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Department of Agriculture

Animal and Plant Health Inspection Service

9 CFR Parts 50, 51, et al.

Food Safety and Inspection Service

9 CFR Parts 309, 310, 311, 318, and 319

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 589

Federal Measures To Mitigate BSE Risks: Considerations for Further Action; Proposed Rule

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, and 85

[Docket No. 04–047–1]

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Food Safety and Inspection Service

9 CFR Parts 309, 310, 311, 318, and 319

[Docket No. 04–021ANPR]

RIN 0583–AC88

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 589

[Docket No. 2004N–0264]

RIN 0910–AF46

Federal Measures To Mitigate BSE Risks: Considerations for Further Action

AGENCIES: Animal and Plant Health Inspection Service and Food Safety and Inspection Service, USDA; and Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; invitation to comment.

SUMMARY: Following detection of bovine spongiform encephalopathy (BSE) in an imported dairy cow in Washington State in December 2003, the Secretaries of the U.S. Departments of Agriculture and Health and Human Services announced a series of regulatory actions and policy changes to strengthen protections against the spread of BSE in U.S. cattle and against human exposure to the BSE agent. The Secretary of Agriculture also convened an international panel of experts on BSE to review the U.S. response to the Washington case and make recommendations that could provide meaningful additional public or animal health benefits. The purpose of this advance notice of proposed rulemaking is to inform the public about the panel's recommendations and to solicit comment on additional measures under consideration based on those recommendations and other considerations.

DATES: APHIS and FSIS will consider all comments received on or before September 13, 2004. FDA will consider all comments received on or before August 13, 2004.

ADDRESSES:

You may submit comments to APHIS by any of the following methods:

• Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 04–047–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 04–047–1.

• E-mail: Address your comment to *regulations@aphis.usda.gov.* Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 04–047–1'' on the subject line.

• Agency Web Site: Go to *http://www.aphis.usda.gov/ppd/rad/cominst.html* for a form you can use to submit an e-mail comment through the APHIS web site.

• Federal eRulemaking Portal: Go to *http://www.regulations.gov* and follow the instructions for locating this docket and submitting comments.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

You may submit comments to FSIS by any of the following methods:

• Mail, including floppy disks or CD–ROM's, and hand-or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102 Cotton Annex, Washington, DC 20250.

• Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions at that site for submitting comments.

Instructions: All submissions received must include the Agency name and Docket No. 04–021ANPR.

Other information: All comments submitted in response to this advance notice of proposed rulemaking, as well as research and background information used by FSIS in developing this document, will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday. The comments also will be posted on the Agency's Web site at *http://www.fsis.usda.gov/OPPDE/rdad/FRDockets.htm.*

You may submit comments to FDA by any of the following methods:

• Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

• Agency web site: *http://www.fda.gov/dockets/comments.* Follow the instructions for submitting comments.

• E-mail: *fdadockets@oc.fda.gov.* Include Docket No. 2004N–0264 or Regulatory Identification No. (RIN) 0910–AF46 in the subject line of your e-mail message.

• Fax: (301) 827–6870.

• Mail/hand delivery/courier (for paper, disc, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions must include the Agency name and Docket No. 2004N–0264 or Regulatory Identification No. (RIN) 0910–AF46.

Other information: All comments received, including any personal information provided, will be posted without change to *http://www.fda.gov/dockets/ecomments,* For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments* or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

APHIS: Dr. Anne Goodman, Supervisory Staff Officer, Regionalization Evaluation Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

FSIS: Daniel L. Engeljohn, Ph.D., Deputy Assistant Administrator, Office of Policy, Program, and Education Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700, Telephone (202) 205–0495, Fax (202) 401–1760. Copies of references cited in this document are available in the FSIS Docket Clerk's Office (see **ADDRESSES**).

FDA: Burt Pritchett, D.V.M., Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7500

Standish Pl., Rockville, MD 20855, 301–827–0177, e-mail: *burt.pritchett@fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Purpose

Bovine spongiform encephalopathy (BSE), widely referred to as ''mad cow disease,'' is a progressive and fatal neurological disorder of cattle. The disease was first diagnosed in 1986 in the United Kingdom, but had never been detected in a native animal in North America until May 2003 when it was diagnosed in a single dairy cow in Canada. Subsequently, in December 2003, BSE was diagnosed in a single dairy cow in Washington State that had been imported from Canada. Variant Creutzfeld-Jakob disease, a chronic and fatal neurodegenerative disease that affects humans, has been linked to the consumption of beef products contaminated with the BSE agent. The U.S. Government—specifically, the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA)—has implemented a number of measures to protect the public from health risks associated with BSE and to prevent the spread of the disease in U.S. cattle. The agencies are currently considering additional safeguards based on the recommendations of an international review team convened by the Secretary of Agriculture and on other considerations. The purpose of this advance notice of proposed rulemaking (ANPRM) is to inform the public about the report and recommendations of the international review team and to solicit public comment on the additional measures under consideration.

II. Background

A. Bovine Spongiform Encephalopathy

BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). In addition to BSE, TSEs include, among other diseases, scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and Creutzfeldt-Jakob disease (CJD) in humans. The agent that causes BSE and other TSEs has yet to be fully characterized. The theory that is most accepted in the scientific community is that the agent is a prion, which is an abnormal form of a normal protein known as cellular prion protein, although other agents have also been implicated. There is currently no test to detect the disease in a live animal. BSE is confirmed by postmortem microscopic examination of an animal's brain tissue or by detection of the abnormal form of the prion protein in an animal's tissues. The pathogenic form of the protein is both less soluble and more resistant to degradation than the normal form. The BSE agent is extremely resistant to heat and to normal sterilization processes. It does not evoke any demonstrated immune response or inflammatory reaction in host animals.

Since November 1986, there have been more than 180,000 confirmed cases of BSE in cattle worldwide. The disease has been confirmed in native-born cattle in 22 European countries in addition to the United Kingdom, and in some non-European countries, including Japan, Israel, and Canada. Over 95 percent of all BSE cases have occurred in the United Kingdom, where the epidemic peaked in 1992/1993, with approximately 1,000 new cases in cattle reported per week. Agricultural officials in the United Kingdom have taken a series of actions to eliminate BSE, including making it a reportable disease, banning mammalian meat-and-bone meal in feed for all food-producing animals, prohibiting the inclusion of animals more than 30 months of age in the animal and human food chains, and destroying all animals showing signs of BSE and other potentially exposed animals at high risk of developing the disease. As a result of these actions, most notably the feed bans, the rate of newly reported cases of BSE in the United Kingdom has decreased sharply and continues a downward trend.

In 1996, a newly recognized form of the human disease CJD, referred to as variant CJD (vCJD), was reported in the United Kingdom. Scientific and epidemiological studies have linked vCJD to exposure to the BSE agent, most likely through human consumption of cattle products contaminated with the agent that causes BSE. To date, approximately 150 probable and confirmed cases of vCJD have been reported in the United Kingdom, where there had been a high level of consumption of contaminated cattle product. In the United States, where measures to prevent the introduction and spread of BSE have been in place for some time, there is far less potential for human exposure to the BSE agent. The Centers for Disease Control and Prevention (CDC) leads a surveillance system for vCJD in the United States, and as of December 2003, had not detected vCJD in any resident of the United States that had not lived in or traveled to the United Kingdom for extended periods of time. In 2002, a probable case of vCJD was reported in a Florida resident who had lived in the United Kingdom during the BSE epidemic. Epidemiological data indicate that the patient likely was exposed to the BSE agent before moving to the United States.

B. Prevention of BSE in the United States

The United States Government has implemented a number of measures since 1989 to prevent BSE from entering the United States and to prevent the spread of the disease should it be introduced into the United States.

Import Restrictions and 1997 Feed Ban

Since 1989, USDA's Animal and Plant Health Inspection Service (APHIS) has prohibited the importation of live cattle and other ruminants and certain ruminant products, including most rendered protein products, into the United States from countries where BSE is known to exist. In 1997, due to concerns about widespread risk factors and inadequate surveillance for BSE in many European countries, APHIS extended importation restrictions on ruminants and ruminant products to all of the countries in Europe.

Also in 1997, HHS' Food and Drug Administration (FDA) prohibited the use of all mammalian protein, with the exception of pure pork and pure equine protein from single species processing plants, in animal feeds given to cattle and other ruminants (62 FR 30936; June 5, 1997; codified at 21 CFR 589.2000). The rule allows exceptions for certain products believed at the time to present a low risk of transmitting BSE: blood and blood products; gelatin; inspected meat products that have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings, referred to below as ''plate waste''); and milk products (milk and milk protein). Firms must keep specified records on the manufacture of feed, have processes in place to prevent commingling of ruminant and nonruminant feed containing prohibited materials, and ensure that nonruminant feed containing materials prohibited in ruminant feed is labeled conspicuously with the statement, ''Do not feed to cattle or other ruminants.''

