（参考資料）

１　米国食品医薬品局が平成１７年１０月６日に公表した飼料規則改正案について

（参考）

米国食品医薬品局が公表した飼料規則改正案の概要
（２００５年１０月４日プレスリリース、１０月６日官報掲載）

１　今回の改正はＢＳＥの媒体となりうる高リスク原料について全ての動物に対する飼料等としての使用を禁止するものであり、油脂に関するものを除き、１９９７年以降牛に対する飼料へは適用済みのものである。

２　今回禁止される高リスク原料とは以下のとおり。

(1) ３０か月齢以上の牛の脳及び脊髄

(2) 検査の結果、人の食用に不合格となった場合には、全ての月齢の牛の脳及び脊髄

(3) 検査の結果、人の食用に不合格となり、かつ、脳及び脊髄が除去されない場合には、その牛の全体

(4) 上記(1)～(3)で禁止された原料から製造された機械回収肉

(5) 上記(1)～(3)で禁止された原料から製造された動物性油脂（不溶性不純物０．１５％以下の場合を除く）

３　ＦＤＡは２００４年６月に公表された規則改正案に寄せられた意見を分析し、２００４年６月の改正案におけるその他の規制については、今回の規則案で特定された高リスク部位を飼料から排除すれば必要ないと判断した。

４　今回の規則改正案は官報掲載（１０月６日）から７５日間（１２月２０日まで）のパブリックコメント募集を実施したのち、寄せられたコメントに対して回答の上、速やかに最終規則を発出することとしている。

Federal Register

Thursday,
October 6, 2005

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 589
Substances Prohibited From Use in Animal Food or Feed; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 589

[Docket No. 2002N-0273] (formerly Docket No. 02N-0273)

RIN 0910-AF46

Substances Prohibited From Use in Animal Food or Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the agency's regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals. These materials include the following: The brains and spinal cords from cattle 30 months of age and older, the brains and spinal cords from cattle of any age not inspected and passed for human consumption, the entire carcass of cattle not inspected and passed for human consumption if the brains and spinal cords have not been removed, tallow that is derived from the materials prohibited by this proposed rule that contains more than 0.15 percent insoluble impurities, and mechanically separated beef that is derived from the materials prohibited by this proposed rule. These measures will further strengthen existing safeguards designed to help prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle.

DATES: Submit written or electronic comments by December 20, 2005. Submit written comments on the information collection provisions by November 7, 2005.

ADDRESSES: You may submit comments, identified by [Docket No. 2002N-0273 or RIN 0910-AF46], by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the Electronic Submissions portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). or Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Burt Pritchett, Center for Veterinary Medicine (HFV-222), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6860, e-mail: *burt.pritchett@fda.gov*.

SUPPLEMENTARY INFORMATION:

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I. Background

A. Bovine Spongiform Encephalopathy

BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). In addition to BSE, TSEs also include 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 most widely accepted theory in the scientific community is that the agent is an abnormal form of a normal cellular prion protein. The abnormal form of the prion protein is less soluble and more resistant to heat degradation than the normal form. The abnormal prion does not evoke any demonstrated immune response or inflammatory reaction in host animals. BSE is diagnosed by postmortem microscopic examination of an animal's brain tissue and by detection of the abnormal form of the prion protein in an animal's brain tissue. There is currently no available test to detect the disease in a live animal.

Since November 1986, there have been more than 180,000 confirmed cases of BSE in cattle worldwide. 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 reported

per week. In addition to the United Kingdom, the disease has been confirmed in native-born cattle in 22 European countries and in some nonEuropean countries, including Japan, Israel, Canada, and the United States.

Epidemiological studies have characterized the outbreak of BSE in the United Kingdom as a prolonged epidemic arising at various locations, with all occurrences due to a common source, and have suggested that feed contaminated by a TSE agent was the cause of the disease outbreak (Ref. 1). The subsequent spread of BSE was associated with the feeding of meat-and-bone-meal from rendered BSE-infected cattle to non-infected cattle (Ref. 1). It appears likely that the BSE agent was transmitted among cattle at an increasing rate by ruminant-to-ruminant feeding until the United Kingdom ban on such practices went into effect in 1988 (Ref. 2).

