CFR 589.2000], Animal Proteins Prohibited in Ruminant Feed. This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). You failed to follow the requirements of this regulation; products being manufactured and distributed by your facility are misbranded within the meaning of Section 403(a)(1) [21 USC 343(a) (1)] of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found you failed to provide measures, including sufficient written procedures, to prevent commingling or cross-contamination and to maintain sufficient written procedures [21 CFR 589.2000(e)] because:

You failed to use clean-out procedures or other means adequate to prevent carryover of protein derived from mammalian tissues into animal protein or feeds which may be used for ruminants. For example, your facility uses the same equipment to process mammalian and poultry tissues. However, you use only hot water to clean the cookers between processing tissues from each species. You do not clean the auger, hammer mill, grinder, and spouts after processing mammalian tissues.

You failed to maintain written procedures specifying the clean-out procedures or other means to prevent carryover of protein derived from mammalian tissues into feeds which may be used for ruminants.

As a result . the poultry meal you manufacture may contain protein derived from mammalian tissues prohibited in ruminant feed. Pursuant to 21 CFR 589.2000(e)(1)(i), any products containing or may contain protein derived from mammalian tissues must be labeled, "Do not feed to cattle or other ruminants." Since you failed to label a product which may contain protein derived from mammalian tissues with the required cautionary statement. the poultry meal is misbranded under Section 403(a)(1) [21 USC 343(a)(1)] of the Act.

This letter is not intended as an all-inclusive list of violations at your facility. As a manufacturer of materials intended for animal feed use, you are responsible for ensuring your overall operation and the products you manufacture and distribute are in compliance with the law. You should take prompt action to correct these violations, and you should establish a system whereby violations do not recur. Failure to promptly correct these violations may result in regulatory action, such as seizure and/or injunction, without further notice.

You should notify this office in writing within 15 working days of receiving this letter, outlining the specific steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating corrections have been made.

Your reply should be directed to Mark W. Rivero, Compliance Officer, U.S. Food and Drug Administration, 2424 Edenborn Avenue, Suite 410, Metairie, Louisiana 70001. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 219-8818, extension 103.

Sincerely,

S

Carol S. Sanchez Acting District Director New Orleans District

http://www.fda.gov/foi/warning_letters/g5883d.htm

3. WHY still now only partial ruminant feed ban, with the fact that now we seem to have 3 cases of nvCJD to humans i.e. humanbovineTSE that were responsible from blood, and the fact the last 2 mad cows documented in the USA were that of an Atypical strain, would it not seem prudent to remove blood as well from ruminant feed ?

WOULD it not seem prudent to improve and expand the SRM list now? as per your own thinking ;

> If transmission occurs, tissue distribution comparisons will be made between cattle

> infected with the atypical BSE isolate and the U.S. BSE isolate. Differences in

> tissue distribution could require new regulations regarding specific risk material

> (SRM) removal.

FULL text;

Research Project: Study of Atypical Bse

Location: Virus and Prion Diseases of Livestock

Project Number: 3625-32000-073-07 Project Type: Specific C/A

Start Date: Sep 15, 2004 End Date: Sep 14, 2007

Objective:

The objective of this cooperative research project with Dr. Maria Caramelli from the Italian BSE Reference Laboratory in Turin, Italy, is to conduct comparative studies with the U.S. bovine spongiform encephalopathy (BSE) isolate and the atypical BSE isolates identified in Italy. The studies will cover the following areas: 1. Evaluation of present diagnostics tools used in the U.S. for the detection of atypical BSE cases. 2. Molecular comparison of the U.S. BSE isolate and other typical BSE isolates with atypical BSE cases. 3. Studies on transmissibility and tissue distribution of atypical BSE isolates in cattle and other species.

Approach:

This project will be done as a Specific Cooperative Agreement with the Italian BSE Reference Laboratory, Istituto Zooprofilattico Sperimentale del Piemonte, in Turin, Italy. It is essential for the U.S. BSE surveillance program to analyze the effectiveness of the U.S diagnostic tools for detection of atypical cases of BSE. Molecular comparisons of the U.S. BSE isolate with atypical BSE isolates will provide further characterization of the U.S. BSE isolate. Transmission studies are already underway using brain homogenates from atypical BSE cases into mice, cattle and sheep. It will be critical to see whether the atypical BSE isolates behave similarly to typical BSE isolates in terms of transmissibility and disease pathogenesis. If transmission occurs, tissue distribution comparisons will be made between cattle infected with the atypical BSE isolate and the U.S. BSE isolate. Differences in tissue distribution could require new regulations regarding specific risk material (SRM) removal.

http://www.ars.usda.gov/research/projects/projects.htm?ACCN_NO=408490

HOWEVER, JAPAN has already shown infectivity in tissues other than CNS in there atypical TSE in cattle, so why should we wait, and expose many to this agent needlessly, since the last two mad cows in the USA were also atypical TSE ?

PrPSc distribution of a natural case of bovine spongiform encephalopathy

Yoshifumi Iwamaru, Yuka Okubo, Tamako Ikeda, Hiroko Hayashi, Mori- kazu Imamura, Takashi Yokoyama and Morikazu Shinagawa

Priori Disease Research Center, National Institute of Animal Health, 3-1-5 Kannondai, Tsukuba 305-0856 Japan gan@affrc.go.jp

Abstract

Bovine spongiform encephalopathy (BSE) is a disease of cattle that causes progressive neurodegeneration of the central nervous system. Infectivity of BSE agent is accompanied with an abnormal isoform of prion protein (PrPSc).

The specified risk materials (SRM) are tissues potentially carrying BSE infectivity. The following tissues are designated as SRM in Japan: the skull including the brain and eyes but excluding the glossa and the masse- ter muscle, the vertebral column excluding the vertebrae of the tail, spinal cord, distal illeum. For a risk management step, the use of SRM in both animal feed or human food has been prohibited. However, detailed PrPSc distribution remains obscure in BSE cattle and it has caused controversies about definitions of SRM. Therefore we have examined PrPSc distribution in a BSE cattle by Western blotting to reassess definitions of SRM.

The 11th BSE case in Japan was detected in fallen stock surveillance. The carcass was stocked in the refrigerator. For the detection of PrPSc, 200 mg of tissue samples were homogenized. Following collagenase treatment, samples were digested with proteinase K. After digestion, PrPSc was precipitated by sodium phosphotungstate (PTA). The pellets were subjected to Western blotting using the standard procedure. Anti-prion protein monoclonal antibody (mAb) T2 conjugated horseradish peroxidase was used for the detection of PrPSc.

PrPSc was detected in brain, spinal cord, dorsal root ganglia, trigeminal ganglia, sublingual ganglion, retina. In addition, PrPSc was also detected in the peripheral nerves (sciatic nerve, tibial nerve, vagus nerve).

Our results suggest that the currently accepted definitions of SRM in BSE cattle may need to be reexamined.

T. Kitamoto (Ed.)PRIONSFood and Drug Safety===========

ALSO from the International Symposium of Prion Diseases held in Sendai, October 31, to November 2, 2004;

Bovine spongiform encephalopathy (BSE) in Japan

snip...

"Furthermore, current studies into transmission of cases of BSE that are atypical or that develop in young cattle are expected to amplify the BSE prion"

NO. Date conf. Farm Birth place and Date Age at diagnosis

- 1. 8. 2003.10.6. Fukushima Tochigi 2001.10.13. 23
- 2. 9. 2003.11.4. Hiroshima Hyogo 2002.1.13. 21

Test results

8b, 9c cows Elisa Positive, WB Positive, IHC negative, histopathology negative

b = atypical BSE case

c = case of BSE in a young animal

b,c, No PrPSc on IHC, and no spongiform change on histology

International Symposium of Prion Diseases held in Sendai, October 31, to November 2, 2004.

Tetsuyuki Kitamoto Professor and Chairman Department of Prion Research Tohoku University School of Medicine 2-1 SeiryoAoba-ku, Sendai 980-8575, JAPAN TEL +81-22-717-8147 FAX +81-22-717-8148 e-mail; <u>kitamoto@mail.tains.tohoku.ac.jp</u> Symposium Secretariat Kyomi Sasaki TEL +81-22-717-8233 FAX +81-22-717-7656 e-mail: <u>kvomi-sasaki@mail.tains.tohoku.ac.ip</u>

Atypical Proteinase K-Resistant Prion Protein (PrPres) observed in an Apparently Healthy 23-Month-Old Holstein Steer

Jpn. J. Infect. Dis., 56, 221-222, 2003

Laboratory and Epidemiology Communications

Atypical Proteinase K-Resistant Prion Protein (PrPres) Observed in an Apparently Healthy 23-Month-Old Holstein Steer

Yoshio Yamakawa*, KenÕichi Hagiwara, Kyoko Nohtomi, Yuko Nakamura, Masahiro Nishizima, Yoshimi Higuchi1, Yuko Sato1, Tetsutaro Sata1 and the Expert Committee for BSE Diagnosis, Ministry of Health, Labour and Welfare of Japan2

Department of Biochemistry & Cell Biology and 1Department of Pathology, National Institute of Infectious Diseases, Tokyo 162-8640 and 2Miistry of Health, Labour and Welfare, Tokyo 100-8916

Communicated by Tetsutaro Sata

(Accepted December 2, 2003)

*Corresponding author: Mailing address: Department of Biochemistry and Cell Biology, National Institute of Infectious Diseases, Toyama 1-23-1, Shinjuku-ku, Tokyo 1628640, Japan. Tel: +81-3-5285-1111, Fax: +81-3-5285-1157, E-mail: <u>yamakawa@nih.go.jp</u>

Since October 18, 2001, 'bovine spongiform encephalopathy (BSE) examination for all cattle slaughtered at abattoirs in the country' has been mandated in Japan by the Ministry of Health, Labour and Welfare (MHLW). 'Plateria' ELISA-kit (Bio-Rad Laboratories, Hercules, Calif., USA) is routinely used at abattoirs for detecting proteinase K (PK)-resistant prion protein (PrPSc) in the obex region. Samples positive according to the ELISA screening are further subjected to Western blot (WB) and histologic and immunohistochemical examination (IHC) at the National Institute of Infectious Diseases (NIID) or Obihiro University. If PrPSc is detected either by WB or by IHC, the cattle are diagnosed as BSE. The diagnosis is approved by the Expert Committee for BSE Diagnosis, MHLW. From October 18, 2001 to September 30, 2003, approximately 2.5 million cattle were screened at abattoirs. A hundred and ten specimens positive according to ELISA were subjected to WB/IHC. Seven showed positive by both WB and IHC, all exhibiting the typical electrophoretic profile of a high content of the di-glycosylated molecular form of PrPSc (1-3) and the distinctive granular deposition of PrPSc in neuronal cells and neuropil of the dorsal nucleus of vagus.

An ELISA-positive specimen from a 23 month-old Holstein steer slaughtered on September 29, 2003, in Ibaraki Prefecture (Ibaraki case) was sent to the NIID for confirmation. The animal was reportedly healthy before slaughter. The OD titer in ELISA was slightly higher than the 'cut-off' level given by the manufacturer. The histology showed no spongiform changes and IHC revealed no signal of PrPSc accumulation typical for BSE. However, WB analysis of the homogenate that was prepared from the obex region and used for ELISA revealed a small amount of PrPSc with an electrophoretic profile different from that of typical BSEassociated PrPSc (1-3). The characteristics were (i) low content of the di-glycosylated molecular form of PrPSc, (ii) a faster migration of the non-glycosylated form of PrPSc on SDS-PAGE, and (iii) less resistance against PK digestion as compared with an authentic PrPSc specimen derived from an 83-month-old Holstein (Wakayama case) (Fig. 1). Table 1 summarizes the relative amounts of three distinctive glycoforms (di-, mono, non-glycosylated) of PrPSc calculated by densitometric analysis of the blot shown in Fig. 1. As 2.5 mg wet weight obex-equivalent homogenate of the Ibaraki case (Fig. 1, lane 4) gave slightly stronger band intensities of PrPSc than an 8 mg wet weight obex-equivalent homogenate of a typical BSE-affected Wakayama case (Fig. 1, lane 2), the amount of PrPSc accumulated in the Ibaraki case was calculated to be 1/500 - 1/1000 of the Wakayama case. In the Ibaraki case, the PrPSc bands were not detectable in the homogenates of the proximal surrounding region of the obex. These findings were consistent with the low OD value in ELISA, i.e., 0.2 -0.3 for the Ibaraki case versus over 3.0 for the Wakayama case. The DNA sequence of the PrP coding region of the Ibaraki case was the same as that appearing in the database (GenBank accession number: AJ298878). More recently, we encountered another case that resembled the Ibaraki case. It was a 21monthold Holstein steer from Hiroshima Prefecture. WB showed typical BSE-specific PrPSc deposition though IHC did not detect positive signals of PrPSc (data not shown).

Though the clinical onset of BSE is usually at around 5 years of age or later, a 20-month-old case showing the clinical signs has been reported (4). Variant forms of BSE similar to our cases, i.e., with atypical histopathological and/or biochemical phenotype, have been recently reported in Italy (5) and in France (6). Such variant BSE was not associated with mutations in the prion protein (PrP) coding region as in our case (5,6).

The Ministry of Agriculture, Forestry and Fisheries of Japan (MAFF) announced a ban of feeding ruminants with meat bone meal (MBM) on September 18, 2001, and a complete ban was made on October 15 of the same year. According to the recent MAFF report, the previous seven cases of BSE in Japan were cattle born in 1995 - 1996 and possibly fed with cross-contaminated feed. However, the two cattle in this report were born after the complete ban. Whether contaminated MBM was implicated in the present cases remains to be investigated.

REFERENCES

Collinge, J., Sidle, K. C. L., Meads, J., Ironside, J. and Hill, A. F. (1996): Molecular analysis of prion strain variation and the aetiology of 'new variant' CJD. Nature, 383, 685

690. Bruce, M. E., Will, R. G., Ironside, J. W., McConnell, I., Drummond, D., Suttie, A., McCardle, L., Chree, A., Hope, J., Birkett, C., Cousens, S., Fraser, H. and Bostock, C. J. (1997): Transmissions to mice indicate that 'new variant' CJD is caused by the BSE agent. Nature, 389, 498-501. Hill, A. F., Desbruslais, M., Joiner, S., Sidle, K. C. L., Gowland, I. and Collinge, J. (1997): The same prion strain causes vCJD and BSE. Nature, 389, 448-450. Matravers, W., Bridgeman, J. and Smith, M.-F. (ed.)(2000): The BSE Inquiry. p. 37. vol. 16. The Stationery Office Ltd., Norwich, UK. Casalone, C., Zanusso, G., Acutis, P. L., Crescio, M. I., Corona, C., Ferrari, S., Capobianco, R., Tagliavini, F., Monaco, S. and Caramelli, M. (2003): Identification of a novel molecular and neuropathological BSE phenotype in Italy. International Conference on Prion Disease: from basic research to intervention concepts. Gasreig, Munhen, October 8-10. Bicaba, A. G., Laplanche, J. L., Ryder, S. and Baron, T. (2003): A molecular variant of bovine spongiform encephalopatie. International Conference on Prion Disease: from basic research to intervention concepts. Gasreig, Munhen, October 8-10. Asante, E. A., Linehan, J. M., Desbruslais, M., Joiner, S., Gowland, I., Wood, A. L., Welch, J., Hill, A. F., Lloyd, S. E., Wadsworth, J. D. F. and Collinge, J. (2002). BSE prions propagate as either variant CJD-like or sporadic CJD-like prion strains in transgenic mice expressing human prion protein. EMBO J., 21, 6358-6366.

9/13/2005

Page 12 of 17

SEE SLIDES IN PDF FILE;

http://www.nih.go.jp/JJID/56/221.pdf

http://www.fsis.usda.gov/OPPDE/Comments/03-025IFA/03-025IFA-2.pdf

4. WHAT does USDA/FDA ET AL intend to do about the risks of atypical BSE/TSE in cattle now that infectivity shows in tissue samples other than CNS in Japan, the fact now that the last Texas mad cow and that last mad cow in Alabama were indeed of the atypical strain, the fact that the studies long ago in Mission, Texas of USA sheep scrapie transmission to the USA bovine, which proved an 'atypical tse' in the USA bovine, the fact also that USDA/FDA are still floundering on the last SRM regulations, but with the BASE strain now in cattle that is not similar to nvCJD, but very similar to the sporadic CJD, and sporadic CJD has tripled in the last few years in the USA. WHAT do you plan to do to protect human health from these atypical strains of TSE, in relations to SRMs ?

5. THE 2004 Enhanced BSE surveillance program, that tested all those cows, but then we found just how terribly flawed the program was, from testing protocols, to testing the most likely to have BSE i.e. high risk, to the geographical distribution of the testing and high risk areas, to letting the tissue samples of one mad cow sit on a shelf

for 7+ months and then having to have an act of Congress to ever get that cow finally confirmed, to that other Texas mad cow they decided to not even bother testing at all, just rendered that very suspect cow, to suspect to test evidently, back to that Alabama mad cow that they could only give a guess as to age with dentition where we all know that the age of that cow was so close to 10 years it could have been 9 years 7 months to 10 years 3 months, thus possibly being an BAPB i.e. USA 'born after partial ban', to all those rabies suspect cows that did not have rabies, and DID NOT get tested for BSE/TSE in that June 2004 enhanced surveillance program, even though the common lay person knows the suspect rabies negative cows are suppose to be BSE/TSE tested, how does one correct all these blatant failures and will they be corrected?

SEE FAILURES ;

Finding 2 Inherent Challenges in Identifying and Testing High-Risk Cattle Still Remain Our prior report identified a number of inherent problems in identifying and testing high-risk cattle. We reported that the challenges in identifying the universe of high-risk cattle, as well as the need to design procedures to obtain an appropriate representation of samples, was critical to the success of the BSE surveillance program. The surveillance program was designed to target nonambulatory cattle, cattle showing signs of CNS disease (including cattle testing negative for rabies), cattle showing signs not inconsistent with BSE, and dead cattle. Although APHIS designed procedures to ensure FSIS condemned cattle were sampled and made a concerted effort for outreach to obtain targeted samples, industry practices not considered in the design of the surveillance program reduced assurance that targeted animals were tested for BSE. In our prior report, we recommended that APHIS work with public health and State diagnostic laboratories to develop and test rabies-negative samples for BSE. This target group is important for determining the prevalence of BSE in the United States because rabies cases exhibit clinical signs not inconsistent with BSE; a negative rabies test means the cause of the clinical signs has not been diagnosed. Rabies Negative Samples APHIS agreed with our recommendation and initiated an outreach program with the American Association of Veterinary Laboratory Diagnosticians, as well as State laboratories. APHIS also agreed to do ongoing monitoring to ensure samples were obtained from this target population. Although APHIS increased the samples tested from this target group as compared to prior years, we found that conflicting APHIS instructions on the ages of cattle to test resulted in inconsistencies in what samples were submitted for BSE testing. Therefore, some laboratories did not refer their rabies negative samples to APHIS in order to maximize the number tested for this critical target population. In addition, APHIS did not monitor the number of submissions of rabies negative samples for BSE testing from specific laboratories. According to the Procedure Manual for BSE Surveillance, dated October 2004, the target population includes: Central nervous system (CNS) signs and/or rabies negative - sample animals of any age (emphasis added): a. Diagnostic laboratories -samples submitted due to evidence of CNS clinical signs. USDA/OIG-A/50601-10-KC Page 19 USDA/OIG-A/50601-10-KC Page 20

b. Public health laboratories – rabies negative cases. c. Slaughter facilities – CNS ante mortem condemned at slaughter, sampled by FSIS. d. On-the-farm – CNS cattle that do not meet the criteria for a foreign animal

disease investigation. For FYs 2002, 2003, and 2004 (through February 2004), NVSL received 170, 133, and 45 rabies-negative samples, respectively. Between June 1, 2004, and May 29, 2005, the number of samples received for testing increased to 226 rabies suspect samples. The collection sites submitting these samples follow. Collection Site Number of Rabies Suspect Submissions * Slaughter Plant 0 Renderer 2 On-Farm 11 Public Health Lab 94 Diagnostic Lab 81 3D-4D 8 Other 4 Total 200 * 26 were tested but not counted by APHIS towards meeting the target goals because the obex was not submitted. We obtained a copy of a memorandum, dated July 13, 2004, that APHIS sent to diagnostic and public health laboratories providing them instructions on submitting samples for cattle showing signs of CNS diseases, but testing negative for rabies. The letter was sent to about 170 State veterinary diagnostic and public health laboratories and discussed the need to submit specimens to NVSL of all adult cattle (emphasis added) that showed signs of CNS diseases, but tested negative for rabies. This directive did not specify the age of the cattle. The Procedure Manual for BSE Surveillance, dated October 2004, specified samples of cattle of any age should be submitted. We contacted laboratories in six States to determine if it was standard procedure to submit all negative rabies samples to NVSL. We found that, because of the lack of specificity in the APHIS letter and inadequate followup by APHIS, there were inconsistencies in the age of cattle samples submitted for BSE testing. For those States contacted, the following samples were submitted versus tested as negative for rabies. USDA/OIG-A/50601-10-KC Page 21