In December 2000, APHIS expanded its prohibitions on imports of rendered ruminant protein products from BSE-restricted regions to include rendered protein products of any animal species because of concern that cattle feed supposedly free of ruminant protein may have been cross contaminated with the BSE agent. FDA also issued import alerts on animal feed ingredients for APHIS-listed countries.

Animal Surveillance Program and Emergency Response Plan

The United States has had an active surveillance program for BSE since 1990. Historically, the sampling strategy was designed to detect one BSE-infected animal per million cattle and to take into account regional differences while striving for uniform surveillance throughout the country. Since 1993, BSE surveillance in the United States has met or exceeded international standards as outlined in the *Terrestrial Animal Health Code* of the Office International des Epizooties (OIE), the world organization for animal health. For additional details on BSE surveillance since 1990, see *http://www.aphis.usda.gov/lpa/issues/bse/bse-surveillance.html.*

Since its inception, animal surveillance for BSE in the United States has been designed to sample those cattle in which BSE is most likely to occur and in which the disease would most likely be detected. The targeted surveillance population has, therefore, included adult cattle displaying clinical signs that could be considered to be consistent with BSE. This includes cattle exhibiting signs of central nervous system (CNS) abnormalities, cattle that are non-ambulatory, cattle that have died on the farm from unexplained causes, and cattle that display other clinical signs that could be compatible with BSE. The BSE surveillance program has historically not included apparently healthy cattle presented for routine slaughter because that is not the population where the disease would most likely be detected.

Further, APHIS, in cooperation with USDA's Food Safety and Inspection Service (FSIS), prepared an emergency response plan to be used in the event that BSE is identified in the United States (*http://www.aphis.usda.gov/lpa/issues/bse/bsesum.pdf*). FDA and other Federal agencies have also developed contingency plans that would operate in association with the USDA plan. USDA and HHS have held various outreach and tabletop exercises to test various components of their contingency plans.

C. Risk of BSE in the United States

In April 1998, USDA contracted with the Harvard Center for Risk Analysis (HCRA) at Harvard University and the Center for Computational Epidemiology at Tuskegee University to conduct a comprehensive investigation of BSE risk in the United States. The report,[1] widely referred to as the Harvard Risk Assessment or the Harvard Study, is referred to in this document as the Harvard-Tuskegee Study. It was completed in 2001 and released by the USDA. Following a peer review of the Harvard-Tuskegee Study in 2002, the authors responded to the peer review comments and released a revised risk assessment in 2003.[2]

The Harvard-Tuskegee Study reviewed available scientific information related to BSE and other TSEs, assessed pathways by which BSE could potentially occur in the United States, and identified measures that could be taken to protect human and animal health in the United States. The assessment concluded that the United States is highly resistant to any proliferation of BSE or similar disease and that measures taken by the U.S. Government and industry make the United States robust against the spread of BSE to animals or humans should it be introduced into this country.

The Harvard-Tuskegee Study concluded that the most effective measures for reducing potential introduction and spread of BSE are: (1) The ban placed by APHIS on the importation of live ruminants and ruminant meat-and-bone meal from the United Kingdom since 1989 and all of Europe since 1997; and (2) the feed ban instituted in 1997 by FDA to prevent recycling of potentially infectious cattle tissue. The Harvard-Tuskegee Study further indicated that, if introduction of BSE had occurred via importation of live animals from the United Kingdom prior to 1989, mitigation measures already in place would have minimized exposure and begun to eliminate the disease from the cattle population.

The Harvard-Tuskegee Study also identified three pathways or practices that could facilitate human exposure to the BSE agent or the spread of BSE should it be introduced into the United States: (1) Non-compliance with FDA's ruminant feed regulations prohibiting the use of certain proteins in feed for cattle and other ruminants; (2) rendering of animals that die on the farm and use (through illegal diversion or cross contamination) of the rendered product in ruminant feed; and (3) the inclusion of high-risk tissues from cattle, such as brain and spinal cord, in products for human consumption. The Harvard-Tuskegee Study's independent evaluation of the potential risk mitigation measures predicts that a prohibition against rendering of animals that die on the farm would reduce the potential cases of BSE in cattle following hypothetical exposure by 82 percent as compared to the base case scenario,[3] and that a ban on specified risk materials (SRMs)[4], including brain, spinal cord and vertebral column, from inclusion in human and animal food would reduce potential BSE cases in cattle by 88 percent and potential human exposure to BSE by 95 percent as compared to the base case scenario.

In 2003, following the identification of BSE in a native-born cow in Canada, the HCRA evaluated the implications of a then hypothetical introduction of BSE into the United States[5], using the same simulation model developed for the initial Harvard-Tuskegee Study. This assessment confirmed the conclusions of the earlier study—namely, that the United States presents a very low risk of establishing or spreading BSE should it be introduced.

In May 2004, USDA contracted with the HCRA to revise and update the BSE risk assessment model to reflect recent events that have occurred in the United States. These recent events include such increased risk mitigation measures as the prohibition of SRMs in human food.

[1] Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, ''Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States,'' *http://www.aphis.usda.gov/lpa/issues/bse/risk_assessment/mainreporttext.pdf,* 2001.

[2] Research Triangle Institute, ''Review of the Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States,'' accessed online at *http://www.aphis.usda.gov/lpa/issues/bse/BSE_Peer_Review.pdf,* 2002. Harvard Center for Risk Analysis, Harvard School of Public Health, ''Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States: Response to Reviewer Comments Submitted by Research Triangle Institute,'' *http://www.aphis.usda.gov/lpa/issues/bse/ResponsetoComments.pdf,* 2003. Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, ''Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States,'' *http://www.aphis.usda.gov/lpa/issues/bse/madcow.pdf,* 2003.

[3] Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, ''Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States,'' section 3, ''Simulation Model and Base Case Assumptions,'' *http://www.aphis.usda.gov/lpa/issues/bse/risk_assessment/mainreporttext.pdf,* 2001.

Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, ''Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States,'' *http://www.aphis.usda.gov/lpa/issues/bse/madcow.pdf,* 2003.

[4] Specified risk materials (SRMs) are ruminant tissues that have demonstrated infectivity at some point during the BSE incubation period.

[5] Harvard Center for Risk Analysis, Harvard School of Public Health, ''Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada,'' accessed online at *http://www.aphis.usda.gov/lpa/issues/bse/harvard_10–3/text_wrefs.pdf,* 2003.

In addition, USDA requested that the HCRA specifically analyze the recommendations of the international review team to determine whether the recommendations would provide significant differences in risk mitigation levels. While this information will be valuable as we analyze any future actions concerning domestic policy changes, the existing Harvard-Tuskegee model demonstrates that, with the safeguards in place—even before the case of BSE was detected in Washington State in December 2003—the risk of spread of BSE from any introduction was very low, due largely to import restrictions and the 1997 feed ban. Because control measures have been increased and strengthened since that time, it is anticipated that any changes to the model reflecting additional control measures would continue to demonstrate a further decrease in risk of spread.

III. The Case in Washington State and U.S. Actions in Response

On December 23, 2003, USDA announced a presumptive positive case of BSE in a dairy cow in Washington State. Samples had been taken from the cow on December 9 as part of USDA's BSE surveillance program. The BSE diagnosis was made on December 22 and 23 by histopathology and immunohistochemical testing at the National Veterinary Services Laboratories in Ames, IA, and verified on December 25 by the international reference laboratory, the Veterinary Laboratories Agency in Weybridge, England. This case followed the identification of BSE in a single cow in Alberta, Canada, in May 2003.

A. The Epidemiological Investigation and Related Activities

Upon detection of the BSE-positive cow in Washington State, USDA, FDA and other Federal and State agencies immediately began working together closely to perform a full epidemiological investigation [6], trace any potentially infected cattle, trace potentially contaminated rendered product, increase BSE surveillance, and take additional measures to address human and animal health.

The epidemiological investigation and DNA test results confirm that the infected cow was not indigenous to the United States, but rather was born and most likely became infected in Alberta, Canada, prior to Canada's 1997 implementation of a ban on feeding mammalian protein to ruminants.

The infected cow entered the United States on September 4, 2001, as part of a shipment of 81 animals from the source herd in Canada. Of these 81 animals, 25 were determined, as a result of the epidemiological investigation, to be higher risk as defined by the OIE. A higher risk animal is one born on premises known to be a source of an infected animal within 12 months before or after the birth of the infected cow.

Counting the infected cow, USDA definitively accounted for 14 of the 25 animals considered to be higher risk, along with 15 others from the source herd that were in the initial shipment, plus 7 additional animals dispersed from the birth herd. The number of animals found—35 in addition to the infected cow—is consistent with the number expected after analysis of regional culling rates.