Agricultural officials in the United Kingdom have taken a series of actions to eliminate BSE. These actions include making BSE 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. 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 on 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 beef products contaminated with the agent. To date, approximately 150 probable and confirmed cases of vCJD have been reported in the United Kingdom, where there had likely been a high level of contamination of beef products. It is believed that 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. To date, CDC has 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. Current Animal Feed Safeguards in the United States

In the **Federal Register** of June 5, 1997 (62 FR 30936) (the 1997 ruminant feed final rule), FDA published a final rule to provide that animal protein derived from mammalian tissues is prohibited for use in ruminant feed. Although BSE had not been identified in the United States at that time, the 1997 ruminant feed final rule was put in place to prevent the establishment and amplification of BSE in the United States through animal feed and thereby minimize risk to humans and animals. The 1997 ruminant feed final rule created a new § 589.2000 (21 CFR 589.2000), Animal proteins prohibited in ruminant feed, and established a system of controls to ensure that ruminant feed did not contain animal protein derived from mammalian tissues. The 1997 ruminant feed final rule set out requirements for persons who manufacture, process, blend, or distribute certain animal protein products or ruminant feeds containing such products.

The 1997 ruminant feed final rule (§ 589.2000) prohibits the use of mammalian-derived proteins in ruminant feed, with the exception of certain proteins believed at that time not to pose a risk of BSE transmission. These exceptions to the definition of "protein derived from mammalian tissues" included: Blood and blood products; gelatin; inspected meat products which 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 herein as "plate waste" milk products (milk and milk protein); and any product whose only mammalian protein consists entirely of porcine or equine protein. The 1997 ruminant feed final rule does not prohibit ruminant animals from being fed processed animal proteins derived from nonmammalian species (e.g., avian or aquatic animals). The 1997 ruminant feed final rule permits the manufacture of non-ruminant feed containing prohibited mammalian protein and ruminant feed on the same premises, provided that separate equipment is used in the production of ruminant feed or that documented adequate clean-out procedures are used between production batches.

Following the discovery of a BSE positive cow in Washington State in December 2003, FDA provided guidance on the use of materials from BSE positive cattle. In Guidance for Industry, "Use of Material from BSE Positive Cattle in Animal Feed," published in the **Federal Register** in September 2004 (69 FR 58448), FDA stated its view that under section 402(a)(5) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342(a)(5)), animal feed and feed ingredients containing materials derived from a BSE-positive animal are considered adulterated and should be recalled or otherwise removed from the marketplace.

C. Risk of BSE in North America

In April 1998, the United States Department of Agriculture (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 the BSE risk in the United States. The report, (Ref. 3) widely referred to as the Harvard Risk Assessment or the Harvard Study, is referred to in this document as the Harvard-Tuskegee Study. The study was completed in 2001 and released by USDA. Following a peer review of the Harvard-Tuskegee Study in 2002, the authors released a revised risk assessment in 2003 (Ref. 4).

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, and that measures taken by the U.S. Government and industry make the United States robust against the spread of BSE.

The Harvard-Tuskegee Study concluded that the most effective measures for reducing potential introduction and spread of BSE are as follows: (1) The ban placed by USDA's Animal and Plant Health Inspection Service 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 before 1989, mitigation measures already in place would have minimized exposure and begun to eliminate the disease from the cattle

population even assuming less than complete compliance with the feed ban.

The Harvard-Tuskegee Study also identified pathways or practices that, if addressed, would further decrease the already low risk of spread BSE if it were introduced into the United States. These include the following: (1) Failing to comply with FDA's ruminant feed regulations that prohibit the use of certain proteins in feed for cattle and other ruminants; and (2) rendering of animals that die on the farm (considered the highest risk cattle), and then incorporating (through illegal diversion or cross-contamination) the rendered product in ruminant feed. The Harvard-Tuskegee Study's independent evaluation of the potential additional risk mitigation measures predicts that a prohibition against rendering of animals that die on the farm would reduce potential new cases of BSE in cattle following a hypothetical introduction of 10 infected animals by 80 percent (from 4.3 to 0.77 cases) as compared to the base case scenario, (i.e., present state of the U.S. cattle population, along with government regulations and prevailing agricultural practices, and an assumption of less than complete compliance with the feed ban) (Ref. 4). Further, the study evaluated the impact of a specified risk materials (SRMs) ban that would prohibit high risk materials such as the brain, spinal cord, vertebral column and animals that die on the farm, from inclusion in human and animal food. The analysis predicts that this measure would reduce potential new BSE cases in cattle following a hypothetical introduction of ten infected animals by 90 percent (from 4.3 to 0.53 cases).