Rabies Negative Tests Not Sent for BSE Testing Since June 1, 2004 State Negative Rabies Tests Sent for BSE Testing Not Sent for BSE Testing Pennsylvania a/ 33 15 18 Kansas b/ 85 69 16 Wisconsin c/ 12 1 11 South Dakota d/ 7 0 7 Arizona e/ 5 5 0 Mississippi e/ 4 4 0 Total 146 94 52 a/ A Pennsylvania laboratory official said only rabies negative cattle over 20 months of age were submitted for BSE testing. The laboratory did not submit 18 samples for BSE testing because the animals were less than 20 months of age. b/ Kansas laboratory officials said early in the expanded surveillance program, there was confusion as to the cattle ages that should be submitted for BSE testing. They did not know if cattle should be submitted that were above 20 months or 30 months of age. Of the 16 animals not submitted for BSE testing, 14 were under 20 months of age from early in the expanded surveillance program. The other two animals were not tested due to internal laboratory issues. The Kansas and Nebraska area office officials contacted the laboratory and told the officials to submit rabies negative cattle of any age for BSE testing. The laboratory now submits all rabies negative cattle for BSE testing. c/ A Wisconsin laboratory official said only rabies negative cattle samples 30 months of age or older are submitted for BSE testing. Of the 11 animals not submitted for BSE testing, 8 were less than 30 months of age. Wisconsin laboratory officials were not certain why the other three samples were not submitted. d/ Laboratory officials from South Dakota said they did not receive notification from APHIS regarding the submission of rabies negative cases for BSE testing. The section supervisor and laboratory director were not aware of any letter sent to the laboratory. The section supervisor said most bovine rabies tests at the laboratory are performed on calves. We confirmed the laboratory's address matched the address on APHIS' letter distribution list. However, there was no evidence

that the South Dakota area office contacted the laboratory. The laboratory was not listed on the documentation from the APHIS regional office detailing the area office contacts with laboratory personnel. We contacted the South Dakota area office and were advised that while some contact had been made with the laboratory, the contact may have involved Brucellosis rather than BSE. On May 4, 2005, the area office

advised us they recently contacted the laboratory regarding the submission of rabies negative samples for BSE testing. e/ Arizona and Mississippi laboratory officials said they submitted all rabies negative samples for BSE testing regardless of the age of the animal. An NVSL official stated that APHIS is not concerned with rabies negatives samples from cattle less than 30 months of age. This position, however, is contrary to APHIS' published target population. Our prior audit recognized the significant challenge for APHIS to obtain samples from some high-risk populations because of the inherent problems with obtaining voluntary compliance and transporting the carcasses for testing. USDA issued rules to prohibit nonambulatory animals (downers) from entering the food supply at inspected slaughterhouses. OIG recommended, and the International Review Subcommittee33 emphasized, that USDA should take additional steps to assure that facilitated pathways exist for dead and nonambulatory cattle to allow for the collection of samples and proper disposal of carcasses. Between June 1, 2004, and May 31, 2005, the APHIS database documents 27,617 samples were collected showing a reason for submission of nonambulatory and 325,225 samples were collected with reason of submission showing "dead." Downers and Cattle that Died on the Farm APHIS made extensive outreach efforts to notify producers and private veterinarians of the need to submit and have tested animals from these target groups. They also entered into financial arrangements with 123 renderers and other collection sites to reimburse them for costs associated with storing, transporting, and collecting samples. However, as shown in exhibit F, APHIS was not always successful in establishing agreements with non-slaughter collection sites in some States. APHIS stated that agreements do not necessarily reflect the entire universe of collection sites and that the presentation in exhibit F was incomplete because there were many collection sites without a payment involved or without a formal agreement. We note that over 90 percent of the samples collected were obtained from the 123 collection sites with agreements and; therefore, we believe agreements offer the best source to increase targeted samples in underrepresented areas. We found that APHIS did not consider industry practices in the design of its surveillance effort to provide reasonable assurance that cattle exhibiting possible clinical signs consistent with BSE were tested. Slaughter facilities do not always accept all cattle arriving for slaughter because of their business requirements. We found that, in one State visited, slaughter facilities pre-screened and rejected cattle (sick/down/dead/others not meeting business

USDA/OIG-A/50601-10-KC Page 22

33 Report from the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases, February 13, 2004.

USDA/OIG-A/50601-10-KC Page 23

standards) before presentation for slaughter in areas immediately adjacent or contiguous to the official slaughter establishment. These animals were not inspected and/or observed by either FSIS or APHIS officials located at

the slaughter facilities. FSIS procedures state that they have no authority to inspect cattle not presented for slaughter. Further, APHIS officials stated they did not believe that they had the authority to go into these sorting and/or screening areas and require that the rejected animals be provided to APHIS for BSE sampling. Neither APHIS nor FSIS had any process to assure that animals left on transport vehicles and/or rejected for slaughter arrived at a collection site for BSE testing. FSIS allows slaughter facilities to designate the area of their establishment where federal inspection is performed; this is designated as the official slaughter establishment.34 We observed animals that were down or dead in pens outside the official premises that were to be picked up by renderers. Animals that were rejected by plant personnel were transported off the premises on the same vehicles that brought them to the plant.35 A policy statement36 regarding BSE sampling of condemned cattle at slaughter plants provided that effective June 1, 2004, FSIS would collect BSE samples for testing: 1) from all cattle regardless of age condemned by FSIS upon ante mortem inspection for CNS impairment, and 2) from all cattle, with the exception of veal calves, condemned by FSIS upon ante mortem inspection for any other reason. FSIS Notice 28-04, dated May 20, 2004, informed FSIS personnel that, "FSIS will be collecting brain samples from cattle at federally-inspected establishments for the purpose of BSE testing." The notice further states that, "Cattle off-loaded from the transport vehicle onto the premises of the federally-inspected establishment (emphasis added), whether dead or alive, will be sampled by the FSIS Public Health Veterinarian (PHV) for BSE after the cattle have been condemned during ante mortem inspection. In addition, cattle passing ante mortem inspection but later found dead prior to slaughter will be condemned and be sampled by the FSIS PHV." 34 FSIS regulations do not specifically address the designation of an establishment's "official" boundaries; however, FSIS Notices 29-04 (dated May 27, 2004) and 40-04 (dated July 29, 2004) make it clear that FSIS inspection staff are not responsible for sampling dead cattle that are not part of the "official" premises. 35 APHIS' area office personnel stated that it was their understanding that some establishments in the State were not presenting cattle that died or were down on the transport vehicle to FSIS for ante mortem inspection. The dead and down cattle were left in the vehicle, if possible. In rare circumstances, dead cattle may be removed from the trailer by plant personnel to facilitate the unloading of other animals. 36 A May 20, 2004, Memorandum between the Administrators of APHIS and FSIS. USDA/OIG-A/50601-10-KC Page 24 APHIS has the responsibility for sampling dead cattle off-loaded onto plant-owned property that is adjoining to, but not considered part of, the "official premises.37 FSIS procedures38 provide that "Dead cattle that are off-loaded to facilitate the off-loading of live animals, but that will be

re-loaded onto the transport vehicle, are not subject to sampling by FSIS. While performing our review in one State, we reviewed the circumstances at two slaughter facilities in the State that inspected and rejected unsuitable cattle before the animals entered the official receiving areas of the plants. This pre-screening activity was conducted in areas not designated by the facility as official premises of the establishment and not under the review or supervision of FSIS inspectors. The plant rejected all nonambulatory and dead/dying/sick animals delivered to the establishment. Plant personnel refused to offload any dead or downer animals to facilitate the offloading of ambulatory animals. Plant personnel said that the driver was responsible for ensuring nonambulatory animals were humanely euthanized and disposing of the carcasses of the dead animals. Plant personnel informed us that they did not want to jeopardize contracts with business partners by allowing unsuitable animals on their slaughter premises. In the second case, one family member owned a slaughter facility while another operated a livestock sale barn adjacent to the slaughter facility. The slaughter facility was under FSIS' supervision while the sale barn was not. Cattle sometimes arrived at the sale barn that were sick/down/dead or would die or go down while at the sale barn. According to personnel at the sale barn, these animals were left for the renderer to collect. The healthy ambulatory animals that remained were marketed to many buyers including the adjacent slaughter facility. When the slaughter facility was ready to accept the ambulatory animals for processing, the cattle would be moved from the sale barn to the slaughter facility where they were subject to FSIS' inspection. We requested the slaughter facilities to estimate the number of cattle rejected on a daily basis (there were no records to confirm the estimates). We visited a renderer in the area and found that the renderer had a contract with APHIS to collect samples for BSE testing. In this case, although we could not obtain assurance that all rejected cattle were sampled, the renderer processed a significant number of animals, as compared to the slaughter plants' estimates of those rejected. Due to the close proximity (less than 5 miles) of the renderer to the slaughter facilities, and the premium it paid for dead cattle that were in good condition, there was a financial incentive for transport drivers to dispose of their dead animals at this renderer. 37 FSIS Notice 40-04, dated July 29, 2004. 38 FSIS Notice 29-04, dated May 27, 2004.

USDA/OIG-A/50601-10-KC Page 25

In our discussions with APHIS officials in Wisconsin and Iowa, they confirmed that there were plants in their States that also used pre-screening practices. On May 27, 2005, we requested APHIS and FSIS to provide a list of all slaughter facilities that pre-screened cattle for slaughter in locations away from the area designated as the official slaughter facility. Along with this request, we asked for information to demonstrate that either APHIS or FSIS confirmed there was a high likelihood that high-risk animals were sampled at other collection sites. In response to our request, the APHIS BSE Program Manager stated that APHIS did not have information on slaughter plants that pre-screen or screen their animals for slaughter suitability off their official plant premises. To their knowledge, every company or producer that submits animals for slaughter pre-sorts or screens them for suitability at various locations away from the slaughter facility. For this reason, USDA focused its BSE sample collection efforts at other types of facilities such as renderers, pet food companies, landfills, and dead stock haulers. Further, in a letter to OIG on June 14, 2005, the administrators of APHIS and FSIS noted the following: "...we believe that no specific actions are necessary or appropriate to obtain reasonable assurance that animals not presented for slaughter are being tested for BSE. There are several reasons for our position. First, we do not believe that the practice is in fact causing us to not test a significant enough number of animals in our enhanced surveillance program to invalidate the overall results. Second,

OIG has concluded that because of the geographical proximity and business relationships of the various entities involved in the case investigated, there is reasonable assurance that a majority of the rejected cattle had been sampled. Third, it is also important to remember that the goal of the enhanced surveillance program is to test a sufficient number of animals to allow us to draw conclusions about the level of BSE (if any) in the American herd...We believe that the number we may be not testing because of the "pre-sorting" practice does not rise to a significant level. The number of animals tested to date has far exceeded expectations, so it is reasonable to infer that there are few of the animals in question, or that we are testing them at some other point in the process...APHIS estimated...there were approximately 446,000 high risk cattle...[and APHIS has]...tested over 375,000 animals in less than 1 year. This indicated that we are missing few animals in the high-risk population, including those that might be pre-sorted before entering a slaughter facility's property." We obtained 123 APHIS sampling agreements and contracts with firms and plotted their locations within the United States (see exhibit F). We also analyzed the samples tested to the BSE sampling goals allocated to each State under the prior surveillance program. This analysis showed that there are

USDA/OIG-A/50601-10-KC Page 26

sampling gaps in two large areas of the United States where APHIS did not have contracts with collection sites. These two areas are shown in the following chart (Montana, South Dakota, North Dakota and Wyoming – Group 1 and Louisiana, Oklahoma, Arkansas, and Tennessee – Group 2): State Original Sampling Goal Based on (268,500 sampling goal) Samples collected as of May 31, 2005 Deficit No. of BSE Sampling Agreements/ Contracts39MT 5,076 182 4,894 2 SD 6,938 2,792 4,146 1 ND 3,616 174 3,442 0 WY 2,513 61 2,452 0 AREA TOTAL 14,934 OK 7,792 2,407 5,385 1 AR 3,672 353 3,319 0 TN 4,938 3,050 1,888 1 LA 2,312 452 1,860 1 AREA TOTAL 12,452 APHIS notes that for the current surveillance program, it had established regional goals and APHIS was not trying to meet particular sampling levels in particular States. However, we believe that it would be advantageous for APHIS to monitor collection data and increase outreach when large geographical areas such as the above States do not provide samples in proportion to the numbers and types of cattle in the population. We also disagree with APHIS/FSIS' contention that because they have tested over 375,000 of their 446,000 estimate of high risk cattle, few in the high-risk population are being missed, including those that might be pre-screened before entering a slaughter facility's property. In our prior audit, we reported that APHIS underestimated the high-risk population; we found that this estimate should have been closer to 1 million animals (see Finding 1). We recognize that BSE samples are provided on a voluntary basis; however, APHIS should consider industry practice in any further maintenance surveillance effort. Animals unsuitable for slaughter exhibiting symptoms not inconsistent with BSE should be sampled and their clinical signs recorded. However, this cited industry practice results in rejected animals not being made available to either APHIS or FSIS veterinarians for their observation and identification of clinical signs exhibited ante mortem. Although these animals may be sampled later at other collection sites, the animals are provided post mortem without information as to relevant clinical signs exhibited ante mortem. For these reasons, we believe APHIS needs to 39APHIS noted that

sites with agreements do not necessarily reflect the entire universe of collection sites and at some sites APHIS collects samples with no payment involved and no agreement in place. OIG agrees that not all collection sites are reflected in our presentation of the 123 sites with reimbursable agreements. OIG believes obtaining sampling agreements is one of the primary methods available to increase sample numbers in areas with sampling gaps. USDA/OIG-A/50601-10-KC Page 27 observe these animals ante mortem when possible to assure the animals from the target population are ultimately sampled and the clinical signs evaluated. Recommendation 3......

http://www.usda.gov/oig/webdocs/50601-10-KC.pdf

[GAO-05-101] Mad Cow Disease: FDA's Management of the Feed Ban Has Improved, but Oversight Weaknesses Continue to Limit Program Effectiveness Size: 104986, Score: 1000, TEXT, PDF, SUMMARY

http://frwebgate.access.gpo.gov/cgi-bin/useftp.cgi? IPaddress=162.140.64.88&filename=d05101.txt&directory=/diskb/wais/data/gao

[2]

[GAO-05-101] Mad Cow Disease: FDA's Management of the Feed Ban Has Improved, but Oversight Weaknesses Continue to Limit Program Effectiveness Size: 104986, Score: 1000, TEXT, PDF, SUMMARY

http://frwebgate.access.gpo.gov/cgi-bin/useftp.cgi? IPaddress=162.140.64.88&filename=d05101.txt&directory=/diskb/wais/data/gao

6. WHAT happened to the test results and MOUSE BIO-ASSAYS of those imported sheep from Belgium that were confiscated and slaughtered from the Faillace's, what sort of TSE did these animals have ?

Imported Belgium/Netherlands Sheep Test Results Background Factsheet Veterinary Services April 2002 APHIS

snip...

Additional tests will be conducted to determine exactly what TSE the animals have BSE or scrapie. These tests involve the use of bioassays that consist of injecting mice with tissue from the infected animals and waiting for them to develop disease. This testing may take at least 2 to 3 years to complete.

http://www.aphis.usda.gov/lpa/pubs/fsheet_faq_notice/fs_ahvtsheeptr.pdf

DECLARATION OF EXTRAORDINARY EMERGENCY BECAUSE OF AN ATYPICAL T.S.E. (PRION DISEASE) OF FOREIGN ORIGIN IN THE UNITED STATES

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2000_register&docid=fr20jy00-31

DECLARATION OF EXTRAORDINARY EMERGENCY BECAUSE OF AN ATYPICAL T.S.E (PRION DISEASE) OF FOREIGN ORIGIN IN THE UNITED STATES [2]

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2000_register&docid=fr20jy00-32

- >> DEPARTMENT OF AGRICULTURE
- >>
- >> Office of the Secretary
- >>
- >>[Docket No. 00-072-2]
- >>
- >> Declaration of Emergency Because of an Atypical Transmissible
- >> Spongiform Encephalopathy (Prion Disease) of Foreign Origin
- >>
- >> A transmissible spongiform encephalopathy (TSE) (prion disease) of
- >> foreign origin has been detected in the United States. It is different
- >> from TSE's previously diagnosed in the United States. The TSE was
- >> detected in the progeny of imported sheep. The imported sheep and
- >> their progeny are under quarantine in Vermont. Transmissible
- >> spongiform encephalopathies are degenerative fatal diseases that can
- >> affect livestock. TSE's are caused by similar, as yet uncharacterized,
- >> agents that usually produce spongiform changes in the brain.
- >> Post-mortem analysis has indicated positive results for an atypical
- >> TSE of foreign origin in four sheep in Vermont. Because of the
- >> potentially serious consequences of allowing the disease to spread to
- >> other livestock in the United States, it is necessary to seize and
- >> dispose of those flocks of sheep in Vermont that are affected with or
- >> exposed to the disease, and their germ plasm. The existence of the
- >> atypical TSE of foreign origin represents a threat to U.S. livestock.
- >> It constitutes a real danger to the national economy and a potential
- >> serious burden on interstate and foreign commerce. APHIS has
 > insufficient funds to carry out the seizure and disposal of animals
- >> and germ plasm necessary to eliminate this disease risk. These funds
- >> would be used to compensate the owners of the animals and germ plasm
- >> for their seizure and disposal in accordance with 21 U.S.C. 134a.
- >> Therefore, in accordance with the provisions of the Act of September

>> 25, 1981, as amended (7 U.S.C. 147b), I declare that there is an >> emergency that threatens the livestock industry of this country and >> hereby authorize the transfer and use of such funds as may be >> necessary from appropriations or other funds available to agencies or >> corporations of the United States Department of Agriculture to seize >> and dispose of animals that are affected with or exposed to this TSE, >> and their germplasm, in accordance with 21 U.S.C. 134a. >> >> Dated: This declaration of emergency shall become effective July 14, >> 2000. Dan Glickman, Secretary of Agriculture. [FR Doc. 00-18368 Filed >>7-19-00; 8:45 am] BILLING CODE 3410-34-P >>>> >> I was told that ; >> >> >>----- Original Message ------>> Subject: Re: hello Dr. Sutton...question please...scrapie...TSS >> Date: Thu, 20 May 2004 14:36:09 -0400 >> From: Jim.D.Rogers@aphis.usda.gov >>To: flounder@wt.net >>> snip... >>> FULL TEXT AND THREAD BETWEEN TSS, MAFF, USDA AND DR. DETWILER HERE ;

https://web01.aphis.usda.gov/regpublic.nsf/168556f5aa7a82ba85256ed00044eb1f/eff9eff1f7c5cf2b87256ecf000df08d? OpenDocument

7. WHY is it that the Farm of the Mad Sheep of Mad River Valley were quarantined for 5 years, but none of these farms from Texas and Alabama with Atypical TSE in the Bovine, they have not been quarantined for 5 years, why not, with the real risk of BSE to sheep, whom is to say this was not BSE ?

SOME DISTURBING TSE DATA FROM BELGIUM ;

Increased incidence of sporadic Creutzfeldt-Jakob disease in the age groups between 70 and 90 years in Belgium B. Van Everbroeck1, A. Michotte2, R. Sciot3, C. Godfraind4, M. Deprez5, S. Quoilin6, J. -J. Martin1 and P. Cras1, 7

Born-Bunge Institute (BBI), University of Antwerp (UA), Campus Drie Eiken (CDE), Antwerp, Belgium
 Department of Neuropathology, Academic hospital, Free University of Brussels, Brussels, Belgium

(3) Department of Pathology, Catholic University of Leuven, Leuven, Belgium

- (4) Pathology Laboratory, Catholic University of Louvain, Brussels, Belgium
- (5) Laboratory of Neuropathology, University of Liège, Sart Tilman, Liège, Belgium
- (6) Institute of Public Health-Louis Pasteur, Brussels, Belgium
- (7) Laboratory of Neurobiology, BBI, UA, CDE, Universiteitsplein 1, B-2610 Wilrijk, Belgium

Received: 28 October 2005 Accepted: 28 March 2006 Published online: 12 July 2006

Abstract From 1998 a prospective surveillance study of Creutzfeldt-Jakob disease (CJD) has been initiated in Belgium. In addition to epidemiological data, information on cerebrospinal fluid biomarkers, prion protein gene and brain neuropathology was collected. From 1-1-1998 to 31-12-2004, 188 patients were referred to the surveillance system. In 85 patients a 'definite' diagnosis of sporadic CJD (sCJD) could be made, whereas 26 patients remained 'probable'. We further identified two unrelated patients with an E200K mutation, and two patients with a seven octapeptide repeat insertion in one family. In one patient a familial history was noted but genetic analysis was not performed. In 72 patients different final diagnoses were made, Alzheimer's disease being the most frequent (N = 20). The demographic parameters of the Belgian population were similar to those observed in the rest of Europe. We did notice a significantly increased age-specific incidence (‰>‰6/106/year) of sCJD patients between 70 and 90 years old in the period 2002–2004 compared to 1998–2001 and retrospectively obtained data (1990–1997, p) < 0.01). We undertook a detailed clinical and biochemical analysis to investigate this increase but could not identify any reason other than an increased vigilance for the diagnosis.

In conclusion, our study identified that in the past sCJD may have been underestimated in patients over age 70 although these patients are both clinically and neurobiochemically similar to the general sCJD phenotype.

Keywords Diagnosis - Epidemiology - Prion disease - Transmissible spongiform encephalopathy

http://www.springerlink.com/(tqxxirqg4xx3c4r4ay0ixz45)/app/home/contribution.asp? referrer=parent&backto=issue,1,11;journal,1,155;linkingpublicationresults,1:102883,1

BASE in cattle in Italy of Identification of a second bovine amyloidotic spongiform encephalopathy: Molecular similarities with sporadic Creutzfeldt-Jakob disease

http://www.pnas.org/cgi/content/abstract/0305777101v1

Atypical Case of Bovine Spongiform Encephalopathy in an East-Flemish Cow in Belgium

H. De Bosschere, DVM, PhD

S. Roels, DVM, PhD

E. Vanopdenbosch, DVM, Lic

Veterinary and Agrochemical Research Centre (CODA/CERVA)

National Reference Laboratorium for Veterinary TSEs

Groeselenberg 99, B-1180

Ukkel (Brussels), Belgium

KEY WORDS: Bovine spongiform encephalopathy, BSE, Western blot, atypical BSE.

ABSTRACT

For many years, researchers believed that only one bovine spongiform encephalopathy (BSE) strain existed, in contrast to the many different scrapie strains found. However, only very recently reports emerged about unconventional BSE strains seen in Italy, France, and Japan. The present case describes an atypical strain of BSE in Belgium in a 64-month-old East-Flemish cow with an electrophoretic profile and other features similar to those described in Japan.

INTRODUCTION

Transmissible spongiform encephalopathies (TSEs), or prion diseases, are a group of fatal neurodegenerative diseases including sheep and goat scrapie, bovine spongiform encephalopathy (BSE), and Creutzfeldt-Jakob disease (CJD) in humans. They are characterized by the accumulation of an abnormal protein, called PrPsc, which is formed post-translationally from the normal isoform (PrPc).1,2 At present, the agent causing TSEs is still incompletely characterized, although PrPsc is believed to be its major if not unique constituent.3

Research in mice showed the existence of different scrapie strains.4,5 Scrapie strain discrimination is currently based on biologic typing in a panel of inbred mice, using incubation time and brain pathology scoring as criteria.6 However, no large-scale studies of the molecular features of PrPsc have been reported for bovine BSE to date. Till now, the BSE strain seemed to maintain constant biologic and molecular properties even after experimental or accidental passages into different species, such as mice, humans, primates, and sheep.7–10 However, very recently, variant forms of BSE have been reported in Japan, Italy, and France.11-13 These forms were characterized by atypical histopathologic, immunohistochemical, or biochemical phenotypes. The present case is the description of the first atypical BSE case in Belgium.

