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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*.

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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

converting a facility back to SRM-free rendering.

One comment addressed the use of rendered SRM material as an alternative fuel source for cement kilns, indicating that ruminant meat and bone meal and fat are being used as a fuel source in Europe and Japan. According to the comment, these materials burn efficiently, and the heat from the kiln leaves virtually no organic residue.

f. *Verification of SRM removal and SRM marking.* One comment stated that, in the absence of a practical test for verification of SRM removal, the documentation required by HACCP plans should be sufficient to show that SRMs at slaughter are excluded from animal feed channels. Thus, inspections of records could be used to verify SRM removal. Also, the comment stated that FDA can verify SRM removal by shifting resources from inspections of thousands of feed mills and farms to the much smaller number of slaughter plants and renderers.

One comment stated that rendering plants are capable of keeping raw materials from various sources separated and capable of using production, inventory, and shipping records to document the movement of both SRM and SRM-free materials. Such management practices can be verified by inspection, much like those conducted at USDA-inspected cattle slaughter facilities. The comment went on to say that, if a rendering plant is dedicated to rendering only SRMs, such a plant will have to be inspected to determine how it disposes of SRMs.

Two comments suggested that raw or SRM-derived rendered materials can be effectively marked using automatic dosage pumps to dispense markers like glyceroltriheptanoate (GTH). GTH is a C7 synthetic fatty acid not found in nature. A gas chromatography (GC) method for its detection is available. Charcoal was mentioned as another potential marker for use in rendered products.

II. Proposed Measures to Strengthen Animal Feed Safeguards

A. FDA Response to Comments to the 2004 ANPRM

FDA agrees with the numerous comments saying that it is important to keep the BSE risk in the United States in proper perspective. FDA acknowledges that the risk is likely low, and acknowledges that it is inappropriate to compare the BSE situation in the United States to the situation in Europe. However, FDA disagrees with comments concluding that for these reasons no additional measures are needed. Even though strong control measures have been put in place and compliance with the current BSE feed regulation is high by renderers, protein blenders and feed mills, the Agency is concerned, as discussed further below, about such issues as the presence of high risk material in the non-ruminant feed supply and cross-contamination of ruminant feed during the rendering or feed manufacturing process. For example, without fully dedicated equipment, it may not be possible to verify that there is zero carryover of feed or feed ingredients in equipment, even where a firm's cleanout procedures have been judged to be adequate. In addition, resource constraints limit FDA's ability to assure full compliance by all segments of the industry that are subject to the current BSE feed regulation. For example, resources are not available to the FDA and its state counterparts to fully verify compliance on over 1 million farms where cattle are being fed.

FDA does not agree with comments that the agency should wait until USDA completes its enhanced BSE surveillance program before deciding if additional feed controls are needed. As stated in the July 2004 ANPRM, FDA had tentatively decided based on clear evidence that the BSE agent had been introduced into the North American animal feed supply, and based on the recommendation of the IRT, that SRMs should be removed from all animal feed. Results from the enhanced surveillance that was being conducted concurrent with our rulemaking process indicated that BSE had been introduced into the United States, but was present at a very low level. These results reinforced FDA's decision that the measures being proposed are appropriate.

With respect to the definition of SRMs, FDA agrees that prohibiting the full list of SRMs would achieve greater risk reduction than prohibiting a partial list, but also agrees with comments saying that the infrastructure does not currently exist to handle the volume of material that would require non-feed disposal if the full list of SRMs were diverted from animal feed use. Therefore, FDA agrees that focusing on brain and spinal cord is an effective approach for achieving additional animal and public health protection while minimizing the economic, environmental, and public health concerns associated with disposal of the full list of SRMs. FDA, however, seeks comments on whether a full SRM ban is warranted.

Comments were mixed on the feasibility of removing SRMs from dead stock. FDA therefore concluded that some firms would elect to remove SRMs and render the remainder of the carcass, and that this could lessen difficulties associated with alternative disposal. FDA does not agree that allowing test-negative animals to be rendered for animal feed use is appropriate. Unlike Europe, rapid screening tests in the United States have been used only for surveillance purposes. These tests have not been used as food or feed safety tests because currently available tests can detect BSE only in the late stages of disease. Finally, although FDA agrees that vacuum rendering is less effective at inactivating TSEs than atmospheric rendering, the Agency disagrees that vacuum rendering should be prohibited. Modeling results submitted with the comment showed that such a prohibition would result in an additional one percent reduction in risk. In light of other measures being proposed and the fact that few plants use vacuum rendering, FDA does not believe that prohibiting this rendering process would appreciably improve animal or public health protection.

B. Additional Measures to Further Strengthen Feed Protection

The United States and Canadian feed regulations implemented in 1997 were necessary because of uncertainty about whether BSE infectivity had already been introduced into North America before new import restrictions on live cattle and meat and bone meal from Europe were put in place. It is now clear from the five North American BSE cases that the BSE agent was introduced into the North American animal feed supply at some point in time. While FDA continues to believe that compliance with the feed regulation has provided strong protection against the spread of BSE, the agency believes that the recent cases are an indication that additional animal feed protections are needed to remove residual infectivity that may be present in the animal feed supply. FDA also believes that of all the options considered since publication of the 2002 ANPRM, excluding the highest risk tissues from all animal feed is the best approach to address the risks of BSE in the United States. In the 2004 ANPRM, FDA announced its tentative conclusion that it should propose a prohibition on the use of SRMs in all animal feed.

The decision to propose banning SRMs from all animal feed led to the following questions: (1) Which material to exclude, (2) what alternative disposal methods could be used, (3) what the economic and environmental impacts of diverting material to alternative disposal would be, and (4) how an SRM ban could be enforced. As the IRT reported,

exclusion of large volumes of raw material is a massive burden for all countries affected by BSE. FDA received valuable information pertaining to these issues in comments submitted in response to the 2004 ANPRM.

In reaching a decision about what specific additional measures should be proposed at this time, FDA considered the magnitude of the BSE risk in the United States. While the recent North American cases clearly show the BSE agent was introduced, the USDA enhanced BSE surveillance program indicates that the prevalence of the disease in the United States is very low. As of July 2005, USDA has tested over 418,000 high-risk cattle under its enhanced BSE surveillance program (Ref. 11), and has found one positive animal in addition to the cow identified in Washington State in December 2003. Therefore, FDA believes that the additional measures being proposed are appropriate at this time. The agency proposes to prohibit from use in all animal feed the brains and spinal cords from cattle 30 months of age and older, the brains and spinal cords from all cattle not inspected and passed for human consumption, and the entire carcass of cattle not inspected and passed for human consumption from which brains and spinal cords were not removed. The agency also proposes to prohibit from use in all animal feed mechanically separated beef and tallow that are derived from materials prohibited by the rule. However, the rule proposes to exempt tallow from this requirement if it contains no more than 0.15 percent insoluble impurities.

C. Basis for Proposing to Apply Additional Measures to All Animal Food and Feed

The current U.S. ruminant feed regulation prohibits the use of certain mammalian-origin proteins in ruminant feed, but allows the use of these materials in feed for non-ruminant species. FDA believes that the presence of high-risk materials in the non-ruminant feed supply presents a potential risk of BSE to cattle in the United States. European experience showed that, in countries with high levels of circulating BSE infectivity, controls on only ruminant feed were not sufficient to prevent further transmission of BSE. Until SRMs were removed from all animal feed, a significant number of new cases continued to be found in cattle born in the United Kingdom after implementation of a ruminant-to-ruminant feed ban (Ref. 12). These new cases were attributed to either cross-contamination during feed manufacture and transport, or to intentional or unintentional misfeeding on the farm.

The 1997 ruminant feed regulation requires feed manufacturers and distributors that handle both ruminant feed and feed ingredients and materials prohibited in ruminant feed to control cross-contamination by either: (1) Maintaining separate equipment or facilities or (2) using adequate clean-out procedures or other means adequate to prevent carry-over of prohibited material into feed for ruminant animals. FDA has been concerned about the adequacy of such clean-out procedures and sought public comment on this issue in the 2002 ANPRM. Although many firms using the clean-out option have written procedures in place, evaluating their adequacy is difficult because of wide variation in equipment and practices used by the feed industry, and because there is currently no definitive test method to detect prohibited proteins.

Further increasing FDA's concerns about cross-contamination are preliminary data from an unpublished study showing that the minimum infectious dose for BSE may be lower than previously thought. Interim results at approximately 5 years post exposure of an oral challenge experiment have demonstrated transmission of BSE to 1 out of 15 animals that received 0.01 gram of brain tissue from a BSE-infected animal (Ref. 13). The lowest dose previously tested was 1.0 gram of brain tissue which showed transmission of BSE in 7 out of 10 animals in the trial group. This finding of a lower minimum infectious dose for BSE would suggest that the risk from cross-contamination is greater than previously thought. We seek comment on this interpretation of theses interim results.

Instances of cattle being exposed to prohibited material through noncompliance with the 1997 feed bans have been identified in both Canada and the United States. The investigation by the Canadian Food Inspection Agency of the BSE case identified in May 2003 found several instances where cattle might have had access to non-ruminant feed containing prohibited material. In the United States, FDA inspections have identified situations where cattle could have been exposed to material prohibited in ruminant feed as a result of ruminant feed being contaminated with non-ruminant feed, or non-ruminant feed not being properly labeled.

In fiscal year 2004 and the first half of fiscal year 2005, federal and state inspections identified 41 instances (0.4 percent of inspections) of cross-contamination or commingling problems in firms that handle animal feeds containing prohibited mammalian protein (Ref. 14). During this same period, inspections identified 165 instances (1.7 percent of inspections) in which non-ruminant feeds containing prohibited material were not properly labeled with the caution statement ''Do Not Feed to Cattle or Other Ruminants''. Firms receiving mislabeled feed would not be aware of the need to take steps to prevent cross-contamination of ruminant feed with such products. Furthermore, inspections during this period identified 604 instances (6.3 percent of inspections) in which firms handling animal feeds containing prohibited mammalian protein did not meet the recordkeeping requirements. These instances involved a variety of recordkeeping deficiencies, including not maintaining sales records for feeds received or distributed, not establishing written protocols for avoiding commingling, and not fully documenting clean-out measures utilized. Such deficiencies are typically corrected by the involved firms without further action by the agency. However, the occurrence of these deficiencies nonetheless supports the need for additional measures to address concerns about the presence of high-risk materials in the non-ruminant feed supply. Without sales records, it is difficult to verify the source of feed or feed ingredients or to track distributed feeds when conducting recalls in response to known instances of product contamination. Without appropriate documentation of procedures related to commingling or cross-contamination, it is difficult to verify that workers are informed of such procedures or that the procedures are adequate.

FDA has issued warning and untitled letters to firms addressing noncompliance with the current ruminant feed ban regulation and a feed manufacturer has been permanently enjoined in connection with noncompliance with the current feed ban regulation.

FDA is also concerned about intentional and unintentional misfeeding of non-ruminant feed to ruminants on the farm. Financial incentives for intentional misfeeding could occur any time inexpensive sources of prohibited protein are locally available to the feeder. The use of salvaged pet food that contains ruminant meat and bone meal is an example. There may be other incentives to intentionally feed non-ruminant feed to cattle. For example, the Florida Department of Agriculture and Consumer Services issued a statement cautioning against the misuse of pet

food as feed for show cattle as a way to increase the shine in the cattle coat (Ref. 15). Unintentional feeding could occur on the farm from feeding ruminants and non-ruminant in close proximity to each other. If intentional or unintentional uses occur, this proposed rule would protect cattle by removing the highest risk material from the non-ruminant feed being used in cattle feed. Assuring that misfeeding does not occur on the farm is particularly difficult due to the large number of cattle feeding operations in the United States, and FDA's extremely limited resources to inspect these operations, which number over 1 million.

Therefore, although overall compliance with the 1997 ruminant feed rule has been high for renderers, protein blenders, and feed mills, removal of the highest risk tissues from animal feed channels should serve to address noncompliance with the rule that could result in cattle exposure to prohibited material through cross-contamination, mislabeling, or intentional or unintentional misfeeding.