In 2003, following the detection 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 (Ref. 5), using the same simulation model developed for the initial Harvard-Tuskegee Study. The results of this assessment were consistent with 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.

On December 23, 2003, USDA announced that a dairy cow in Washington State had tested positive for BSE. The results were confirmed on December 25, 2003, by the Veterinary Laboratories Agency in Weybridge, England. Immediately after the diagnosis was confirmed, USDA, FDA, and other Federal and State agencies initiated an epidemiological investigation (Ref. 6), and began working together to trace any potentially infected cattle, trace potentially contaminated rendered product, increase BSE surveillance, and take additional measures to address risks to human and animal health. The epidemiological investigation and DNA test results confirmed that the infected cow was born and most likely became infected in Alberta, Canada, before Canada's 1997 implementation of a ban on feeding mammalian protein to ruminants.

On January 22 through 24, 2004, the Secretary of Agriculture convened an international panel of experts on BSE. The panel, referred to as the International Review Team (IRT), was asked to: (1) Assess the epidemiological investigation conducted in response to the BSE case in Washington State, (2) provide expert opinion about when the active phase of the investigation should be terminated, (3) consider the response actions of the United States to date, and (4) provide recommendations about actions that could be taken to provide additional meaningful human or animal health benefits in light of the North American experience. The IRT provided its report on February 4, 2004.

In May 2004, USDA contracted with HCRA to update the BSE risk assessment model to reflect its January 2004 rulemaking to prohibit SRMs and certain other cattle material in human food. HCRA was also asked to update the parameters in the model for compliance with FDA's feed ban. HCRA was also asked to model the impact that the IRT recommendation would have on the BSE risk to humans and cattle.

In December 2004, Canada announced that a third North American cow tested positive for BSE. An ongoing epidemiologic investigation found that this animal, an 8-year-old, nonambulatory dairy cow, originated in Alberta, Canada and was born before the Canadian feed ban went into effect in August 1997. Shortly thereafter, in January 2005, another cow in Alberta was found to be positive for BSE. This case involved a beef cow born in March 1998, 6 months after the Canadian feed ban went into effect. Based on preliminary information, Canada believes that the most likely source of infection in this animal was feed produced before implementation of Canada's feed ban (Ref. 7).

In June 2005, USDA announced that a 12-year-old beef cow, born and raised in Texas, was confirmed BSE positive. The BSE-positive cow most likely became infected before FDA's implementation of the 1997 ruminant feed final rule. It was determined that no part of the animal entered the human food or animal feed chains.

D. Additional Measures Considered to Strengthen Animal Feed Safeguards

1. Comments on November 6, 2002, Advance Notice of Proposed Rulemaking (ANPRM)

In the Federal Register of October 5, 2001 (66 FR 50929), FDA announced its plan for an October 30, 2001 public hearing in Kansas City, MO, to solicit comments from the public on the 1997 ruminant feed regulation. Recognizing that new information had emerged since publication of the feed rule in 1997, FDA requested comments on whether changes to the rule or other additional measures were necessary (Ref. 8). Information obtained from the public hearing and from the Harvard-Tuskegee Study was used in the publication of an ANPRM (2002 ANPRM) in the Federal Register of November 6, 2002 (67 FR 67572). This ANPRM sought comment from affected industries and the public on possible ways to strengthen the 1997 ruminant feed regulation. The ANPRM specifically asked for comments on a number of questions related to the following five aspects of the BSE feed regulation: (1) Excluding brain and spinal cord from rendered animal products, (2) prohibiting the use of poultry litter in cattle feed, (3) assessing the improper use of pet food as a feed for ruminants, (4) preventing cross-contamination, and (5) eliminating the plate waste exemption.

The predominant view of those who submitted comments in response to the ANPRM was that the BSE risk in the United States was low enough that no new feed controls were needed. Most said that the current feed ban provided more than adequate protection against BSE, that there was no scientific justification for additional regulations, that compliance with the 1997 ruminant feed final rule was extremely high, and that over 19,900 USDA surveillance samples in 2002 alone failed to detect BSE in U.S. cattle. They also cited the Harvard-Tuskegee Study conclusion that existing control measures made the risk to U.S. cattle and to U.S. consumers from BSE very low.