In addition to those animals, another 220 cattle were culled from 10 premises on which one or more source herd animals were found. These cattle were culled because they could possibly have been from the Canadian source herd. Out of an abundance of caution, all 255 animals were euthanized and tested for BSE; all of the animals tested negative. Because there is a small probability that BSE can be transmitted maternally, the two live offspring of the infected cow were also euthanized. A third had died at birth in October 2001. All carcasses were properly disposed of in accordance with Federal, State, and local regulations.

In conjunction with USDA's investigation, FDA conducted an extensive feed investigation. By December 27, 2003, FDA had located all potentially infectious product rendered from the BSE-positive cow in Washington State. The product was disposed of in a landfill in accordance with Federal, State, and local regulations.

The United States concluded the active investigation and culling activities related to the one infected cow on February 9, 2004, and redirected resources toward planning, implementing, and enforcing national policy measures to promote BSE surveillance and protect human and animal health.

B. International Review Team Convened

Prior to the conclusion of the epidemiological investigation, on January 22–24, 2004, the Secretary of Agriculture convened an international panel of experts to assess the epidemiological investigation, provide expert opinion as to when the active phase should be terminated, consider the response actions of the United States to date, and provide recommendations as to actions that could be taken to provide additional meaningful human or animal health benefits in light of the North American experience.

The international review team was organized as a subcommittee of the Secretary of Agriculture's Foreign Animal and Poultry Disease Advisory Committee. The subcommittee consisted of Prof. U. Kihm (Switzerland), Prof. W. Hueston (USA), Dr. D. Matthews (UK), Prof. S. C. MacDiarmid (New Zealand), and Dr. D. Heim (Switzerland). The subcommittee (referred to below as the IRT) provided its report on February 4, 2004. The complete report, ''*Report on Measures Relating to BSE in the United States,*'' is available for viewing at *http://www.aphis.usda.gov/lpa/issues/bse/BSE_tr_ban_ltr%20_enc_2.pdf.*

In summary, the IRT was complimentary of the scope, thoroughness, and appropriateness of the epidemiological investigation and concluded that the investigation conformed to international standards. The review team members concurred that the investigation should be terminated. In addition, the IRT made several policy recommendations designed to further reduce the risk of cattle being exposed to BSE. These recommendations included several changes that the Federal Government had already embarked upon related to SRMs, non-ambulatory (downer) cows, surveillance, laboratory diagnosis, feed restrictions, traceability (*i.e.*, animal identification), education, control of implementation measures, and lessons learned. These Federal Government policies are discussed in the next section. A formal response to the IRT report, prepared collaboratively by USDA and FDA, may be viewed at *http://www.aphis.usda.gov/lpa/issues/bse/bse_responsetorep.pdf.*

C. Regulatory and Policy Actions

APHIS, FSIS, and FDA have taken additional steps to specifically address the potential pathways or practices that the Harvard-Tuskegee Study said could contribute most either to the spread of BSE in cattle or to human exposure to the BSE agent should BSE be introduced into the United States.

Safeguards on Food and Feed Supplies

FSIS, in a series of three interim final rules that were published and made effective on January 12, 2004, took additional measures to prevent the BSE agent from entering the human food supply. In its interim final rule titled,

[6] A report of the epidemiological investigation, ''A Case of Bovine Spongiform Encephalopathy (BSE) in the United States,'' was issued in March 2004 and is available at *http://www.aphis.usda.gov/lpa/issues/bse/BSE_tr_ban%20_ltr_enc_1.pdf.*

''Prohibition on the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle'' (FSIS Docket No. 03–025IF; 69 FR 1861), and referred to below as the SRM rule, FSIS designated the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle as SRM, and prohibited their use as human food. To ensure effective removal of the distal ileum, the SRM rule requires establishments to remove the entire small intestine and dispose of it as inedible.

To facilitate the enforcement of the SRM rule, FSIS has developed procedures to verify the approximate age of cattle that are slaughtered in official establishments. Such procedures, based on records or examination of teeth, are intended to ensure that SRM from cattle 30 months of age and older are effectively segregated from edible materials.[7]

As provided by the SRM rule, materials designated as SRMs if they are from cattle 30 months of age and older will be deemed to be SRMs unless the establishment can demonstrate that they are from an animal that was younger than 30 months of age at the time of slaughter.

Furthermore, FSIS has developed procedures to verify that cross contamination of edible tissue with SRMs is reduced to the maximum extent practical in facilities that slaughter cattle, or process carcasses or parts of carcasses of cattle, both younger than 30 months of age and 30 months of age and older.[8] If an establishment uses dedicated equipment to cut through SRMs, or if it segregates cattle 30 months of age and older from cattle younger than 30 months of age, then the establishment may use routine operational sanitation procedures (*i.e.*, no special sanitation procedures are required). If the establishment doesn't segregate cattle 30 months of age and older from younger cattle, equipment used to cut through SRMs must be cleaned and sanitized before it is used on carcasses or parts from cattle less than 30 months of age. FSIS believes that, due to the multiple risk mitigation measures implemented in the United States to prevent the spread of BSE, these procedures will reduce to the maximum extent possible cross contamination of carcasses with high-risk tissues. However, to assist in determining whether it should strengthen the measures required of establishments, FSIS issued a press release during the comment period for the SRM rule that specifically requested public comment on methods to prevent cross contamination of carcasses with SRMs.[9]

The SRM rule also declared mechanically separated beef (MS(beef)) to be inedible and prohibited its use for human food. Additionally, the SRM rule prohibited all non-ambulatory disabled cattle for use as human food.

The second interim final rule, titled, ''Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems' (FSIS Docket No. 03–038IF; 69 FR 1874–1885), prohibited products produced by advanced meat recovery (AMR) systems from being labeled as ''meat'' if, among other things, they contain CNS tissue. AMR is a technology that removes muscle tissue from the bone of beef carcasses under high pressure without incorporating significant amounts of bone and bone products into the final meat product. FSIS had previously established and enforced regulations that prohibited spinal cord from being included in products labeled ''meat.'' This interim final rule expanded that prohibition to include dorsal root ganglia (DRG), clusters of cells connected to the spinal cord along the vertebral column. In addition, because the vertebral column and skull of cattle 30 months of age and older have been designated as SRM, they cannot be used for AMR. Because they are not SRMs, the skull and vertebral column from cattle younger than 30 months of age may be used in AMR systems. However, establishments that use skulls and vertebral columns in the production of beef AMR product must be able to demonstrate that such materials are from cattle younger than 30 months of age.

The third interim final rule, titled ''Prohibition on the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter'' (FSIS Docket No. 01–0331IF; 69 FR 1885–1891), prohibited the use of penetrative captive bolt stunning devices that deliberately inject air into the cranial cavity of cattle because they may force large fragments of CNS tissue into the circulatory system of stunned cattle where they may become lodged in edible tissues.

Also on January 12, 2004, FSIS published a notice announcing that it would no longer pass and apply the mark of inspection to carcasses and parts of cattle selected for BSE testing by APHIS until the sample is determined to be negative (FSIS Docket No. 03–048N; 69 FR 1892; ''Bovine Spongiform Encephalopathy Surveillance Program'').

FDA continues to conduct inspections to monitor compliance of feed mills, renderers, and protein blenders with the 1997 feed ban rule and is expanding the scope of its inspections to include other segments of animal feed production and use, such as transportation firms, farms that raise cattle, and animal feed salvage operations. Compliance by feed mills, renderers, and protein blenders with the feed ban is currently very high. Information on inspections and compliance is available at *http://www.fda.gov/cvm/index/bse/RuminantFeedInspections.htm.*

FDA, like FSIS, has taken additional measures to prevent the BSE agent from entering the human food supply. In an interim final rule published in the Rules and Regulations section of today's **Federal Register**, FDA prohibits SRMs, the small intestine of all cattle, material from non-ambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and MS (beef) from use in FDA-regulated human food, including dietary supplements, and cosmetics (FDA Docket No. 2004N–0081; ''Use of Materials Derived from Cattle in Human Food and Cosmetics'').

This interim final rule on human food and cosmetics, as well as a second one related to animal feed, were announced by FDA on January 26, 2004. The interim final rule on animal feed was to remove the current exemptions in 21 CFR 589.2000 for blood and blood products and plate waste, prohibit the use of poultry litter in ruminant feed, and require equipment, facilities, or production lines to be dedicated to nonruminant animal feed if firms use protein that is prohibited in ruminant feed.