D. Cattle Materials Proposed to be Prohibited From Use in All Animal Food and Feed

1. Brain and Spinal Cord From Cattle 30 months of Age and Older

The USDA interim final rule published on January 12, 2004, provides a full description of the scientific rationale for identifying the list of tissues and selection of the 30-month age criterion used in its definition of SRMs. FDA has adopted an identical definition of SRMs in its interim final rule regarding FDA-regulated human food and cosmetics. In the preamble of its July 14, 2004 interim final rule regarding human food, including dietary supplements, and cosmetics, FDA includes a detailed discussion of its rationale for the SRM definition. As discussed in the preamble to the USDA and FDA interim final rules, infectivity is not present in most tissues that harbor BSE infectivity until more than 30 months after the animal was exposed to the agent. Although the epidemiological and experimental data indicate that BSE can develop in animals less than 30 months of age, the evidence available to date indicates that this was a very rare occurrence, and was associated with high levels of circulating infectivity at the peak of the BSE epidemic in the United Kingdom. The agency continues to believe that the rationale for the 30-month age criterion described previously for human food and cosmetics is appropriate and proposes that it be applied to animal feed as well.

In response to a question posed in the 2004 ANPRM as to which tissues should be defined as SRMs for animal feed, FDA received suggestions ranging from defining all animal protein as SRMs to limiting the SRM definition to the head only. FDA considered prohibiting from animal feed the same materials defined as SRMs that are currently prohibited from use in food for humans, but decided that proposing to require the removal of brain and spinal cord is the most appropriate approach at this time.

In reaching the decision to propose to exclude only the brain and spinal cord from animal feed, FDA considered information regarding the tissue distribution of BSE infectivity. Under field conditions, BSE infectivity has been found in the brain, spinal cord, and retina of the eye in animals with clinical disease (Ref. 16). The Scientific Steering Committee (SSC) of the European Union (Ref. 17) has also reported on the proportion of total infectivity in various tissues.[1] According to the report, in an animal with clinical BSE, approximately 64 percent of the infectivity is in the brain, 26 percent is in the spinal cord, 4 percent is in the dorsal root ganglia, 2.5 percent is in the trigeminal ganglia, and 3 percent is in the distal ileum. The eyes are estimated to contain less than 1 percent of the infectivity. Although available data are limited on the distribution of tissue infectivity, data from both naturally infected and experimentally infected cattle support the finding that the brain and spinal cord are the tissues with the highest level of infectivity.

Because available data indicate that the brain and spinal cord contain about 90 percent of BSE infectivity (Ref. 17), FDA believes that the most appropriate course of action is to concentrate efforts on excluding these highest risk tissues from animal feed. In deciding to propose to prohibit brain and spinal cord only, rather than the same list of materials previously defined as SRMs, FDA also considered the following: (1) Surveillance data indicate the current risk of BSE to U.S. cattle is very low, (2) the existing ruminant feed regulation provides strong protection against BSE, and (3) the new measures considered in this proposed rule represent a secondary level of protection to address failures in compliance that may occur with the existing ruminant feed rule. FDA believes that the existing ruminant feed rule provides the primary line of defense by prohibiting the use in ruminant feed of all material with potential BSE infectivity. The measures proposed by this rule will effectively reinforce existing ruminant feed protection measures by removing the tissues with the highest infectivity from all animal feed. As a result, these measures greatly minimize BSE risks if cross-contamination of ruminant feed with non-ruminant feed, or diversion of non-ruminant feeds to ruminants, were to occur.

2. Cattle Not Inspected and Passed for Human Consumption

As noted earlier in this document, the term ''cattle not inspected and passed for human consumption'' includes cattle not inspected and passed for human consumption by the appropriate regulatory authority as well as nonambulatory disabled cattle.

European surveillance data indicate that cattle found dead or culled onsite, where the carcass was submitted to rendering (fallen stock), and cattle with health-related problems unfit for routine slaughter (emergency slaughter) have a greater incidence of BSE than healthy slaughter cattle. Surveillance data in the European Union in 2002 showed that there were 27.95 positive animals per 10,000 emergency slaughter bovine animals tested and 6.15 positive animals per 10,000 fallen stock bovine animals tested compared to 0.31 positive animals per 10,000 healthy slaughter animals tested (Ref. 18). In Switzerland, the odds of finding a BSE case in fallen stock and emergency slaughter cattle were found to be 49 and 58 times higher, respectively, compared to the odds of finding a BSE case through passive surveillance (Ref. 19). These findings suggest that cattle not inspected and passed for human consumption are more likely to test positive for BSE than healthy cattle that have been inspected and passed for human consumption.

Because cattle not inspected and passed for human consumption are included in the population of cattle at highest risk for BSE (Refs. 18 and 19), and processes are currently not established in the rendering industry for verifying the age of such cattle through inspection, the agency is proposing to define brains and spinal cords from all cattle not inspected and passed for human consumption, regardless of age, to be cattle materials prohibited in animal feed. As noted previously, the

[1] A more recent report (Comer and Huntly, 2004, *Journal of Risk Research*, 7, (5) 523-543) attributes 84.3 percent of infectivity to brain and spinal cord and 9.6 percent to distal ileum. We chose not to use the data from this more recent report because its author (personal communications) explained that the newer data suggesting that the level of infectivity in the distal ileum at 6 to 18 months of age is higher than earlier estimates also suggest that it is lower than earlier estimates at 32 months of age.

term cattle not inspected and passed for human consumption is defined in this proposed rule to include nonambulatory disabled cattle as defined by FDA in its interim final rule on human food and cosmetics and USDA in its interim final rule on human food. If the brains and spinal cords are removed from these animals, FDA is proposing that the remaining material can still be used in animal feed. FDA notes that for cattle not inspected and passed that are diseased or that die other than by slaughter, the entire carcass of such animals is adulterated under section 402(a)(5) of the act. FDA has traditionally exercised enforcement discretion with regard to the use of such animals in animal feed. For example, see Compliance Policy Guide 675.400. FDA intends to continue exercising such discretion for the use in animal feed of the remaining material from cattle that are diseased or that die other than by slaughter when the brain and spinal cord are removed. Because comments to the ANPRM were mixed on the feasibility of removing SRMs from cattle mortalities, FDA requests further comment on which tissues should be removed from this class of animals and the feasibility of removing them.

In deciding to propose to allow these remaining materials to be used in animal feed, FDA considered the following: (1) brain and spinal contain about 90 percent of BSE infectivity (Ref. 17), (2) surveillance data indicate the current risk of BSE to U.S. cattle is very low, (3) the existing ruminant feed rule provides strong protection against BSE, and (4) the new measures considered in this proposed rule represent a secondary level of protection to address failures in compliance that may occur with the existing ruminant feed rule. FDA believes that the existing ruminant feed rule provides the primary line of defense by prohibiting the use in ruminant feed of all material with potential BSE infectivity. If the brains and spinal cords are not removed from such animals, FDA proposes that all parts of ''cattle not inspected and passed for human consumption'' be prohibited.

3. Mechanically-Separated Beef (MS)

Mechanically-separated (MS) beef is a finely comminuted meat food product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses. This proposed definition of MS beef is consistent with, but not identical to, the definition of the term used by USDA in its 2004 interim final rule (69 FR 1862) prohibiting its use in human food and by FDA in its 2004 interim final rule (69 FR 42255) prohibiting its use in human food, including dietary supplements and cosmetics. Those definitions provide that MS beef means a meat food product that meets the specification in 9 CFR 319.5. This USDA regulation applies to MS beef for human food use. Because there is MS beef produced solely for animal feed use that would not fall within the USDA specification, the definition of MS beef as proposed in this rule is meant to refer to beef that is the product of the mechanical separation process, regardless of whether it meets the USDA specifications for MS species in 9 CFR 319.5. The definition of MS beef is not meant to include product produced by Advanced Meat Recovery (AMR) systems used in the meat industry.

Although MS beef was not considered in the 2002 ANPRM, 2004 ANPRM, or in the IRT report, FDA has included this material in this animal feed proposed rule to ensure that any such material that is used in animal feed is not contaminated with the other material prohibited by this proposed rule. A comment submitted in response to the 2004 ANPRM said that FDA should allow mechanically separated beef to be used for pet food if SRMs are removed from material going into the mechanical deboning equipment that separates meat from bone, because some pet food operations are very similar to slaughter establishments and are capable of removing SRMs.

Because the mechanical separation process may result in the contamination of the MS beef product with spinal cord, FDA proposes to designate MS beef as cattle materials prohibited in animal feed if it is derived from carcasses or parts of carcasses from which cattle materials prohibited in animal feed were not previously removed.

4. Tallow

Tallow is an animal-derived hard fat that has been heat processed; most tallow is derived from cattle. Any risk of BSE transmission from tallow is a result of protein that is present as an impurity in the tallow. Taylor et al. (Refs. 20 and 21) found, in rendering studies with abnormal prion protein, that the prion protein did not preferentially migrate into the fat fraction, but remained with the protein fraction. Therefore, there is no reason to believe that tallow is likely to contain unusually high amounts of prion protein as a constituent of the insoluble impurities fraction that remains in tallow after rendering. Taylor et al. (Refs. 20 and 21) also reported that the various rendering processes used for tallow production in the United Kingdom were sufficient to produce tallow that did not result in infection when injected into the brains of mice, even though the starting material was highly spiked with the scrapie agent. Wilesmith et al. (Ref. 22) noted that the geographical variation in the incidence of BSE in the United Kingdom was not consistent with the use of tallow in cattle feed and concluded that the most likely source of infection in cattle was BSE-contaminated meat and bone meal.

The Office International des Epizooties (OIE), the world organization for animal health, categorizes tallow with insoluble impurities of no more than 0.15 percent as protein-free tallow. OIE guidelines recommend that tallow that meets this standard can be safely traded regardless of the BSE status of the exporting country (Ref. 23). FDA's Transmissible Spongiform Encephalopathy Advisory Committee (TSEAC) considered the safety of tallow and tallow derivatives in 1998 (Ref. 24). Members of the committee indicated that tallow is a food with negligible or no risk of transmitting BSE to humans or animals.

For the purposes of this proposed rule, tallow is defined as the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues. The 1997 ruminant feed final rule did not include tallow, fats, oils, and grease in the definition of animal proteins prohibited in ruminant feed because they are not proteins and were not considered to contain BSE infectivity. The agency said that infectivity studies conducted on some of these products (e.g., tallow) had demonstrated that they were at low risk of transmitting the TSE agent and; thus, it was unnecessary to restrict their use in ruminant feed (62 FR 30935). While the agency is not aware of any new scientific information suggesting that infectivity is present in tallow itself, the agency is concerned about potential BSE risks that tallow poses as a result of protein that is present as an impurity. These impurities may be of greater concern now because, as previously noted, new preliminary data suggest that the minimum infectious dose for BSE may be substantially lower than previously thought. We seek comment on this interpretation of the preliminary results.

The agency is proposing to prohibit the use of tallow in animal food or feed that is derived from cattle materials prohibited in animal feed. However, the agency proposes to exempt from this requirement tallow that contains no

more than 0.15 percent insoluble impurities. The proposal would require that impurities be measured by the method entitled ''Insoluble Impurities'' (AOCS Official Method Ca 3a–46), American Oil Chemists' Society, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to A.O.C.S. Official Method Ca 3a–46. In response to the 2004 ANPRM, comments were submitted to the agency requesting that the primary method for the impurity determination for tallow be one other than the method in the Food Chemicals Codex. Comments stated that the domestic tallow industry primarily uses a method of AOCS to measure insoluble impurities. In comparison to the Food Chemicals Codex method, comments stated that the AOCS method is less expensive, requires less solvent, and has lower solvent disposal costs. In addition, it does not require specialized equipment or supplies. FDA agrees with these comments, and proposes that the primary method for the impurity determination for tallow be the method from AOCS rather than the method in the Food Chemicals Codex.

This proposed requirement for tallow would apply to all animal feed, including feed for ruminants. Since the existing ruminant feed rule § 589.2000 (21 CFR 589.2000) does not include provisions relative to tallow, this proposal represents a new requirement for ruminant feed as well as for feed for non-ruminants. To make clear that this proposed requirement would apply to ruminant feed, FDA is proposing to amend § 589.2000 to include the tallow requirements.