In the 2002 ANPRM, FDA said that the Harvard-Tuskegee Study identified the removal of high-risk bovine tissues, such as brain, spinal cord, intestine, and eyes, from human food and from rendered material for all animal feed as a way to reduce the potential exposure of cattle and humans to the BSE agent. The 2002 ANPRM then asked for comments on the following three questions related to SRMs: (1) Should high risk materials be excluded from rendered products?; (2) how feasible would it be for the rendering industry

to implement such an exclusion?; and (3) what will be the adverse and positive economic, environmental, and health impacts from an exclusion?

Comments in support of an SRM ban included one comment from USDA citing conclusions from the Harvard-Tuskegee Study that this action would significantly reduce the amount of infectivity in the animal feed chain, and would reduce risks resulting from "leaks" in the feed ban. Other comments stressed the infectivity of these tissues, and the recommendation by the World Health Organization (WHO) that countries exclude these tissues from the animal and human food chain (Ref. 9).

Comments opposing an SRM ban said that the measure would be redundant because the 1997 ruminant feed final rule already prohibits this high-risk material in ruminant feed. Therefore, the ban would only be beneficial if BSE were present in the United States and there were significant non-compliance with the feed ban. The comments also cited the conclusions of the Harvard-Tuskegee Study that the risks of BSE in the United States are low. One comment said that restrictions on SRMs in animal feed should be decoupled from restrictions for human food because of the substantial reduction in infectivity obtained during rendering. Another comment said that an SRM ban would give only the perception of a risk reduction, not a real reduction, and that it would send the message to our trading partners that our BSE risks are such that more controls are needed. Australia asked that, if an SRM ban is implemented, the ban not apply to Australia because of its widely recognized status as a low-risk BSE country.

Numerous comments addressed the feasibility and the adverse economic impacts of an SRM ban. One comment pointed out that it is not feasible to remove central nervous system (CNS) tissue from decomposing carcasses. Comments from a trade association said that an SRM ban would require costly restructuring of facilities that would force many small rendering plants out of business, depriving some parts of the country access to rendering as a means of animal disposal. A June 2002 Sparks Report estimated disposal costs of an SRM ban to be $54 million, based on the assumption that the ban would apply to all cattle because of the difficulty of determining the age of cattle at slaughter (Ref. 10). According to an earlier 1996 Sparks Report, the cost of disposal of 1.7 billion pounds of CNS tissue and dead stock would exceed $400 million. Another estimate for disposal was $50 million for the beef industry alone. One comment said that feed costs account for 70 percent of poultry production cost, and that renderers would pass on the costs of excluding brains and spinal cords to the poultry industry.

Several comments mentioned the environmental impact of an SRM ban. One comment stated that a total ban on SRMs in rendered animal products would create a waste stream with no economic value. Another comment said that a ban on SRMs would encourage improper disposal of dead stock because there are no federal regulations on disposal of dead animals.

2. Actions in Response to Washington State Case

In response to the BSE case identified in Washington State, USDA published an interim final rule in the Federal Register of January 12, 2004 (69 FR 1861), excluding high-risk tissues from human food. The interim final rule prohibited the use of SRMs and certain other cattle material in USDA-regulated human food. USDA defined SRMs as brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebra of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (DRG) of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of cattle of all ages. To ensure effective removal of the distal ileum, USDA requires that the entire small intestine be removed and disposed of as inedible product. In its January 12, 2004, interim final rule, USDA took the additional step of making cattle that are unable to rise from a recumbent position, referred to in this document as nonambulatory disabled cattle, ineligible to be slaughtered for human consumption.

On January 26, 2004, FDA announced its intention to implement additional measures to strengthen existing BSE safeguards for FDA-regulated products. These measures included the issuance of an interim final rule to implement additional measures related to animal feed. The interim final rule would have implemented four specific measures related to animal feeds. These measures included the elimination of the exemptions for blood and blood products and "plate waste" from the 1997 ruminant feed rule, a prohibition on the use of poultry litter in ruminant feed, and a requirement for dedicated equipment and facilities to prevent cross-contamination.

However, on February 4, 2004, IRT released its report on measures related to BSE in the United States. The report recommendations included a somewhat different set of measures for reducing the risks associated with animal feed than the measures FDA had announced that it intended to implement through an interim final rule. Although FDA believed its previously announced measures would serve to reduce the already small risk of BSE spread through animal feed, the broader measures recommended by the IRT, if implemented, could make some of the previously announced measures unnecessary. FDA believed that additional information was needed to determine the best course of action in light of the IRT recommendations and decided to publish an ANPRM, which requested comments on the recommendations of the IRT, as well as on other measures under consideration to protect the animal feed supply.