MATERIALS AND METHODS

Since January 2001, all cattle older than 30 months are tested for TSE via a rapid test (TeSeE-kit, Bio-Rad, Nazareth, Belgium) after EC regulation 999/2001.14,15 Samples positive according to the enzyme-linked immunosorbent assay (ELISA) screening are further subjected to scrapie-associated fibrils (SAF), histopathology, immunohistochemistry, and Western blot (WB) testing16,17 at the National Reference Laboratory (NRL).

RESULTS

A positive ELISA sample from a 64-month-old East-Flemish cow or Belgian white and red (Figure 1) was presented at the NRL for confirmation. The animal was reported healthy before slaughter. The optical density (OD) titers at the local laboratory were 2.324 and 2.116.16 The OD titers at the NRL were 0.953 and 0.708 (sample taken at the contralateral side of the first sampling side of the obex region). The histopathology of the obex, pons, and midbrain

showed no spongiform changes; immunohistochemistry of the brainstem revealed no signal of PrPsc accumulation typical for BSE; and SAF was negative. However, WB analysis (Bovine WB, Bio-Rad, France; antibodies 12F10 and SAF60) of the same homogenate that was prepared from the obex region for ELISA revealed a small amount of PrPsc with an electrophoretic profile different from that of typical BSE-associated PrPsc.18,19 The band on the gel of the non-glycosylated form of PrPsc of the present case clearly showed a lower migration pattern compared with that of a typical BSE case (Figure 2).

DISCUSSION

For many years, researchers assumed that only one BSE strain existed.7–10 Only in the past months, reports of atypical BSE cases were announced.11–13 The Japanese case11 describes a very young bull (23 months) characterized by the absence of spongiform changes and PrPsc deposits immunohistochemically. The WB analysis revealed an electrophoretic profile different from that of typical BSE, characterized by low content of the di-glycosylated molecular form of PrPsc and a faster migration of the nonglycosylated form of PrPsc. In Italy,12 two BSE affected cattle with a previously unrecognized neuropathologic profile and PrPsc type were seen. These cases were determined using a different staining pattern on immunohistochemistry, a difference in size and glycoform ratio of PrPsc on immunoblot and a difference in regional distribution of lesions. The two cases in France13 showed variant molecular features with a different PrPsc electrophoretic profile from other BSE cases, mainly characterized by a higher molecular mass of the nonglycosylated PrPsc. The present case shows the most similarities (ie, identical electrophoretic profile, only ELISA and WB positive and histopathology and immunohistochemistry negative) with the Japanese case,11 although the cow in the Japanese case was only 23 months old, and the cow in this case was 64 months old.

The fact that these strains were detected worldwide and in several breeds suggest that there is no local or breeddependent feature involved. It could be that the WB techniques have become more specific within the past year in the detection of minor differences in di-, mono-, and nonglycosylated molecular forms of PrPsc. Infection of cattle by scrapie could also be considered since scrapie can be transmitted by direct contact between animals or through environmental contamination.13

In conclusion, this Belgian case should be added to the list of atypical BSE strains only very recently detected worldwide and may contribute to further research studies about epidemiologic significance. Current continued research on BSE would appear to reveal different BSE strains in analogy with the different scrapie strains.

ACKNOWLEDGMENTS

The authors wish to thank Rita Geeroms, Patrick Van Muylem, Stephanie Durand, Raphaël Foubert and Amina Chama for their technical assistance. Mario Vanpoucke is acknowledged for providing references.

REFERENCES

1. Oesch B, Westaway D, Walchii M, et al: A cellular gene encodes PrP 27–30 protein. Cell 40:735–746, 1985.

2. Prusiner SB, De Armond SJ: Prion diseases and neurodegeneration. Annu Rev Neurosci 17:311–339, 1994.

3. Prusiner SB: Scrapie prions. Annu Rev Microbiol 43:345–374, 1989.

4. Bruce M, Dickinson AG: Biological evidence that scrapie agent has an independent genome. J Gen Virol 68:79–89, 1987.

5. Fraser H, Dickinson AG: Scrapie in mice: Agent strain differences in the distribution and intensity of grey matter vacuolation. J Comp Pathol 83:29–40, 1973.

6. Bruce M, McConnell I, Fraser H, Dickinson AG: The disease characteristics of different strains of scrapie in Sinc Congenic mice lines: Impications for the nature of the agent and host control of pathogenesis. J Virol 72:595–603, 1991.

7. Bruce M, Chree A, McDonnell I, et al: Transmission of bovine spongiform encephalopathy and scrapie to mice: Strain variation and the species barrier. Philos Trans R Soc Lon Ser B 343:405–411, 1994.

8. Bruce M, Will RG, Ironside JW, et al: Transmissions to mice indicate that "new variant" CJD is caused by the BSE agent. Nature 389:498–501, 1997.

9. Foster JD, Bruce M, McDonnell I, et al: Detection of BSE infectivity in brain and spleen of experimentally infected sheep. Vet Rec 138:546–548, 1996.

10. Lasmezas CI, Fournier J-G, Nouvel V, et al: Adaptation of the bovine spongiform encephalopathy agent to primates and comparison with Creutzfeldt-Jakob disease: Implications for human health. Proc Natl Acd Sci U S A 98:4142–4147, 2001.

11. Yamakawa Y, Hagiwara K, Nohtomi K, et al, for the Expert Commitee for BSE Diagnosis, Ministry of Health, Labour and Welfare of Japan: Atypical proteinase K-resistant prion protein (PrPres) observed in an apparently healthy 23-month-old Holstein steer. Jpn J Infect Dis 56:221–222, 2003.

12. Casalone C, Zanusso G, Acutis PL, et al: Identification of a novel molecular and neuropathological BSE phenotype in Italy: International Conference on Prion Disease: from basic research to intervention concepts. Gasreig, München, 8–10 October, 2003.

13. Biacabe AG, Laplanche JL, Ryder S, Baron T: A molecular variant of bovine spongiform encephalopathy. International Conference on Prion Disease: From basic research to intervention concepts. Gasreig, München, 8–10 October, 2003.

14. De Becker D, Roels S, Vanopdenbosch E: BSE onderzoek: opsporen van PrPres door middel van de BIO-RAD Platelia BSE-kit. Vlaams Diergeneeskundig Tijdschrift 69:382–384, 2000.

15. Roels S, Demeyer G, Tedik K, et al: Variance of mass (volume) taken with the calibrated syringe and of the results provided by the Bio-Rad Platelia BSE test upon storage of brainstem samples at -20° C. Anim Res 51:493–499, 2002.

16. Roels S, De Bosschere H, Saegerman C, et al: BSE and scrapie testing in Belgium: general overview. New Food: accepted, 2004.

17. Vanopdenbosch E, Dechamps P, Dufey J, et al: Le premier cas d'encephalopathie spongioforme bovine diagnostique en Belgique. Annales de Médicine Vétérinaire 142:111–118, 1998.

18. Collinge J, Sidle KCL, Meads J, et al: Molecular analysis of prion strain variation and the aetiology of new variant CJD. Nature 383:685–690, 1996.

19. Hill AF, Desbruslais M, Joiner S, et al: The same prion strain causes vCJD and BSE. Nature 389:448–450, 1997.

Figure 1. Photograph of the East-Flemish cattle breed or the Belgian white and red.

Figure 2. Bovine Western blot (Bio-Rad, France) using antibodies 12F10 and SAF60. MM, Magic mark; Atyp. BSE, Atypical BSE case (present case); Ref1, Reference 1 of a classical BSE case; Ref2, Reference 2 of a classical BSE case. The third band of the non-glycosylated PrPsc of the Atyp. BSE case (left rectangle) shows a markedly faster migration compared to the Ref1 and Ref2 cases (right rectangle).

http://www.jarvm.com/articles/Vol2Iss1/DEBOSSCHERE.htm

8. Scrapie in sheep and goat, CWD in deer and elk, are both running rampant and have been for decades, you cannot and have not controled it, what do you plan to do about that, anything different since everything else has failed so far ?

Subject: SCRAPIE and CWD USA UPDATE July 19, 2006 Date: July 19, 2006 at 12:06 pm PST SCRAPIE USA UPDATE MAY 31, 2006

Infected and Source Flocks

As of May 31, 2006, there were 93 scrapie infected and source flocks (Figure 3). There were 12 new infected and source flocks reported in May (Figure 4) with a total of 67 flocks reported for FY 2006 (Figure 5). The total infected and source flocks that have been released in FY 2006 are 53 (Figure 6), with 7 flocks released in May. The ratio of infected and source flocks released to newly infected and source flocks for FY 2006 = 0.79 : 1. In addition, as of May 31, 2006, 216 scrapie cases have been confirmed and reported by the National Veterinary Services Laboratories (NVSL), of which 33 were RSSS cases (Figure 7). This includes 33 newly confirmed cases in May 2006 (Figure 8). Eighteen cases of scrapie in goats have been reported since 1990 (Figure 9). The last goat case was reported in March 2006. New infected flocks, source flocks, and flocks released for FY 2006 are depicted in Chart 3. New infected and source statuses from 1997 to 2006 are depicted in Chart 4.

snip...

Scrapie Testing

In FY 2006, 26,185 animals have been tested for scrapie : 22,634 RSSS*; 2063 regulatory field cases; 61 necropsy validations, 5 rectal biopsy and 1427 regulatory third eyelid biopsies (Chart 9). ...

snip...END

http://www.aphis.usda.gov/vs/nahps/scrapie/monthly_report/monthly-report.html

CWD MAP

NOTICE CWD creeping its way to TEXAS, literally to it's border. ...

http://www.aphis.usda.gov/vs/nahps/cwd/images/counties_lg.jpg

THEN NOTICE CWD sample along that border in TEXAS, Three Year Summary of Hunter-Kill CWD sampling as of 31 August 2005 of only 191 samples, then compare to the other sample locations ;

http://www.tahc.state.tx.us/animal_health/diseases/cwd/CWD_Sampling_Aug2005.pdf

THREE NEW CASES OF CWD were announced in this same location this month ;

FOR IMMEDIATE RELEASE, JULY 7, 2006:

3 SOUTHERN NEW MEXICO DEER TEST POSITIVE FOR CHRONIC WASTING DISEASE

SANTA FE - Three deer in southern New Mexico have tested positive for chronic wasting disease, bringing the total number of confirmed CWD-infected deer in the state to 15 since the first infected deer was discovered in 2002.

The Department received test results Wednesday from the state Veterinary Diagnostic Services laboratory in Albuquerque that two wild deer captured near the White Sands Missile Range headquarters east of Las Cruces had tested positive for chronic wasting disease. A third wild deer captured in the small community of Timberon in the southern Sacramento Mountains also tested positive for the disease.

The discoveries of the infected deer were part of the Department's ongoing efforts to monitor the disease, which to date has been confined to the southern Sacramento Mountains southeast of Cloudcroft and areas surrounding the Organ Mountains near Las Cruces. Two wild elk from the southern Sacramento Mountains tested positive for the disease in December 2005.

Chronic wasting disease is a fatal neurological illness that afflicts deer, elk and moose. There is no evidence of CWD being transmitted to humans or livestock. The disease causes animals to become emaciated, display abnormal behavior and lose control of bodily functions. To date, it has been found in captive and wild deer, elk and moose in eight states and two Canadian provinces.

For more information about CWD in New Mexico and how hunters can assist in research and prevention, please visit the New Mexico Department of Game and Fish Web site, <u>www.wildlife.state.nm.us</u>. More information about CWD also can be found on the Chronic Wasting Disease Alliance site at <u>www.cwd-info.org/</u>.

###

http://www.wildlife.state.nm.us/publications/press_releases/documents/2006/0707CWD.htm

SEE MAP NM

http://www.wildlife.state.nm.us/documents/cwdcontrolmap.pdf

STATE CWD INFORMATION

http://www.aphis.usda.gov/vs/nahps/cwd/cwd-stateinfo.html

WITH ANIMAL TSE in the USA rampant (the USA is the most documented Nation in the world with the most species with TSE, all of which have been rendered and fed back to animals for human and animal consumption for decades), with atypical TSE now in the USA, when will you start testing all animals susceptible to a TSE ?

I find it deeply disturbing that now USDA et al in fact are cutting BSE/TSE testing in the USA bovine down to 40,000 a year for the following reasons ;

BSE monitoring in bovine animals EU Jan 1 to June 6 2006 COMPARED to USA (how not to find BSE)

BSE monitoring in bovine animals EU Jan 1 to June 6 2006

Total positives :

Austria 2

Belgium 0

Cyprus 0

Czech Repulic 1

Denmark 0

Estonia 0

Finland 0

Germany 17

Hungary 0

Ireland 25

Italy 3

Latvia 0

Lithuania 0

Luxemburg 0

Malta 0

Portugal 14

Slovakia 0

Slovenia 0

Spain 17

Sweden 0

United Kingdom 75

TOTAL EU 155

http://ec.europa.eu/food/food/biosafety/bse/bse_6evol6-06_en.pdf

COMPARING APPLES TO ORANGES I.E. USA TESTING FIGURES FOR BSE TO CATTLE RATIO

before June 2004 Enhanced BSE surveillance, during June 2004 Enhanced BSE cover-up, and

AFTER, which was proposed this week to be around 40,000 annually from here on out, in a cattle population for USA of about 100 million every year.

THEN COMPARE TO E.U. COUNTRIES TESTING FIGURES FOR BSE TO CATTLE RATIO.

PLEASE note besides the total tests *** country, I have added total cattle population along with some additional information on some countries below. While you are analyzing the additional information, check out some of the imports to USA from documented BSE countries and please note, among other things, the infamous, non-species coding system for feed, mbm, and such. Seems those USA BSE triple firewalls have been seeping all along.

USA TOTAL CATTLE POPULATION

livestock (million): cattle: 98

http://www.library.uu.nl/wesp/populstat/Americas/usag.htm

The total cattle population of the European Union in 2002 was 78.3 million animals. http://www.eds-destatis.de/en/downloads/sif/nn_04_08.pdf

AFTER analyzing for yourself, then ask yourself, who is fooling whom? ... TSS

Total tests :

*** Austria 86 642

 $\underline{http://www.idexx.com/production/livestockpoultrynews/200602.jsp}$

Bovine Spongiform Encephalopathy, Austria

Impact Worksheet, December 18, 2001

Summary: The first case of bovine spongiform encephalopathy (BSE) in Austria was confirmed on December 13, 2001. The six-year old cow presented no clinical signs and was detected through routine BSE surveillance at slaughter. In 1990, Austria had banned feeding of meat-and-bone meal to cattle and sheep. In January 2001, Austria began testing all slaughter cattle over 30 months of age for BSE.

Austria had almost 2.2 million cattle in 2001 and accounted for 1.6 percent of the world's live cattle exports in 1999. Most of the live cattle exports in 1999 went to Italy and Germany. Austria accounted for 1.1 percent of the world's beef and veal exports in 1999. In rank order, destination countries were Italy, the Netherlands, Germany, Russia, and Belgium. Austria also exports about 34,000 metric tons of meat-and-bone meal annually, primarily to the Netherlands, Hungary, Poland, and Germany.

In December 1997, APHIS prohibited the importation of live ruminants and most ruminant products from all of Europe including Austria. In December 2000, import restrictions regarding BSE were expanded by prohibiting all imports of rendered animal protein products, regardless of species, from Europe. Between 1998 and June 2001, US imports from Austria included goat meat, animal feeds, and sausage. The sausage and animals feeds were from unspecified species.

How extensive is the outbreak of BSE in Austria, and what was Austria's disease status prior to the outbreak?

The first case of bovine spongiform encephalopathy (BSE) in Austria was confirmed on December 13, 2001. The sixyear old cow presented no clinical signs and was detected through routine BSE surveillance at slaughter. The animal was from a 60-cattle beef and dairy operation in the district of Gmünd in northeastern Austria. Both the affected operation and the slaughterhouse have been shut down pending further testing on the other cattle, feeds, and milk replacer. Possible causes speculated for the BSE transmission include imported meat-and-bone meal that was illegally fed to cattle, or imported calf milk replacer that had beef tallow as an ingredient.

Source: OIE Disease Information Report; Reuters, Dec 14, 2001; USDA-FAS Gain Report #AU1033, Dec 12, 2001.

What is Austria's production and trade in affected animals and animal products?

Austria has almost 2.2 million cattle in 2001 and accounted for 1.6 percent of world cattle exports in 1999. Stocks of sheep and goats and trade in these animals were generally less than 0.1 percent of global stocks.

Almost 90 percent of the live cattle imports in 1999 came from Germany. USDA-FAS also reported that Austria imported 234 live cattle from the UK between 1988 and 1990, and 253 cattle from the Netherlands between 1993 and 1997. Most of the live cattle exports in 1999 went to Italy and Germany, with lesser numbers going to Bosnia-Herzegovina, the Netherlands, the Czech Republic, and Croatia.

Table 1. Austria's live animal stocks (2001) and imports and exports of live animals (1999).

Live Animal Year 2001 Stocks 1999 Trade

1999 Imports
Head % World Head % World Head % World
Cattle 2,155,447 0.2 146,890 1.6 25,245 0.3
Sheep 357,888 <0.1 18,597 0.1 100 <0.1
Goats 69,618 <0.1 1,807 <0.1 94 <0.1

1999 Exports

Source: United Nations FAO

Austria accounted for 1.1 percent of world beef and veal exports in 1999. In rank order, destination countries were Italy, the Netherlands, Germany, Russia, and Belgium. Austria also exports about 34,000 metric tons of meat-and-bone meal annually, primarily to the Netherlands, Hungary, Poland, and Germany. Austrian imports of beef and veal in 1999 came primarily from Germany and the Netherlands. In 1997 and 1998, Austria also imported meat-and-bone meal for non-ruminant feed, mainly from Germany.

Table 2. Production (2001) and trade (1999) in relevant products by Austria.

Products Year 2000 Production 1999 Trade

1999 Exports 1999 Imports Metric ton % World Metric ton % World Metric ton % World Beef and veal 216,700 0.4 77,205 1.1 19.694 0.3 Mutton and lamb 1 7,200 < 0.1 60 < 0.1 1,950 0.2 Goat meat 1 580 < 0.1 4 < 0.17 < 0.1

Source: United Nations FAO

1 Sheep and goats were included in Table 1 and Table 2 as 'affected' animals because USDA/APHIS includes all ruminants and ruminant products in its restrictions pertaining to BSE.

Source: United Nations FAO; USDA-FAS Gain Report #AU0031, Aug 10, 2000; USDA-FAS Gain Report #AU1033, Dec 10, 2001

Has Austria taken any precautions in regard to BSE?

Austria had banned feeding of meat-and-bone meal to cattle and sheep in 1990. Additional laws pertaining to processed mammalian proteins (PMP) were enacted in January 2001, including a ban on feeding PMP to animals used for food production, and a ban on the marketing and import of PMP intended for livestock. Austria began testing all slaughter cattle over 30 months of age in January 2001.

Source: USDA-FAS Gain Report #AU1001, Feb 1, 2001; Reuters, Dec 14, 2001

What are the US imports of affected animals or animal products from Austria?

Between 1998 and June 2001, US imports from Austria included goat meat, animal feeds, and sausage. The sausage and animals feeds were from unspecified species.

Source: World Trade Atlas

Table 3. Relevant US imports from Austria in 1998, 1999, 2000, and Jan-Jun 2001

HS Code Description Unit 1998 1999 2000 2001 (Jan-Jun)

Feed - non species specific 2309909500 Preparations Used in Animal Feedings, NESOI KG 0 0 0 1,000

Meat & offal - ruminant

020450 Goat Fresh, Frozen KG 0 656 0 0

Meat & offal - non species specific

1601006080 Sausage/Smlr Prdct Meat Etc NESOI Food Prep Nt Cnd KG 514 0 0 12,154

Source: World Trade Atlas

Did the US have restrictions on ruminant imports from Austria prior to this case?

In December 1997, APHIS prohibited the importation of live ruminants and most ruminant products from all of Europe including Austria until a thorough assessment of the risks of introduction of BSE into the US could be made. Prior to December 1997, import restrictions were applied only to those countries which had reported cases of BSE in native animals. Also, importation of ruminant meat from BSE-affected countries was permitted if the meat was deboned and free of visually identifiable lymphatic and nervous tissue and if it met other restrictions. Import regulations enacted December 1997 extended the import restrictions to countries which had not had a declared BSE case, yet had risk factors for BSE occurrence.

These regulatory changes also removed provisions that allowed importation of ruminant meat from the restricted

countries, and thereby prohibited importation of ruminant meat from all Europe. These import restrictions also applied to bone meal, blood meal, meat meal, offal, fat, glands, and serum from ruminants. In December 2000, APHIS expanded its import restrictions regarding BSE by prohibiting all imports from Europe of rendered animal protein products, regardless of species.

Source: USDA, APHIS, VS

What is the level of passenger traffic arriving in the United States from Austria?

A total of 168,598 passengers on direct flights from Austria arrived at US airports in fiscal year 2000. An undetermined number of passengers from Austria arrived in the US via indirect flights.

Under APHIS-PPQ's agricultural quarantine inspection monitoring, 565 air passengers from Austria were sampled for items of agricultural interest in fiscal year 2000. Ten (10) of these passengers, or 1.7 percent, carried a total of 23 kg meat (non-pork) items that could potentially harbor the pathogen(s) that cause BSE. None of these passengers from whom meat items were confiscated reported plans to visit or work on a ranch or farm during their visit to the US.

Source: US Dept. of Transportation; APHIS-PPQ

CEI's plans for follow up:

Currently, CEI has no plans for supplemental reporting of this outbreak of BSE in Austria. If you need more information or if you want to comment on this worksheet, you may reply to this message, or contact David Cummings at (970) 490-7895 or Chris Kopral at (970) 490-7819.

http://www.aphis.usda.gov/vs/ceah/cei/taf/iw_2001_files/foreign/bse_austria1201.htm

*** Belgium 155 307

Belgium is a country with about ten million

inhabitants and approximately 3,000,000

cattle, 188,000 sheep, 39,000 goats and

15,000 deer

snip...