FDA is also proposing to exempt tallow derivatives from the requirements of this rulemaking. Tallow derivatives are produced by subjecting tallow to chemical processes (hydrolysis, transesterification, and saponification) that involve high temperature and pressure. FDA's TSEAC considered tallow derivatives in 1998 (Ref. 24), and determined that the rigorous conditions of manufacture are sufficient to reduce the BSE risk in tallow derivatives to insignificant levels. In addition, according to OIE guidelines tallow derivatives produced by hydrolysis, saponification, or transesterification using high temperature and pressure can be safely traded regardless of the BSE risk status of the country of origin (Ref. 23).

E. Disposal of Cattle Materials Prohibited in Animal Feed

FDA agrees with comments from the affected industry that a comprehensive plan would be needed to safely dispose of approximately 2.5 billion pounds of material if FDA decided to prohibit all dead stock and the full list of SRMs, as defined in the USDA interim final rule (69 FR 1862) and the FDA interim final rule (69 FR 42255), from being rendered for use in animal feed. The 2.5 billion pounds of cattle material includes approximately 1.4 billion pounds of material from cattle slaughtered for human consumption and 1.1 billion pounds of material from cattle not inspected and passed for human consumption that are currently being rendered for use in animal feed. FDA is concerned about the feasibility of establishing a new infrastructure to safely dispose of this large quantity of material, as well as the time it would take to implement these processes.

Limiting the list of SRMs as proposed by this rule reduces the volume of slaughter byproducts that would require alternative disposal. First, this proposal does not require the diversion from use in animal feed the small intestine and tonsils from the 28 million head of cattle under 30 months of age that are slaughtered annually. Second, only the brain and spinal cord (weighing 1.3 pounds per animal) rather than the head, spinal column, and small intestine, (weighing 88.5 pounds per animal) are diverted from the estimated 7 million head of cattle over 30 months of age that are slaughtered annually in the U.S. FDA believes that this more limited amount of material from slaughter operations can be disposed of through landfill, incineration, or alkaline digestion.

Based on comments received, FDA acknowledges that there is some uncertainty regarding the amount of material that will require alternative disposal as a result of the proposed requirements pertaining to cattle not inspected and passed for human consumption (i.e., dead stock and nonambulatory disabled cattle). FDA is including in this proposed rule the option to remove brain and spinal cord from cattle not inspected and passed for human consumption so that most of this material could continue to be rendered for use in animal feed. As previously noted, FDA intends to continue exercising enforcement discretion for the use in animal feed of the remaining material from cattle that are diseased or that die other than by slaughter when the brain and spinal cord are removed. As discussed in more detail in Section IV, Analysis of Economic Impacts, FDA acknowledges that while the proposed rule will result in additional material from these animals being disposed of by means other than rendering, FDA believes such increases will be modest. FDA seeks comment and further information on the feasibility of removing brain and spinal cord from cattle not inspected and passed for human consumption and on the impact of this proposed rule on the number of these cattle that would be disposed of by rendering.

In summary, FDA believes that the measures proposed by this rule can be more feasibly implemented than a full SRM ban, and can add substantially to the protection provided by the current BSE feed regulation. With this approach, the resulting volume of material requiring special disposal would be manageable in the short term. This approach is also consistent with the advice of the IRT that a staged approach may be necessary in implementation of an SRM ban. Further, FDA believes that other feed controls that FDA previously considered, such as dedicated facilities, are not needed if these high-risk tissues are excluded from animal feed channels. Therefore, at this time FDA is not proposing rulemaking to address other feed control recommendations of the IRT or the additional planned measures announced by FDA on January 26, 2004.

III. Description of Proposed Rule and Legal Authority

FDA is proposing to establish a new § 589.2001 (21 CFR 259.2001), Cattle materials prohibited in animal food or feed. While the existing § 589.2000 outlines requirements related to ruminant feeds only, proposed § 589.2001 outlines requirements intended to apply to food or feed for all animal species. The terms and requirements of proposed § 589.2001 are described in section IV.A of this document.

A. Definitions

The proposed § 589.2001(a) defines the following terms for the purposes of this regulation:

(1) *Cattle materials prohibited in animal feed includes*: (i) the brains and spinal cords of cattle 30 months of age and older; (ii) the brains and spinal cords of cattle of any age not inspected and passed for human consumption; (iii) the entire carcass of cattle not inspected and passed for human consumption from which brains and spinal cords were not removed; (iv) mechanically separated beef that is derived from cattle materials prohibited

under (i), (ii), or (iii) above; and (v) tallow that is derived from cattle materials prohibited under (i), (ii), or (iii) above. Tallow that is derived from cattle materials prohibited under (i), (ii), or (iii) above that contains no more than 0.15 percent insoluble impurities and tallow derivatives are not considered cattle materials prohibited in animal feeds.

(2) *Cattle not inspected and passed for human consumption* means cattle of any age that were not inspected and passed for human consumption by the appropriate regulatory authority. This term includes nonambulatory disabled cattle. Non-ambulatory disabled cattle are cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

(3) *Mechanically separated beef* means a meat food product that is finely comminuted, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses.

(4) *Renderer* means any firm or individual that processes slaughter byproducts, animals unfit for human consumption, or meat scraps. The term includes persons who collect such materials and subject them to minimal processing, or distribute them to firms other than renderers (as defined in paragraph (a)(1)) whose intended use for the products may include animal feed, industrial use, or other uses. The term includes renderers that also blend animal protein products.

(5) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues.

(6) *Tallow derivative* means any product obtained through initial hydrolysis, saponification, or trans-esterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or trans-esterification may be applied to obtain the desired product.

B. Proposed Requirements

Proposed § 589.2001(b)(1) provides that no animal food or feed shall be manufactured from, processed with, or otherwise contain cattle materials prohibited in animal feed. Proposed § 589.2001(b)(2) provides new requirements for renderers that handle cattle material prohibited in animal feed. Proposed § 589.2001(b)(3) provides new requirements for renderers that handle any cattle material.

1. Proposed Requirements for Renderers That Manufacture, Process, Blend, or Distribute Cattle Materials Prohibited in Animal Feed

The proposed § 589.2001(b)(2) requires that renderers that handle cattle materials prohibited in animal feed use separate equipment or containers to handle such material once it has been separated from other cattle materials. This requirement is intended to ensure that equipment used to manufacture, process, blend, store, or transport cattle materials prohibited in animal feed or products that contain or may contain cattle materials prohibited in animal feed do not serve as a source of cross-contamination for materials intended for animal feed. In addition, proposed § 589.2001(b)(2) requires renderers that manufacture, process, blend, or distribute cattle materials prohibited in animal feed or products that contain or may contain cattle materials prohibited in animal feed must: (1) Label the prohibited materials in a conspicuous manner with the statement ''Do not feed to animals''; (2) mark the prohibited material with an agent that can be readily detected on visual inspection; and (3) establish and maintain records sufficient to track the prohibited materials to ensure such material is not introduced into animal feed, and make the records available for inspection and copying by FDA. These proposed requirements are intended to ensure that cattle materials prohibited in animal feed do not enter the animal feed chain and thus have no opportunity for inclusion in animal food or feed. FDA believes that such material must be both labeled and marked to ensure that it does not enter the feed channels since without such measures this material would be indistinguishable from cattle materials not prohibited by this proposed rule. Marking the material will provide a readily detectable method on visual examination by which all persons in the animal feed chain can be made aware that the a product is prohibited material or contains prohibited material. Marking also will serve as a way to make the status of the material known if, for some reason, the label ''Do not feed to animals'' is separated from the product.

2. Proposed Requirements for Renderers that Manufacture, Process, Blend, or Distribute Any Cattle Materials

Proposed § 589.2001(b)(3) requires that renderers that handle any cattle materials shall: (1) Establish and maintain records sufficient to demonstrate that material rendered for use in animal feed was not manufactured from, processed with, or does not otherwise contain, cattle materials prohibited in animal feed, (2) make copies of records available for inspection and copying by FDA, and (3) be in compliance with requirements under § 589.2000 regarding animal proteins prohibited in ruminant feed.

C. Proposed Recordkeeping and Access Requirements

The proposed recordkeeping requirements associated with this rule are focused on renderers because FDA believes this is the point at which cattle material prohibited in animal feed could enter the animal feed channel. Renderers, as defined in this proposed rule, receive cattle materials from slaughter facilities or receive entire cattle carcasses that were not inspected and passed for human consumption and further process that material so that it may be used in animal feed. FDA believes this is the critical control point in the feed and feed ingredient processing channel at which the exclusion of cattle material prohibited in animal feed must be documented. Once material is removed from cattle and further processed, we may not be able to obtain the information necessary to determine whether it is cattle material prohibited in animal feed. There is currently no way to reliably test feed or feed ingredients for the presence of the BSE agent or for the presence of cattle materials prohibited in animal feed.

This proposed rule requires that no animal feed or feed ingredient be manufactured from, processed with, or otherwise contain cattle materials prohibited in animal feed. However, FDA does not believe it is necessary for persons, other than renderers, that are involved in the manufacture or processing of feed or feed ingredients to maintain records documenting the exclusion of cattle materials prohibited in animal feed. FDA believes, for the reasons cited previously, that it is critical that such records be maintained at the point of the renderer. However, FDA believes that requiring the maintenance of such records at all manufacturing and processing points downstream would be redundant and provide little additional information of value. FDA seeks comments on the need to require that records be maintained by persons other than renderers.

Because at this time there is no way to test reliably for the presence of the BSE agent or the presence of the cattle materials prohibited in proposed § 589.2001(b)(1), renderers must depend

on records to ensure that the materials prohibited by this proposed rule are excluded from material intended for use in animal feed and that such material is appropriately disposed. Similarly, without adequate records kept by renderers and access to the records by the agency, FDA may not know whether renderers have complied with the requirements. We are proposing in § 589.2001(b)(2)(iv) that renderers that manufacture, process, blend, or distribute cattle materials prohibited in animal feed establish and maintain records sufficient to demonstrate that such material was not introduced into animal feed. Furthermore, we are proposing in § 589.2001(b)(3)(i) that renderers that manufacture, process, blend, or distribute cattle materials establish and maintain records sufficient to demonstrate that material rendered for use in animal feed was not manufactured from, processed with, or does not otherwise contain, cattle materials prohibited in animal feed.

Proposed § 589.2001(d) requires that the records required by this proposed rule be maintained for a minimum of 1 year. The 1-year record retention period is consistent with the existing requirements for ruminant feeds in § 589.2000(h). We believe that for the purposes of the recordkeeping requirements, 1 year is appropriate in light of the time that the products will be in the animal feed production and distribution systems. Extending the record retention period would have little practical value in determining the source of BSE in an animal. This is also considering the potentially long time period from ingestion of the BSE agent in feed to manifestation of clinical signs and lesions and the lack of a reliable estimate for the latency period.

The proposed rule does not specify the types of records that would need to be maintained in order to comply with the recordkeeping requirements. The agency seeks comments on what type of records would be appropriate and whether further detail is needed in the regulation regarding specific record requirements such as the specific data elements that must be included in such records.

D. Conforming Changes to § 589.2000—Animal Proteins Prohibited in Ruminant Feed

The requirements related to tallow in the proposed § 589.2001 are intended to apply to all animal feed, including feed for ruminants. Since the existing ruminant feed rule (§ 589.2000) does not include provisions relative to tallow, this proposal represents a new requirement for ruminant feed as well as for feed for non-ruminants. Therefore, due to concerns about protein impurities present in tallow, FDA is proposing to amend § 589.2000 to include tallow in the definition of ''protein derived from mammalian tissues'' and to add language that excludes from the definition of ''protein derived from mammalian tissues'' tallow containing no more than 0.15 percent insoluble impurities and tallow derivatives as specified in proposed § 589.2001.

E. Legal Authority

FDA is issuing this proposed regulation on animal feed under the food adulteration provisions in sections 402(a)(2)(C), (a)(3), (a)(4), (a)(5), 409, and 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342(a)(2)(C), (a)(3), (a)(4), (a)(5), 348, and 371(a)). The term ''food'' is defined to include articles used for food ''for man or other animals.'' See section 201 of the act (21 U.S.C. 321(f)). We note that the material that would be prohibited under this proposed rule from use in animal feed continues to meet the definition of food. Therefore, this material would be adulterated or misbranded under the act based on violations of the proposed rule, as well as any animal feed or feed ingredients that were manufactured from, processed with, or otherwise contained, the prohibited material.