Consistent with measures implemented by USDA to exclude high-risk cattle tissues from human food (69 FR 1861), FDA published an interim final rule on July 14, 2004 (69 FR 42255), prohibiting a similar list of risk materials from FDA-regulated human food, including dietary supplements, and cosmetics.

3. Comments on July 14, 2004, ANPRM

In the Federal Register of July 14, 2004 (69 FR 42287), FDA published an ANPRM (2004 ANPRM) jointly with USDA in which FDA announced its tentative conclusion that it should propose banning SRMs in all animal feed. In this ANPRM, FDA asked for comment on this measure and also on the IRT's recommendations to require dedicated equipment or facilities for feed manufacture and transport, and its recommendation to prohibit the use of all mammalian and poultry protein in ruminant feed. Finally, FDA also asked for comment on the set of measures that the agency had announced in January 2004. Comments submitted in response to the 2004 ANPRM that relate to SRMs are summarized in sections I.D.3a through I.D.3f by general topic area.

a. *Need for SRM ban.* As with the comments received in response to the 2002 ANPRM, many comments questioned the need for an SRM ban at the time of the 2004 ANPRM. Several comments argued that the comparison made by the IRT between the BSE situations in Europe and the United States is inappropriate. One reason given for the invalid comparison was that there were an estimated 3 to 4 million undiagnosed BSE cases in the United Kingdom, compared to two diagnosed cases in North America in cattle born before feed restrictions were implemented. Another comment said

that the United States did, in fact, learn from the European experience and implemented controls early so that potential animal exposure to the BSE agent in the United States remains exceedingly small compared to the massive exposure in the United Kingdom. One comment submitted by the agriculture department of a state with a large agriculture industry said that its findings from 600 inspections do not support the premise of the IRT's recommendation that an SRM ban is needed to address problems of cross-contamination and on-farm misfeeding. The state indicated that, in these inspections, it did not observe any prohibited materials or feed containing prohibited materials on farms where ruminant feeds were being mixed.

Other comments said that the reduction in risk obtained through an SRM ban would be minimal, mostly citing the effectiveness of the current firewalls in reducing BSE infectivity in the cattle population. One comment said that the Harvard-Tuskegee Study conclusion that an SRM ban will reduce potential cattle exposure to BSE infectivity by 88 percent sounds more impressive than it really is. Reducing a very small risk by 88 percent does not necessarily provide significant risk reduction.

Finally, many comments questioned FDA's decision to ban SRMs from animal feed before the results of USDA's enhanced BSE surveillance program are known. USDA's one-time effort to test as many high-risk cattle as possible was started on June 1, 2004, and was expected to be completed by the end of 2005. One comment pointed out that the IRT's recommendations for defining SRMs are predicated on the outcome of this aggressive surveillance program.

In support of FDA's tentative conclusion that it should propose to ban SRMs from all animal feed, many comments cited the conclusion of the Harvard-Tuskegee Study that an SRM ban will provide additional risk reduction, and also cited the recommendation of the IRT that SRMs should be excluded from all animal feed, including pet food. One comment said that an SRM ban would restore confidence in U.S. beef exports.

b. *Definition of SRMs.* SRMs are typically defined as the tissues in which BSE infectivity has been demonstrated in experimentally or naturally infected animals. SRMs are further defined by the OIE Terrestrial Animal Health Code based on the age of the animal and the BSE risk status of a country. In the 2004 ANPRM, FDA asked how SRMs should be defined for animal feed, specifically, if the SRM list should be the same list as for human food. FDA also asked what information is available to support having two different lists.

Comments from one organization included data from the Harvard-Tuskegee Report on the relative infectivity of specific tissues. These data were based on pathogenesis studies carried out in the United Kingdom and showed the fraction of total infectivity of each tissue to be: Brain 64.1 percent; spinal cord 25.6 percent; dorsal root ganglia 3.8 percent; trigeminal ganglia 2.6 percent; distal ileum 3.3 percent; tonsil <0.1 percent; and eyes <0.1 percent. The comment used the data to make the point that 90 percent of infectivity could be removed by excluding only the brain and spinal cord. A different comment citing the same data pointed out that the infectivity distribution represents more than a worst case scenario because, in the pathogenesis study, the BSE dose administered orally to calves was substantially greater than would reasonably be expected under field conditions. This second comment went on to point out that FDA's interim final rule on food and cosmetics said that in cattle infected under field conditions, BSE infectivity had been demonstrated only in the brain, spinal cord, and retina of the eye at the end stages of the disease.