In Belgium, GBR class III, the rapid BSE

Bio-Rad Platelia ELISA test (recently replaced by

Bio-Rad TeSeE test) is performed in 18 private

laboratories under the supervision of the VAR as National Reference Laboratory. All samples with doubtful or positive test results have to be further analysed in the VAR, to confirm the BSE diagnosis using the above-mentioned three reference tests and a Western Blot. In total to date, 118 cases have been detected in Belgium. snip...

Figure 1: Geographical distribution of the BSE cases in Belgium (1997-2003) http://www.russellpublishing.com/newfood/nf10436.pdf

*** Cyprus 3 455

Report on the assessment of the Geographical BSE-risk of CYPRUS April 2003

- 1 -

Final report on the

updated assessment of the

Geographical BSE-Risk

(GBR) of

THE REPUBLIC OF CYPRUS - 2003

10 April 2003

snip...

Cattle population structure

8/3/2006

§ According to the CD, the total cattle population of the Republic of Cyprus in 1999

was 54,023 headssnip

5. CONCLUSION ON THE GEOGRAPHICAL BSE-RISK

5.1 The current GBR as function of the past stability and challenge

· The current geographical BSE-risk (GBR) level is III, i.e. it is likely but not

confirmed that domestic cattle are (clinically or pre-clinically) infected with the

BSE-agent. ...snip...end

http://ec.europa.eu/food/fs/sc/ssc/out345_en.pdf

*** Czech Republic 74 472

Bovine Spongiform Encephalopathy, Czech Republic

Impact Worksheet, June 14, 2001

Summary: The Czech Republic confirmed on June 8, 2001 the first case of bovine spongiform encephalopathy (BSE) in a native-born cow. This is the first confirmed case of BSE in a native-born animal outside of western Europe.

The Czech Republic has less than 1% of world cattle stocks, and less than 0.1% of sheep and goats. The country's exports of beef and veal accounted for less than 0.1% of world beef and veal exports in 1999 and are negligible in terms of world trade in these products. In 2001, the Czech Republic exported beef and live cattle to Austria, Germany, France, Greece, Bulgaria, Italy, Portugal, Slovakia, and Russia.

In December 1997, the USDA, APHIS enacted regulations which prohibited the importation of live ruminants and ruminant meat from Europe, including the Czech Republic. These import restrictions also applied to bone meal, blood meal, meat meal, offal, fat, glands, and serum from ruminants. In December 2000, APHIS expanded its import restrictions regarding BSE by prohibiting all imports of rendered animal protein products, regardless of species, from Europe.

How extensive is the situation in the affected country and what was the country's disease status prior to the outbreak?

On June 8, 2001 the Czech Republic reported to the OIE the first case of bovine spongiform encephalopathy (BSE) in a native-born cow. The initial two positive tests in the Czech Republic were subsequently confirmed on June 14, 2001 by the German BSE Reference Center. This confirmation of BSE is the first confirmed occurrence of BSE in a native-born

animal outside of western Europe.

The six year old cow with clinical signs of BSE came from a breeding herd of 138 cows owned by a cooperative farm. No other animals on the farm showed clinical signs of BSE. As a result of the current case, all susceptible animals in the herd will be destroyed and tested. In addition, the Czech government will extend BSE testing to all slaughtered bovine animals older than 30 months. Before this case, the Czech government had randomly tested around 11 thousand slaughtered bovines this year, all with negative results.

The source of the infectious agent is not yet known. The Czech government banned feeding all meat-and-bone meal to cattle in 1991. However, the Czech government has initiated an investigation to determine if the contamination could have happened through feeding of imported milk feed substitutes in which milk fat was replaced by rendering-plant fat.

In April 2001 the European Commission listed the Czech Republic as a Category III country "likely to present a BSE risk", based on assessments of the amount of live cattle and feed of animal origin imported into countries in question. Other countries listed in the same category were Poland, Hungary, Estonia, Lithuania, Slovakia, Cyprus, and Switzerland.

Source: OIE; Reuters; ProMED

What is the country's production and trade in affected animals and animal products?

The Czech Republic has less than 0.2% of the world cattle stocks. In 1999 live cattle exports accounted for less than 0.6% of world cattle exports (Table A). No official data are available pertinent to the destination of exported cattle for that time period. However, recent news reports stated that this year the Czech Republic exported beef and live cattle to Austria, Germany, France, Greece, Bulgaria, Italy, Portugal, Slovakia, and Russia. Production and trade in live sheep and goats are very small, making up less than 0.1% of world production and trade in these animals.

Table A: Stocks and Trade in Live Animals, Czech Republic

Trade 1999 Exports 1999 Imports Head % World Head % World Head % World Cattle 1,573,530 < 0.2% 53,880 < 0.6% 13.228 < 0.2%

Live Animal 2000 Stocks

Sheep 84,108 <0.1% 791 <0.1% 93 <0.1% Goats 31,988 <0.1% 115 <0.1% 21 <0.1%

The Czech Republic's exports of beef and veal accounted for less than 0.1% of world beef and veal exports in 1999 and are negligible in terms of world trade in these products (Table B). In addition, no mutton, lamb, or goat meats were exported in 1999.

Table B: Production and Trade in Relevant Products, Czech Republic

Products 2000 Production, provisional Trade

1998 Exports 1998 Imports

Metric ton % World Metric ton % World Metric ton % World

Beef and veal 110,261 <0.2% 2,249 <0.1% 3,325 <0.1%

Mutton and lamb 2,950 <0.1%

- 0 0.0% 179 <0.1%
- Goat meat 290 <0.1% 0 0.0% 0 0.0%

Note: Sheep and goats were included here as 'affected' animals because APHIS has included all ruminants and ruminant products in restrictions pertaining to BSE.

Sources: UN Food and Agriculture Organization, Reuters.

Did the US have restrictions on ruminant imports from the Czech Republic prior to the current case?

In December 1997, APHIS prohibited the importation of live ruminants and most ruminant products from all of Europe including the Czech Republic until a thorough assessment of the risks of introduction of BSE into the US could be made. Prior to December 1997, import restrictions were applied only to those countries which had reported cases of BSE in native animals. In addition, the importation of ruminant meat from BSE-affected countries was permitted if the meat was deboned and free of visually identifiable lymphatic and nervous tissue and if it met other restrictions. The import regulations enacted in December 1997 extended the import restrictions to countries that had not had a declared case of BSE, yet had risk factors for the occurrence of BSE.

These regulatory changes also removed the provisions which allowed the importation of ruminant meat from the restricted countries, essentially prohibiting the importation of ruminant meat from all of Europe. These import restrictions also applied to bone meal, blood meal, meat meal, offal, fat, glands, and serum from ruminants. Additionally, in December 2000, APHIS expanded its import restrictions regarding BSE by prohibiting all imports of rendered animal protein products, regardless of species, from Europe.

Source: USDA, APHIS, VS

What are the US imports of affected animals or animal products from the country?

In accordance with the 1997 ban on the importation of live ruminants and most ruminant products including meat from Europe, the World Trade Atlas data show no such imports from the Czech Republic in 2000 or January - March 2001. The Czech Republic has two meat processing establishments approved to ship pork products to the US. However, according to available data, during 2000 and January - March 2001 no product from these plants was exported to the US.

The US imports some dairy products such as butter and cheese from the Czech Republic. These products are unlikely sources of BSE.

Source: World Trade Atlas; USDA, APHIS, VS; USDA, FSIS.
What is the level of passenger traffic arriving in the United States from the affected country?

A total of 45,438 passengers arrived in the US on direct flights from the Czech Republic in fiscal year 2000. It is likely that additional passengers originating in the Czech Republic traveled to the US on non-direct flights.

As part of APHIS-PPQ's Agriculture Quarantine Inspection Monitoring, 238 air passengers from the Czech Republic were inspected for items of agricultural interest in fiscal year 2000. Of these, 10, or 4.2%, were found to be carrying a total of 17 kg of items that could potentially present a risk for BSE. None of the passengers with items reported plans to visit or work on a farm or ranch while in the US.

Source: US Department of Transportation, and APHIS-PPQ Agricultural Quarantine Inspection data base

CEI's plans for follow-up:

CEI has no further plans regarding this case. However, if you seek more information or wish to comment on this worksheet, please reply to this message or contact Milo Muller at (970) 490-7844 or Chris Kopral at (970) 490-7819.

http://www.aphis.usda.gov/vs/ceah/cei/taf/iw_2001_files/foreign/bse_cz0601.htm

*** Denmark 78 682

BSE in Denmark, March 2000

Short Report

On February 28, 2000, Denmark confirmed its first case of BSE in a native born cow. In 1992, Denmark had one case of BSE in a cow imported from the UK. CEI does not plan to complete an Impact Worksheet on the current situation as the risk to the US from Denmark's BSE case is negligible.

Importation of live ruminants and most ruminant products including meat and meat products has been banned from Denmark since December 12, 1997.

No live ruminants have been imported into the US from Denmark since 1994 as recorded in the US Department of Commerce's trade data.

Quantities of guts, bladders and stomachs of animals (not hogs or fish) prepared for use as sausage casings were imported into the US during the years 1999 - 1994 as reported in the US Department of Commerce's trade data. Also reported is the importation of guts, bladders and stomachs of animals (not fish) not prepared for use as sausage casings during the years 1999 - 1997 and 1995. Importation of stomachs from countries with cases of BSE is allowed under current requirements as this product is not considered to be of risk. In addition, National Center for Import and Export staff reports that companies in Denmark consolidate and store shipments of casing materials (guts, bladders and stomachs) from other countries, then export these materials. This storage and transit of products is allowed because the product is not coming from a country at risk for BSE, yet the trade data would show the product as coming from Denmark.

Bones (crude, steamed or ground) have been imported from Denmark during the years 1998 - 1994. This listing is not species specific and therefore is probably bones from non-ruminant animals.

Prior to the December 1997 ban, small amounts (approximately 200 kg) of beef were imported into the US from Denmark in 1997 and in 1996. And in 1994, almost 24,000 kg of beef were imported.

US Imports from Denmark, 1999 - 1994 Quantities (kg)

Meat of bovine animals, cuts with bone in, except processed, NESOI, frozen 0202208000 220

Meat of bovine animals NESOI cuts with bone in processed 0202203000 204

Meat of bovine animals, boneless, except processed, frozen 0202306000 19,522

Meat of bovine animals, cuts with bone in, except processed, fresh or chilled 0201206000 693

Meat of bovine animals, boneless, except processed, fresh or chilled, 0201306000 629

Beef cuts, high-quality, with bone in, processed, frozen 0202202000 2,790

Guts, bladders and stomachs of animals except hog and fish, whole and pieces, prepared for use as sausage casings 0504000040

11,200 6,455 194,981 218,844 395,652 283,681

Guts, bladders and stomachs of animals (other than fish), whole and pieces thereof, not prepared for use as sausage casings 0504000060 312,187 238,000 2,400 1,680

Bones, crude, steamed or ground 0506900020 18,925

Page 39 of 98

1,000 4,000 29,075 22,300

http://www.aphis.usda.gov/vs/ceah/cei/taf/iw_2000_files/foreign/bsedenmark.htm

*** Estonia 12 918

Beef production. The number of cattle has gradually fallen in Estonia. As of the end of 2000, the number of cattle was 243,800, which is nearly 10 percent less than last year. As the number of dairy cattle decreased and beef production depends on the number of cows, beef production decreased to 14,400 t in 2000. ...

http://www.fao.org/ag/AGP/AGPC/doc/Counprof/Estonia/estonia.htm#4.%20RUMINANT%20LIVESTOCK% 20PRODUCTION%20SYSTEMS

Scientific Steering Committee April 2003

Opinion of the

Scientific Steering Committee

on the

GEOGRAPHICAL RISK OF

BOVINE SPONGIFORM

ENCEPHALOPATHY (GBR) in

Estonia

adopted by the SSC on 10 April 2003

snip...

CONCLUSION ON THE CURRENT GBR

The BSE-agent may have reached the territory of Estonia before its independence in 1991. After

1995 significant amounts of MBM were imported from BSE risk countries. A significant risk that BSE infectivity entered processing therefore exists since some years, at the latest since 2000, when domestic cattle potentially exposed to contaminated imported MBM around 1995, could have entered processing while approaching the end of the incubation period. Given the instability of the system, this could have lead to BSE cases.

It is concluded that it is likely but not confirmed that domestic cattle are (clinically or pre-clinically) infected with the BSE-agent (GBR III).

EXPECTED DEVELOPMENT OF THE GBR

As long as the system remains unstable, the probability of cattle to be (pre-clinically or clinically) infected with the BSE-agent will further increase, even if no additional external challenges occur.

snip...

http://ec.europa.eu/food/fs/sc/ssc/out335_en.pdf

*** Finland 58 668

Bovine Spongiform Encephalopathy, Finland,

Impact Worksheet, December 13, 2001

Summary: The Ministry of Agriculture and Forestry, Helsinki reported to the OIE Finland's first case of bovine spongiform encephalopathy (BSE) on December 7, 2001. The disease was detected in a dairy cow born in 1995 in Finland. No meat-and-bone meal had reportedly been used in the herd for more than 20 years.

Finland had less than one percent of the world's cattle, sheep, and goat stocks in 2000 and produced less than one percent of the world's total beef and veal, mutton and lamb, and goat meat. Live cattle, sheep, and goat exports from Finland were less than 1.0 percent of the world's trade in these animals during 1999. Likewise, Finland exported less than one percent of the world's total exports of these products during 1999.

In December 1997, APHIS prohibited the importation of live ruminants and most ruminant products from all of Europe including Finland. In December 2000, import restrictions regarding BSE were expanded by prohibiting all imports of rendered animal protein products, regardless of species, from Europe. Some offal (animal species not specified) was

imported into the US from Finland in 1998 and 2000.

How extensive is the outbreak of BSE in Finland, and what was Finland's disease status prior to the outbreak?

The Ministry of Agriculture and Forestry, Helsinki reported to the OIE Finland's first case of bovine spongiform encephalopathy (BSE) on December 7, 2001. The disease was detected in northern Finland in a dairy cow born in 1995 in Finland. The cow showed clinical signs of disorder and was emergency slaughtered. The diagnostic tests used were: Prionics Check test (29 November 2001); immunohistochemistry, histopathology (7 December 2001). Neither the source of agent nor the origin of infection has been established. Epidemiological investigations are underway. No meat-and-bone meal has been used in the herd for more than 20 years. Control measures include removal and slaughter.

Source: OIE Disease Information Report

What is the Finland's production and trade in affected animals and animal products?

Finland was responsible for less than one percent of the world's cattle, sheep, and goat stocks in year 2000 (Table 1). Live cattle, sheep, and goat exports from Finland were less than 1.0 percent of the world's trade in these animals during year 1999. Finland imported less than 1.0 percent of the world's imports of live cattle, sheep, and goats.

Table 1. Finland's live animal stocks (year 2000) and imports and exports of live animals (year 1999).

Live Animal Year 2000 Stocks 1999 Trade 1999 Exports 1999 Imports Head % World Head % World Head % World Cattle 1,068,000 <<1.0 20 <<<1.0 9 <<<1.0 Sheep 106,000 <<1.0 30 0 0 0

Goats 7,900 <<<1.0 0 0 0

Finland produced less than one percent of the world's total beef and veal, mutton and lamb, and goat meat during year 2000 (Table 2). Finland exported less than one percent of the world's total exports of these products during year 1999. Finland imported three percent of the world's total imports of mutton and lamb, but less than one percent of the total imports of beef, veal, and goat meat during year 1999.

Table 2. Production (year 2000) and trade (year 1999) in relevant products by Finland.

Products Year 2000 Production 1999 Trade 1999 Exports 1999 Imports Metric ton % World Metric ton % World Metric ton % World Beef and veal 90,000 <<1.0 1,506 <<<1.0 2,121 <<1.0 Mutton and lamb 1 750 <<1.0 41 <<1.0 964 <<1.0 Goat meat 1 0 0.0 0

0.0 10 <<1.0

Source: United Nations FAO

1 Sheep and goats were included in Table 1 and Table 2 as 'affected' animals because USDA/APHIS includes all ruminants and ruminant products in its restrictions pertaining to BSE.

Source: United Nations FAO

What are the U.S. imports of affected animals or animal products from Finland?

No live ruminants nor any meat from ruminants were imported into the US from Finland between 1998 and June 2001. Some offal (animal species not specified) was imported into the US from Finland in 1998 and 2000 (Table 3).

Source: World Trade Atlas; USDA APHIS VS Import Tracking System

Table 3. Relevant US imports from Finland in 1998, 1999, 2000, and Jan-Jun 2001

HS Code Description Unit 1998 1999 2000 2001 (Jan-Jun)

BSE meat & offal-non species specific Totl 120,516 0 19,482 0 0504000040 Gut/Bladder/Stomach of Animals For Sausage Casing, Not Hog KG 120,516 0 0 0 0504000060 Guts, Bladders and Stomachs of Animals, NESOI KG 0 0 19,482 0

Source: World Trade Atlas

Did the US have restrictions on ruminant imports from Finland prior to this case?

In December 1997, APHIS prohibited the importation of live ruminants and most ruminant products from all of Europe including Finland until a thorough assessment of the risks of introduction of BSE into the US could be made. Prior to December 1997, import restrictions were applied only to those countries which had reported cases of BSE in native animals. Also, importation of ruminant meat from BSE-affected countries was permitted if the meat was deboned and free of visually identifiable lymphatic and nervous tissue and if it met other restrictions. Import regulations enacted December 1997 extended the import restrictions to countries which had not had a declared BSE case, yet had risk

factors for BSE occurrence.

These regulatory changes also removed provisions that allowed importation of ruminant meat from the restricted countries, and thereby prohibited importation of ruminant meat from all Europe. These import restrictions also applied to bone meal, blood meal, meat meal, offal, fat, glands, and serum from ruminants. In December 2000, APHIS expanded its import restrictions regarding BSE by prohibiting all imports from Europe of rendered animal protein products, regardless of species.

Source: USDA, APHIS, VS

What is the level of passenger traffic arriving in the United States from Finland?

A total of 102,450 passengers on direct flights from Finland arrived at US airports in fiscal year 2000. An undetermined number of passengers from Finland arrived in the US via indirect flights.

Under APHIS-PPQ's agricultural quarantine inspection monitoring, 250 air passengers from Finland were sampled for items of agricultural interest in fiscal year 2000. Of these 250 passengers, 9 carried a total of 11.5 kg meat (non-pork) items that could potentially harbor the pathogen(s) that cause BSE. None of these passengers from whom meat items were confiscated reported plans to visit or work on a ranch or farm during their visit to the US.

Source: US Dept. of Transportation; APHIS-PPQ

CEI's plans for follow up:

Currently, there are no plans for supplemental reporting of this outbreak of BSE in Finland. If you need more information or if you want to comment on this worksheet, you may reply to this message, or contact Reg Johnson at (970) 490-7896 or Chris Kopral at (970) 490-7819.

http://www.aphis.usda.gov/vs/ceah/cei/taf/iw_2001_files/foreign/bse_finland1201.htm

GEOGRAPHICAL RISK OF

BOVINE SPONGIFORM

ENCEPHALOPATHY (GBR) in

Finland

Update adopted by the SSC on 16/5/2002

CONCLUSION ON THE CURRENT GBR

The BSE-agent was most likely imported into the country via live cattle or MBM and it could

have reached domestic cattle, before 1990 via deliberate inclusion of MBM into cattle feed and

thereafter via cross-contamination in feed mills, during transport or on farm. It is therefore concluded that it is likely that one or several cattle that are (pre-clinically or clinically) infected with the BSE agent are currently present in the domestic herd of Finland (GBR-III). This is confirmed by the domestic BSE case that was identified in Finland in 2001.

http://ec.europa.eu/food/fs/sc/ssc/out260_en.pdf

*** France 672 110

Table 1: Production and trade in live animals and animal products, France,

2000 (Production) and 1999 (Trade)

France % of World

Live animal stocks (# head)

Cattle 20,194,000 1.5

http://www.aphis.usda.gov/vs/ceah/cei/taf/iw_2001_files/foreign/fmd_france0301e.htm

Euro Surveill 2000;5(9):97-100 Published online September 2000 Key words: variant Creutzfeldt-Jakob disease. France. Epidemiological status of BSE in France – update on 'born after the ban' cases

http://www.eurosurveillance.org/em/v05n09/0509-224.asp

http://www.eurosurveillance.org/em/v05n09/v05n09.pdf

*** Germany 872 625

Livestock Holdings with cattle and stock of cattle Holding / type of livestock Holdings / livestock May 2005 November 2005

in 1 000

Holdings with cattle, total 183.4 179.1 incl.: with dairy cows 110.4 108.0 with multiple and single suckling cows 47.6 45.8 Cattle, total 13 034.5 12 918.6

http://www.destatis.de/basis/e/forst/forsttab10.htm

Bovine Spongiform Encephalopathy, Germany

Impact Worksheet, December 2000

Summary: Germany announced on November 26, 2000 the first case of BSE in a native-born cow. Until this time, Germany had declared itself as free of BSE, despite the fact that it had reported 6 prior cases of BSE between 1992 and 1997. However, all previously reported cases were in imported animals.

Although Germany has only about 1% of world cattle stocks, 1998 live cattle exports accounted for 8% of world cattle exports. Approximately 50% of live bovine animals were exported to the Netherlands, and the rest went to other EU countries, including Lebanon, Algeria, Morocco, and Bosnia-Hercegovina. Germany's exports of beef and veal accounted for 5.5% of world beef and veal exports, and shipments were destined principally to Russia and other EU countries.

In December 1997, the USDA enacted regulations which prohibited the importation of live ruminants and ruminant meat from Germany. These import restrictions also applied to bone meal, blood meal, meat meal, offal, fat, glands, and serum from ruminants.

The US imported no live ruminants from Germany in 1999 or 2000. Imports of a wide variety of miscellaneous animal products were reported during 1999 and 2000. For many of these miscellaneous animal products the species of origin is not specified but, in keeping with current US import restrictions, these products are most likely of swine or poultry

origin. Some of the miscellaneous animal products imported are allowed only under restriction, such as for industrial usage. Among the miscellaneous animal product imports reported is fetal bovine serum. Imports of fetal bovine serum from Germany would have been a violation of APHIS regulations. It is possible that these imports represent imports of some other product miscoded as fetal bovine serum. CEI will follow up with the Department of Commerce to verify any imports which should not have entered the country.