The IRT recommendations provide a different set of measures for reducing the risks associated with animal feed. The IRT approach is to prevent potentially infective tissues from ever entering animal feed channels. Although FDA believes the measures previously announced would serve to reduce the already small risk of BSE

[7] See FSIS Notice 05–04, ''Interim Guidance for Non-Ambulatory Disabled Cattle and Age Determination,'' January 12, 2004, *http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=/oppde/rdad/fsisnotices/5–04.pdf;* and FSIS Notice 10–04, ''Questions and Answers Regarding the Age Determination of Cattle and Sanitation,'' January 29, 2004, *http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=/oppde/rdad/fsisnotices/10–04.pdf.*

[8] See FSIS Notice 10–04.

[9] FSIS press release of March 31, 2004.

spread through animal feed, the broader measures recommended by the IRT, if implemented, could make some of the previously announced measures unnecessary. Either approach would require a significant change in current feed manufacturing practices. Therefore, FDA believes that additional information is needed to determine the best course of action in light of the IRT recommendations and has decided not to issue an interim final rule with the changes to the feed ban described in the January 26 announcement. Instead, FDA is requesting additional information through this ANPRM on the recommendations of the IRT, as well as on other measures under consideration to protect the animal feed supply.

The Federal Government has also taken additional significant nonregulatory actions in response to the detection of BSE in North America. These actions include enhancing surveillance for BSE; implementing a national animal identification system; enhancing laboratory diagnosis; and obtaining and providing guidance and strategies for the future.

Animal Surveillance

On March 15, 2004, Secretary of Agriculture Ann Veneman announced a one-time enhanced BSE surveillance plan, targeting cattle from populations considered at highest risk for BSE, as well as a sampling of animals from the clinically normal, aged cattle population (over 30 months as evidenced by the eruption of at least one of the second set of permanent incisors). The plan, implemented on June 1, 2004, incorporates recommendations from the IRT and the Harvard Center for Risk Analysis. Notably, the IRT has reviewed the surveillance plan and indicated that it is comprehensive and science-based, and that it addresses the important issues with regard to BSE surveillance in cattle.

Over a period of 12–18 months, APHIS will test as many cattle as possible in the targeted high-risk population. Data obtained in this effort will help determine the probable prevalence of BSE in the United States and whether risk management policies need to be adjusted. If at least 268,500 targeted high-risk animals are sampled, we will be able to detect BSE even if as few as 5 animals in this targeted population are positive. The key to surveillance is to look at the population of animals where the disease is likely to occur. Thus, if BSE is present in the U.S. cattle population, there is a significantly better chance of finding the BSE within this targeted high-risk cattle population than within the general cattle population.

In addition, FSIS public health veterinarians have begun assisting in APHIS' BSE animal surveillance efforts by collecting brain samples from all cattle condemned during ante-mortem inspection at federally inspected establishments. This allows APHIS to focus on sample collection at locations other than federally inspected establishments, such as rendering operations and farms.

APHIS ensured access to slaughterhouses and rendering plants for sample collection via a final rule published March 4, 2004 (APHIS Docket No. 99–017–3, 69 FR 10137, ''Blood and Tissue Collection at Slaughtering and Rendering Establishments''). Samples may also be collected on the farm, at veterinary diagnostic laboratories, at public health laboratories, at veterinary clinics, sale barns, livestock auctions, etc.

Strengthening of the passive surveillance system for BSE through outreach and education is an integral part of the USDA surveillance plan. In this regard, APHIS has developed plans to enhance existing educational materials and processes in conjunction with other Federal and State agencies. These outreach efforts will inform veterinarians, producers, and affiliated industries of the USDA surveillance goals and the sometimes subtle clinical signs of BSE, and will encourage reporting of suspect or targeted cattle on farm and elsewhere. One of the tools for reporting high-risk cattle, announced on June 8, 2004, is a toll-free number (1–866–536–7593).

To help cover additional costs incurred by industries participating in the surveillance plan, and to help encourage reporting and collection of targeted samples, USDA may provide payments for certain transportation, disposal, cold storage, and other costs.

For a complete discussion of the enhanced BSE surveillance plan that will be carried out over the next 12–18 months, refer to APHIS' Bovine Spongiform Encephalopathy (BSE) Surveillance Plan of March 15, 2004 (available at *http://www.aphis.usda.gov/lpa/issues/bse/BSE_Surveil_Plan03–15–04.pdf).*

Laboratory Diagnosis

Testing of BSE surveillance samples is conducted at APHIS' National Veterinary Services Laboratories (NVSL) and at a participating network of State and Federal veterinary diagnostic laboratories throughout the continental United States. USDA has approved 12 geographically dispersed laboratories to assist with BSE surveillance.

USDA has also approved five rapid screening test kits and has provided funding for high-throughput laboratory equipment as necessary. The rapid screening test kits are commercially produced diagnostic test kits, intended for use in surveillance programs such as these. These kits are best used as screening tests—*i.e.*, they are very sensitive and are intended to identify anything that might possibly be positive. Each of the laboratories will use one or more of the rapid screening tests with the goal of having initial results available within 24 to 72 hours after the sample is collected.

NVSL remains the national reference laboratory for BSE. If any sample reacts on the initial screening test, the tissues will be immediately forwarded to NVSL for confirmatory testing. Samples with this type of initial reaction will be reported as inconclusives. Samples will only be determined to be negative or positive by NVSL using immunohistochemistry and/or western blot confirmatory testing. NVSL will also conduct quality assurance check testing and test a certain number of routine samples to ensure proficiency in conducting all approved rapid screening tests.

USDA will make public the number of tests conducted and the results on a periodic basis. Updates are available at *http://www.aphis.usda.gov/lpa/issues/bse-enhan_surv/bse_test_results.html.*

The United States Government encourages and supports the development of new diagnostic tests for BSE and other TSEs. USDA researchers regularly discuss advancements in this area with their counterparts throughout the world and will evaluate all scientific data submitted as part of an application for USDA approval of a diagnostic test.

Animal Identification (Traceability)

Animal disease outbreaks around the globe over the past decade and the detection of a BSE-positive cow in the United States in December 2003 have intensified public interest in developing a national animal identification program for the purpose of protecting animal health.

Having a system that can identify individual animals or groups, the premises where they are located, and the date of entry to each premises is fundamental to controlling any disease threat, foreign or domestic, to U.S. animal resources. Further, we must be able to retrieve this information in a timely manner after confirmation of disease outbreak in order to implement successful intervention strategies.

While there is currently no nationwide animal identification system in the United States for all animals of a given species, some segments of certain species are required to be identified as part of current APHIS disease eradication activities. In addition, some significant regional voluntary identification programs are in place, and others are currently being developed and tested.

USDA has defined several key objectives for a national system. These include: (1) Allowing producers, to the extent possible, the flexibility to use current systems or adopt new ones; (2) having a system that is technology neutral, so that all existing effective technologies and new technologies that may be developed in the future may be utilized; (3) having a system that builds upon national data standards to ensure that a uniform and compatible system evolves; (4) having a system that does not preclude producers from being able to use it with production management systems that respond to market incentives; and (5) designing the architecture so that the system does not unduly increase the role and size of the Government.

Design and implementation of such a national animal identification system are well under way (see *http://www.aphis.usda.gov/lpa/issues/nais/nais.html*). USDA is moving forward first on a voluntary basis, to integrate the various types of animal identification programs that currently exist in the United States, and then will scale up to the national level, to include those producers and animals that are not currently in an animal identification program. The goal is to create an effective, uniform, consistent, and efficient national system.

APHIS will initially fund cooperative agreements to help State and Tribal governments establish premises identification systems and to evaluate additional identification pilot projects that could also become a part of the overall animal identification system. Associations and other segments of the livestock industry may participate in State and Tribal projects. APHIS posted a request for proposals for these cooperative agreements in June and will accept applications until July 15, 2004. APHIS anticipates initiating projects funded through these cooperative agreements in August. USDA is currently conducting a series of listening sessions (June–August 2004) across the country, inviting public discussion on the national animal identification program.

Guidance and Strategy

The Federal Government has several existing mechanisms to ensure appropriate guidance and involvement from outside experts and interested stakeholders. The Secretary of Agriculture's Advisory Committee on Foreign Animal and Poultry Diseases (SACFAPD), which has 17 members from industry, States, and academia, advises the Secretary on program operations, measures to prevent the introduction of foreign animal diseases into the United States, and contingency measures should such a disease be introduced into the United States. This group meets regularly and can also solicit public and expert advice. In fact, the IRT was convened as a subcommittee of the SACFAPD. Similarly, FDA obtains guidance from outside experts through its Transmissible Spongiform Encephalopathy Advisory Committee (TSEAC). In addition, FDA's TSEAC includes a representative from APHIS.