Under section 402(a)(3) of the act, a food is deemed adulterated ''if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.'' ''Otherwise unfit for food'' is an independent clause in section 402(a)(3). The statute does not require that a food be filthy, putrid, or decomposed for it to be ''otherwise unfit for food.'' In FDA's interim final rule on the Use of Materials Derived from Cattle in Human Food and Cosmetics (69 FR 42256 at 42264), we concluded that a food can be ''otherwise unfit for food'' based on health risks, and sought comments on that interpretation. Because of the possibility of intentional or unintentional use of the materials that would prohibited under this proposed rule in ruminant feed and the risk of BSE to ruminants and humans from these materials, we have tentatively concluded that these materials would be ''otherwise unfit for food'' under section 402(a)(3) of the act. We seek comment on this interpretation.

Under section 402(a)(4) of the act, a food is deemed adulterated ''if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.'' The failure to ensure that animal feed is prepared, packed, or held under conditions in which cattle materials prohibited in animal feed under this proposed rule do not contaminate animal feed would constitute an insanitary condition whereby the feed may have been rendered injurious to health. Thus, this insanitary condition would render the animal feed adulterated under section 402(a)(4) of the act.

Under section 402(a)(5) of the act, food is deemed adulterated ''if it is, in whole or in part, the product * * * of an animal which has died otherwise than by slaughter.'' Some cattle are not inspected and passed because they are diseased or have died before slaughter. Material from these cattle that are diseased or that die otherwise than by slaughter that is used as animal feed would render that feed adulterated under section 402(a)(5) of the Act. FDA has traditionally exercised enforcement discretion with regard to the use of such animals in animal feed. For example, see Compliance Policy Guide 675.400. FDA intends to continue exercising such discretion for the use in animal feed of the remaining material from cattle that are diseased or that die other than by slaughter when the brain and spinal cord are removed.

We are also relying on the adulteration provision in section 402(a)(2)(C)(i) of the act. Section 402(a)(2)(C)(i) deems a food adulterated if it is or bears or contains a food additive that is unsafe under section 409 of the act. Section 201(s) of the act, (21 U.S.C. 321(s)), defines as a food additive any substance whose intended use results or may reasonably be expected to result in it becoming a component of food unless, among other things, it is the subject of a prior sanction (explicit approval for a specific use by USDA or FDA before September 6, 1958), or is generally recognized as safe (GRAS). Section 409 of the act provides that a food additive is unsafe unless it and its use conform to a food additive regulation or an exemption under section 409(j).

Prior sanctions are described in part 570 (21 CFR part 570). FDA is not aware of any prior sanctions that relate to the present animal feed use of the cattle material that would be prohibited in animal feed under this proposed rule. Any person who intends to assert or rely on such sanction is required to submit proof of the existence of the applicable prior sanction. The failure of any person to come forward with proof of such an applicable prior sanction in response to this notice will constitute a waiver of

the right to assert or rely on such sanction at any later time.

A determination that a substance added directly or indirectly to a food is GRAS, for its intended use is generally based on scientific information regarding the composition of the substance, its use, method of preparation, methods for detecting its presence in food, and information about its functionality in food as determined by experts qualified by scientific training and experience to evaluate the safety of such a substance (§ 570.30). A substance added to food becomes GRAS as a result of a common understanding about the substance throughout the scientific community familiar with the safety of such substances. The basis of expert views may be either scientific procedures, or, in the case of a substance used in food before January 1, 1958, experience based on common use in food (§ 570.30(a)). Substances that are GRAS based on use before January 1, 1958, must be currently recognized as safe based on their pre–1958 use (See *United States* v. *Naremco*, 553 F. 2d 1138 (8th Cir. 1977; compare *United States* v. *Western Serum*, 666 F. 2d 335 (9th Cir. 1982)).

General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient (21 CFR 570.30(b)). (See *United States* v. *Naremco*, 553 F.2d at 1143). A substance is not GRAS if there is a genuine dispute among experts as to its recognition (*An Article of Drug * * * Furestrol Vaginal Suppositories*, 294 F. Supp 1307 (N.D. Ga. 1968), aff'd 415 F.2d 390 (5th Cir. 1969)). It is not enough, in attempting to establish that a substance is GRAS, to establish that there is an absence of scientific studies that demonstrate the substance to be unsafe; there must be studies that show the substance to be safe (*United States* v. *An Article of Food * * * CoCo Rico*, 752 F.2d 11 (1st Cir. 1985)). Conversely, a substance may be ineligible for GRAS status if studies show that the substance is, or may be, unsafe, or if there is a conflict in studies.

Expert opinion that cattle materials that would be prohibited in animal feed under this proposed rule are GRAS would need to be supported by scientific literature and other sources of data and information, establishing that there is a reasonable certainty of no harm from the material under the intended conditions of use. Expert opinion would need to address topics such as whether BSE infectivity can be detected, and whether it is reasonably certain that the BSE agent will not be transmitted through cattle materials that would prohibited in animal feed under this proposed rule. The burden of establishing that a substance is GRAS is on the proponent of the substance. (See *CoCo Rico, supra.*)

For the reasons discussed in other sections of this document, the agency is tentatively concluding that cattle materials prohibited in animal feed under this proposed rule are not GRAS by qualified experts for use in animal food and, therefore, would be food additives. Section 402(a)(2)(C)(i) and (ii) of the act deems food adulterated ''if it is or it bears or contains any food additive which is unsafe within the meaning of section 409 * * * .'' Under section 409(a), a food additive is unsafe unless a food additive regulation or an exemption is in effect with respect to its use or its intended use. Therefore, in the absence of a food additive regulation or an exemption, the cattle materials that would be prohibited in animal feed under this proposed rule would be adulterated under section 402(a)(2)(C)(i) of the act because it bears or contains an unsafe food additive, and their presence in animal feed would render the food adulterated.

Under section 701(a) of the act, FDA is authorized to issue regulations for the act's efficient enforcement. The proposed regulation would require measures to prevent animal food from being unfit for food, being or bearing an unsafe food additive, being the product of an animal that died otherwise than by slaughter. The measures will also be required to prevent animal food from being held under insanitary conditions whereby it may have been rendered injurious to health. These proposed measures would allow for the efficient enforcement of the act. Under the proposed regulations, renderers would be required to establish and maintain records to track cattle materials prohibited in animal feed to ensure that such material is not introduced into animal feed and make such records available to FDA for inspection and copying. Once material is removed from cattle, we may not be able to obtain the information necessary to determine whether it is prohibited cattle material. Because at this time there is no way to test reliably for the presence of the BSE agent or the presence of the cattle materials prohibited in proposed § 589.2001(b)(1), renderers must depend on records to ensure that their products do not contain cattle materials prohibited from animal feed. In addition, without adequate records, FDA cannot know whether renderers have complied with the regulations that prohibit the use of certain cattle material in rendered products intended for animal feed. For example, we would not know from examination of a spinal cord whether the source animal was over 30 months of age at the time of slaughter or whether the cattle had been inspected and passed. Therefore, the proposed recordkeeping and records access requirements are necessary for the efficient enforcement of the proposed rule. Under the proposed rule, failure to comply with the recordkeeping and records access requirements would render the cattle material and any animal feed manufactured from, processed with, or otherwise containing, the cattle material adulterated under section 402(a)(4) of the act.

Furthermore, the proposed marking provision in § 589.2001 is necessary for the efficient enforcement of the act. Because there is currently no reliable method to determine which cattle materials would be the prohibited materials, marking is necessary to ensure compliance with the proposed requirement that animal feed is not manufactured from, processed with, or otherwise contains the prohibited cattle materials. Under the proposed rule, failure to comply with this marking requirement would render the cattle material and any animal feed manufactured from, processed with, or otherwise containing, the cattle material adulterated under section 402(a)(4) of the act.

FDA is issuing the proposed labeling requirement under sections 403(a)(1) and 201(n) of the act (21 U.S.C. 343(a)(1)). Section 403(a)(1) provides that a food is deemed misbranded if its labeling is false or misleading in any particular. Section 201(n) provides that:

> * * * in determining whether the labeling of a product is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling * * * fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use of the article to which the labeling * * * relates under conditions of use prescribed in the labeling * * * or under such conditions of use as are customary or usual.

The proposed rule would require cattle material prohibited in animal feed to be labeled ''Do not feed to animals.'' We believe this statement is material with respect to the consequences that may result from the use of this material within the meaning of section 201(n) of the act. As discussed in other sections of this document, the use of the material

that would be prohibited under this proposed rule presents a risk of BSE. Furthermore, there are no available definitive tests to detect this material in feed. Therefore, under this proposed rule, the failure to include this labeling statement would render the cattle material or feed containing the prohibited cattle material misbranded under section 403(a)(1) of the act. We are also proposing that such statement be made in a conspicuous manner. Under section 403(f) of the act, (21 U.S.C. 343(f)), a food is misbranded if ''any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness * * * and in such terms as to render it likely to be read and understood by the ordinary individual under customary condition of purchase and use.'' Therefore, under the proposed rule, the failure to include the statement ''Do not feed to animals'' in a conspicuous manner would render the cattle materials or any feed containing the cattle materials misbranded under section 403(f) of the act.

IV. Analysis of Economic Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts, and equity).

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

FDA tentatively finds that the proposed rule does not constitute an economically significant regulatory action as defined in Section 3(f)(1) of Executive Order 12866. We base this conclusion on both a study of the impacts on industry of the proposed rule (on file at the Division of Dockets Management (see **ADDRESSES**) conducted for FDA by the Eastern Research Group (ERG)), a private consulting firm, and the discussion in the remainder of this section (Ref. 25). The agency has further tentatively determined that the proposed rule may have a significant impact on a substantial number of small entities. This proposed rule imposes no mandates on government entities, and would not be expected to require the expenditure of over $115 million in any 1 year by the private sector. As such, no further analysis of anticipated costs and benefits is required by the Unfunded Mandates Reform Act.

The following regulatory impact analysis begins with a summary of the proposed rule and the expected benefits and costs. Next, in section V.B of this document, we discuss the need for the regulation. In section V.C, we discuss the benefits of the proposed rule, while in section V.D, we discuss the costs. In section V.E, we discuss the costs to the government. Finally, in section V.F, we discuss the regulatory flexibility analysis.

A. Summary of Proposed Regulatory Impact Analysis

The proposed regulation would prohibit the use of certain cattle materials in any animal feed. The cattle materials prohibited in animal feed (CMPAF) would include the brain and spinal cord of all cattle 30 months of age or older, as well as the brain and spinal cord of cattle not inspected and passed for human consumption regardless of age, the entire carcass of cattle not inspected and passed if brain and spinal cord is not removed (again, regardless of age), as well as other materials. For the purposes of this proposed rule, the term ''cattle not inspected and passed for human consumption'' includes nonambulatory disabled cattle. Tallow derived from any of the prohibited materials named previously would also be banned from use in animal feed unless it contains no more than 0.15 percent insoluble impurities. MS beef from any of the prohibited materials named above would be prohibited from use in animal feed. Additional provisions of the proposed rule would require renderers that handle cattle materials prohibited in animal feed to use separate equipment or containers to handle this material once it has been separated from other cattle materials. Such renderers will also be required to follow certain procedures for labeling and marking prohibited material and recordkeeping and records access.

The benefits of the proposed rule include the elimination of the vast majority of the risk of spreading BSE to other cattle from intentional or unintentional use of non-ruminant feed for ruminants or cross-contamination of ruminant feed with non-ruminant feed or ingredients intended for non-ruminant feed. FDA believes that the proposed rule would effectively remove from use in non-ruminant feeds those cattle tissues that account for approximately 90 percent of potential BSE infectivity. Although the animal and public health benefit associated with the additional BSE risk reduction is paramount, the U.S. economy may also benefit from increased exports to the extent that the proposed rule, if finalized, persuades foreign governments that U.S. beef products are safe to import. Although we are unable to quantify these benefits, they are potentially large, because the expected loss of exports from the discovery of one infected cow in Washington State in December 2003 amounted to approximately $3.4 billion in the first year (Ref. 26).