How extensive is the situation in the affected country and what was the country's disease status prior to the outbreak?

Germany announced on November 26, 2000 the first case of BSE in a native-born cow. The animal was a normal slaughter animal and was tested as part of a private program by the slaughterhouse. The initial positive test was subsequently confirmed by the German BSE Reference Center. The cow, born in 1996, came from a breeding herd of 167 animals in the state of Schleswig-Holstein.

Until this time, Germany had declared itself as free of BSE. Although Germany has had 6 prior cases of BSE between 1992 and 1997, all of these were in imported animals.

As a result of the current case, Germany immediately imposed a ban on the use of animal feeds containing meat and bone meal.

Source: OIE; Reuters; ProMED

What is the country's production and trade in affected animals and animal products?

Although Germany has only about 1% of world cattle stocks, 1998 live cattle exports accounted for 8% of world cattle exports (Table A). About half of live cattle exports went to the Netherlands. The remainder were exported to other EU countries, as well as to Lebanon, Algeria, Morocco, and Bosnia-Hercegovina . Production and trade in live sheep and goats are minor, making up less than 1% of world production and trade in these animals.

Table A: Stocks and Trade in Live Animals, Germany

Live Animal 2000 Stocks Trade

1998 Exports 1998 Imports

Head % World Head % World Head % World

Cattle 14,574,000 1.1% 735,638 8.1% 167,666 2.1%

Sheep 2,290,000 0.2% 69,652 0.4% 62,438 0.4% Goats 114,000 <0.1% 36 <0.1% 349

549 <0.1%

Germany's exports of beef and veal accounted for 5.5% of world beef and veal exports in 1998 (Table B). Primary importers of German beef and veal were Russia and other EU countries. German exports of sheep and goat meat are negligible in terms of world trade in these products.

Table B: Production and Trade in Relevant Products, Germany

Products 2000 Production, provisional Trade

1998 Exports 1998 Imports

Metric ton % World Metric ton % World Metric ton % World

Beef and veal 1,420,000 2.5% 376,985 5.5% 211,279 3.2%

Mutton and lamb 44,000

1,800 0.2% 40,984 4.9% Goat meat 270 <0.1% 2 <0.1% 131 0.4%

0.6%

Note: Sheep and goats were included here as 'affected' animals because APHIS has included all ruminants and ruminant products in restrictions pertaining to BSE.

Sources: UN Food and Agriculture Organization; USDA FAS Attache Report, 7/25/2000

Did the US have restrictions on ruminant imports from Germany prior to the current case?

In December 1997, APHIS prohibited the importation of live ruminants and most ruminant products from all of Europe until a thorough assessment of the risks of introduction of BSE into the US could be made. Prior to December 1997, import restrictions were applied only to those countries which had reported cases of BSE in native animals. In addition, the importation of ruminant meat from BSE-affected countries was permitted if the meat was deboned and free of visually identifiable lymphatic and nervous tissue and if it met other restrictions. The import regulations enacted in December 1997 extended the import restrictions to countries that had not had a declared case of BSE, yet had high risk factors for the occurrence of BSE. Germany was among the countries considered to have high risk factors. These regulatory changes also removed the provisions which allowed the importation of ruminant meat from the restricted countries, essentially prohibiting the importation of ruminant meat from all of Europe. These import restrictions also applied to bone meal, blood meal, meat meal, offal, fat, glands, and serum from ruminants.

Source: APHIS, VS

What are the US imports of affected animals or animal products from the country?

In accordance with the 1997 ban on the importation of live ruminants and most ruminant products including meat from Europe, the World Trade Atlas data show no such imports from Germany in 1999 or 2000. There were, however, a wide variety of miscellaneous animal products imported during this time period, including fetal bovine serum (Table C). It should be noted that many of the items listed in Table C are animal products not specifically identified as to their species of origin. They are most likely of swine or poultry origin and thus allowed into the US since they are of no risk regarding introduction of BSE. In addition, some of the items listed (e.g. gelatin and animal glues) are allowed into the US under restriction, such as for industrial usage. Dairy products and animal fat products have not been included in Table C since those products are unlikely sources of BSE. Imports of fetal bovine serum from Germany would have been a violation of APHIS regulations. It is possible that these imports represent imports of some other product miscoded as fetal bovine serum. CEI will follow up with the Department of Commerce to verify any imports which should not have entered the country.

Table C: US Imports of Animals or Products from Germany, 1999-2000 (includes some animal products whose origin

is unspecified)

(NESOI = not elsewhere specified or included)

Product QUANTITY

Jan - Sep 2000 1999

1. MISC. ANIMAL PRODUCTS

Soups, Broths, and Other Preparations 821,881 kg 2,138,530 kg

Sausages and Similar Products of Meat, Meat Offal or Blood, NESOI, Food Preparations Based on These Products, Canned 0 41,618 kg

41,010 Kg

Guts, Bladders and Stomachs of Animals Other than Fish not Prepared for Use as Casings 1,940 kg 7,480 kg

Guts,Bladders and Stomachs of Animals Except Hogs and Fish for Use as Casings 82, 475 kg 47, 463 kg

2. ANIMAL FEED PREPARATIONS

Dairy Cows , Prep 0 2 tons

Dog and Cat Food, Retail 277,123 kg 181,971 kg

Other Livestock Feed Prep 0 2 tons

Mixed Feeds or Mixed Feed Ingredients used in Animal Feedings, NESOI 5,640 tons 437 tons

Preparations of a Kind Used in Animal Feeding, NESOI 72,777 kg 133,134 kg

3. PHARMACEUTICAL PRODUCTS

Organ Extracts of Glands or Other Organs or of their Secretions 892 kg 8,680 kg Organ Extracts Other Glands and Other Organs, Dried, Whether or not Powdered 801 kg 3,600 kg Fetal Bovine Serum 94 kg 60 kg Other Blood Fractions, NESOI 52,169 kg 42,804 kg Cantharides; Glands, Except Pancreas, Organs and Other Animal Products Used in the Preparation of Pharmaceutical Products, Fresh, Chilled, Frozen, Preserved 23,619 kg 2,775 kg **Bile and Other Animal Secretions** 0 300 kg Peptones, Other Proteins & Derivates, Hide Powder 244,554 kg 242,799 kg Enzymes, Prepared Enzymes NESOI 699,853 kg 1,667,370 kg Albumines, Albuminates and Other Albumin Derivates, NESOI 373,892 kg 258, 440 kg Inedible Gelatin, and Animal Glue 0 23,255 kg Gelatin and Gelatin Derivates, Other Glues of Animal Origin, **Except Caesin Glues** 172, 287 kg 247,364 kg

Medicaments Containing Adrenal Cortical Hormones but Not Containing Antibiotic 20,788 kg

8/3/2006

52,341 kg

Medicaments Containing Antigens or Hyaluronic Acid 71 kg 4,109 kg

Sterile Surgical Catgut 65 kg 3,644 kg

Source: World Trade Atlas, US Dept. of Commerce

What is the level of passenger traffic arriving in the United States from the affected country?

A total of 3.3 million passengers arrived in the US on direct flights from Germany in 1998, although many of these passengers would not have originated in Germany. As part of APHIS-PPQ's Agriculture Quarantine Inspection Monitoring, 8,247 air passengers from Germany were inspected for items of agricultural interest. Of these, 198, or 2.3%, were found to be carrying a total of 304 kg of items that could potentially present a risk for BSE. Thirty (30) of the passengers with items reported plans to visit or work on a farm or ranch while in the US. Reported destination states of these 30 passengers were CA, CO, DE, FL, LA, MT, OH, VA, and WY.

Source: US Department of Transportation, and APHIS-PPQ Agricultural Quarantine Inspection data base

CEI's plans for follow-up:

Aside from any follow-up to verify the accuracy of import data, CEI has no further plans regarding this case. However, if you would like additional information, please contact Chris Kopral at (970) 490-7819 or Milo Muller at (970) 490-7844.

http://www.aphis.usda.gov/vs/ceah/cei/taf/iw_2000_files/foreign/bse_germany1200e.htm

Bovine Spongiform Encephalopathy, Greece

Impact Worksheet, July 6, 2001

http://www.aphis.usda.gov/vs/ceah/cei/taf/iw_2001_files/foreign/bse_greece0701.htm

*** Hungary 28 867

Table 1. Livestock population as of 31 December, 1995 (in thousands)

Denomination
Average of 1986-1990
1991
1992
1993
1994
199s*
Cattle, total
1650
1420
1159
999
910
944
cows
658
559
497
450
415
419

http://www.fao.org/DOCREP/006/AD250E/ad250e0c.htm

http://www.fao.org/Regional/SEUR/QMP/Hun_en.htm

Opinion of the

Scientific Steering Committee

on the

GEOGRAPHICAL RISK OF

BOVINE SPONGIFORM

ENCEPHALOPATHY (GBR) in

8/3/2006

HUNGARY

Adopted on 30/03/2001

snip...

It is concluded that it is likely but not confirmed that one or several cattle that are (pre-clinically or clinically) infected with the BSE agent are currently present in the domestic herd of Hungary (GBR III).

Given the extremely unstable system and the fact that the BSE-agent is likely to be already present in the country due to live cattle and MBM imports, it is assumed that the GBR is increasing.

snip...

http://ec.europa.eu/food/fs/sc/ssc/out187_en.pdf

*** Ireland 384 055

Even today, when a quarter of the population of the Republic lives in Dublin, the cattle population is of the order of 6.7 million.

http://en.wikipedia.org/wiki/Culture_of_Ireland

Report on the assessment of the Geographical BSE-risk of IRELAND July 2000

- 1 -

Report on

the Assessment of

the Geographical BSE-Risk

(GBR) of

8/3/2006

IRELAND

July 2000

snip...

EXECUTIVE SUMMARY

OVERALL ASSESSMENT

The current geographical BSE-risk (GBR) level is III, i.e. BSE is confirmed in domestic cattle at a lower level.

However, the observed incidence of clinical cases over the last 12 months (March 1999 to January 2000) was 29.5 per 1 Million adult cattle. This figure is generated by an essentially passive surveillance system that is not able to identify all clinical BSE-cases.

snip...

http://ec.europa.eu/food/fs/sc/ssc/out121_en.pdf

*** Italy 216 396

BSE, Italy, January 2001

(Short Report)

Contained herein is a brief summary of the newly reported outbreak of bovine spongiform encephalopathy (BSE) in Italy. There are no plans to distribute a complete impact worksheet about this outbreak of BSE.

Summary:

The Italian Ministry of Public Health reported to the OIE on January 17, 2001 the discovery of the first case of BSE in a native-born cow from Italy. The preliminary diagnosis of January 12, 2001 was confirmed on January 16, 2001. The affected animal was slaughtered, and the dairy farm of origin was "... placed under restrictions".

Italy has less than 0.5% (one-half of one percent) of the world's cattle stocks. Italy's 1999 live cattle exports were only 1.2% of the world's cattle exports. More than 70% of Italy's exports of 140,000 metric tons of beef and beef products were sent to other countries in the European Union (EU). Russia received 17,000 metric tons as part of the EU food aid programs.

In December 1997, the USDA enacted regulations that prohibit the importation of live ruminants and ruminant meat from members of the EU, including Italy. These import restrictions also were applicable to bone meal, blood meal, meat meal, offal, fat, glands, and serum from ruminants. The U.S. imported no live ruminants from Italy during years 1999 and 2000. Imports of a variety of miscellaneous animal products were reported during 1999 and 2000. For many of these miscellaneous animal products the species of origin is not specified but, in keeping with current U.S. import restrictions, these products probably are not of bovine origin.

If you have questions, you may contact Reginald Johnson at 970-490-7896 or Miloslav Muller at 970-490-7844.

Sources:

- 1. Promed-ahead-edr., January 14, 2001.
- 2. Office International Des Epizooties, Disease Information 14(3), January 19, 2001.
- 2. Food and Agriculture Organization (FAO), FAOSTAT Database.
- 3. World Trade Atlas, U.S. Edition, 2000.
- 4. Foreign Agricultural Service (FAS) Attache Reports, GAIN Report #IT0026.

http://www.aphis.usda.gov/vs/ceah/cei/taf/iw_2001_files/foreign/bse_italy0101.htm

Report on the assessment of the Geographical BSE-risk of ITALY July 2000

5. CONCLUSION ON THE GEOGRAPHICAL BSE-RISK

5.1 The current GBR

The current geographical BSE-risk (GBR) level is III, i.e. it is likely that

domestic cattle are infected with the BSE-agent but it is not confirmed.

 $\underline{http://ec.europa.eu/food/fs/sc/ssc/out122_en.pdf}$

Bovine Spongiform Encephalopathy, Poland

Impact Worksheet, May 7, 2002

 $\underline{http://www.aphis.usda.gov/vs/ceah/cei/taf/iw_2002_files/foreign/bse_poland0502.htm}$

*** Latvia 14 854

livestock (1000s): cattle: 378

http://www.library.uu.nl/wesp/populstat/Europe/latviag.htm

Report on the assessment of the Geographical BSE-risk of Latvia June 2002

5. CONCLUSION ON THE GEOGRAPHICAL BSE-RISK

5.1 The current GBR as function of the past stability and challenge

§ The current geographical BSE-risk (GBR) level is III, as it is likely but not confirmed

that domestic cattle are (clinically or pre-clinically) infected with the BSE-agent.

http://ec.europa.eu/food/fs/sc/ssc/out274_en.pdf

*** Lithuania 31 228

livestock (1000s): cattle: 898

http://www.library.uu.nl/wesp/populstat/Europe/lithuang.htm

Report on the assessment of the Geographical BSE risk of LITHUANIA 09/02/01

5. CONCLUSION ON THE GEOGRAPHICAL BSE-RISK

5.1 The current GBR as function of the past stability and challenge

The current geographical BSE-risk (GBR) level is III, i.e. it is likely but not confirmed

that domestic cattle are (clinically or pre-clinically) infected with the BSE-agent.

http://ec.europa.eu/food/fs/sc/ssc/out167_en.pdf

Scientific Steering Committee - Opinion on the GBR of LITHUANIA April 2003

http://ec.europa.eu/food/fs/sc/ssc/out337_en.pdf

*** Luxemburg 7 916

livestock (1000s): cattle: 205

http://www.library.uu.nl/wesp/populstat/Europe/luxembgg.htm

Report on the assessment of the Geographical BSE-risk of LUXEMBOURG July 2000

5. CONCLUSION ON THE GEOGRAPHICAL BSE RISK

5.1 The current GBR

The current geographical BSE-risk (GBR) level is III, i.e. BSE is confirmed in

domestic cattle (last and only case in 1997) at a lower level.

http://ec.europa.eu/food/fs/sc/ssc/out123_en.pdf

*** Malta 1 133

livestock (1000s): cattle: 19-21

http://www.library.uu.nl/wesp/populstat/Europe/maltag.htm

Report on the assessment of the Geographical BSE-risk of MALTA September 2002

5. CONCLUSION ON THE GEOGRAPHICAL BSE-RISK

5.1 The current GBR as function of the past stability and challenge

The current geographical BSE-risk (GBR) level is III, i.e. it is likely but not confirmed that domestic cattle are (clinically or pre-clinically) infected with the BSE-agent.

http://ec.europa.eu/food/fs/sc/ssc/out287_en.pdf

*** Portugal 46 615

Report on the assessment of the Geographical BSE-risk of PORTUGAL July 2000

- 5. Conclusion on the Geographical BSE-Risk (GBR)
- 5.1 The current GBR
- The current geographical BSE-risk (GBR) level is IV: BSE is confirmed in

domestic cattle at a higher level.

http://ec.europa.eu/food/fs/sc/ssc/out125_en.pdf

http://ec.europa.eu/food/fs/inspections/vi/reports/portugal/vi_rep_port_7214-2004_en.pdf

*** Slovakia 35 193

Bovine Spongiform Encephalopathy, Slovakia

Impact Worksheet, October 9, 2001

Summary:

BSE was confirmed on October 4 in a 6-year old cow in Slovakia. The cow was detected as part of regular sampling for BSE in slaughter cattle. This is the first case of BSE in Slovakia.

Slovakia had less than 0.1 percent of the world's stocks in cattle, goats, and sheep in 2000. Slovakia's meat exports are minimal; however, exports of live animals number in the tens of thousands. Destination countries for the live animal exports were not specified. No products that would be of risk for transmission of BSE were imported into the US from Slovakia during 2000 or 2001. In 1998 and 1999, small quantities of animals feeds were imported from Slovakia; however, it is not known whether these feeds contained ruminant materials.

In December 1997, APHIS prohibited the importation of live ruminants and most ruminant products from all of Europe including Slovakia. In December 2000, import restrictions regarding BSE were expanded by prohibiting all imports of rendered animal protein products, regardless of species, from Europe.

How extensive is the outbreak of BSE in Slovakia?

It was reported by Reuters that BSE was confirmed on October 4 in a 6-year old cow in Slovakia. The cow was detected as part of regular sampling for BSE in slaughter cattle. Confirmation was done by the Research Laboratory for Viral Diseases of Animals in Tuebingen, Germany. This is the first case of BSE in Slovakia.

Using trace-back, it was determined that the positive cow was transported to the slaughterhouse on September 24, and originated from a farm with about 200 cows, located in Horná Zdana in the Ziar nad Hronom district. The district veterinary authorities immediately isolated the farm and banned any movement of animals to and from the farm.

Source: OIE Weekly Disease Information Report, Sep 28, 2001; Reuters, Oct 4, 2001

What actions has Slovakia taken to protect its livestock from BSE?

Imports of cattle, beef, and beef products from countries with BSE are banned by Slovakia. However, it is not clear when this ban was enacted, as small numbers of live cattle from France (which has had cases of BSE since 1991) were imported as recently as 1999.

Meat and bone meal (MBM) has reportedly not been fed to ruminants for many years because it is too expensive. Even so, a ban on the feeding of MBM to ruminants was implemented in 1994. Some MBM for feeding to non-ruminants has been imported, primarily from Austria.

Testing for BSE began in 1996. Brains were tested from cattle exhibiting unusual behavior, cattle that are fallen, and 'emergency slaughter' cattle. Since the appearance of BSE in the Czech Republic in June 2001, Slovakia has been testing all slaughtered cows aged over 30 months.

Source: USDA, FAS, Slovak Measure to Prevent BSE, Mar 2, 2001; Reuters, Oct 4, 2001

What is Slovakia's production and trade in affected animals and animal products?

Slovakia had less than 0.1 percent of the world's stocks in cattle, goats, and sheep in 2000 (Table 1). Slovakia exported 120,000 live cattle, goats, and sheep in 1999. Destination countries for the live animal exports were not specified. Slovakia had less than 0.1 percent of imports of cattle, goats, and sheep in 1999.

Table 1. Slovakia's live animal stocks and imports and exports of live animals.

Live Animal 2000 Stocks Trade 1999 Exports 1999 Imports Head % World Head % World Head % World Cattle 665,055 0.05 12,556 0.13 150 < 0.01 Goats 51,075 < 0.01 30,501 1.1 560 0.02 Sheep 340,346 0.03 77,246 0.43 810 < 0.01

Slovakia had less than 0.1 percent of the world's 2000 production of beef and veal, mutton and lamb, and goat meat in 2000 (Table 2). Slovakia also had less than 0.1 percent of world exports of beef and veal, and mutton and lamb, and imports of beef and veal in 1999. Quantities were not available for goat meat imports and exports or mutton and lamb imports.

Table 2. Production and trade in relevant products by Slovakia.

Products 2000 Production Trade 1999 Exports 1999 Imports Metric ton % World Metric ton % World Metric ton % World Beef and Veal 42,932 0.08 144 < 0.01 2,993 0.06 Mutton and Lamb1 1,476 0.02 109 0.01 -_ Goat Meat1 110 < 0.01 _ _ _

Source: United Nations FAO

1 Sheep and goats were included in Table 1 and Table 2 as 'affected' animals because USDA/APHIS includes all ruminants and ruminant products in its restrictions pertaining to BSE.

What are the U.S. imports of affected animals or animal products from Slovakia?

No products that would be of risk for transmission of BSE were imported into the US from Slovakia during 2000 or 2001. Small quantities of animals feeds were imported during 1998 and 1999; however, it is not known whether these feeds contained ruminant materials (Table 3). Canada and Mexico did not import any items of risk from Slovakia in 1998, 1999, 2000, or 2001.

Table 3. U.S. Imports from Slovakia

1998 1999

Value (\$millions) Quantity Value (\$millions) Quantity

mixed feeds or mixed feed ingredients used in animal feedings, nesoi 0.350 114 metric tons 0.509 243 metric tons

```
preparations of a kind used in animal feeding, nesoi
0.000
0 kg
0.013
4,000 kg
```

Source: World Trade Atlas

Did the US have restrictions on ruminant imports from Slovakia prior to this case?

In December 1997, APHIS prohibited the importation of live ruminants and most ruminant products from all of Europe including Slovakia until a thorough assessment of the risks of introduction of BSE into the US could be made. Prior to December 1997, import restrictions were applied only to those countries which had reported cases of BSE in native animals. Also, importation of ruminant meat from BSE-affected countries was permitted if the meat was deboned and free of visually identifiable lymphatic and nervous tissue and if it met other restrictions. Import regulations enacted December 1997 extended the import restrictions to countries that had not had a declared case of BSE, yet had risk factors for occurrence of BSE.

These regulatory changes also removed the provisions which allowed importation of ruminant meat from the restricted countries, essentially prohibiting the importation of ruminant meat from all of Europe. These import restrictions also applied to bone meal, blood meal, meat meal, offal, fat, glands, and serum from ruminants. In December 2000, APHIS expanded its import restrictions regarding BSE by prohibiting all imports of rendered animal protein products, regardless of species, from Europe.

Source: USDA, APHIS, VS

What is the level of passenger traffic arriving in the United States from Slovakia?

There were no direct flights from Slovakia to the US in fiscal year 2000.

Under APHIS-PPQ's agriculture quarantine inspection monitoring, 42 air passengers from Slovakia were sampled for items of agricultural interest in fiscal year 2000. None of these passengers were carrying meat (non-pork) items that could potentially harbor the pathogen(s) that cause BSE.