The Federal Government also obtains guidance and advice from experts within the Government. USDA has an internal Transmissible Spongiform Encephalopathy (TSE) Working Group that provides scientific recommendations related to TSEs, including BSE. This technical group meets regularly and includes representatives from FSIS and USDA's Agricultural Research Service, as well as from HHS' Centers for Disease Control and Prevention, the National Institutes of Health, and FDA, and the Department of Defense, as needed. There is also a policy level Interagency TSE Working Group that provides support and advice.

Furthermore, USDA and HHS participate on international working groups set up to prevent the spread of BSE to new areas of the world and to standardize approaches for addressing BSE surveillance and response. USDA and HHS participate in OIE meetings as members and consultants, and U.S. representatives offer technical advice on BSE-related issues and uphold U.S. interests in the World Health Organization and the Pan American Health Organization as well. Since 1986, the United States has exchanged scientists with several European countries, and U.S. officials have historically and routinely met with their counterparts in many countries on animal health risk mitigation measures. A standing North American Animal Health Committee that includes chief veterinary officers from Canada, Mexico, and the United States has developed and is working to implement a North American BSE strategy. After the finding of the BSE-positive cow in Canada in May 2003, U.S., Canadian, and Mexican officials sent a letter to the OIE regarding a scientific approach to BSE and trade issues. The United States has also taken a leadership role by proposing a new ''minimal risk'' BSE classification and criteria for trade in low-risk products for countries with established mitigation measures and a low incidence of BSE (APHIS Docket No. 03–080–1; 68 FR 62386–62405; November 4, 2003: ''Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities'').

IV. OIE Standards

As recognized in the Agreement on the Application of Sanitary and Phytosanitary Measures (''SPS Agreement'') under the auspices of the World Trade Organization (''WTO''), the OIE is the relevant international organization responsible for development and periodic review of standards, guidelines, and recommendations with respect to animal health and zoonoses (diseases that are transmissible from animals to humans). The OIE criteria for terrestrial animals (mammals, birds, and bees) are detailed in the *Terrestrial Animal Health Code* (available on the OIE Web site at *http://www.oie.int*).

Chapter 2.3.13 of the *Terrestrial Animal Health Code* describes the OIE standards with regard to BSE and is supplemented by Appendix 3.8.4 on surveillance and monitoring systems for BSE. The OIE standards for diagnostic tests with regard to BSE are described in Chapter 2.3.13 of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.* However, the OIE standards are constantly evolving and are subject to change in response to new scientific findings and perspectives.

The current OIE standards contain criteria for establishing the BSE risk status of a country or zone. Under the current standards, the BSE-risk status of a country or zone is determined on the basis of a risk assessment identifying all potential factors for BSE occurrence and their historic perspective; an assessment of the likelihood that a TSE agent has been introduced via the importation of potentially contaminated animals or commodities (*i.e.*, meat-and-bone meal or greaves (the protein-containing residue obtained after the partial separation of fat and waste during the process of rendering), live animals, animal feed and feed ingredients, and products of animal origin for human consumption); and an assessment of the likelihood of exposure of the BSE agent to cattle, based on a consideration of a number of criteria, including the

existence and duration of a feed ban and BSE surveillance and monitoring programs. In addition, risk status levels are based on the length of time for demonstrated compliance with these criteria and on the reporting of BSE cases or BSE incidence rate.

To increase the likelihood of detecting BSE, the OIE recommends surveillance targeting cattle displaying clinical signs compatible with BSE and cattle that have died or been killed for reasons other than routine slaughter. In countries or zones not free of BSE, the OIE recommends routine sampling at slaughter. Surveillance should focus primarily on cattle over 30 months of age. The OIE also recommends a minimum number of samples to be taken from the targeted population for effective surveillance, based on the total cattle population over 30 months of age.

The OIE currently specifies five BSE status levels for countries or zones: Free, provisionally free, minimal risk, moderate risk, and high risk. The purpose of the categorization system is to enable and encourage appropriate risk mitigation measures to be applied to commodities for trade.

The OIE also sets international standards for trade in live cattle, fresh meat and meat products, gelatin and collagen prepared from bones, tallow and tallow derivatives, and dicalcium phosphate, according to the BSE risk status of a country or zone. In order to protect public and animal health, the OIE currently recommends different risk mitigating measures, with increased requirements as the status of a country or zone moves from lower to higher levels of BSE risk. The present OIE Code does not suggest a total embargo of animals and animal products coming from BSE affected countries, not even from countries considered as having high BSE risk, as long as the proper risk mitigation measures are applied.

The OIE also identifies certain commodities that should not require any BSE-related restrictions, regardless of the BSE status of the exporting country or zone. For example, the *Terrestrial Animal Health Code* does not recommend any restrictions, regardless of the BSE status of the country, in trade of semen, embryos, milk, milk products, and gelatin and collagen coming from hides and skins because these products or tissues have not demonstrated BSE infectivity in cattle.

The actions taken by the U.S. Government to prevent the introduction and spread of BSE in the United States are generally consistent with international standards for BSE, although not in all cases exactly the same. For example, U.S. surveillance for BSE in cattle has exceeded the OIE standards since 1993. Based on an adult cattle population of approximately 40 million, the OIE standard (Terrestrial Animal Health Code Appendix 3.8.4) calls for a minimum of 433 samples. By comparison, the United States has increased the number of samples from approximately 700 in fiscal year 1993 to approximately 20,000 in fiscal year 2002.

USDA appreciates the significant contributions of the OIE to science-based understanding of the true BSE-related risks in international trade and will continue to work with the OIE and other relevant international organizations. The United States is also taking a leadership role by proposing criteria for low-risk product trade with countries that have a low incidence of BSE and historically strong risk mitigation measures, mentioned previously in this document in section III, *The Case in Washington State and U.S. Actions in Response,* under *Guidance and Strategy.*

V. Recommendations of the IRT and Additional Measures for Consideration

A. Response Actions

In its general remarks about actions taken by the United States in response to the case of BSE in Washington State, the IRT, under ''Response actions,'' recommended that policy actions under consideration by the United States achieve the following objectives:

- Reduce public health risk for consumer protection.
- Limit recycling and amplification of the agent.
- Establish the level of effectiveness of measures through surveillance.
- Prevent any inadvertent introduction of BSE from abroad in the future.
- Contribute to the prevention of the spread of the epidemic worldwide [p. 3].

The IRT report further stated:

> To achieve the above objectives, a system of complementary barriers, and implementation and enforcement of all measures on the national level, is necessary.
>
> The objectives cannot be successfully achieved by government alone; effective implementation of measures requires a shared commitment and action on the part of national and state governments, producers, consumers, private industry, and veterinary professionals. Extensive national coordination and cooperation is imperative, and should be extended to include the continent of North America. We suggest that a BSE task force, which includes governmental and non governmental stakeholders, is established under the leadership of the USDA in order to assure that policies are developed and implemented in a consistent, scientifically valid manner. [p. 3]

As noted earlier in section III, *The Case in Washington State and U.S. Actions in Response,* under *Guidance and Strategy,* both the Secretary of Agriculture and the Commissioner of FDA have advisory committees, which include both governmental and nongovernmental stakeholders, to provide guidance on issues concerning BSE and other TSEs. There are also technical and policy level interagency working groups on TSEs.

USDA welcomes comment on the following question:

1. Would there be value in establishing a specialized advisory committee or standing subcommittee on BSE?

The IRT also evaluated actions taken by the U.S. Government in response to the confirmation of the case of BSE in the United States and made recommendations regarding further actions that could provide additional public or animal health benefits. We are requesting public comment below on additional measures we are considering based on the IRT's recommendations. Because we believe that prior actions taken by the Federal Government already address IRT recommendations related to surveillance, laboratory diagnosis, non-ambulatory (downer) cattle, and certain other recommendations (*e.g.,* concerning the mechanical removal of bone from beef) (see the discussions in section III, *The Case in Washington State and U.S. Actions in Response),* we are not specifically requesting comment on those recommendations.

B. The Human Food Supply

In the section of the IRT report headed, ''Specified Risk Materials (SRM),'' the IRT stated:

> Unless aggressive surveillance proves the BSE risk in the USA to be minimal according to OIE standards, the [IRT] recommends that the SRM identified below be excluded from both the human and animal food chains.
>
> - Brain and spinal cord of all cattle over 12 months of age.
> - Skull and vertebral column of cattle over 12 months of age—these are not inherently infected, but cannot be separated from dorsal root/trigeminal ganglia or from residual contamination with CNS tissue.
> - Intestine—from pylorus to anus—from all cattle.
>
> In the mean time, until the level of BSE risk has been established, the [IRT] concedes that exclusion of CNS, skull, and vertebral column from cattle over 30 months, and intestines from cattle of all ages, for use in human food is a reasonable temporary compromise. [pp. 3–4]

USDA has initiated an aggressive and comprehensive surveillance program that will assist in estimating the prevalence of BSE in the United States and provide a basis for further assessments of whether and how U.S. actions related to BSE should be adjusted. Also, FSIS and FDA require the exclusion of CNS tissue, skull, and vertebral column from cattle 30 months of age and older, and the small intestine and tonsils from cattle of all ages, from human food, including dietary supplements, and cosmetics.