The total costs to industry of complying with the proposed rule range from roughly $14 million to $24 million per year annualized over 10 years assuming a 7-percent discount rate (at a 3-percent discount rate, the cost would range from $14 million to $23 million). These estimated costs are the sum of the costs including: (1) The ban on the use of certain tissues from cattle 30 months of age or older and cattle not inspected and passed for human consumption in any animal feed and (2) feed substitution costs. We discuss the proposed brain and spinal cord prohibitions as direct costs to the affected firms (including disposal costs, where applicable) and the firms' lost revenues from the ban on these raw materials used in feed product inputs. Then, we discuss the costs incurred by feed substitution costs. Table 1 of this document shows a summary of these costs.

The proposed ban on the use of certain tissues from cattle 30 months of age or older and cattle not inspected and passed for human consumption in any animal feed would require slaughterers and renderers that process cattle 30 months of age or older and firms that process dead, down, disabled, and diseased cattle to separate the CMPAF from the remaining cattle offal that could still be used for animal feed. We estimate that, for slaughterers, the separation of these materials from cattle

30 months of age or older and cattle not inspected and passed for human consumption regardless of age would require about $555,000 in one-time capital costs (or $79,000 annualized at 7 percent and $65,000 annualized at 3 percent, over 10 years) (see table 1 of this document). We estimate that the annual cost of the additional labor to separate these CMPAF from other cattle offal is estimated to cost about $597,000 annually. Although compliance costs for these activities would be borne initially by slaughterers, and are presented as such by ERG, a portion of the costs are likely to be passed along to cattle producers and consumers. For renderers, capital investments and labor for separation and segregation of CMPAF would range from about $1.88 million to $4.65 million annually.

Our analysis does not project a specific disposal route for CMPAF due to the uncertainty inherent in disposing of such low volumes of material. Instead, it describes various disposal methods that may be employed and estimated a $12 per 100 lbs. (cwt) of CMPAF disposal cost (including transportation costs) for the low-cost end of the range of disposal methods. The cost to dispose of the CMPAF is estimated to range from $7.72 million to $9.97 million annually. Additional on-farm disposal of dead and nonambulatory disabled cattle is expected to increase compliance costs from about $1.02 million to $2.53 million annually (including labor and equipment). The annual revenues foregone from meat and bone meal (MBM) sales due to the prohibition of CMPAF in animal feeds are estimated at $1.41 million to $2.78 million, and foregone tallow sales are estimated at $1.37 million to $2.62 million. This includes the value from CMPAF from cattle 30 months of age or older and cattle not inspected and passed for human consumption regardless of age, as well as from whole carcasses of cattle not inspected and passed for human consumption that could not be rendered due to this proposed rule.

We considered including a provision in this proposed rule that would limit the use of all tallow in animal feed to that which contains no more than 0.15 percent insoluble impurities, not just tallow derived from the materials proposed to be prohibited in animal feed that contains no more than 0.15 percent insoluble impurities. Analysis of this alternative concluded that it would result in annualized costs of about $1.78 million. These costs would consist of capital and operating costs for polishing centrifuges that would be needed by a small segment of independent renderers. We have not included a provision requiring that all tallow meet the 0.15 percent limit in the proposal because the CMPAF ban would effectively negate the risk of infectivity in non-CMPAF-derived tallow. We invite public comments and data on the need for, and impacts of, a provision that would require all tallow used in animal feeds meet the 0.15 percent limit.

TABLE 1.—TOTAL COSTS ($ MILLIONS)

Cost Item	One-Time Cost	Annual Costs	Annualized Costs[1]
Slaughter Facilities			
Capital Investments	$0.56	N/A	$0.08
Labor		$0.60	$0.60
Lost Value of MBM (cattle 30 months of age or older, cattle not inspected and passed)		$1.41—$2.76	$1.41—$2.78
Lost Value of Tallow (cattle 30 months of age or older, cattle not inspected and passed)		$1.37—$2.62	$1.37—$2.62
Disposal of cattle not inspected and passed			
Labor		$0.12—$0.29	$0.12—$0.29
Equipment		$0.9—$2.23	$0.9—$2.23
Renderer Facilities			
Capital Investments	$3.11–$7.67	$0.04—$0.11	$0.49—$1.20
Labor		$1.40—$3.45	$1.40—$3.45
Disposal of CMPAF from cattle 30 months of age or older, cattle not inspected and passed		$7.72—$9.97	$7.72—$9.97
CMPAF Marking (High Estimate)		$0.01	$0.01
Recordkeeping/Labeling	$0.10	$0.05	$0.06
Feed Substitution		$0.30—$0.46	$0.30—$0.46
Proposed Rule Total Costs	$3.76	$13.91—$22.56	$14.44—$23.75

[1] Annualized costs equal to annual costs plus one-time costs at 7 percent over 10 years. Using a 3 percent rate, annualized costs equal $23,535,000.

FDA believes that this proposal, when evaluated in terms of its incremental cost-effectiveness at reducing risks from BSE, is more consistent with efficient science-based risk management than other regulatory approaches that it identified in the 2004 ANPRM. This proposal limits use of animal tissues for which infectivity is high relative to

tissue weight. Weight is a key determinant of the incremental costs from excluding tissues from rendering for animal feed. The approach adopted in this proposal is likely to be relatively cost-effective because it is directed primarily at those tissues for which infectivity is likely to be high relative to control compliance costs.

In the 2004 ANPRM, FDA stated it was considering prohibiting a larger list of cattle tissues (the full SRM list) from use in all animal feeds. Under this option, SRMs would be defined as the skull, brain, eyes, spinal cord, trigeminal ganglia, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) and dorsal root ganglia of all cattle over 30 months of age or older, including the tonsils and distal ileum of all cattle regardless of age. Additionally, this option would prohibit the small intestine of all cattle, all material from nonambulatory disabled cattle, all material from cattle that are not inspected and passed for human consumption, and MS beef. Lastly, tallow derived from other prohibited materials and containing more than 0.15 percent insoluble impurities would also be prohibited from use in all animal feeds under this SRM option. As detailed later in the analysis of alternatives, we have not included all of these measures in this proposed rule because we believe the proposed rule adequately addresses the risk from the presence of the highest risk cattle material in the animal feed chain. We also note that the proposed rule offers a more cost-effective approach to achieving nearly the same level of protection against the spread of BSE with regard to the presence of high-risk material in the non-ruminant feed supply.

The approach described in the 2004 ANPRM is itself a refinement of an approach announced early in 2004. In January 2004, shortly after USDA reported finding a BSE-infected cow in Washington State, HHS announced its intention to amend the current animal feed regulations by adding several materials to the list of substances prohibited from use in ruminant feed (Ref. 27). These materials included mammalian blood and blood products; inspected meat products that have been cooked, offered for human food, and then further heat-processed for feed (such as plate waste and used cellulosic casings); and poultry litter. Further, FDA planned to require establishments that manufacture, process, blend, or distribute both products containing mammalian-derived proteins and ruminant feed to use separate equipment or facilities in their manufacture, processing and handling.

Preliminary analysis of the regulatory approach described in the January 2004 announcement (Ref. 27) suggests that it is relatively less effective in risk reduction compared to the CMPAF and SRM bans because it would not remove the highest risk tissue (brain and spinal cord) from animal feed channels. Instead, the approach described in the January 2004 announcement would continue to allow the highest risk cattle material in non-ruminant feed, but includes measures intended to prevent cross-contamination of ruminant feed. Although we have not been able to quantify the risk reduction associated with the approach announced in January 2004, it is comparable in costs to the full SRM ban described in the 2004 ANPRM. As a result we are not proposing it here.

In developing this proposed rule we also considered other alternatives (not included here), including combinations of bans of various cattle tissues, from cattle of various ages (>30 months and <30 months) and various states (slaughtered for human food, deads, downers). All of these resulted in costs over $100 million per year with potential infective tissue reductions between 80 percent and 99 percent, when compared to the base case scenario.

Table 2 of this document lists the proposed rule (the CMPAF ban), the SRM ban, and one of the options mentioned previously, namely a ban on brain and spinal cord from slaughter cattle 30 months of age or older, and a ban on the entire carcass of all dead and downed cattle. The table lists both the expected costs of these options, and our best estimate of the percent reduction in cattle tissues known to harbor BSE infectivity. The proposed rule would reduce cattle oral ID50s (the amount of infective material that would result in a case of BSE in 50 percent of the cattle that consumed it) that are available for use in animal feed by about 90 percent as much as a ban on the full list of SRMs (option 3), while imposing only 7 to 10 percent of the costs of the SRM option (0.07 = $14 million/$195 million; 0.10 = $24 million/$240 million). The second option would reduce the cattle oral ID50s by more than 90 percent (a less than 10 percent increase over option 1), but would impose costs that are about five to nine times greater than option 1, though still only about 50 percent to 70 percent of the costs of option 3. Based on the level of protection provided against the spread of BSE and its cost-effectiveness, we believe the proposed rule to be the most appropriate. FDA seeks further comment and scientific and risk information on this analysis of additional regulatory options for strengthening animal feed safeguards.

TABLE 2.—COST-EFFECTIVENESS OF ALTERNATIVE POLICIES

Option (Description of Banned Tissues/Materials)	Infectivity Reduction[1]	Annual Cost ($ millions)
CMPAF list from (1) Cattle 30 months or older, (2) deads, (3) downers and (4), MS beef if CMPAF not removed from carcass, dedicated equipment/container requirement; tallow restriction (proposed rule)	90%	$14—$24
Brain and spinal cord from cattle 30 months or older, carcasses of all deads and downs, MS Beef	>90%	$115—$135[2]
Full SRM list from cattle 30 months or older, tonsils and distal ileum from cattle of all ages, carcass of all deads and downers, MS beef, tallow restriction	>99%	$195—$240

[1] Percent of ID_{50}s from an infected animal that would be banned from use in animal feed.
[2] Detailed cost estimate of this alternative is not included in the regulatory flexibility analysis section of this document.

B. Need for Regulation

Executive Order 12866 directs agencies to assess the need for any significant regulatory action and an explanation of how the regulation will meet that need. In this instance, FDA tentatively concludes that private incentive systems for both suppliers and purchasers in markets for cattle, rendering, and ruminant feed may inadequately address the risk of BSE. This market failure is a result of inadequate information being available to buyers of potentially infective animal feed. Because of the risk of cross contamination during feed production and the risk of inadvertently feeding non-ruminant feed to ruminants on an integrated farm, buyers of ruminant and non-ruminant feed would likely value a decrease in risk of BSE transmission if the market were able to provide it. Buyers, however, have little information about the BSE infectivity of feed because the costs to them of ascertaining infectivity are very high and higher than the costs to the feed producers. As a result, buyers may, without the current or proposed feed rules, unknowingly buy feed contaminated with BSE because of the presence of CMPAF.

The potential market failures created by the continued use of materials that this proposed rule would eliminate are the same as in the 1997 ruminant feed final rule. If feed purchasers could easily identify the risk of the infective agent associated with products from specific suppliers, they could more easily reduce these risks by refusing to buy feed products derived from ruminants known to have consumed prohibited CMPAF. Feed purchasers are unlikely to obtain the information they need due to the long incubation period for BSE that could lead to a suboptimal level of risk prevention by purchasers during the incubation period. Ruminant producers have no way of knowing whether a particular batch of feed or feed ingredients intended for ruminants are free of potentially infective proteins due to the possibility of CMPAFs being introduced through cross-contamination with feed or feed ingredients intended for non-ruminants.

C. Benefits

The purpose of the proposed rule is to further reduce the risk of BSE spreading within the cattle population. Reduced risk of BSE among cattle also reduces human exposure to variant Cruetzfeldt-Jakob disease (vCJD) believed to be caused by consumption of beef products contaminated with the BSE agent as well as increases the potential for exports by reducing foreign governments' concerns about the quality of U.S. beef. In this section, we first address the reductions in the risk of BSE to cattle in the United States and the corresponding protection of human health from the major provisions of the proposal. We then summarize the available evidence about the likely effect of this proposed rule on U.S. exports of beef and other livestock products.