Many comments recommended that the human food list of SRMs be used to define which SRMs should be excluded from animal feed. Several comments recommended expanding the list beyond the human food list by applying it to tissues from cattle 12 months of age or older, or to tissues from all cattle. Others advocated eliminating bovine or animal protein from ruminant feed altogether. Reasons given by the comments for these recommendations were the large risk reduction that could be achieved and the desirability of being consistent with the requirements for human food.

Those who submitted comments in support of a more limited SRM list mostly did so to minimize the volume of material that would require nonfeed disposal. The comments stated that reducing this volume of material that would require nonfeed disposal would lessen the adverse impact of an SRM ban on the livestock, meat, and animal feed industries. One company used the Harvard model to simulate three different SRM scenarios and then submitted data showing that limiting the SRM list to brain and spinal cord (while also prohibiting use of dead stock and downers over 30 months of age), eliminating vacuum rendering, and keeping the existing feed ban in place, achieved a risk reduction equivalent to that obtained by banning the full human list of SRMs.

The following are other suggestions provided in comments submitted in response to the 2004 ANPRM for reducing the volume of SRM material needing alternative disposal: (1) Allow the use of SRMs from animals that test negative for BSE, (2) designate only the head as an SRM which reduces by 64 percent the potential BSE infectivity in feed, (3) allow the use of intestines from veal calves whose carefully controlled diets consist of low-risk formulas, and (4) allow mechanically separated beef from pet food plants to be used if SRMs are removed before meat is mechanically separated from bones.

c. *Cattle not inspected and passed for human consumption.* The term "cattle not inspected and passed for human consumption" is used in this document to mean cattle that were not inspected and passed for human consumption by the appropriate regulatory authority. For the purposes of this document, this term also includes nonambulatory disabled cattle, i.e., cattle that could not rise from a recumbent position or that could not walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions. This proposed definition is consistent with the use of the terms "inspected and passed and nonambulatory disabled cattle" as defined in USDA's interim final rule on human food (69 FR 1862) and FDA's interim final rule on human food and cosmetics (69 FR 42255). For the purposes of this proposed rule, nonambulatory disabled cattle are included in the definition of cattle not inspected and passed, since nonambulatory disabled cattle cannot be passed for human consumption.

A number of questions were included in the 2004 ANPRM regarding the use of materials from cattle not inspected and passed for human consumption as previously defined. Comments received discussed both the advantages and disadvantages of excluding these animals from being rendered for use in animal feed.

Advantages mentioned included the additional risk reduction that would be provided by the measure. A number of comments cited the Harvard-Tuskegee Study, which showed that removing dead stock from the feed chain would reduce potential exposure of cattle to the BSE agent by 88 percent. However, other comments noted that such a ban would result in dead stock being disposed of on the farm, impacting USDA's surveillance program and

increasing environmental problems due to improper disposal of animal carcasses. Concerns were also expressed about lack of infrastructure for non-feed disposal of dead stock, and the serious economic impact of diverting these animals to alternative disposal.

In response to the question in the 2004 ANPRM about effective removal of SRMs from dead stock and nonambulatory disabled cattle, several comments stated that such removal would not be economically or technically feasible. Other comments stated that SRM material could be effectively removed because there is no substantial difference between the processing of dead and nonambulatory animals at rendering facilities and the processing of healthy cattle at slaughter plants. One other comment mentioned instances where some USDA-inspected deboning facilities already remove SRMs from dead cattle at the request of pet food manufacturers. This comment also said that, based on their experience, SRMs can be removed from dead cattle in all but the hottest months of the year when the rate of decomposition increases. Another comment said that removing SRMs from dead stock may increase exposure of plant employees to pathogens and zoonotic diseases.