With regard to the age of cattle from which SRMs should be removed, FSIS and FDA have specified that CNS tissue, skull and vertebral column should be removed from cattle 30 months of age and older. Research to date indicates that 30 months is the appropriate threshold for removal of these materials unless surveillance indicates that there is a high prevalence of BSE in the U.S. cattle population, which the agencies believe is unlikely because of the feed and import restrictions that the Federal Government has imposed. The reason that age matters at all is that levels of infectious agent in certain tissues vary with the age of animal. Pathogenesis studies, where tissues obtained from orally infected calves were assayed for infectivity, have shown that infectivity was not detected in most tissues until at least 32 months post-exposure.[10] The exception to this is the distal ileum, the distal portion of the small intestine, where infectivity was confirmed from experimentally infected animals as early as 6 months post-exposure and tonsils, where infectivity was confirmed at 10 months post-exposure.

Although a few cases of BSE have been found in cattle under 30 months of age, research demonstrates that the shorter incubation period (*i.e.*, infection developing in less than 30 months) is apparently linked to younger animals receiving a relatively large infectious dose.[11] The younger cases have occurred primarily in countries with significant levels of circulating infectivity. Specifically, BSE has been found in animals less than 30 months of age in the United Kingdom in the late 1980s to early 1990s, when the incidence of BSE was extremely high. This research also suggests that a calf must receive an oral dose of 100 grams of infected brain material containing high levels of the infectious agent to produce disease within a minimum of approximately 30 months.[12]

BSE testing in the European Union (EU) was conducted throughout the year 2001. This testing revealed only two positive animals that were younger than 30 months of age in a total of 2,147 positive cases. Of note is that these animals were 28 and 29 months of age. For reference, in 2001, a total of 8,516,227 tests were conducted within the EU, and, of those, 1,366,243 tests were conducted on animals less than 30 months of age. In 2002, there were no animals less than 30 months of age that were positive in the EU testing scheme. Approximately 10.2 million tests were conducted in EU Member States in 2002, and, of these, 1.6 million were conducted on animals less than 30 months of age. The average mean age of positive animals in the EU in 2002 was 96.9 months, an increase from 85.9 months in 2001.[13]

This suggests an effective and prudent dividing line for purposes of mitigating risk. Infected cattle over 30 months of age may have levels of the abnormal prion in affected tissues that are sufficient to infect other animals fed protein derived from these tissues. Infected cattle younger than 30 months of age are unlikely to have infectious levels of the prion protein.[14] The 30-month age limit is accepted internationally in BSE standards set by various countries and is consistent with OIE recommendations.

With respect to the IRT recommendation that the entire intestine from cattle of all ages should be excluded from the human and animal food chains, FSIS noted in its SRM rule that BSE infectivity has only been confirmed in the distal ileum of the small intestine. FSIS requires the entire small intestine to be removed and disposed of as inedible to ensure effective removal of the distal ileum. Consistent with USDA's restrictions, FDA prohibits the use of the small intestine in FDA-regulated human food and cosmetics.

Note: The aspect of this recommendation pertaining to removal of SRMs from animal feed is addressed below under ''Animal Feed Restrictions.'')

FSIS and FDA request comment, especially scientific information, on the following question:

2. What data or scientific information is available to evaluate the IRT recommendation described above, including that aspect of the recommendation concerning what portion of the intestine should be removed to prevent potentially infective material from entering the human food and animal feed chains?

C. Animal Feed Restrictions

Specified Risk Materials (SRMs)

In the ''Feed Restrictions'' section of the report, the IRT recommended: ''All SRM should be excluded from all animal feed, including pet food.'' [p. 5] FDA has prohibited the use of most mammalian proteins in ruminant feed since 1997. The IRT report stated that, ''Considering the BSE situation in North America, the [IRT] believes the partial (ruminant to ruminant) feed ban that is currently in place is insufficient to prevent exposure of cattle to the BSE agent.'' [p. 5] The IRT further stated that, ''While science would support the feed bans limited to the prohibition of ruminant derived [meat and bone meal] MBM in ruminant feed, practical difficulties of enforcement demand more pragmatic and effective solutions.'' [p. 6] Specifically, the IRT cited epidemiological evidence in the United Kingdom that highlight the dangers of cattle infection through the consumption of feed that had been contaminated accidentally when manufactured in premises that legitimately used mammalian meat and bone meal in feed for pigs and poultry. [p. 5] In addition, the IRT report cited an ongoing attack rate study at the Veterinary Laboratories Agency in the United Kingdom that demonstrates

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[10] Wells, G.A.H., *et al.* 1994. Infectivity in the ileum of cattle challenged orally with bovine spongiform encephalopathy. Veterinary Record. 135 (2): 40–41.

Wells, G.A.H., *et al.* 1998. Preliminary observations on the pathogenesis of experimental bovine spongiform encephalopathy (BSE): An update. Veterinary Record. 142: 103–106.

European Union Scientific Steering Committee (EU SSC), 2002. Update of the opinion on TSE infectivity distribution in ruminant tissues (initially adopted by the Scientific Steering Committee at its meeting of 10–11 January 2002 and amended at its meeting of 7–8 November 2002) following the submission of (1) a risk assessment by the German Federal Ministry of Consumer Protection, Food, and Agriculture and (2) new scientific evidence regarding BSE infectivity distribution in tonsils; European Commission, Scientific Steering Committee, Health and Consumer Protection Directorate General; *http://www.europa.eu.int/comm./food/fs/sc/ssc/outcome_en.pdf.*

[11] EU SSC 2002 (see footnote 9).

[12] EU SSC 2002 (see footnote 9).

Department for Environment, Food and Rural Affairs (DEFRA), U.K., 2003; DEFRA BSE information, *http://www.defra.gov.uk/animalh/bse/index.htm.*

[13] European Commission (EC), 2002; Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathy (TSE) in 2001, European Commission Health and Consumer Protection Directorate-General; *http://europa.eu.int/comm/food/fs/bse/bse45_en.pdf.*

European Commission (EC), 2003; Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathy (TSE) in 2002, European Commission Health and Consumer Protection Directorate-General; *http://europa.eu.int/comm/food/fs/bse/testing/annual_%20report_2002_en.pdf.*

[14] Wells, *et al.*. 1994; Wells, *et al.*. 1998; EU SSC 2002 (see footnote 9).

transmission of BSE with 10 mg of infectious brain tissue. [p. 5] Although not yet published, more recent results from this study have demonstrated transmission with a lower dose of infectious brain tissue. These levels are significantly lower than the 1 gram infectious dose that had been demonstrated in the same study at the time the 1997 BSE feed rule was issued. Further, the Harvard-Tuskegee Study showed that removing SRMs from all animal feed reduces by 88 percent the potential exposure of cattle to the BSE agent when 10 BSE infected cattle are introduced into the United States. Accordingly, FDA has tentatively concluded that it should propose removing SRMs from all animal feed to adequately control the risks associated with cross contamination throughout feed manufacture and distribution and with intentional or unintentional misfeeding on the farm. FDA is currently working on a proposal to accomplish this goal.

To assist FDA in completing that proposal, FDA seeks comment on the following questions:

3. What information, especially scientific data, is available to support or refute the assertion that removing SRMs from all animal feed is necessary to effectively reduce the risks of cross-contamination of ruminant feed or of feeding errors on the farm? What information is available on the occurrence of on-farm feeding errors or cross-contamination of ruminant feed with prohibited material?

4. If SRMs are prohibited from animal feed, should the list of SRMs be the same list as for human food? What information is available to support having two different lists?

5. What methods are available for verifying that a feed or feed ingredient does not contain SRMs?

6. If SRMs are prohibited from animal feed, what requirements (labeling, marking, denaturing) should be implemented to prevent cross-contamination between SRM-free rendered material and material rendered from SRMs?

7. What would be the economic and environmental impacts of prohibiting SRMs from use in all animal feed?

8. What data are available on the extent of direct human exposure (contact, ingestion) to animal feed, including pet food? To the degree such exposure may occur, is it a relevant concern for supporting SRM removal from all animal feed?