1. Risk Reduction

FDA estimates that banning CMPAFs from use in any animal feed would effectively remove about 90 percent of any remaining potential infectivity from possible spread through the feed system. To derive this estimate of the risk reduction from the proposed CMPAF ban, we assume that the number of new BSE cases is proportional to the amount of all infectious material included in feed. Given this assumption, we can estimate the percentage reduction in the risk of new BSE cases as the percentage reduction in infectious material. A 1999 report by the Scientific Steering Committee of the European Union suggests that the brain and spinal cord constitute 89.7 percent of the total infective load in a case of BSE (Ref. 28). This rule would prohibit use in all animal feed of these tissues (CMPAFs) from cattle 30 months of age or older and all cattle not inspected and passed for human consumption. CMPAF, when taken from slaughtered cattle less than 30 months of age, would not be prohibited from use in all animal feed because the probability is very low that tissues from cattle of this age would contain BSE infectivity. Thus, banning CMPAF would effectively remove about 90 percent of total infectivity from animal feed. The absolute level of animal health risk reduced by this rule would depend on the number of infected animals in the United States and the extent to which cattle get exposed to infected material.

The potential human exposure to infectious materials from consuming beef is already small since USDA and FDA prohibit the use of certain cattle materials, including SRMs, from human food. In its preliminary analysis (Ref. 26), USDA modified the Harvard-Tuskegee model and estimated that the two interim final rules issued in January 2004 reduced human exposure to infectious materials by an average of 80 percent. For example, USDA estimated if 5 BSE infected bulls were introduced in 2003 and its control measures take effect in 2004, consumers would be exposed to 4 animal ID50s between 2004 and 2020 compared to 18.5 animal ID50s without these measures (Ref. 26, Table 13). The estimate of percent reduction in exposure is insensitive to the assumed number of infected animals introduced into the United States. To the extent this rulemaking further reduces the likelihood of the spread of BSE, it further reduces the already small likelihood of human exposure to the infectious material.

Assessing the public health implications from estimates of the human exposure to the BSE agent is difficult because there is no agreed upon dose-response relationship between human exposure to cattle ID50s and vCJD cases. Nonetheless, the experience of the United Kingdom suggests that the BSE agent is many times less infective in humans than in cattle. During the 1980s and 1990s, in the absence of preventive control measures, millions of ID50s may have been available for consumption by residents of the United Kingdom, since each cow with clinical symptoms of BSE contains about 7,800 ID50s. The cumulative number of definitive or probable vCJD cases identified in the United Kingdom as of September 1, 2005, is 157 (Ref. 29). Thus, human exposure to a few, or even a few dozen ID50s, may represent a relatively small risk to public health. FDA solicits additional information on the dose response relationship between ID50s and incidence of vCJD.

2. Increased Export Potential

A second major category of benefits pertains to the potential for increased exports of U.S. cattle products to countries that have acted to curtail exports since the discovery of the infected cow in Washington State in December 2003. However, we are unable to quantify the value of such increased exports, because of limits to the data and resources available to us. We note however, that USDA assessed this category of benefits in the interim final regulation that it issued in January 2004. In its assessment, it concluded that ''the 2004 beef export demand forecast has been reduced by 90 percent'' (Ref. 26, page 58). It reported that U.S. exports of beef, veal, and variety meats amounted to $3.8 billion in sales in 2003, and exports of live cattle resulted in an additional $63 million. The preventive measures contained in this proposed rule are expected to increase the likelihood that foreign governments ease some restrictions on imports of U.S. beef products and cattle.

Another indirect and incomplete measure of the potential benefits of this rule can be seen in measures of the commodities markets' reactions to the discovery of BSE cases. When the first BSE case was reported in Washington

State on December 23, 2003, beef prices had risen to record highs, but were expected to decline in 2004. After the discovery of the BSE case, the 5 area monthly weighted average steer price reported by USDA's Agricultural Marketing Service declined by about 14 percent from December 2003 to February 2004 (Ref. 30). By April 2004, the weighted average monthly price appeared to recover much of the loss. Although never fully reaching pre-BSE record levels, prices by mid–2004 appeared to be close to what they would have been had the BSE-infected cow not been identified. Such volatility in commodities markets may adversely affect independent beef producers who are risk averse and have hedged against such risks inadequately. To the extent that this proposed rule would prevent the development of a BSE-infected cow in the U.S., it may provide benefits to such beef producers by reducing their risk of financial loss and the cost to them of insuring against such risks.

D. Costs

We address the costs to industry of complying with this proposed regulation by considering in turn each of the individual provisions of this proposal. The costs of this proposed rule can be estimated as the sum of the costs of the different provisions.

FDA contracted with ERG to prepare an analysis of the impacts of the ban or restriction on use of CMPAF in proposed

§ 589.2001. Additionally, ERG analyzed the likely impacts of alternative options (on file at the Division of Dockets Management (see **ADDRESSES**) and henceforth referred to as the Alternatives Report) (Ref. 31)). In particular, these alternatives include the following: (1) A prohibition on the use of specified risk materials in animal feed, (2) the requirement for the use of separate facilities or equipment by those that process both mammalian protein prohibited in ruminant feed and ruminant feeds, and (3) a ban on the use of blood and blood products in ruminant feeds. The ERG analysis of this proposed rule presents estimates of costs for the meatpacking or slaughtering, rendering, and animal producer sectors. In addition, the ERG report provides estimates of impacts on representative small firms in the sectors that are impacted, to a significant degree, to fulfill requirements of a regulatory flexibility analysis. In the development of the Alternatives Report, ERG contacted establishments in the FDA inspection database that were likely to be affected by these regulatory options. Two separate telephone surveys were conducted, covering feed mills, renderers, and agricultural product transporters (the latter including trucking services at feed mills, renderers, and contract haulers). In some cases, written questionnaires were provided to the industry members. In addition, ERG used the services of industry consultants and other contractors for their technical expertise. The sector-specific surveys taken by ERG for the analysis of alternatives were each administered to fewer than ten industry members. In its development of the report on the proposed rule that would prohibit the use of CMPAF in animal feed, ERG again contacted industry members it had identified through its previous work on alternative policies, as well as industry consultants and industry associations.

A study prepared for an industry association concluded that about 35 percent of cattle (42 percent by weight) not inspected and passed for human consumption are currently rendered (Ref. 32). Our analysis estimated the number of cattle at about 17 percent. Whereas our analysis is based on other industry-supplied data that may be less dated, the industry analysis is based on USDA/APHIS data, that while older, resulted from several different USDA surveys.

The industry association's analysis differs from our analysis in the following three ways: (1) The percentage of animals currently rendered, (2) the number of animals, and (3) the weight of prohibited cattle material from each animal. Because of these differences, it may be potentially misleading to make a direct comparison of the findings of the two analyses. For example, if we substitute industry's percentages of animals currently rendered into our analysis, our estimate increases from 17 percent to 33 percent, but not to the industry association's estimate of 35 percent. The slight difference between our findings and those of industry (i.e., 33 percent compared to 35 percent) should be attributed to the difference in the number of animals rendered in each individual category of cattle.

Aside from the percentage of cattle not inspected and passed for human consumption currently rendered, the biggest source of variation between the two estimates can be attributed to the assumptions about the weight of CMPAF being rendered. The industry analysis assumed that the entire carcass would be affected by the ban on cattle not inspected and passed for human consumption. Discussions between ERG and industry experts convince us that, in most cases, renderers can adequately separate CMPAF from the other parts of a carcass. Adjusting the industry analysis to include only CMPAF and to include the same number of cattle as used in our analysis, decreases their estimate of the percentage of tissues rendered from 42 to 33 percent. This contrasts to our finding that only 17 percent of the volume of CMPAF from cattle not inspected and passed for human consumption is currently rendered.

Nevertheless, we acknowledge the uncertainty in all of these estimates. Due to the significance of this factor in estimating compliance costs for this proposed rule, we have adopted the 42 percent figure as the upper bound of the acceptable range and include cost estimates using this factor, where appropriate, within the cost methodology developed in the ERG analysis.

In general, the proposed ban on the use of CMPAF would impose three types of costs. First, it requires firms to buy equipment and to reallocate workers to change their production processes. This requirement imposes direct costs. Second, it prohibits the use of CMPAF by renderers who would use it to produce MBM and tallow. This prohibition reduces the revenue to slaughterhouses that sell CMPAF. Third, it also may oblige the buyers of MBM to turn to alternative ingredients that may be more costly or nutritionally inferior. Furthermore, prohibitions on the use of CMPAF in animal feeds can impose additional disposal costs, insofar as a previously valuable commodity is now turned into an undesirable by-product that requires disposal. Thus, we assess the lost revenue, direct costs, additional disposal costs, and feed substitution costs that may result from this proposed rule.

1. Lost Value of CMPAF

The proposed rule would prohibit the use of CMPAF in all animal feeds. Our analysis concluded that the proposed rule would cause slaughtering operations to incur additional capital investment costs and labor costs to modify and operate their plants in order to separate CMPAF from the rest of the cattle offal. Further, we project the value of the MBM and tallow based on historical prices, and discusses possible CMPAF or MBM disposal options for the industry. We also project the costs of additional disposal of on-farm dead and nonambulatory disabled cattle, CMPAF marking costs, recordkeeping, and labeling costs required by the proposal.

ERG used industry data to estimate the CMPAF quantities that would be removed from cattle 30 months of age or

older slaughtered for human food and cattle not inspected and passed for human consumption based on various factors including the age of the cattle, size of slaughter plant (federal or state inspection authority), and, for dead and nonambulatory disabled cattle of any age, the type and size of animal (beef or dairy cattle). ERG also used industry data on yield to project MBM and tallow production resulting from the current level of CMPAF quantities. Using 4-year averages of byproduct market prices ($180/ton for ruminant or mixed species MBM, and $360/ton for tallow), the annual value of the MBM and tallow originating from CMPAF is estimated at $976,000 and $794,000, respectively. Using the high end of the range discussed previously, the annual value of MBM and tallow would be $1,714,000 and $1,194,000, respectively. Additionally, the annual value of the MBM and tallow from the carcasses of deads and nonambulatory disabled cattle that would no longer be collected by renderers (and would likely be disposed of on the farm) is estimated by ERG at $430,000 and $576,000, respectively. The high end of this range of costs is estimated at $1,064,000 for MBM and $1,422,000 for tallow. The total value of the loss of MBM is estimated to range from $1,406,000 to $2,777,000, and the total value of the lost tallow is estimated to range from $1,370,000 to $2,616,000. The cost of the proposed provision that restricts tallow based on an impurity level is addressed in a later section of this analysis.

2. Direct Costs

There are 5 categories of direct costs, including: (1) Capital and labor for slaughtering and rendering, (2) the tallow restriction, (3) MS beef restriction, (4) CMPAF marking costs, and (5) labeling and recordkeeping costs. We turn to each of these below.

a. *Capital and labor costs—slaughtering and rendering.* The proposed rule would result in cattle slaughter operations separating CMPAF and arranging for its disposal separate from other cattle offal. This change in activity may be similar to the new activities required by the 2004 USDA interim final rule, pertaining to the prohibition of SRM for use in human food. It is likely, however, that SRM segregation activities required under the 2004 USDA interim final rule that banned SRM from use in human foods would differ to some extent from those that would result from this proposed rule. The 2004 USDA interim final rule, for example, would allow SRMs that are no longer available for human consumption to go to rendering for processing into MBM and tallow for use in feed for non-ruminant animal species. Under the FDA proposal, the CMPAFs (which are a small subset by volume of SRMs) could not be used in any animal feeds. Therefore, slaughterers would need to use separate offal lines for offal of non-CMPAF-origin and offal of CMPAF-origin.

For projected capital investment and labor, because of the relatively small volume of CMPAF per plant, and current high rate of brain and spinal cord removal, the rule should result in only modest compliance costs. After consulting with slaughter operations, ERG projected that all slaughter facilities would need additional offal bins designated solely for CMPAFs. Additionally, modifications of processes and procedures would be necessary for those slaughter facilities that handle larger volumes of animals. These offal bin and modification estimates ranged from only $150 for the smallest facilities up to $15,000 for the two largest operations in the United States. Aggregate one-time capital expenditures are estimated to be about $555,000, or about $79,000 annually (based on a 7-percent discount rate over 10 years).

Additional labor costs would be incurred at slaughtering facilities to handle CMPAF segregation and disposal. ERG, using its discussion with industry members, estimated that the smallest facilities would incur no additional labor costs, while the level of additional labor would range from only a few minutes at the next smallest facilities to slightly more than one production worker at the largest establishments. Based on the average pay for this worker of $20,420 (plus a 40 percent increase for benefits), ERG estimated the additional labor costs for this industry at $597,000. Per facility labor costs are expected to range from $313 annually for the smallest plants to $30,000 annually for the largest plants. Total capital and labor costs for slaughtering facilities are estimated at $676,000 ($597,000 in labor costs plus $555,000 annualized at 7 percent over 10 years; annualizing at 3 percent would reduce the cost by about $14,000 annually).