Source: US Department of Transportation, and APHIS-PPQ Agricultural Quarantine Inspection data base

CEI's plans for follow up:

CEI is trying to ascertain the destination countries of Slovakia's live animal exports and will send out a brief message with this information. If you need more information or want to comment on this worksheet, you may reply to this message or contact Ken Geter at (970) 490-7817 or Chris Kopral at (970) 490-7819.

http://www.aphis.usda.gov/vs/ceah/cei/taf/iw_2001_files/foreign/bse_slovakia1001.htm

BOVINE SPONGIFORM

ENCEPHALOPATHY (GBR) in the

SLOVAK REPUBLIC

Adopted on 30/03/2001

It is concluded that it is likely but not confirmed that one or several cattle that are

(pre-clinically or clinically) infected with the BSE agent are currently present in

the domestic herd of the Slovak Republic (GBR III).

http://ec.europa.eu/food/fs/sc/ssc/out183_en.pdf

*** Slovenia 15 768

Bovine Spongiform Encephalopathy, Slovenia

Impact Worksheet, November 23, 2001

Summary: In Slovenia, BSE was confirmed in a five-year old domestically bred cow; this is the first case of BSE in that country. Slovenia identified the cow as a suspected BSE case during mandatory prionic testing in slaughter cattle. The Ljubljana, Slovenia National Veterinary Institute confirmed the BSE test through histopathological and immunohistochemical examinations on 16 November. Positive results were corroborated by the Institute of Animal Neurology at the University of Bern in Switzerland on 20 November.

In December 1997, APHIS prohibited the importation of live ruminants and most ruminant products from all of Europe including Slovenia. In December 2000, import restrictions regarding BSE were expanded by prohibiting all imports of rendered animal protein products, regardless of species, from Europe. Slovenia had less than 0.1 percent of the world's stocks in cattle, goats, and sheep in 2000. Slovenia's meat exports were minimal, and destination countries for the live animal exports were not specified. Slovenia exported meat and bone meal to Austria, Bosnia-Hercegovina and Croatia in 1999. The US imported no products from Slovenia during 2000 or 2001 that would be of risk for BSE transmission. In 1998, the US imported small quantities of animal feeds from Slovenia, however, it is not known if these feeds contained ruminant materials. The infected cow came from a farm in northeast Slovenia.

How extensive is the outbreak of BSE in Slovenia?

BSE has been confirmed in a five-year old cow in Slovenia on 16 November. This is the first case of BSE in Slovenia, and the cow was domestically bred. Slovenia first identified the cow as a suspected BSE case during routine and mandatory Western blot prionic testing for BSE in slaughter cattle. The Ljubljana, Slovenia National Veterinary Institute and the Institute of Animal Neurology Laboratory in Switzerland confirmed the BSE test. The infected cow came from a small, extensive farm with nine animals in the Zgornja Savinsjka valley in northeast Slovenia. Veterinary authorities immediately isolated the farm and banned all movement of animals to and from the farm.

Source: Reuters; AgWorldwide Internet news; OIE Weekly Disease Information Reports, 16 and 23 November 2001

What actions has Slovenia taken to protect its livestock from BSE?

Slovenia has a national BSE testing program in place, feeding of meat and bone meal is banned,, and bovine product imports have been restricted. Use of meat and bone meal has been banned since 1996 as a feed for ruminants, and for non-ruminants since late 2000.

Beginning February 2001, quick post mortem prionic testing for all slaughtered animals has been mandatory in Slovenia for all slaughtered animals older than 30 months. In January 2000, Slovenian authorities had conducted 700 histological tests after reports of BSE in Germany and Italy. In February 2000, the government was reportedly performing 250 prionic tests daily. In 1996 a policy of random testing for animals older than 36 months was introduced. Since 1992, Slovenia has routinely performed pathohistologic analysis of bovine brains for cattle exhibiting clinical signs of a central nervous system malady.

Since 1991, Slovenia has incrementally added to the list of European countries from which it bans imports of live bovine animals, semen and embryos, meat products, gelatin, collagen, raw materials for pharmaceutical use, and other

Page 66 of 98

bovine products:

Imports banned from Beginning in year

United Kingdom 1991

Ireland, Switzerland, France, Portugal 1996

Belgium, Netherlands 1998

Germany 2000

Italy 2001

Source: USDA, Foreign Agricultural Service GAIN Report #SI1001, March 27, 2001

What is Slovenia's production and trade in affected animals and animal products?

Slovenia's stocks of cattle, goats and sheep were less than 0.1 percent of world stocks in 2000 (Table 1). Imports of cattle were 0.35 percent of the world export trade in 1999, but goat and sheep imports were both less than 0.1 percent. Cattle imports were exclusively from Central and Eastern Europe and Hungarian imports dominated the Slovenian market. Slovenia exported only 19 metric tons of cattle in 1999; the number of live animals in this figure was not available. Goat export values were not available, and sheep exports were less than 0.1 percent of world sheep exports.

Table 1. Slovenia's live animal stocks and exports and imports of live animals.

Live Animal 2000 Stocks Trade

1999 Exports 1999 Imports

Head % World Head % World Head % World

Cattle 471,425 <0.1% -30,000 .36% Goats 14,643 <0.1% -19 <0.1% Sheep 72,533 <0.1% 1 <0.1% 180 <0.1%

Slovenian production was less than 0.1 percent of the world's production of beef and veal and mutton and lamb in 2000 (Table 2). Slovenia imported less than 0.1 percent of the world's beef and veal and mutton and lamb in 1999. Slovenia also imported 121 metric tons of meat and bone meal from Austria in 1999. Slovenia exported beef and veal in 2000, accounting for 0.2 percent of world exports; destinations of the beef and veal exports were not specified. Slovenian exports of meat and bone meal in 1999 totaled 1,527 metric tons to Austria, Bosnia-Hercegovina and Croatia. Information on goat imports and exports was not available.

Table 2. Production and trade in relevant products by Slovenia.

Products 2000 Production Trade

1999 Exports 1999 Imports

Metric ton % World Metric ton % World Metric ton % World

Beef and Veal 42,200 <0.1% 3,200 .2%

Page 68 of 98

- 130 <0.1%
- Mutton and Lamb1 930 <0.1% --11 <0.1%

Source: United Nations FAO; USDA, Foreign Agricultural Service GAIN Report #SI1001, March 27, 2001

1 Sheep were included in Table 1 and Table 2 as 'affected' because USDA/APHIS includes all ruminants and ruminant products in its restrictions pertaining to BSE. Goat production and trade information was unavailable.

What are the U.S. imports of affected animals or animal products from Slovenia?

In 2001, 2000 and 1999, no affected animals or animal products were imported from Slovenia. In 1998, the only affected product imported into the US from Slovenia was 260,000 kg of "Preparations Used in Animal Feedings, Not Otherwise Specified." It is not known whether this feed contained ruminant materials.

Source: World Trade Atlas

Did the US have restrictions on ruminant imports from Slovenia prior to this case?

In December 1997, APHIS prohibited the importation of live ruminants and most ruminant products from all of Europe including Slovenia until a thorough assessment of the risks of introduction of BSE into the US could be made. Prior to December 1997, import restrictions were applied only to those countries which had reported cases of BSE in native animals. Also, importation of ruminant meat from BSE-affected countries was permitted if the meat was deboned and free of visually identifiable lymphatic and nervous tissue and if it met other restrictions. Import regulations enacted December 1997 extended the import restrictions to countries which had not had a declared BSE case, yet had risk factors for BSE occurrence.

These regulatory changes also removed provisions that allowed importation of ruminant meat from the restricted countries, and thereby prohibited importation of ruminant meat from all Europe. These import restrictions also applied to bone meal, blood meal, meat meal, offal, fat, glands, and serum from ruminants. In December 2000, APHIS expanded its import restrictions regarding BSE by prohibiting all imports from Europe of rendered animal protein products, regardless of species.

Source: USDA, APHIS, VS

What is the level of passenger traffic arriving in the United States from Slovenia?

There were no direct flights from Slovenia to the US in fiscal year 2000.

APHIS-PPQ's agriculture quarantine inspection monitoring sampled 27 air passengers from Slovenia for items of agricultural interest in fiscal year 2000. One of these 27 passengers was carrying two kilograms of a meat item that could potentially harbor pathogens that cause BSE. This passenger arrived to Elizabeth, New York, in June 2000 and

declared no intention to visit a farm or ranch in the US.

Source: US Department of Transportation, and APHIS-PPQ Agricultural Quarantine Inspection data base

CEI's plans for follow up:

Prior to CEI's January 2002 quarterly summary of disease events October-December 2001, CEI will review any further developments in this Slovenian outbreak.

If you need more information or wish to comment, you may reply to this message or contact Jennifer Grannis at (970) 490-7844 or David Cummings at (970) 490-7895.

http://www.aphis.usda.gov/vs/ceah/cei/taf/iw_2001_files/foreign/bse_slovenia1101.htm

Scientific Steering Committee – Opinion on the GBR of SLOVENIA September 2002

CONCLUSION ON THE CURRENT GBR

The BSE-agent was potentially imported into the country via infected MBM in the mid 90s when MBM imports peaked. This MBM reached cattle via feed. It can be expected that the 1997 birth cohort had a much lower chance to be infected because MBM imports decreased dramatically and the first feed ban was introduced. Although the rendering system was able to reduce BSE infectivity since 1992, some recycling and propagation may have occurred because SRM were not removed and therefore rendered.

The first domestic BSE-case in Slovenia was identified in November 2001 and a second case was confirmed in January 2002. It is therefore confirmed (GBR III) that domestic cattle in Slovenia are (clinically or pre-clinically) infected with the BSE-agent at a low incidence.

http://ec.europa.eu/food/fs/sc/ssc/out285_en.pdf

*** Spain 145 880

livestock (million): cattle: 6,3

http://www.library.uu.nl/wesp/populstat/Europe/spaing.htm

Report on the assessment of the Geographical BSE-risk of SPAIN July 2000

5. CONCLUSION ON THE GEOGRAPHICAL BSE-RISK

5.1 The current GBR

The current geographical BSE-risk (GBR) level is III, i.e. it is likely that

domestic cattle are infected with the BSE-agent but it is not confirmed.

http://ec.europa.eu/food/fs/sc/ssc/out126_en.pdf

*** Sweden 11 231

Animal health in Sweden Animal health in Swedish dairy and calf-rearing herds is internationally on a very good level. Today, Sweden has about 1.7 million cattle, of which 450 000 are dairy cows.

http://www.sva.se/static/1.html

Report on the assessment of the Geographical BSE-risk of SWEDEN July 2000

5. CONCLUSION ON THE GEOGRAPHICAL BSE RISK

5.1 The current GBR

The current geographical BSE risk (GBR) level is II, i.e. it is unlikely

that domestic cattle are (clinically or pre-clinically) infected with the

BSE-agent, but it cannot be excluded.

http://ec.europa.eu/food/fs/sc/ssc/out127_en.pdf

http://www.efsa.europa.eu/science/tse_assessments/gbr_assessments/572_en.html

*** United Kingdom 270 124

Report on the assessment of the Geographical BSE-risk of THE UNITED KINGDOMJuly 2000

5. CONCLUSION ON THE GEOGRAPHICAL BSE-RISK (GBR)

5.1 The current GBR

The current geographical BSE-risk (GBR) level is IV: BSE is confirmed in domestic cattle at a higher level.

The observed incidence of clinical cases over the last 12 months (March 1999-February 2000) was 428.4 per Million adult cattle. This figure is generated by a

reordary 2000) was 420.4 per winnon adult eather. This figure is generated by a

passive surveillance system that is not able to identify all cases. It includes private

submissions and cases that were discovered in the context of a survey.

http://ec.europa.eu/food/fs/sc/ssc/out128_en.pdf

*** TOTAL EU 3 224 139

http://ec.europa.eu/food/biosafety/bse/bse_6evol6-06_en.pdf

PLEASE NOTE, while your are analyzing this information, please note just how terribly flawed

the June 2004 Enhanced BSE surveillance program was in the USA, all those cattle tested are

meaningless. 1st off, the following does not make any sense to me and even at that, why so

many?

It should be noted that since the enhanced surveillance program began, USDA has also conducted approximately 9,200 routine

IHC tests on samples that did not first undergo rapid testing. This was done to ensure that samples inappropriate for the rapid screen

test were still tested, and also to monitor and improve upon IHC testing protocols. Of those 9,200 routine tests, one test returned a

non-definitive result on July 27, 2005.

http://www.aphis.usda.gov/lpa/issues/bse_testing/test_results.html

CAN you imagine how many might have been positive, IF proper BSE testing protocols were used. WE know the infamous IHC gold standard for BSE the USDA et al boast about so much, is not as gold as they claim. COME to find out, it is the least likely to find BSE, and maybe that is why it was so gold to the USDA. IT also reminds me of the other infamous 'gold standard' the USDA preach about all the time ;

*** Suppressed peer review of Harvard study October 31, 2002 ***

http://www.fsis.usda.gov/oa/topics/BSE_Peer_Review.pdf

WE found out just how inept the program was from the TEXAS mad cow that USDA et al tried to cover-up, but got caught by the Honorable Phyllis Fong of the OIG.

SEE FAILURES ;
Finding 2 Inherent Challenges in Identifying and Testing High-Risk Cattle Still Remain Our prior report identified a number of inherent problems in identifying and testing high-risk cattle. We reported that the challenges in identifying the universe of high-risk cattle, as well as the need to design procedures to obtain an appropriate representation of samples, was critical to the success of the BSE surveillance program. The surveillance program was designed to target nonambulatory cattle, cattle showing signs of CNS disease (including cattle testing negative for rabies), cattle showing signs not inconsistent with BSE, and dead cattle. Although APHIS designed procedures to ensure FSIS condemned cattle were sampled and made a concerted effort for outreach to obtain targeted samples, industry practices not considered in the design of the surveillance program reduced assurance that targeted animals were tested for BSE. In our prior report, we recommended that APHIS work with public health and State diagnostic laboratories to develop and test rabies-negative samples for BSE. This target group is important for determining the prevalence of BSE in the United States because rabies cases exhibit clinical signs not inconsistent with BSE; a negative rabies test means the cause of the clinical signs has not been diagnosed. Rabies Negative Samples APHIS agreed with our recommendation and initiated an outreach program with the American Association of Veterinary Laboratory Diagnosticians, as well as State laboratories. APHIS also agreed to do ongoing monitoring to ensure samples were obtained from this target population. Although APHIS increased the samples tested from this target group as compared to prior years, we found that conflicting APHIS instructions on the ages of cattle to test resulted in inconsistencies in what samples were submitted for BSE testing. Therefore, some laboratories did not refer their rabies negative samples to APHIS in order to maximize the number tested for this critical target population. In addition, APHIS did not monitor the number of submissions of rabies negative samples for BSE testing from specific laboratories. According to the Procedure Manual for BSE Surveillance, dated October 2004, the target population includes: Central nervous system (CNS) signs and/or rabies negative - sample animals of any age (emphasis added): a. Diagnostic laboratories -samples submitted due to evidence of CNS clinical signs. USDA/OIG-A/50601-10-KC Page 19

USDA/OIG-A/50601-10-KC Page 20

b. Public health laboratories – rabies negative cases. c. Slaughter facilities – CNS ante mortem condemned at slaughter, sampled by FSIS. d. On-the-farm – CNS cattle that do not meet the criteria for a foreign animal disease investigation. For FYs 2002, 2003, and 2004 (through February 2004), NVSL received 170, 133, and 45 rabies-negative samples, respectively. Between June 1, 2004, and May 29, 2005, the number of samples received for testing increased to 226 rabies suspect samples. The collection sites submitting these samples follow. Collection Site Number of Rabies Suspect Submissions * Slaughter Plant 0 Renderer 2 On-Farm 11 Public Health Lab 94 Diagnostic Lab 81 3D-4D 8 Other 4 Total 200 * 26 were tested but not counted by APHIS towards meeting the target goals because the obex was not submitted. We obtained a copy of a memorandum, dated July 13, 2004, that APHIS sent to diagnostic and public health laboratories providing them instructions on submitting samples for cattle showing signs of CNS diseases, but testing negative for rabies. The letter was sent to about 170 State veterinary diagnostic and public health laboratories and discussed the need to submit specimens to NVSL of all adult cattle (emphasis added) that showed signs of CNS diseases, but tested negative for rabies. This directive did not specify the age of the cattle. The Procedure Manual for BSE Surveillance, dated October 2004, specified samples of cattle of any age should be submitted. We contacted laboratories in six States to determine if it was standard procedure to submit all negative rabies samples to NVSL. We found that, because of the lack of specificity in the APHIS letter and inadequate followup by APHIS, there were inconsistencies in the age of cattle samples submitted for BSE testing. For those States contacted, the following samples were submitted versus tested as negative for rabies. USDA/OIG-A/50601-10-KC Page 21

Rabies Negative Tests Not Sent for BSE Testing Since June 1, 2004 State Negative Rabies Tests Sent for BSE Testing Not Sent for BSE Testing Pennsylvania a/ 33 15 18 Kansas b/ 85 69 16 Wisconsin c/ 12 1 11 South Dakota d/ 7 0 7 Arizona e/ 5 5 0 Mississippi e/ 4 4 0 Total 146 94 52 a/ A Pennsylvania laboratory official said only rabies negative cattle over 20 months of age were submitted for BSE testing. The laboratory did not submit 18 samples for BSE testing because the animals were less than 20 months of age. b/ Kansas laboratory officials said early in the expanded surveillance program, there was confusion as to the cattle ages that should be submitted for BSE testing. They did not know if cattle should be submitted that were above 20 months or 30 months of age. Of the 16 animals not submitted for BSE testing, 14 were under 20 months of age from early in the expanded surveillance program. The other two animals were not tested due to internal laboratory issues. The Kansas and Nebraska area office officials contacted the laboratory and told the officials to submit rabies negative cattle of any age for BSE testing. The laboratory now submits all rabies negative cattle for BSE testing. c/ A Wisconsin laboratory official said only rabies negative cattle samples 30 months of age or older are submitted for BSE testing. Of the 11 animals not submitted for BSE testing, 8 were less than 30 months of age. Wisconsin laboratory officials were not certain why the other three samples were not submitted. d/ Laboratory officials from South Dakota said they did not receive notification from APHIS regarding the submission of rabies negative cases for BSE testing. The section supervisor and laboratory director were not aware of any letter sent to the laboratory. The section supervisor said most bovine rabies tests at the laboratory are performed on calves. We confirmed the laboratory's address matched the address on APHIS' letter distribution list. However, there was no evidence that the South Dakota area office contacted the laboratory. The laboratory was not listed on the documentation from the APHIS regional office detailing the area office contacts with laboratory personnel. We contacted the South Dakota area office and were advised that while some contact had been made with the laboratory, the contact may have involved Brucellosis rather than BSE. On May 4, 2005, the area office

advised us they recently contacted the laboratory regarding the submission of rabies negative samples for BSE testing. e/ Arizona and Mississippi laboratory officials said they submitted all rabies negative samples for BSE testing regardless of the age of the animal. An NVSL official stated that APHIS is not concerned with rabies negatives samples from cattle less than

30 months of age. This position, however, is contrary to APHIS' published target population. Our prior audit recognized the significant challenge for APHIS to obtain samples from some high-risk populations because of the inherent problems with obtaining voluntary compliance and transporting the carcasses for testing. USDA issued rules to prohibit nonambulatory animals (downers) from entering the food supply at inspected slaughterhouses. OIG recommended, and the International Review Subcommittee33 emphasized, that USDA should take additional steps to assure that facilitated pathways exist for dead and nonambulatory cattle to allow for the collection of samples and proper disposal of carcasses. Between June 1, 2004, and May 31, 2005, the APHIS database documents 27,617 samples were collected showing a reason for submission of nonambulatory and 325,225 samples were collected with reason of submission showing "dead." Downers and Cattle that Died on the Farm APHIS made extensive outreach efforts to notify producers and private veterinarians of the need to submit and have tested animals from these target groups. They also entered into financial arrangements with 123 renderers and other collection sites to reimburse them for costs associated with storing, transporting, and collecting samples. However, as shown in exhibit F, APHIS was not always successful in establishing agreements with non-slaughter collection sites in some States. APHIS stated that agreements do not necessarily reflect the entire universe of collection sites and that the presentation in exhibit F was incomplete because there were many collection sites without a payment involved or without a formal agreement. We note that over 90 percent of the samples collected were obtained from the 123 collection sites with agreements and; therefore, we believe agreements offer the best source to increase targeted samples in underrepresented areas. We found that APHIS did not consider industry practices in the design of its surveillance effort to provide reasonable assurance that cattle exhibiting possible clinical signs consistent with BSE were tested. Slaughter facilities do not always accept all cattle arriving for slaughter because of their business requirements. We found that, in one State visited, slaughter facilities pre-screened and rejected cattle (sick/down/dead/others not meeting business

USDA/OIG-A/50601-10-KC Page 22

33 Report from the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases, February 13, 2004.

USDA/OIG-A/50601-10-KC Page 23

standards) before presentation for slaughter in areas immediately adjacent or contiguous to the official slaughter establishment. These animals were not inspected and/or observed by either FSIS or APHIS officials located at the slaughter facilities. FSIS procedures state that they have no authority to inspect cattle not presented for slaughter. Further, APHIS officials stated they did not believe that they had the authority to go into these sorting and/or screening areas and require that the rejected animals be provided to APHIS for BSE sampling. Neither APHIS nor FSIS had any process to assure that animals left on transport vehicles and/or rejected for slaughter arrived at a collection site for BSE testing. FSIS allows slaughter facilities to designate the area of their establishment where federal inspection is performed; this is designated as the official slaughter establishment.34 We observed animals that were down or dead in pens outside the official premises that were to be picked up by renderers.