Cross Contamination

The ''Feed restrictions'' section of the IRT report also stated:

> Cross contamination must be prevented throughout the feed chain, from reception and transportation of feed ingredients, during the manufacturing process, through transportation and storage of finished feed, and on farm where mixing, blending, and feeding will occur. [p. 6]

The 1997 feed rule required manufacturers and distributors that handle both prohibited and nonprohibited material to control cross contamination by either: (1) Maintaining separate equipment or facilities; or (2) using clean-out procedures or other means adequate to prevent carry-over of prohibited material into feed for ruminant animals. In response to the finding of a BSE-positive cow in Washington State, FDA announced its intention to strengthen measures to prevent cross contamination by requiring dedicated equipment or facilities. However, in light of the IRT's recommendations, if SRMs are prohibited in all animal feed, dedicated facilities may no longer be necessary to reduce the risk associated with cross contamination. Therefore, FDA is reevaluating the need for requiring dedicated facilities.

FDA seeks comment on the following questions:

9. What information, especially scientific data, is available to show that dedicated facilities, equipment, storage, and transportation are necessary to ensure that cross contamination is prevented? If FDA were to prohibit SRMs from being used in animal feed, would there be a need to require dedicated facilities, equipment, storage, and transportation? If so, what would be the scientific basis for such a prohibition?

10. What would be the economic and environmental impacts of requiring dedicated facilities, equipment, storage, and transportation?

11. What information, especially scientific data, is available to demonstrate that clean-out would provide adequate protection against cross contamination if SRMs are excluded from all animal feed?

All Mammalian and Avian Protein

As reported in the ''Feed restrictions'' section of the IRT report:

> The [IRT] recommends that the current feed ban be extended to exclude all mammalian and poultry protein from all ruminant feeds, and that this ban as well as measures to prevent cross contamination be strongly enforced. This recommendation must be enforced through an inspection program including sampling and testing of feed. [p. 6]

As noted previously, although the IRT agreed that ''science would support the feed bans limited to the prohibition of ruminant derived MBM in ruminant feed,'' the IRT stated that ''practical difficulties of enforcement demand more pragmatic and effective solutions.'' [p. 6] In particular, the IRT said:

> The prohibition of the use of all MBM (including avian) in ruminant feed is justified partly due to the issues of cross contamination as well as the current problems in differentiating mammalian and avian MBM. It also prevents the inclusion of ruminant derived protein contained within the lumen of porcine or avian intestines at slaughter in animal feed that may be used for ruminants. [p. 6]

Although the IRT discussed the problems with rendered MBM, the IRT report did not specifically address the potential risks from other mammalian and avian protein, such as milk, blood, gelatin, and tallow (rendered fat) that may contain small amounts of protein. The 1997 final rule, which banned the use of most mammalian protein in ruminant feed, did not include these materials in the definition of animal proteins prohibited in ruminant feed because they were not considered to pose a risk of BSE transmission. Prior to release of the IRT recommendations, FDA had announced its intentions to eliminate exemptions in the current ruminant feed rule for blood and blood products and plate waste, and to prohibit the practice of incorporating poultry litter into ruminant feed. FDA is now evaluating whether the announced measures need to be modified in light of the IRT recommendations. With respect to tallow, the OIE categorizes tallow with a maximum level of insoluble impurities of 0.15 percent as protein-free tallow and recommends that tallow that meets this standard be freely traded regardless of the BSE status of the country of origin.

FDA seeks comment on the following questions:

12. What information, especially scientific data, supports banning all mammalian and avian MBM in ruminant feed?

13. If SRMs are required to be removed from all animal feed, what information, especially scientific data, is available to support the necessity to also prohibit all mammalian and avian MBM from ruminant feed, or to otherwise amend the existing ruminant feed rule?

14. What would be the economic and environmental impacts of prohibiting all mammalian and avian MBM from ruminant feed?

15. Is there scientific evidence to show that the use of bovine blood or blood products in feed poses a risk of BSE transmission in cattle and other ruminants?

16. What information is available to show that plate waste poses a risk of BSE transmission in cattle and other ruminants?

17. If FDA were to prohibit SRMs from being used in animal feed, would there be a need to prohibit the use of poultry litter in ruminant feed? If so, what would be the scientific basis for such a prohibition?

18. What would be the economic and environmental impacts of prohibiting bovine blood or blood products, plate waste, or poultry litter from ruminant feed?

19. Is there any information, especially scientific data, showing that tallow derived from the rendering of SRMs, dead stock, and non-ambulatory disabled cattle poses a significant risk of BSE transmission if the insoluble impurities level in the tallow is less than 0.15 percent?

Non-Ambulatory (Downer) Cattle

In the ''Non-ambulatory (downer) cows'' section of the report, the IRT noted the need to prevent potentially infective tissues from entering the feed chain. [p. 4] In addition to downer cattle, FDA is concerned about cattle that die on the farm or are killed for humane reasons (*i.e.*, dead stock) because they are also among the highest risk cattle population. Furthermore, little, if any, infrastructure is in place for removal of SRMs from cattle that are not slaughtered as part of the routine process that occurs at government inspected slaughter establishments. As previously discussed, the Harvard-Tuskegee Study showed that prohibiting rendering of animals that die on the farm would reduce the potential cases of BSE following hypothetical exposure by a further 82 percent from the base case scenario. Thus, FDA is evaluating the need to prohibit materials from non-ambulatory disabled cattle and dead stock from use in all animal feed.

FDA seeks comment on the following questions:

20. Can SRMs be effectively removed from dead stock and non-ambulatory disabled cattle so that the remaining materials can be used in animal feed, or is it necessary to prohibit the entire carcass from dead stock and non-ambulatory disabled cattle from use in all animal feed?

21. What methods are available for verifying that a feed or feed ingredient does not contain materials from dead stock and non-ambulatory disabled cattle?

22. What would be the economic and environmental impacts of prohibiting materials from dead stock and non-ambulatory disabled cattle from use in all animal feed?

Disposal of SRMs and Non-Ambulatory Disabled Cattle

Additionally, in the ''Feed restrictions'' section of the report, the IRT stated:

> Recognising the absence of an established infrastructure for the separation and disposal of SRM or MBM the subcommittee accepted that a staged approach may be necessary for implementation. Exclusion and destruction of such a high volume of raw material is a massive burden on all countries currently affected by BSE. Given the susceptibility of cattle to low dose exposure, and the fact that no processing system exists at present to guarantee destruction of infectivity in commercial processes, it is probable that restoration of traditional uses in feed may be impossible. More radical and innovative solutions are required to enable the safe use of such materials in future. This should include adding value through their use for purposes other than the manufacture of feed and fertilisers (*e.g.* as a fuel source.) [p. 6]

USDA's Rural Business-Cooperative Service announced on May 18, 2004, a pilot project to provide guaranteed loans to rural small businesses for developing renewable energy systems primarily through use of specified risk materials, non-ambulatory cattle, or other cattle deemed to be at risk of carrying BSE (69 FR 28111–29119). Applications must be received by August 16, 2004.

APHIS welcomes comment on the following question:

23. What other innovative solutions could be explored?

D. Animal Identification (Traceability)

In the section of the IRT report headed, ''Traceability,'' the IRT acknowledged that the U.S. Government has ''recognized the importance of effective identification and traceability systems, that have value not only for the cost-effective and rapid tracing of animals for culling, but also for containment of contagious diseases.'' [p. 6] The IRT ''encourages the implementation of a national identification system that is appropriate to North American farming.'' [p. 6]

As discussed in section III, *The Case in Washington State and U.S. Actions in Response,* under *Animal Identification (Traceability),* APHIS is implementing a national animal identification system.

The national animal identification system will allow the Federal Government to trace back and trace forward animals potentially exposed to a disease of concern. Traceback refers to the ability to track an animal's location over its lifespan and the ability to determine which animals may have been in contact with the diseased animal or shared a contaminated feed supply. Trace forward data provides locations of animals moved out of the premises of concern that may have been exposed to the disease. When fully implemented, the national animal identification system calls for a trace to be completed within 48 hours of detecting a disease, thereby helping to contain an outbreak. The ability to achieve the 48-hour goal is directly related to the completeness of animal movement data that is reported to the national system. Developing and establishing all components of this national system present significant challenges.

APHIS recognizes the need to be able to ensure that data provided by producers is protected, and that all components of the system are in place and have been tested, before making the system mandatory. APHIS also recognizes that market forces will affect producer involvement (*e.g.*, some establishments may begin to accept only animals that are identified under the national system).

APHIS invites comment on the following questions:

24. When and under what circumstances should the program transition from voluntary to mandatory?

25. What species should be covered, both initially and in the longer term? Specifically, should the initial emphasis be on cattle, or also cover other species? If so which? Which species should be covered by the program when it is fully implemented? What priority should be given to including different species?