Renderers would also incur additional capital and labor costs to handle CMPAF segregation from cattle not inspected and passed for human consumption. After consulting an equipment manufacturer, ERG projected the cost of equipment purchases and installation for renderers based on the size of the operation. These costs ranged from about $7,300 at the smallest rendering operations to about $72,000 for the largest operations. Total capital costs for renderers are estimated at $3.1 million (annualized at $442,000 over 10 years at a 7-percent discount rate, or at $486,000 with a 10 percent maintenance cost included). Using the upper end of the range of cattle not inspected and passed for human consumption that are currently rendered, we estimate the capital costs for renderers at about $7.67 million (annualized at $1.09 million over 10 years at a 7 percent discount rate, or at $1.20 million with a 10 percent maintenance cost).

Renderer labor costs would also increase due to the CMPAF separation, segregation and disposal. Using the same labor rates as slaughterers, ERG projected that the additional labor would range from slightly over $1,000 at the smallest facility to about $56,500 at the largest facilities. The low end of the range of total incremental payroll costs at renderers are estimated at about $1.4 million annually. The high end of the range of annual labor costs is estimated at $3.5 million. Although no labor overhead is included, we believe it would be negligible because most facilities would hire less than one additional laborer. Total capital and labor costs at rendering establishments are projected to range from about $1.88 million to $3,938,000 annually ($1.4 million to $3.5 million in labor costs plus $486,000 in capital costs after annualizing at 7 percent over 10 years; annualizing at 3 percent would reduce costs by about $78,000).

b. *Tallow restriction.* The proposed rule would ban the use of tallow derived from the brains and spinal cords of cattle 30 months of age or older, the brains and spinal cords of all cattle not inspected and passed for human consumption, and the entire carcass of cattle not inspected and passed for human consumption, if the brains and spinal cords are not removed. An exception to this ban is provided for tallow from these sources that has no more than 0.15 percent insoluble impurities. We do not believe, however, that it would be economical for renderers or tallow manufacturers to further process the brains and spinal cords from these animals into tallow while complying with the proposed equipment separation and tallow purification requirements. We have, therefore, not included additional costs for this proposed provision. The lost value of this tallow (and MBM) has already been accounted for earlier in this analysis.

c. *MS beef restriction.* We do not project any compliance costs for the proposed MS beef provision. The proposed rule would prohibit the use of

MS beef from use in animal feeds if the brain and spinal cord of cattle 30 months of age or older, the brain and spinal cord of all cattle not inspected and passed for human consumption, or the entire carcass of cattle not inspected and passed for human consumption has not been previously removed from the cattle material used to make MS beef. USDA and FDA have already banned MS beef from use in human food. Through contacts with industry members, the analysis projected that about 20 firms, about one-half of which are renderers, would be affected by this proposed provision. These businesses, known as ''4D'' firms, collect dead and downer (nonambulatory disabled) cattle and sell the meat to pet food manufacturers, zoos and other animal feeding operations. The number of pet food manufacturers using this MS beef as an input has been declining in recent years, however, due to public perceptions concerning pet food inputs. The analysis assumes many of these firms use mechanical separation equipment as part of their operation. Census data does not separately estimate the sales volume of red meat from 4D animals and MS beef from 4D animals. ERG estimated the size of the market at about $100 million per year, based on an industry contact. Further, the analysis estimated that 75 percent of the value of this product is generated from revenues unrelated to the animal or carcass pick-up fees. Of this 75 percent, about 20 percent to 25 percent is believed to represent MS beef sales. Industry contacts report that the brain and spinal cords of dead and downer cattle are already removed prior to any mechanical separation of muscle tissue, thereby negating the need of further compliance efforts. We invite public comment and analysis of the proposed rule's expected impact on 4D animals and current 4D industry practices related to MS beef.

d. *CMPAF marking costs*. The proposed rule would require that renderers that handle CMPAF or products containing CMPAF mark this material or product so that it can be identified by visual inspection. The analysis determined that the use of dyes would most likely be used as the marking agent. Although the industry lacks experience with the use of these dyes, it is believed to be a relatively simple process that would be performed at the end of the rendering process. Using a range of current dye costs, ERG estimated total industry compliance costs of this requirement to be from about $1,700 to $13,000 per year. At the high end of the range of cattle not inspected and passed for human consumption, compliance costs of this provision would range from about $2,200 to $16,000 per year.

e. *Labeling and recordkeeping/access costs*. The proposed rule would require additional measures be taken by renderers that handle CMPAF or products containing CMPAF to ensure that the prohibited materials are not used in animal feed. The proposed requirements include labeling the material ''Do not feed to animals'', establishing and maintaining records sufficient to track cattle materials prohibited in animal feed to ensure such material is not introduced into animal feed, and making such records available to FDA. The proposed rule would also require renderers that handle any cattle materials to establish and maintain records sufficient to ensure that materials rendered for use in animal feed do not contain CMPAF. ERG judged that the proposed labeling and recordkeeping requirements would result in modest additional costs to all renderers. Although past FDA rulemakings have shown that labeling requirements can impose a substantial cost on industry, the analysis assumed that this rulemaking's simple new labeling requirements (applying primarily to bulk shipments) could be incorporated into current labeling practices. We solicit comment on this assumption. Likewise, any recordkeeping rules would only require incremental administrative activities (to modify procedures and periodically review and file) beyond current renderer recordkeeping requirements. Total industry costs are estimated at about $62,000 annually (one-time costs of $101,000 annualized at 7 percent over 10 years plus annual costs of $48,000). We anticipate that records access costs would be negligible. We invite public comment on the projected level of effort by industry and estimated compliance costs of the proposed labeling and recordkeeping/access requirements.

3. Disposal Costs

After separation from the material allowed to be used in animal feed, an estimated 64.3 million lbs. of CMPAF would no longer be rendered for use in animal feeds, and therefore would need to go to disposal. The analysis identified five options for the disposal of these SRMs. These options include landfilling of the CMPAFs without rendering, rendering for disposal, disposal through alkaline hydrolysis digesters, incineration, and composting. Due to the relatively small volume of CMPAFs, rendering for disposal option would likely not be economically viable. Contacts with industry members elicited various responses concerning the disposal method that would be employed under the CMPAF scenario. While landfilling the CMPAF may be a possibility in some areas, other states do not allow the disposal of animal carcasses in landfills. Our analysis concluded that landfilling would likely be one of several methods used to dispose of the CMPAFs.

Based on industry information gathered for both this analysis (the CMPAF option) and the Alternatives Report, ERG estimated the disposal costs at $12 per 100 lbs. (cwt) of CMPAF. This is substantially higher than its estimate in the Alternatives Report of the cost of SRM disposal. Higher per cwt transportation costs (which are included in the $12 per cwt estimate) are expected under the CMPAF scenario than under the SRM alternative due to the much smaller volume of materials requiring disposal under the CMPAF option. Other reasons for the higher disposal cost rate include the uncertainty in the disposal methods that will be used, and limited industry experience with at least some of these methods. This led ERG to project a conservative estimate that fully accounts for some uncertainty in cost factors. It is possible that future industry efficiency in CMPAF disposal under any of the disposal methods would lead to a reduction in projected $12 per cwt disposal cost. Nevertheless, the 64.3 million lbs. of CMPAF that would result under this proposed rule is estimated to result in $7.72 million in disposal costs ($6.19 million to slaughterers and $1.53 million to renderers). Using the 42 percent estimate of cattle not inspected and passed for human consumption, we estimate that the 83.1 million lbs. of CMPAF would result in disposal costs of about $9.97 million annually.

Cattle producers are also expected to incur additional disposal costs for cattle not inspected and passed for human consumption in the form of an increase in on-farm disposals. An increase in pick-up fees for cattle not inspected and passed for human consumption due to the slight loss in value of the rendered MBM would likely cause some of these animals to be disposed of at a lower cost (than the pickup fee) to the producer by burial on the farm. As previously discussed, our analysis estimated that about 17 percent of all cattle not inspected and passed for human consumption are currently rendered. Additionally, it predicted that about 26,000 less cattle (0.6 percent of all cattle not inspected and passed for human consumption, or about 3.5 percent of all cattle not inspected and

passed for human consumption that are rendered) would be disposed of in this manner, comprised of beef cows (no additional feedlot cattle included) and cattle under 500 lbs (calves). ERG estimates of the incremental labor and equipment cost of this activity sum to $1.02 million annually. Using the 42 percent estimate of cattle not inspected and passed for human consumption and the same 3.5 percent relative change in the reduction in renderer pick-ups of cattle not inspected and passed for human consumption, we project that at the high end of the range about 64,000 additional cattle would no longer be rendered, at a disposal cost of about $2.53 million.

In forecasting the change in percentages to be disposed on-site, the analysis considered in qualitative terms all factors in the formula renderers use to determine whether they will make pickups. These factors include the travel distance to the location and the expected quantities of animals to be recovered at the location. All pickup charges vary over time with the value of meat and bone meal and tallow, so pickup patterns are subject to market-driven price changes that are addressed in the agreements between renderers and dead animal suppliers.

The analysis also considered that exclusions of prohibited materials reduced the prospective value of the animals to be recovered. Further, the potential latitude for renderers to increase fees was considered, although renderers were fairly tentative in their own forecasts of whether and how much they might increase pickup charges in response to a potential new regulation.

ERG also considered that many relatively remote locations had already been excluded from renderer pickups due to price and regulatory changes over the past ten years. Thus, remaining pickup locations were likely to have reasonably favorable characteristics, although presumably some locations remained marginal in terms of the existing market economics. The data in Table 2–1 of the ERG report (market prices of rendered materials, and MBM and tallow yields) and data on animal weights was used to consider the value of the dead animal to the renderer.

The final forecast of the response in pickups is the judgment of the apparent significance of the regulatory change to the economics of the renderer pickups. Because the brain and spinal cord exclusion affected a relatively small portion of the animal carcass for nondecomposed animals, it followed that the effect on rendering economics was similarly fairly modest. The analysis concluded that the prohibition of these materials would not trigger wider, rippling effects through the renderers' situation.

While there was considerable data about market prices for rendered products and other aspects of pickup economics, data on the distribution of relative costs among dead animal suppliers across the United States was lacking. Such data would have been needed to make a more rigorous forecast of the likely changes in rendering pickup patterns. Given the dominating importance of local economic considerations in rendering economics, even a national distribution of such data would have been of uncertain value to the estimation process.

The industry association report (Ref. 32) (submitted in response to the 2004 ANPRM seeking comment on a more restrictive full SRM ban in animal feed) asserts that there would be no incentive to pick-up cattle not inspected and passed for human consumption if it is banned from animal feed absent exorbitant fees. While this proposed rule would not ban all tissues from cattle not inspected and passed for human consumption, we acknowledge some uncertainty in the response by renderers in this area due to this proposed rule. We request comment on the number and percent of cattle not inspected and passed for human consumption that are currently rendered, as well as the expected number of additional cattle that would be disposed of on farms or elsewhere due to this proposed rule, and the costs of this activity.

4. Feed Substitution Costs

In both FDA's proposed and final rules concerning the prohibition on the use of mammalian proteins in ruminant feeds in 1997, the agency included the cost of feed that would be substituted for the MBM that would be prohibited from use in ruminants. The same issue arises with the proposed rule's creation of a list of CMPAFs that would be prohibited from use in animal feeds. Animal feed manufacturers would substitute other protein sources for the MBM that was previously manufactured from CMPAF.

In the analysis prepared for the 1997 rule banning the use of mammalian protein in ruminant feeds, the agency assumed a $31.76 per ton price increase ($38.33 adjusted to expected 2005 dollars by the average of general inflation from 1997 through 2004) for the substitute material, in this case soybean meal, as well as additional minerals that would be required to provide the same nutritional level as MBM. We accept this as a conservative estimate of the long-term price differential. The price differential between the two varies constantly based on the weather, feed ingredient imports, slaughter rates, and other factors. Since January 2004, soybean meal has been priced from $58/ton below MBM to $55/ton above MBM (Ref. 33).