Animals that were rejected by plant personnel were transported off the premises on the same vehicles that brought them to the plant.35 A policy statement36 regarding BSE sampling of condemned cattle at slaughter plants provided that effective June 1, 2004, FSIS would collect BSE samples for testing: 1) from all cattle regardless of age condemned by FSIS upon ante mortem inspection for CNS impairment, and 2) from all cattle, with the exception of veal calves, condemned by FSIS upon ante mortem inspection for any other reason. FSIS Notice 28-04, dated May 20, 2004, informed FSIS personnel that, "FSIS will be collecting brain samples from cattle at federally-inspected establishments for the purpose of BSE testing." The notice further states that, "Cattle off-loaded from the transport vehicle onto the premises of the federally-inspected establishment (emphasis added), whether dead or alive, will be sampled by the FSIS Public Health Veterinarian (PHV) for BSE after the cattle have been condemned during ante mortem inspection. In addition, cattle passing ante mortem inspection but later found dead prior to slaughter will be condemned and be sampled by the FSIS PHV." 34 FSIS regulations do not specifically address the designation of an establishment's "official" boundaries; however, FSIS Notices 29-04 (dated May 27, 2004) and 40-04 (dated July 29, 2004) make it clear that FSIS inspection staff are not responsible for sampling dead cattle that are not part of the "official" premises. 35 APHIS' area office personnel stated that it was their understanding that some establishments in the State were not presenting cattle that died or were down on the transport vehicle to FSIS for ante mortem inspection. The dead and down cattle were left in the vehicle, if possible. In rare circumstances, dead cattle may be removed from the trailer by plant personnel to facilitate the unloading of other animals. 36 A May 20, 2004, Memorandum between the Administrators of APHIS and FSIS. USDA/OIG-A/50601-10-KC Page 24

APHIS has the responsibility for sampling dead cattle off-loaded onto plant-owned property that is adjoining to, but not considered part of, the "official premises.37 FSIS procedures38 provide that "Dead cattle that are off-loaded to facilitate the off-loading of live animals, but that will be re-loaded onto the transport vehicle, are not subject to sampling by FSIS. While performing our review in one State, we reviewed the circumstances at two slaughter facilities in the State that inspected and rejected unsuitable cattle before the animals entered the official receiving areas of the plants. This pre-screening activity was conducted in areas not designated by the facility as official premises of the establishment and not under the review or supervision of FSIS inspectors. The plant rejected all nonambulatory and dead/dying/sick animals delivered to the establishment. Plant personnel refused to offload any dead or downer animals to facilitate the offloading of ambulatory animals. Plant personnel said that the driver was responsible for ensuring nonambulatory animals were humanely euthanized and disposing of the carcasses of the dead animals. Plant personnel informed us that they did not want to jeopardize contracts with business partners by allowing unsuitable animals on their slaughter premises. In the second case, one family member owned a slaughter facility while another operated a livestock sale barn adjacent to the slaughter facility. The slaughter facility was under FSIS' supervision while the sale barn was not. Cattle sometimes arrived at the sale barn that were sick/down/dead or would die or go down while at the sale barn. According to personnel at the sale barn,

these animals were left for the renderer to collect. The healthy ambulatory animals that remained were marketed to many buyers including the adjacent slaughter facility. When the slaughter facility was ready to accept the ambulatory animals for processing, the cattle would be moved from the sale barn to the slaughter facility where they were subject to FSIS' inspection. We requested the slaughter facilities to estimate the number of cattle rejected on a daily basis (there were no records to confirm the estimates). We visited a renderer in the area and found that the renderer had a contract with APHIS to collect samples for BSE testing. In this case, although we could not obtain assurance that all rejected cattle were sampled, the renderer processed a significant number of animals, as compared to the slaughter plants' estimates of those rejected. Due to the close proximity (less than 5 miles) of the renderer to the slaughter facilities, and the premium it paid for dead cattle that were in good condition, there was a financial incentive for transport drivers to dispose of their dead animals at this renderer. 37 FSIS Notice 40-04, dated July 29, 2004. 38 FSIS Notice 29-04, dated May 27, 2004.

USDA/OIG-A/50601-10-KC Page 25

In our discussions with APHIS officials in Wisconsin and Iowa, they confirmed that there were plants in their States that also used pre-screening practices. On May 27, 2005, we requested APHIS and FSIS to provide a list of all slaughter facilities that pre-screened cattle for slaughter in locations away from the area designated as the official slaughter facility. Along with this request, we asked for information to demonstrate that either APHIS or FSIS confirmed there was a high likelihood that high-risk animals were sampled at other collection sites. In response to our request, the APHIS BSE Program Manager stated that APHIS did not have information on slaughter plants that pre-screen or screen their animals for slaughter suitability off their official plant premises. To their knowledge, every company or producer that submits animals for slaughter pre-sorts or screens them for suitability at various locations away from the slaughter facility. For this reason, USDA focused its BSE sample collection efforts at other types of facilities such as renderers, pet food companies, landfills, and dead stock haulers. Further, in a letter to OIG on June 14, 2005, the administrators of APHIS and FSIS noted the following: "...we believe that no specific actions are necessary or appropriate to obtain reasonable assurance that animals not presented for slaughter are being tested for BSE. There are several reasons for our position. First, we do not believe that the practice is in fact causing us to not test a significant enough number of animals in our enhanced surveillance program to invalidate the overall results. Second, OIG has concluded that because of the geographical proximity and business relationships of the various entities involved in the case investigated, there is reasonable assurance that a majority of the rejected cattle had been sampled. Third, it is also important to remember that the goal of the enhanced surveillance program is to test a sufficient number of animals to allow us to draw conclusions about the level of BSE (if any) in the American herd...We believe that the number we may be not testing because of the "pre-sorting" practice does not rise to a significant level. The number of animals tested to date has far exceeded expectations, so it is reasonable to infer that there are few of the animals in question, or that we are testing them at some other point in the process...APHIS estimated...there were

approximately 446,000 high risk cattle...[and APHIS has]...tested over 375,000 animals in less than 1 year. This indicated that we are missing few animals in the high-risk population, including those that might be pre-sorted before entering a slaughter facility's property." We obtained 123 APHIS sampling agreements and contracts with firms and plotted their locations within the United States (see exhibit F). We also analyzed the samples tested to the BSE sampling goals allocated to each State under the prior surveillance program. This analysis showed that there are

USDA/OIG-A/50601-10-KC Page 26

sampling gaps in two large areas of the United States where APHIS did not have contracts with collection sites. These two areas are shown in the following chart (Montana, South Dakota, North Dakota and Wyoming – Group 1 and Louisiana, Oklahoma, Arkansas, and Tennessee – Group 2): State Original Sampling Goal Based on (268,500 sampling goal) Samples collected as of May 31, 2005 Deficit No. of BSE Sampling Agreements/ Contracts39MT 5,076 182 4,894 2 SD 6,938 2,792 4,146 1 ND 3,616 174 3,442 0 WY 2,513 61 2,452 0 AREA TOTAL 14,934 OK 7,792 2,407 5,385 1 AR 3,672 353 3,319 0 TN 4,938 3,050 1,888 1 LA 2,312 452 1,860 1 AREA TOTAL 12,452 APHIS notes that for the current surveillance program, it had established regional goals and APHIS was not trying to meet particular sampling levels in particular States. However, we believe that it would be advantageous for APHIS to monitor collection data and increase outreach when large geographical areas such as the above States do not provide samples in proportion to the numbers and types of cattle in the population. We also disagree with APHIS/FSIS' contention that because they have tested over 375,000 of their 446,000 estimate of high risk cattle, few in the high-risk population are being missed, including those that might be pre-screened before entering a slaughter facility's property. In our prior audit, we reported that APHIS underestimated the high-risk population; we found that this estimate should have been closer to 1 million animals (see Finding 1). We recognize that BSE samples are provided on a voluntary basis; however, APHIS should consider industry practice in any further maintenance surveillance effort. Animals unsuitable for slaughter exhibiting symptoms not inconsistent with BSE should be sampled and their clinical signs recorded. However, this cited industry practice results in rejected animals not being made available to either APHIS or FSIS veterinarians for their observation and identification of clinical signs exhibited ante mortem. Although these animals may be sampled later at other collection sites, the animals are provided post mortem without information as to relevant clinical signs exhibited ante mortem. For these reasons, we believe APHIS needs to 39APHIS noted that sites with agreements do not necessarily reflect the entire universe of collection sites and at some sites APHIS collects samples with no payment involved and no agreement in place. OIG agrees that not all collection sites are reflected in our presentation of the 123 sites with reimbursable agreements. OIG believes obtaining sampling agreements is one of the primary methods available to increase sample numbers in areas with sampling gaps. USDA/OIG-A/50601-10-KC Page 27 observe these animals ante mortem when possible to assure the animals from

the target population are ultimately sampled and the clinical signs evaluated. Recommendation 3......SEE OTHER FAILURES ; http://www.usda.gov/oig/webdocs/50601-10-KC.pdf

NOT TO FORGET about the other TEXAS MAD COW they did succeed in covering up ;

FOR IMMEDIATE RELEASE Statement May 4, 2004 Media Inquiries: 301-827-6242 Consumer Inquiries: 888-INFO-FDA

Statement on Texas Cow With Central Nervous System Symptoms

On Friday, April 30 th, the Food and Drug Administration learned that a cow with central nervous system symptoms had been killed and shipped to a processor for rendering into animal protein for use in animal feed.

FDA, which is responsible for the safety of animal feed, immediately began an investigation. On Friday and throughout the weekend, FDA investigators inspected the slaughterhouse, the rendering facility, the farm where the animal came from, and the processor that initially received the cow from the slaughterhouse.

FDA's investigation showed that the animal in question had already been rendered into "meat and bone meal" (a type of protein animal feed). Over the weekend FDA was able to track down all the implicated material. That material is being held by the firm, which is cooperating fully with FDA.

Cattle with central nervous system symptoms are of particular interest because cattle with bovine spongiform encephalopathy or BSE, also known as "mad cow disease," can exhibit such symptoms. In this case, there is no way now to test for BSE. But even if the cow had BSE, FDA's animal feed rule would prohibit the feeding of its rendered protein to other ruminant animals (e.g., cows, goats, sheep, bison).

FDA is sending a letter to the firm summarizing its findings and informing the firm that FDA will not object to use of this material in swine feed only. If it is not used in swine feed, this material will be destroyed. Pigs have been shown not to be susceptible to BSE. If the firm agrees to use the material for swine feed only, FDA will track the material all the way through the supply chain from the processor to the farm to ensure that the feed is properly monitored and used only as feed for pigs.

To protect the U.S. against BSE, FDA works to keep certain mammalian protein out of animal feed for cattle and other ruminant animals. FDA established its animal feed rule in 1997 after the BSE epidemic in the U.K. showed that the disease spreads by feeding infected ruminant protein to cattle.

Under the current regulation, the material from this Texas cow is not allowed in feed for cattle or other ruminant animals. FDA's action specifying that the material go only into swine feed means also that it will not be fed to poultry.

FDA is committed to protecting the U.S. from BSE and collaborates closely with the U.S. Department of Agriculture on all BSE issues. The animal feed rule provides crucial protection against the spread of BSE, but it is only one of several such firewalls. FDA will soon be improving the animal feed rule, to make this strong system even stronger.

####

http://www.fda.gov/bbs/topics/news/2004/NEW01061.html

OR THE TEXAS PURINA MAD COW FEED INCIDENT ;

FOR IMMEDIATE RELEASE P01-05 January 30, 2001 Print Media: 301-827-6242 Consumer Inquiries: 888-INFO-FDA

Note: On Dec. 23, 2003, the U.S. Department of Agriculture reported that a cow in Washington state had tested positive for bovine spongiform encephalopathy (BSE, or mad cow disease). As a result, information on this Web page stating that no BSE cases had been found in the United States is now incorrect. However, because other information on this page continues to have value, the page will remain available for viewing.

FDA ANNOUNCES TEST RESULTS FROM TEXAS FEED LOT

Today the Food and Drug Administration announced the results of tests taken on feed used at a Texas feedlot that was suspected of containing meat and bone meal from other domestic cattle -- a violation of FDA's 1997 prohibition on using ruminant material in feed for other ruminants. Results indicate that a very low level of prohibited material was found in the feed fed to cattle.

FDA has determined that each animal could have consumed, at most and in total, five-and-one-half grams - approximately a quarter ounce -- of prohibited material. These animals weigh approximately 600 pounds.

It is important to note that the prohibited material was domestic in origin (therefore not likely to contain infected material because there is no evidence of BSE in U.S. cattle), fed at a very low level, and fed only once. The potential risk of BSE to such cattle is therefore exceedingly low, even if the feed were contaminated.

According to Dr. Bernard Schwetz, FDA's Acting Principal Deputy Commissioner, "The challenge to regulators and industry is to keep this disease out of the United States. One important defense is to prohibit the use of any ruminant animal materials in feed for other ruminant animals. Combined with other steps, like U.S. Department of Agriculture's (USDA) ban on the importation of live ruminant animals from affected countries, these steps represent a series of protections, to keep American cattle free of BSE."

Despite this negligible risk, Purina Mills, Inc., is nonetheless announcing that it is voluntarily purchasing all 1,222 of the animals held in Texas and mistakenly fed the animal feed containing the prohibited material. Therefore, meat from those animals will not enter the human food supply. FDA believes any cattle that did not consume feed containing the prohibited material are unaffected by this incident, and should be handled in the beef supply clearance process as usual.

FDA believes that Purina Mills has behaved responsibly by first reporting the human error that resulted in the misformulation of the animal feed supplement and then by working closely with State and Federal authorities.

This episode indicates that the multi-layered safeguard system put into place is essential for protecting the food supply and that continued vigilance needs to be taken, by all concerned, to ensure these rules are followed routinely.

FDA will continue working with USDA as well as State and local officials to ensure that companies and individuals comply with all laws and regulations designed to protect the U.S. food supply.

http://www.fda.gov/bbs/topics/NEWS/2001/NEW00752.html

WE KNOW NOW, and we knew then, less than a gram was lethal. ...

EFSA Scientific Report on the Assessment of the Geographical BSE-Risk (GBR) of the United States of America (USA) Last updated: 19 July 2005 Adopted July 2004 (Question N° EFSA-Q-2003-083)

Report Summary Summary of the Scientific Report

The European Food Safety Authority and its Scientific Expert Working Group on the Assessment of the Geographical Bovine Spongiform Encephalopathy (BSE) Risk (GBR) were asked by the European Commission (EC) to provide an up-to-date scientific report on the GBR in the United States of America, i.e. the likelihood of the presence of one or more cattle being infected with BSE, pre-clinically as well as clinically, in USA. This scientific report addresses the GBR of USA as assessed in 2004 based on data covering the period 1980-2003.

The BSE agent was probably imported into USA and could have reached domestic cattle in the middle of the eighties. These cattle imported in the mid eighties could have been rendered in the late eighties and therefore led to an internal challenge in the early nineties. It is possible that imported meat and bone meal (MBM) into the USA reached domestic cattle and leads to an internal challenge in the early nineties.

A processing risk developed in the late 80s/early 90s when cattle imports from BSE risk countries were slaughtered or died and were processed (partly) into feed, together with some imports of MBM. This risk continued to exist, and grew significantly in the mid 90's when domestic cattle, infected by imported MBM, reached processing. Given the low stability of the system, the risk increased over the years with continued imports of cattle and MBM from BSE risk countries.

EFSA concludes that the current GBR level of USA is III, i.e. it is likely but not confirmed that domestic cattle are (clinically or pre-clinically) infected with the BSE-agent. As long as there are no significant changes in rendering or feeding, the stability remains extremely/very unstable. Thus, the probability of cattle to be (pre-clinically or clinically) infected with the BSE-agent persistently increases.

Publication date: 20 August 2004

http://www.efsa.eu.int/science/tse_assessments/gbr_assessments/573_it.html

http://www.efsa.eu.int/science/tse_assessments/gbr_assessments/573/sr03_biohaz02_usa_report_summary_en1.pdf

http://www.efsa.eu.int/science/tse_assessments/gbr_assessments/573/sr03_biohaz02_usa_report_v2_en1.pdf

TO REDUCE TESTING OF BSE IN THE USA TO ONLY 40,000 A YEAR, is simply not scientific regardless of what the OIE BSE testing protocol calls for. ALL one has

to do is look at the countries above that all went down with BSE, that all went by the infamous OIE BSE testing protocols. THEN and only then, after the USA finally fumbled the 'BSE FREE' golden egg and accidently had to document a case or two of mad cow, low and behold, what next? yep, you guessed it, time to move the goal post in the middle of the football game, GWs and his sleeping partners at the OIE, gave birth to the BSE MRR policy, the legal trading of all strains of TSE globally was born. ...

BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, 95, and 96

[Docket No. 03-080-3]

RIN 0579-AB73

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations regarding the importation of animals and animal products to establish a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products and byproducts, and we are adding Canada to this category. We are also establishing conditions for the importation of certain live ruminants and ruminant products and byproducts from such regions. These actions will continue to protect against the introduction of BSE into the United States while removing unnecessary prohibitions on the importation of certain commodities from minimal-risk regions for BSE, currently only Canada.

EFFECTIVE DATE: [Insert date 60 days after date of publication in the Federal Register]. FOR FURTHER INFORMATION CONTACT: For information concerning ruminant products, contact Dr. Karen James-Preston, Director, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 734-4356. For information concerning live ruminants, contact Lee Ann Thomas, Director, Technical Trade Services, Animals, Organisms and Vectors, and Select Agents, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737-1231; (301) 734-4356.

http://www.aphis.usda.gov/lpa/issues/bse/03-080-3_final_rule.pdf

[Federal Register: November 4, 2003 (Volume 68, Number 213)] [Proposed Rules] [Page 62386-62405] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr04no03-5]

Proposed Rules Federal Register

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules. [[Page 62386]]

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, and 95

[Docket No. 03-080-1] RIN 0579-AB73

Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations regarding the importation of animals and animal products to recognize a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products, and are proposing to add Canada to this category. We are also proposing to allow the importation of certain live ruminants and ruminant products and byproducts from such regions under certain conditions. We believe this action is warranted because it would continue to protect against the introduction of BSE into the United States while removing unnecessary prohibitions on certain commodities from Canada and other regions that qualify as BSE minimal-risk regions.

DATES: We will consider all comments that we receive on or before January 5, 2004.

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2003_register&docid=fr04no03-5

[Federal Register: April 8, 2005 (Volume 70, Number 67)] [Rules and Regulations] [Page 18251-18262] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr08ap05-11] [[Page 18251]]

Part VII

Department of Agriculture

Animal and Plant Health Inspection Service

9 CFR Part 93, et al.

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Finding of No Significant Impact and Affirmation of Final Rule; Final Rule

[[Page 18252]]

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, 95, and 98

[Docket No. 03-080-7] RIN 0579-AB73

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Finding of No Significant Impact and Affirmation of Final Rule

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of final rule.

SUMMARY: We are publishing a finding of no significant impact for a final rule concerning bovine spongiform encephalopathy minimal risk regions published January 4, 2005, and, based on that finding, we are affirming the provisions of the final rule. The finding of no significant impact is based on an environmental assessment that documented our review and analysis of potential environmental impacts associated with the final rule and our review of issues raised by the public regarding the environmental assessment. Together, the environmental assessment and our review of the issues raised provide a basis for our conclusion that the provisions of the final rule will not have a significant impact on the quality of the human environment and support our affirmation of the final rule.

DATES: The final rule published January 4, 2005 (70 FR 460), with a partial delay of applicability published March 11, 2005 (70 FR 12112), was effective March 7, 2005. This affirmation of the final rule is effective April 8, 2005.

http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/05-7141.htm

World Animal Health Body Changes Mad Cow Risk Definitions

WASHINGTON, DC, May 31, 2006 (ENS) - Member countries of the World Organization for Animal Health (OIE) last week voted unanimously to revise the three definitions of risk categories for countries affected by mad cow disease, formally known as bovine spongiform encephalopathy (BSE).

The three definitions are - negligible risk, controlled risk, and undetermined risk of cattle being infected with the fatal brain-wasting disease.

Previously, a country that discovered a case of BSE had to wait seven years from the date of its latest discovery before being eligible to be classified as a "negligible risk" country, the category for countries with the least amount of risk from the disease.

Under these guidelines, the United States would have had to wait until the year 2013 to be classified as a negligible risk country after a veterinarian discovered a cow infected with the disease in Alabama in March, the third infected U.S. cow to be found.

Now, as a result of OIE's decision, countries work from the date of birth of the animal discovered to be infected with the BSE agent – misfolded proteins called prions.

The decision was made at the OIE's Annual General Session held in Paris from May 21 to 26.

The General Session notably brings together representatives appointed by the governments of the 167 OIE member countries. Some 600 participants representing member countries and intergovernmental organizations such as the UN Food and Agriculture Organization, the World Health Organization, the World Bank and the World Trade Organization took part in the event.

Many U.S. cattlemen support the change because it more accurately reflects the scientific knowledge surrounding the disease.

"Scientists have determined that BSE is caused by feeding contaminated animal-based feed to cattle, and that cattle are most likely to become infected with BSE during the first year of their lives, so using the infected animal's birth date as a reference point allows countries to determine how recently contaminated feed may have been circulating within their feed system," said Bill Bullard, CEO of R-CALF USA, a cattle industry association.

A ban on feeding animal tissues to cattle was imposed in the United States and Canada in 1997. snip...

http://www.ens-newswire.com/ens/may2006/2006-05-31-02.asp

FEED BAN, what feed ban ???

RECALLS AND FIELD CORRECTIONS: VETERINARY MEDICINE -- CLASS II

PRODUCT a) PRO-LAK, bulk weight, Protein Concentrate for Lactating Dairy Animals, Recall # V-079-6; b) ProAmino II, FOR PREFRESH AND LACTATING COWS, net weight 50lb (22.6 kg), Recall # V-080-6; c) PRO-PAK, MARINE & ANIMAL PROTEIN CONCENTRATE FOR USE IN ANIMAL FEED, Recall # V-081-6; d) Feather Meal, Recall # V-082-6 CODE a) Bulk b) None c) Bulk d) Bulk **RECALLING FIRM/MANUFACTURER** H. J. Baker & Bro., Inc., Albertville, AL, by telephone on June 15, 2006 and by press release on June 16, 2006. Firm initiated recall is ongoing. REASON Possible contamination of animal feeds with ruminent derived meat and bone meal. VOLUME OF PRODUCT IN COMMERCE 10,878.06 tons DISTRIBUTION ***Nationwide***

END OF ENFORCEMENT REPORT FOR July 12, 2006

###

http://www.fda.gov/bbs/topics/enforce/2006/ENF00960.html

Subject: MAD COW FEED BAN WARNING LETTER ISSUED MAY 17, 2006 Date: June 27, 2006 at 7:42 am PST Public Health Service Food and Drug Administration

New Orleans District 297 Plus Park Blvd. Nashville, TN 37217

Telephone: 615-781-5380 Fax: 615-781-5391

May 17, 2006

WARNING LETTER NO. 2006-NOL-06

FEDERAL EXPRESS OVERNIGHT DELIVERY

Mr. William Shirley, Jr., Owner Louisiana.DBA Riegel By-Products 2621 State Street Dallas, Texas 75204

Dear Mr. Shirley:

On February 12, 17, 21, and 22, 2006, a U.S. Food & Drug Administration (FDA) investigator inspected your rendering plant, located at 509 Fortson Street, Shreveport, Louisiana. The inspection revealed significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 [21 CFR 589.2000], Animal Proteins Prohibited in Ruminant Feed. This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). You failed to follow the requirements of this regulation; products being manufactured and distributed by your facility are misbranded within the meaning of Section 403(a)(1) [21 USC 343(a) (1)] of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found you failed to provide measures, including sufficient written procedures, to prevent commingling or cross-contamination and to maintain sufficient written procedures [21 CFR 589.2000(e)] because:

You failed to use clean-out procedures or other means adequate to prevent carryover of protein derived from mammalian tissues into animal protein or feeds which may be used for ruminants. For example, your facility uses the same equipment to process mammalian and poultry tissues. However, you use only hot water to clean the cookers

between processing tissues from each species. You do not clean the auger, hammer mill, grinder, and spouts after processing mammalian tissues.