One comment noted that the European experience has shown that cattle at highest risk for BSE are dead cattle, downer cattle, and ante-mortem condemned cattle over 30 months of age. This comment said that, while it is possible to remove the meat from these carcasses for use in pet food, they are not aware of any way of verifying the removal of SRMs from dead and nonambulatory cattle (short of active government oversight) that would allow this material to be rendered for use in feeds for non-ruminant animals. Another comment suggested that as an option for reducing the amount of material for disposal, dead stock under 30 months of age be allowed to be rendered for feed use. This comment also said that USDA could test dead stock over 30 months of age, allowing material from negative animals to be used in feed.

d. *Small intestine.* The 2004 ANPRM also requested information to evaluate the IRT recommendation that the entire intestine from cattle of all ages should be excluded from the human and animal food chains. With publication of its interim final rule on January 12, 2004, USDA required that the entire small intestine be disposed of as inedible. Likewise, FDA prohibited the use of the entire small intestine in FDA-regulated human food and cosmetics, even though the agency only considers the distal ileum portion of the small intestine to be a specified risk material (69 FR 42259).

However, based on comments received in response to the FDA interim final rule on human food and cosmetics, FDA concluded that processors have the technology to effectively remove the distal ileum portion from the rest of the small intestine. Thus, FDA amended the human food and cosmetics interim final rule to state that the small intestine is not considered prohibited cattle material if the distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine as measured from the caeco-colic junction and progressing proximally towards the jejunum or by a procedure that the establishment can demonstrate is equally effective in ensuring complete removal of the distal ileum (70 FR 53063, September 7, 2005). This amendment is consistent with USDA requirements (70 FR 53043, September 7, 2005).

Many comments in response to the 2004 ANPRM stated that inclusion of the entire small intestine from cattle less than 30 months of age in the list of prohibited material would double the volume of SRMs from slaughter requiring alternative disposal while only marginally decreasing infectivity. Several comments stated that only the distal ileum should be included in the list of SRMs and noted that it is easily identified for separation at slaughter.

One comment questioned the need to designate the intestinal tract as SRM, pointing out that the distal ileum accounts for only 5 percent of infectivity, which is reduced by two logs during rendering. Another comment said that it was unnecessary to designate any portion of the intestinal tract of cattle less than 30 months of age as SRM because these animals were born 4 1/2 years after the feed ban was implemented, and are therefore low risk animals. Several comments said that, if packers can demonstrate a satisfactory technique, they should be allowed to remove only the distal ileum rather than the entire small intestine.

One comment expressing concern about the BSE risk associated with bovine intestines said that research in the United Kingdom found positive immunostaining for the resistant form of the prion protein along the length of the intestine, which provides evidence that the entire intestine should be considered SRM.

e. *Infrastructure for alternative disposal.* We received a number of comments addressing the issue of disposal infrastructure. One comment noted that the IRT recognized that an infrastructure was not in place to dispose of SRM material and that the IRT had suggested that a staged implementation may be necessary to allow this infrastructure to develop. One comment said that before an SRM ban is implemented a comprehensive plan for disposal of this material needs to be developed. Another comment noted that in Texas, SRMs are considered special waste, and that no landfill in the state is capable of accommodating a large volume of this material. Additional comments indicated that this concern was also true for other states, including Nebraska and Utah.

Two organizations submitted slaughter and cattle mortality data to emphasize the amount of waste that would be generated by regulations that would exclude this material from being rendered for use in animal feed. One of these organizations said that it is deeply concerned that FDA fails to recognize that a suitable disposal infrastructure does not exist to deal with the very large quantities of SRMs that would be generated on a daily basis. Its estimate for the volume of waste generated from slaughter and cattle mortalities was 2 billion pounds per year. The other organization submitted similar comments saying that the U.S. system is currently unprepared to manage the waste disposal challenges certain to arise if significant quantities of livestock mortalities and slaughter byproducts require disposal by means other than rendering. The comments further stated that the disposal and environmental challenges resulting from the ban would be faced immediately, but the solutions to these challenges would arise only after significant time and financial investment across the livestock sector. The comments also said that there is an absence of direct regulatory control over alternative methods of disposing of the enormous quantities of this unpleasant material.

Another comment suggested that renderers should be allowed to dedicate lines to SRM material and SRM-free material within a single facility. Equipment for receiving, grinding, cooking, processing, and conveying could be dedicated lines, while the facility itself, including the utilities, odor control, and wastewater treatment systems be shared. Further, another comment suggested FDA work with the rendering industry to develop cleanout procedures that would allow a plant to process both SRMs and SRM-free material. These procedures would be helpful to allow for seasonal deer rendering, for cleaning up after accidental cross-contamination, and for