E. Education

In the section of the IRT report headed, ''Education,'' the IRT stated:

> BSE educational programs must be designed to meet the needs of multiple audiences with variable levels of scientific training. Countries around the world have routinely underestimated the need for a wide variety of educational materials and training techniques to meet both technical and non-technical audiences. The [IRT] recommends that extensive education and training materials be developed in collaboration with academic, professional, trade and consumer organizations so that scientifically sound and accurate information about the nature of BSE and the importance of aggressive prevention and control strategies can be disseminated widely and incorporated into the curricula of schools, college, universities and professional continuing education programs. As traceability, transparency and access to current information increases, so does consumer confidence and effectiveness of the control and prevention measures. [pp. 6–7]

FDA, FSIS, and APHIS continue to develop educational and training materials. BSE became a reportable

disease in the United States in 1986. In May 1990, USDA began educational outreach to veterinarians, cattle producers, and laboratory diagnosticians regarding the clinical signs and diagnosis of BSE. These activities have been broadened both in terms or scope and targeted audiences in recent years, to include awareness programs for personnel involved in the transportation, marketing, and slaughter of cattle, as well as the general public, through various means, including frequent briefings and press conferences, fact sheets, videotapes, and information on its web site. FDA has conducted training for Federal and State investigators conducting inspections of feed mills, rendering establishments, and other regulated facilities, developed educational materials, including a CD, for investigators and the industry on the inspection process, developed guidance documents for each of the industry segments affected by the regulations, available on the Internet and in Spanish; and collaborated with industry organizations to develop educational materials for specific audiences.

All three agencies welcome comment on the following questions:

26. How can training and educational materials be designed or improved to meet the needs of multiple audiences with variable levels of scientific training?

27. How can the Federal Government increase access to these materials?

VI. Other Considerations

A. Animal Feed Measures

FDA believes it is necessary to consider the current state of technology when developing new requirements for animal feeds. The IRT report cites the limitations of sampling techniques and test sensitivity as the rationale, in part, for why further restrictions are needed to prevent cross contamination. The IRT noted:

> If at some point it becomes possible through other means (*e.g.*, inspection, testing, and enforcement) to achieve the equivalent result of assuring that no ruminant proteins are ingested by ruminants, then exclusion of all mammalian protein from feed for ruminants may not be required.

FDA is interested in the impact of technology development on all possible new requirements and seeks comment on the following questions:

28. Should FDA include exemptions to any new requirements to take into account the future development of new technologies or test methods that would establish that feed does not present a risk of BSE to ruminants?

29. If so, what process should FDA use to determine that the technologies or test methods are practical for use by the feed industry and ruminant feeders and provide scientifically valid and reliable results?

B. FDA Authority

FDA requests comments on the following questions:

30. Do FDA's existing authorities under the Federal Food, Drug, and Cosmetic Act (that address food adulteration and misbranding) and under the Public Health Service Act (that address the prevention and spread of communicable diseases) provide a legal basis to ban the use of SRMs and other cattle material in nonruminant animal feed (*e.g.*, feed for horses, pigs, poultry, etc.) notwithstanding that such materials have not been shown to pose a direct risk to nonruminant animals? More specifically, under FDA's existing legal authorities, would the potential occurrence of on-farm feeding errors, of cross contamination of ruminant feed with SRMs and other cattle material, or of human exposure to nonruminant feed (including pet food) provide a basis to ban SRMs and other cattle material from all animal feed?

31. Are there other, related legal issues on which FDA should focus?

C. Sanitation and Cross Contamination

As discussed in section III, *The Case in Washington State and U.S. Actions in Response,* under *Safeguards on Food and Feed Supplies,* to ensure that that establishments that slaughter or process cattle that are 30 months of age or older, as well as cattle that are younger than 30 months of age, are taking appropriate actions to prevent contamination of edible carcasses and parts with SRMs, FSIS has developed procedures for its inspection program personnel to verify that the equipment (*e.g.*, saws and knives) is properly cleaned and sanitized between carcasses or parts. FSIS also issued a press release during the comment period for its SRM rule to specifically solicit public comment on methods used to prevent cross contamination of carcasses with SRMs. One comment has suggested that FSIS require dedicated equipment for the removal and severing of SRMs, noting that the Canadian Food Inspection Agency requires that Canadian establishments use dedicated knives to sever the spinal cord of cattle 30 months of age and older. Also, because cattle infected with BSE are more likely to contain infectious levels of the BSE agent if they are 30 months of age and older, equipment that comes in contact with SRMs exclusively from cattle 30 months of age and older could potentially become contaminated with high levels of the BSE agent and come in contact with edible tissue. Therefore, FSIS is evaluating the need for additional sanitation requirements to prevent cross contamination of edible portions of carcasses with SRMs in establishments that predominantly slaughter cattle 30 months of age and older.

FSIS welcomes comment, especially scientific information, on the following questions:

32. What measures are necessary to prevent cross contamination between carcasses?

33. In establishments that predominantly slaughter cattle 30 months of age and older. are additional sanitation requirements necessary to prevent edible portions of carcasses from being contaminated with SRMs?

D. Equivalence

In response to the FSIS rule that prohibits SRMs and non-ambulatory disabled cattle for use in human food, FSIS has received several comments from countries that consider themselves ''BSE free'' requesting that the Agency exempt countries recognized as ''BSE free'' or ''provisionally free'' from the requirements of the interim final rule. According to these countries, their BSE status provides the same level of protection against BSE that is achieved domestically by the provisions in the FSIS interim final rule. Therefore, these countries assert that their BSE status is an ''equivalent sanitary measure.''

Meat and meat products exported to the United States from another nation must meet all sanitary standards applied to meat and meat products produced in the United States. The United States makes determinations of equivalence by evaluating whether foreign food regulatory systems attain the appropriate level of protection provided by our domestic system. Thus, while foreign food regulatory systems need not be identical to the U.S. system, they must employ equivalent sanitary measures that provide the same level of protection against food safety hazards as achieved domestically.

Currently, the prohibition on the use of materials designated as SRMs in FSIS'' SRM rule applies to all such materials, regardless of the BSE status of the country of origin, as does the prohibition on the slaughter of non-ambulatory disabled cattle. However, as discussed earlier in this document, the OIE standards for trade in bovine-derived products, including meat and meat products, take into consideration the BSE risk status of a country or zone.

Therefore, FSIS is evaluating whether the Agency should consider a country's BSE risk when determining whether a country has implemented equivalent sanitary measures to those required by the United States to prevent human exposure to the BSE agent. Issues under consideration by FSIS include whether the Agency should develop and apply its own standards for determining a country's BSE risk; whether it should adopt and apply existing standards; and whether FSIS should conduct its own evaluation to determine a country's BSE risk for purposes of determining equivalence or whether it should rely on a third party evaluation.

Therefore, FSIS requests comments on the following questions:

34. Should FSIS provide an exemption for ''BSE free'' countries or countries with some other low-risk BSE designation?

35. If FSIS were to exempt ''BSE free'' countries from the provisions of the SRM rule, what standards should the Agency apply to determine a country's BSE status?

36. How would FSIS determine that country meets such standards? For example, should it rely on third party evaluations, such as the OIE, or conduct its own evaluation?

In the interim final rule on prohibited cattle material in human food and cosmetics published in the Rules and Regulations section of this **Federal Register**, FDA also has requested comments on standards to apply when determining another country's BSE status, providing an exemption for ''BSE-free'' countries, and how to determine that countries meet any standards that might be developed. FDA will work with USDA in developing a harmonized U.S. position for dealing with these issues.

VII. Submission of Public Comments

APHIS, FSIS, and FDA invite public comment on the issues and questions presented in this ANPRM. To facilitate each agency's review of comments, we ask that comments be submitted to the agency (APHIS, FSIS or FDA) that is seeking comment on the particular question the comment addresses. The agency or agencies that wish to receive comments on a particular issue are identified before each question or set of questions in sections V or VI. Comments should be submitted to all agencies only when comments address general questions or issues applicable to all agencies. Comment submissions should include the appropriate agency docket number(s). Please refer to the docket numbers and instructions for submitting comments in the **ADDRESSES** section at the beginning of this document.

Please also note that the comment periods established by each agency are different. FDA intends to issue a proposed rule on animal feeds subsequent to publication of this ANPRM. To facilitate FDA's consideration of those comments in developing the proposed rule, please submit comments specific to the FDA issues and questions to FDA prior to close of the 30-day comment period listed for FDA in the **DATES** section of this document. APHIS and FSIS will accept comments for 60 days, as provided in the **DATES** section of this document.

Authority: 7 U.S.C. 8301–8317; 21 U.S.C. 321, 342, 343, 348, 371, and 601–695.

Done in Washington, DC, this 8th day of July, 2004.

Bill Hawks,

Under Secretary, Marketing and Regulatory Programs, USDA.

Elsa Murano,

Under Secretary, Food Safety, USDA.

Dated: Done in Washington, DC, this 8th day of July, 2004.

Lester M. Crawford,

Acting Commissioner of Food and Drugs.

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