You failed to maintain written procedures specifying the clean-out procedures or other means to prevent carryover of protein derived from mammalian tissues into feeds which may be used for ruminants.

As a result . the poultry meal you manufacture may contain protein derived from mammalian tissues prohibited in ruminant feed. Pursuant to 21 CFR 589.2000(e)(1)(i), any products containing or may contain protein derived from mammalian tissues must be labeled, "Do not feed to cattle or other ruminants." Since you failed to label a product which may contain protein derived from mammalian tissues with the required cautionary statement. the poultry meal is misbranded under Section 403(a)(1) [21 USC 343(a)(1)] of the Act.

This letter is not intended as an all-inclusive list of violations at your facility. As a manufacturer of materials intended for animal feed use, you are responsible for ensuring your overall operation and the products you manufacture and distribute are in compliance with the law. You should take prompt action to correct these violations, and you should establish a system whereby violations do not recur. Failure to promptly correct these violations may result in regulatory action, such as seizure and/or injunction, without further notice.

You should notify this office in writing within 15 working days of receiving this letter, outlining the specific steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating corrections have been made.

Your reply should be directed to Mark W. Rivero, Compliance Officer, U.S. Food and Drug Administration, 2424 Edenborn Avenue, Suite 410, Metairie, Louisiana 70001. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 219-8818, extension 103.

Sincerely,

S

Carol S. Sanchez Acting District Director New Orleans District

http://www.fda.gov/foi/warning_letters/g5883d.htm

WHY still now only partial ruminant feed ban, with the fact that now we seem to have 3 cases of nvCJD to humans i.e. humanbovineTSE that were responsible from blood, and the fact the last 2 mad cows documented in the USA were that of an Atypical strain, would it not seem prudent to remove blood as well from ruminant feed ?

WOULD it not seem prudent to improve and expand the SRM list now? as per your own thinking ;

> If transmission occurs, tissue distribution comparisons will be made between cattle

> infected with the atypical BSE isolate and the U.S. BSE isolate. Differences in

> tissue distribution could require new regulations regarding specific risk material

> (SRM) removal.

FULL text;

Research Project: Study of Atypical Bse Location: Virus and Prion Diseases of Livestock

Project Number: 3625-32000-073-07 Project Type: Specific C/A

Start Date: Sep 15, 2004 End Date: Sep 14, 2007

Objective:

The objective of this cooperative research project with Dr. Maria Caramelli from the Italian BSE Reference Laboratory in Turin, Italy, is to conduct comparative studies with the U.S. bovine spongiform encephalopathy (BSE) isolate and the atypical BSE isolates identified in Italy. The studies will cover the following areas: 1. Evaluation of present diagnostics tools used in the U.S. for the detection of atypical BSE cases. 2. Molecular comparison of the U.S. BSE isolate and other typical BSE isolates with atypical BSE cases. 3. Studies on transmissibility and tissue distribution of atypical BSE isolates in cattle and other species.

Approach:

This project will be done as a Specific Cooperative Agreement with the Italian BSE Reference Laboratory, Istituto Zooprofilattico Sperimentale del Piemonte, in Turin, Italy. It is essential for the U.S. BSE surveillance program to analyze the effectiveness of the U.S diagnostic tools for detection of atypical cases of BSE. Molecular comparisons of the U.S. BSE isolate with atypical BSE isolates will provide further characterization of the U.S. BSE isolate. Transmission studies are already underway using brain homogenates from atypical BSE cases into mice, cattle and sheep. It will be critical to see whether the atypical BSE isolates behave similarly to typical BSE isolates in terms of transmissibility and disease pathogenesis. If transmission occurs, tissue distribution comparisons will be made between cattle infected with the atypical BSE isolate and the U.S. BSE isolate. Differences in tissue distribution could require new regulations regarding specific risk material (SRM) removal.

http://www.ars.usda.gov/research/projects/projects.htm?ACCN_NO=408490

HOWEVER, JAPAN has already shown infectivity in tissues other than CNS in there atypical TSE in cattle, so why should we wait, and expose many to this agent needlessly, since the last two mad cows in the USA were also atypical TSE ?

PrPSc distribution of a natural case of bovine spongiform encephalopathy Yoshifumi Iwamaru, Yuka Okubo, Tamako Ikeda, Hiroko Hayashi, Mori- kazu Imamura, Takashi Yokoyama and Morikazu Shinagawa

Priori Disease Research Center, National Institute of Animal Health, 3-1-5 Kannondai, Tsukuba 305-0856 Japan gan@affrc.go.jp

Abstract

Bovine spongiform encephalopathy (BSE) is a disease of cattle that causes progressive neurodegeneration of the central nervous system. Infectivity of BSE agent is accompanied with an abnormal isoform of prion protein (PrPSc).

The specified risk materials (SRM) are tissues potentially carrying BSE infectivity. The following tissues are designated as SRM in Japan: the skull including the brain and eyes but excluding the glossa and the masse- ter muscle, the vertebral column excluding the vertebrae of the tail, spinal cord, distal illeum. For a risk management step, the use of SRM in both animal feed or human food has been prohibited. However, detailed PrPSc distribution remains obscure in BSE cattle and it has caused controversies about definitions of SRM. Therefore we have examined PrPSc distribution in a BSE cattle by Western blotting to reassess definitions of SRM.

The 11th BSE case in Japan was detected in fallen stock surveillance. The carcass was stocked in the refrigerator. For the detection of PrPSc, 200 mg of tissue samples were homogenized. Following collagenase treatment, samples were digested with proteinase K. After digestion, PrPSc was precipitated by sodium phosphotungstate (PTA). The pellets were subjected to Western blotting using the standard procedure. Anti-prion protein monoclonal antibody (mAb) T2 conjugated horseradish peroxidase was used for the detection of PrPSc.

PrPSc was detected in brain, spinal cord, dorsal root ganglia, trigeminal ganglia, sublingual ganglion, retina. In addition, PrPSc was also detected in the peripheral nerves (sciatic nerve, tibial nerve, vagus nerve).

Our results suggest that the currently accepted definitions of SRM in BSE cattle may need to be reexamined.

ALSO from the International Symposium of Prion Diseases held in Sendai, October 31, to November 2, 2004;

Bovine spongiform encephalopathy (BSE) in Japan

snip...

"Furthermore, current studies into transmission of cases of BSE that are atypical or that develop in young cattle are expected to amplify the BSE prion"

NO. Date conf. Farm Birth place and Date Age at diagnosis

8. 2003.10.6. Fukushima Tochigi 2001.10.13. 239. 2003.11.4. Hiroshima Hyogo 2002.1.13. 21 Test results

8b, 9c cows Elisa Positive, WB Positive, IHC negative, histopathology negative

b = atypical BSE case

c = case of BSE in a young animal

b,c, No PrPSc on IHC, and no spongiform change on histology

International Symposium of Prion Diseases held in Sendai, October 31, to November 2, 2004.

Tetsuyuki Kitamoto Professor and Chairman Department of Prion Research Tohoku University School of Medicine 2-1 SeiryoAoba-ku, Sendai 980-8575, JAPAN TEL +81-22-717-8147 FAX +81-22-717-8148 e-mail; <u>kitamoto@mail.tains.tohoku.ac.jp</u> Symposium Secretariat Kyomi Sasaki TEL +81-22-717-8233 FAX +81-22-717-7656 e-mail: <u>kvomi-sasaki@mail.tains.tohoku.ac.ip</u>

Atypical Proteinase K-Resistant Prion Protein (PrPres) observed in an Apparently Healthy 23-Month-Old Holstein Steer

Jpn. J. Infect. Dis., 56, 221-222, 2003

Laboratory and Epidemiology Communications

Atypical Proteinase K-Resistant Prion Protein (PrPres) Observed in an Apparently Healthy 23-Month-Old Holstein Steer

Yoshio Yamakawa*, KenÕichi Hagiwara, Kyoko Nohtomi, Yuko Nakamura, Masahiro Nishizima, Yoshimi Higuchi1, Yuko Sato1, Tetsutaro Sata1 and the Expert Committee for BSE Diagnosis, Ministry of Health, Labour and Welfare of Japan2

Department of Biochemistry & Cell Biology and 1Department of Pathology, National Institute of Infectious Diseases, Tokyo 162-8640 and 2Miistry of Health, Labour and Welfare, Tokyo 100-8916

Communicated by Tetsutaro Sata

(Accepted December 2, 2003)

*Corresponding author: Mailing address: Department of Biochemistry and Cell Biology, National Institute of Infectious Diseases, Toyama 1-23-1, Shinjuku-ku, Tokyo 1628640, Japan. Tel: +81-3-5285-1111, Fax: +81-3-5285-1157, E-mail: <u>yamakawa@nih.go.jp</u>

Since October 18, 2001, 'bovine spongiform encephalopathy (BSE) examination for all cattle slaughtered at abattoirs in the country' has been mandated in Japan by the Ministry of Health, Labour and Welfare (MHLW). 'Plateria' ELISA-kit (Bio-Rad Laboratories, Hercules, Calif., USA) is routinely used at abattoirs for detecting proteinase K (PK)-resistant prion protein (PrPSc) in the obex region. Samples positive according to the ELISA screening are further subjected to Western blot (WB) and histologic and immunohistochemical examination (IHC) at the National Institute of Infectious Diseases (NIID) or Obihiro University. If PrPSc is detected either by WB or by IHC, the cattle are diagnosed as BSE. The diagnosis is approved by the Expert Committee for BSE Diagnosis, MHLW. From October 18, 2001 to September 30, 2003, approximately 2.5 million cattle were screened at abattoirs. A hundred and ten specimens positive according to ELISA were subjected to WB/IHC. Seven showed positive by both WB and IHC, all exhibiting the typical electrophoretic profile of a high content of the di-glycosylated molecular form of PrPSc (1-3) and the distinctive granular deposition of PrPSc in neuronal cells and neuropil of the dorsal nucleus of vagus.

An ELISA-positive specimen from a 23 month-old Holstein steer slaughtered on September 29, 2003, in Ibaraki

Prefecture (Ibaraki case) was sent to the NIID for confirmation. The animal was reportedly healthy before slaughter. The OD titer in ELISA was slightly higher than the 'cut-off' level given by the manufacturer. The histology showed no spongiform changes and IHC revealed no signal of PrPSc accumulation typical for BSE. However, WB analysis of the homogenate that was prepared from the obex region and used for ELISA revealed a small amount of PrPSc with an electrophoretic profile different from that of typical BSE-associated PrPSc (1-3). The characteristics were (i) low content of the di-glycosylated molecular form of PrPSc, (ii) a faster migration of the non-glycosylated form of PrPSc on SDS-PAGE, and (iii) less resistance against PK digestion as compared with an authentic PrPSc specimen derived from an 83-month-old Holstein (Wakayama case) (Fig. 1). Table 1 summarizes the relative amounts of three distinctive glycoforms (di-, mono, non-glycosylated) of PrPSc calculated by densitometric analysis of the blot shown in Fig. 1. As 2.5 mg wet weight obex-equivalent homogenate of the Ibaraki case (Fig. 1, lane 4) gave slightly stronger band intensities of PrPSc than an 8 mg wet weight obex-equivalent homogenate of a typical BSE-affected Wakayama case (Fig. 1, lane 2), the amount of PrPSc accumulated in the Ibaraki case was calculated to be 1/500 - 1/1000 of the Wakayama case. In the Ibaraki case, the PrPSc bands were not detectable in the homogenates of the proximal surrounding region of the obex. These findings were consistent with the low OD value in ELISA, i.e., 0.2 -0.3 for the Ibaraki case versus over 3.0 for the Wakayama case. The DNA sequence of the PrP coding region of the Ibaraki case was the same as that appearing in the database (GenBank accession number: AJ298878). More recently, we encountered another case that resembled the Ibaraki case. It was a 21-monthold Holstein steer from Hiroshima Prefecture. WB showed typical BSE-specific PrPSc deposition though IHC did not detect positive signals of PrPSc (data not shown).

Though the clinical onset of BSE is usually at around 5 years of age or later, a 20-month-old case showing the clinical signs has been reported (4). Variant forms of BSE similar to our cases, i.e., with atypical histopathological and/or biochemical phenotype, have been recently reported in Italy (5) and in France (6). Such variant BSE was not associated with mutations in the prion protein (PrP) coding region as in our case (5,6).

The Ministry of Agriculture, Forestry and Fisheries of Japan (MAFF) announced a ban of feeding ruminants with meat bone meal (MBM) on September 18, 2001, and a complete ban was made on October 15 of the same year. According to the recent MAFF report, the previous seven cases of BSE in Japan were cattle born in 1995 - 1996 and possibly fed with cross-contaminated feed. However, the two cattle in this report were born after the complete ban. Whether contaminated MBM was implicated in the present cases remains to be investigated.

REFERENCES

Collinge, J., Sidle, K. C. L., Meads, J., Ironside, J. and Hill, A. F. (1996): Molecular analysis of prion strain variation and the aetiology of 'new variant' CJD. Nature, 383, 685

690. Bruce, M. E., Will, R. G., Ironside, J. W., McConnell, I., Drummond, D., Suttie, A., McCardle, L., Chree, A., Hope, J., Birkett, C., Cousens, S., Fraser, H. and Bostock, C. J. (1997): Transmissions to mice indicate that 'new variant' CJD is caused by the BSE agent. Nature, 389, 498-501. Hill, A. F., Desbruslais, M., Joiner, S., Sidle, K. C. L., Gowland, I. and Collinge, J. (1997): The same prion strain causes vCJD and BSE. Nature, 389, 448-450. Matravers, W., Bridgeman, J. and Smith, M.-F. (ed.)(2000): The BSE Inquiry. p. 37. vol. 16. The Stationery Office Ltd., Norwich, UK. Casalone, C., Zanusso, G., Acutis, P. L., Crescio, M. I., Corona, C., Ferrari, S., Capobianco, R., Tagliavini, F., Monaco, S. and Caramelli, M. (2003): Identification of a novel molecular and neuropathological BSE phenotype in Italy. International Conference on Prion Disease: from basic research to intervention concepts. Gasreig, Munhen, October 8-10. Bicaba, A. G., Laplanche, J. L., Ryder, S. and Baron, T. (2003): A molecular variant of bovine spongiform encephalopatie. International Conference on Prion Disease: from basic research to intervention concepts. Gasreig, Munhen, October 8-10. Asante, E. A., Linehan, J. M., Desbruslais, M., Joiner, S., Gowland, I., Wood, A. L., Welch, J., Hill, A. F., Lloyd, S. E., Wadsworth, J. D. F. and Collinge, J. (2002). BSE prions propagate as either variant CJD-like or sporadic CJD-like prion strains in transgenic mice expressing human prion protein. EMBO J., 21, 6358-6366.

Page 94 of 98

9/13/2005

Page 12 of 17

SEE SLIDES IN PDF FILE;

http://www.nih.go.jp/JJID/56/221.pdf

http://www.fsis.usda.gov/OPPDE/Comments/03-025IFA/03-025IFA-2.pdf

4. WHAT does USDA/FDA ET AL intend to do about the risks of atypical BSE/TSE in cattle now that infectivity shows in tissue samples other than CNS in Japan, the fact now that the last Texas mad cow and that last mad cow in Alabama were indeed of the atypical strain, the fact that the studies long ago in Mission, Texas of USA sheep scrapie transmission to the USA bovine, which proved an 'atypical tse' in the USA bovine, the fact also that USDA/FDA are still floundering on the last SRM regulations, but with the BASE strain now in cattle that is not similar to nvCJD, but very similar to the sporadic CJD, and sporadic CJD has tripled in the last few years in the USA. WHAT do you plan to do to protect human health from these atypical strains of TSE, in relations to SRMs ?

5. THE 2004 Enhanced BSE surveillance program, that tested all those cows, but then we found just how terribly flawed the program was, from testing protocols, to testing the most likely to have BSE i.e. high risk, to the geographical distribution of the testing and high risk areas, to letting the tissue samples of one mad cow sit on a shelf for 7+ months and then having to have an act of Congress to ever get that cow finally confirmed, to that other Texas mad cow they decided to not even bother testing at all, just rendered that very suspect cow, to suspect to test evidently, back to that Alabama mad cow that they could only give a guess as to age with dentition where we all know that the age of that cow was so close to 10 years it could have been 9 years 7 months to 10 years 3 months, thus possibly being an BAPB i.e. USA 'born after partial ban', to all those rabies suspect cows that did not have rabies, and DID NOT get tested for BSE/TSE in that June 2004 enhanced surveillance program, even though the common lay person knows the suspect rabies negative cows are suppose to be BSE/TSE tested, how does one correct all these blatant failures and will they be corrected?

IT never was about human/animal health, but all about commodities and futures. ... MISSION ACCOMPLISHED \$\$\$

ENFAMOUS NON-SPECIES CODING SYSTEM BY FDA ET AL, another handy tool for importing/exporting all strains of TSE ;

Docket Management Docket: 02N-0276 - Bioterrorism Preparedness; Registration of Food Facilities, Section 305 Comment Number: EC -254 Accepted - Volume 11

8/3/2006

http://www.fda.gov/OHRMS/DOCKETS/DOCKETS/02n0276/02N-0276-EC-254.htm

ONE FINAL THOUGHT ;

OPINION

http://www.efsa.eu.int/science/biohaz/biohaz_opinions/1540/biohaz_op_ej359_qra_vertebral_column_en1.pdf

>>>New methodology, under the auspices of the OIE, is under construction within the EU and EFSA and the Panel recommended that once these classifications had been finalised they should harmonised with those used in the EFSA BSE QRA guidance document. The Panel anticipated that this harmonisation may have a knock-on impact on the QRA calculations, conclusions and recommendations and that, again, future Panel members should review this, and other, inputs of the QRA and address this impact using their "self-tasking mandate" option.<<<

GOD HELP US!

sample survey via oie for bse is about 400 test via 100 million cattle, if i am not mistaken. MOST countries that went by these OIE guidelines all eventually went down with BSE. ...TSS

http://www.oie.int/downld/SC/2005/bse_2005.pdf

THE OIE has now shown they are nothing more than a National Trading Brokerage for all strains of animal TSE. AS i said before, OIE should hang up there jock strap now, since it appears they will buckle every time a country makes some political hay about trade protocol, commodities and futures. IF they are not going to be science based, they should do everyone a favor and dissolve there organization. ...

WHAT ABOUT RISK FACTORS TO HUMANS FROM ALL OTHER TSES, WITH RELATIONS TO SRMS ???

a.. BSE OIE

see full text;

http://p079.ezboard.com/fwolftracksproductionsfrm2.showMessage?topicID=470.topic

IT'S as obvious as day and night, either Larry, Curley, and Mo have been at the helm of the USDA/APHIS/FSIS/FDA/CDC/NIH et al for many many years, or the incompetence of these agencies are so inept, either through ignorance and or just too overweight with industry reps., they then should be all done away with and a single agency brought forth, and if not, how will you correct this ongoing problem ?

Thank you, I am sincerely disgusted,

Terry S. Singeltary Sr. P.O. Box 42 Bacliff, Texas USA 77518

CJD WATCH

http://www.fortunecity.com/healthclub/cpr/349/part1cjd.htm

CJD WATCH MESSAGE BOARD

http://disc.server.com/Indices/167318.html

BMJ

http://www.bmj.com/cgi/eletters/319/7220/1312/b#EL2

BMJ

http://www.bmj.com/cgi/eletters/320/7226/8/b#EL1

Diagnosis and Reporting of Creutzfeldt-Jakob Disease

Singeltary, Sr et al. JAMA.2001; 285: 733-734.

http://jama.ama-assn.org/cgi/content/full/285/6/733?

maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=dignosing+and+reporting+creutzfeldt+jakob+disease&searchid=104

Re: RE-Monitoring the occurrence of emerging forms of Creutzfeldt-Jakob disease in the United States

Email Terry S. Singeltary:

flounder@wt.net

I lost my mother to hvCJD (Heidenhain Variant CJD). I would like to comment on the CDC's attempts to monitor the occurrence of emerging forms of CJD. Asante, Collinge et al [1] have reported that BSE transmission to the 129-methionine genotype can lead to an alternate phenotype that is indistinguishable from type 2 PrPSc, the commonest sporadic CJD. However, CJD and all human TSEs are not reportable nationally. CJD and all human TSEs must be made reportable in every state and internationally. I hope that the CDC does not continue to expect us to still believe that the 85%+ of all CJD cases which are sporadic are all spontaneous, without route/source. We have many TSEs in the USA in both animal and man. CWD in deer/elk is spreading rapidly and CWD does transmit to mink, ferret, cattle, and squirrel monkey by intracerebral inoculation. With the known incubation periods in other TSEs, oral transmission studies of CWD may take much longer. Every victim/family of CJD/TSEs should be asked about route and source of this agent. To prolong this will only spread the agent and needlessly expose others. In light of the findings of Asante and Collinge et al, there should be drastic measures to safeguard the medical and surgical arena from sporadic CJDs and all human TSEs. I only ponder how many sporadic CJDs in the USA are type 2 PrPSc?

http://www.neurology.org/cgi/eletters/60/2/176#535

TSS