We cannot predict the future price differentials between the two feed substitutes, but accept the previous number of $38.33/ton as a reasonable current estimate. Applying this feed cost increase over the 7,800 tons of MBM that would not be created as a result of this proposed regulation as calculated by ERG, results in $299,000 in additional feed costs. Using the high end estimate of the number of cattle not inspected and passed for human consumption that are currently rendered, additional feed costs would amount to about $457,000. We invite comment and data on the feed substitution costs that this proposed rule would impose.

5. Distribution of Impacts of CMPAF From Cattle 30 Months of Age or Older Slaughtered for Human Consumption and Cattle Not Inspected and Passed for Human Consumption

ERG, primarily for the purposes of the Regulatory Flexibility Analysis described in more detail below, estimated that a portion of the costs to slaughterers will be passed through to consumers and animal producers. Similarly, a portion of the costs to independent renderers for handling CMPAF from cattle not inspected and passed for human consumption will likely be passed back to ranchers, dairy farmers, and feedlot operators by way of increased pickup or disposal fees. We request public comment and data on the relative size and distribution of the likely pass through of the impacts of this rulemaking.

ERG also addressed the relative importance of the loss of MBM due to the CMPAF prohibition to both integrated packer/renderers and independent renderers. This analysis projected reductions of up to 0.2 percent of MBM production at independent renderers, while reductions of less than 0.1 percent of MBM production would occur at integrated slaughterers (packer/renderers)as the low impact estimates. Using the high estimate of cattle not inspected and passed for consumption that are currently rendered, we project a reduction of up to 0.4 percent of MBM production at independent renderers. Independent renderers rely to a greater extent on deadstock and, with the January 2004 USDA rule banning the use of nonambulatory disabled cattle in

human food, also on nonambulatory disabled cattle as inputs to their production process, while the integrated slaughterers do not.

E. Government Costs

The proposed rule may require the expenditure of additional funds by the Federal government, but the increased expenditures are not expected to be significant. The tissues that would be included on the list of cattle materials prohibited in animal feed, due to this proposed rule, may increase the number of inspections or the length of time necessary to inspect an establishment to verify compliance with the new proposed requirements. However, the number of establishments inspected is not expected to substantially change as a result of this proposed rule. All establishments that would be inspected for compliance under proposed § 589.2001 would already be subject to § 589.2000 or other federal rules. FDA has not estimated any additional costs due to this based on the assumption that the additional resources would not be significant. We invite comment on the issue concerning additional government resources that would be required by this proposed rule. ERG's discussions with industry members led to the conclusion that no new rendering establishments will be constructed and dedicated to disposal rendering as a result of the CMPAF ban. Without additional renderer establishments subject to this or other FDA regulations, FDA inspection efforts are not expected to noticeably increase as a result of this proposed rule.

F. Sensitivity Analysis

Due to the previously described uncertainty concerning the additional cattle not inspected and passed for human inspection that would no longer be rendered as a result of this proposed rule, we have included a sensitivity analysis around this cost factor. The ERG report projected that an additional 0.6 percent of the current 17 percent of cattle not inspected and passed for human consumption that are currently rendered would not be rendered as a result of this rule and would likely be buried on the farm or elsewhere (a relative reduction of 3.5 percent (0.006/0.17) of the cattle not inspected and passed for human consumption that are currently rendered). Table 3 estimates the total costs of the proposed rule for various estimates including the original 0.6 percent reduction in the number of cattle not inspected and passed for human consumption that are rendered, as well as reductions of 1 percent and 2 percent (representing relative reductions of 5.8 percent (.01/.17) and 11.6 percent (.02/.17), respectively). High end cost estimates (derived from the 42 percent estimate of the number of cattle not inspected and passed for human consumption that are currently rendered) for the same relative percent reductions are also included.

If 42 percent of cattle not inspected and passed for human consumption are currently rendered, and that implementation of this proposal would cause an additional 2 percent of all cattle not inspected and passed for human consumption not to be rendered, then the total incremental costs of the rule would rise to about $36 million per year. FDA solicits comment on the likely effect of this proposal on the percent of cattle not inspected and passed for human consumption that is not rendered and on the costs to society of the disposal methods likely to be used as an alternative to rendering.

TABLE 3. SENSITIVITY ANALYSIS

Reduction in Percent of Cattle Not Inspected and Passed for Human Consumption That are Rendered (Proposed Rule)			
	0.6%	1.0%	2.0%
Total Costs	$14.4—$23.7 million	$16.2—27.8 million	$19.8—$36.3 million

G. Regulatory Flexibility Analysis

1. Small Business Impacts

The Regulatory Flexibility Act requires agencies to prepare a regulatory flexibility analysis if a rule is expected to have a significant impact on a substantial number of small entities. The discussion in this section, as well as data and analysis contained in sections two through four of the ERG report, constitute the agency's compliance with this requirement.

One requirement of the Regulatory Flexibility Act is a succinct statement of any objectives of the rule. As stated previously in this analysis, with this proposed rule the agency intends to strengthen the existing safeguards designed to help prevent the spread of BSE in U.S. cattle, as well as further reduce any risk posed to humans from the agent that causes BSE.

The Regulatory Flexibility Act also requires a description of the small entities that would be affected by the proposed rule, and an estimate of the number of small entities to which the proposed rule would apply. Our analysis focused on renderers and animal slaughterers, and to a lesser extent on 4D firms. Additionally, the Alternatives report addresses possible impacts to small dairy farms from the blood products alternative, and impacts to feed mills from the dedicated equipment/facilities alternative (options summarized in the alternatives section of this document).

Animal slaughterers would be classified in the North American Industrial Classification System (NAICS) under code 311611—Animal (Except Poultry) Slaughtering and renderers under NAICS code 311613—Rendering and Meat Byproduct Processing. The Small Business Administration (SBA) classifies slaughterers and renderers with less than 500 employees as small businesses.

The ERG study estimated the number of small businesses that would be affected by the proposed rule in its analysis of compliance costs. The number of slaughterers and renderers affected by the CMPAF ban (including recordkeeping/labeling and marking costs) were estimated at 689 and 141, respectively. This would include all federally inspected slaughter plants and the all those renderers that handle mammalian proteins that are currently prohibited in ruminant feed. Using U.S. Census and USDA data, ERG then distributed the number of affected entities in each business sector across the size classes of establishments using the same proportions as those presented in the total number of establishments. Using this distribution, it appears that about 97 percent of slaughterer establishments and all renderer establishments would be considered small businesses. However, the existence of many multi-establishment rendering and slaughtering firms would tend to overestimate the number of small businesses within each sector. In fact, other Census data shows that only 79 percent of rendering firms would be considered small businesses (Ref. 34). Nevertheless, we believe that the number of affected small businesses in

both sectors would still be considered substantial.

The CMPAF ban would primarily affect slaughterers and renderers. ERG used its Small Business Impact Model (SBIM) to predict net income and closure impacts for slaughterers and renderers by size of establishment (for a full explanation of the SBIM, see section 4.2 of the Alternatives report (included in the docket (Ref. 31)). The model assumes there is no pass through of compliance costs. Although this is a conservative assumption, smaller businesses in fact are probably less able to pass through compliance costs than larger businesses in the same industry, all other things equal. Under the no pass through assumption, the model predicts moderate net income impacts that could result in the closure of up to one slaughtering and one rendering establishment. We acknowledge that net income impacts would likely be higher under the higher estimate of the percent of cattle not inspected and passed for human consumption that are currently rendered.

Our analysis for simplicity ignores any potential increases in MBM prices that may ensue as a result of this proposed rule. In fact, some modest price increases may occur as foreign demand for MBM increases in response to reduced risk of BSE infectivity. Such price increases may mitigate any reduction in net income of independent renderers.

ERG developed a separate market model to estimate the impact of a CMPAF ban on beef prices and output. It implies that about 50 percent of compliance costs will be passed on to consumers, 38 percent will be passed back to cattle producers, and 12 percent will be incurred by slaughterers. The model predicts that cattle producers would realize only a 0.01 percent reduction in price for cattle, which would not be considered a significant impact. Nevertheless, the agency acknowledges the possibility of significant impacts on a substantial number of small slaughterers and renderers.

The agency believes that the annual feed substitution costs (from about $300,000 to $457,000) would not constitute a significant impact when spread across the thousands of non-ruminant animal producers that currently use ruminant protein in animal feeds. The agency requests comments and additional data on the likely small business impacts on slaughterers, renderers, beef cattle producers, dairy cattle producers, or other animal producers and firms in related industries.

2. Analysis of Alternatives

We considered five other measures that are not included in this proposed rule. These five measures, discussed in turn in the following paragraphs, include: (1) A requirement that those facilities handling both mammalian protein that is currently prohibited in ruminant feed and ruminant feeds use dedicated facilities or equipment for each, (2) a ban on the use of poultry litter in ruminant feeds, (3) a ban on the use of blood and blood products in ruminant feeds, (4) a ban on the use of plate waste in ruminant feeds, and (5) a ban on the use of a larger list of SRM (using the USDA and FDA definition for human food) from all animal feeds.

a. *Dedicated facilities/equipment requirement.* As mentioned previously in this preamble, FDA considered requiring that those facilities that process or otherwise handle both mammalian protein currently prohibited in ruminant feed and prepare feed or feed ingredients for ruminants use separate facilities or equipment in order to prevent cross-contamination. This option was included in the public announcement concerning agency intentions in January 2004. The proposed rule's dedicated equipment requirement concerns the issue of cross-contamination of CMPAFs with other cattle material once it has been separated, whereas the requirement for dedicated equipment/facilities under this option concerns cross-contamination of mammalian protein currently prohibited in ruminant feeds and ruminant feeds under the current mammalian to ruminant feed ban. Due to the large tonnage difference between CMPAFs and all animal protein currently being rendered, this alternative would result in larger industry impacts than would the dedicated equipment requirement concerning CMPAFs alone.

In its Alternatives Report, ERG projects that this option would be expected to reinforce the current trend in which increasing numbers of feed mills discontinue the use of mammalian protein currently prohibited in ruminant feeds in favor of porcine, avian, or plant-based proteins. ERG estimates that only 124 out of more than 5,100 feed mills and 41 out of 235 renderers currently produce ruminant feed or feed ingredients and handle or process ruminant MBM. Based on its small survey of feed mills, ERG estimates that only 27 of these feed mills and 4 renderers would invest in dedicated facilities or equipment in order to continue or begin to distribute both prohibited materials and ruminant feeds or feed ingredients.

ERG consulted an agricultural architecture and engineering firm to prepare cost estimates of investment in dedicated feed mill facilities. Based on these estimates and discussions with feed mill operators, ERG projects that no new mills would be constructed as dedicated facilities to comply with this option, but rather currently operating or idle mills would either be renovated or expanded as dedicated facilities, or would handle a dedicated line of equipment. The annualized costs of these investments for the 27 feed mills were estimated at $6.2 million over 10 years at a 7-percent discount rate (at a 3-percent discount rate over 10 years, the cost would be $5.1 million per year). The effect on the ruminant MBM market caused by the discontinued use by those that currently offer it in feeds but would choose not to invest in dedicated facilities or equipment would be expected to be small.

ERG performed a similar survey of some of the 41 renderers that the FDA inspection database showed as handling mammalian proteins currently prohibited in ruminant feed and produce materials intended for use in ruminant feed. The results of this survey indicate that very few renderers intend to invest in dedicated facilities. Based on its small sample, ERG predicts that only 4 renderers would do so. These were all expected to currently have partial separation or dedication capabilities in place. Based on discussions with renderer operators through this and previous surveys, ERG predicts that the renderers that invest in dedicated facilities would spend, on average, about $2 million each. The total cost of investment in dedicated facilities would be $8 million. Annualizing this total over 10 years at a 7-percent discount rate results in an annual cost of $1.14 million ($940,000 over 10 years at a 3-percent discount rate).

The dedicated facilities/equipment requirement would also extend to the transportation services for mammalian proteins currently prohibited in ruminant feed. Based on another survey of selected feed mills, agricultural trucking companies and renderers concerning their current transportation of products, ERG determined that agricultural transporters would also incur costs as a result of this provision of this option. The option implies that renderer delivery trucks that carry prohibited MBM, including contract haulers providing this service, would no longer be allowed to backhaul ruminant feed or ruminant feed ingredients as part of its delivery routine. Due to this

change in service, ERG estimated a transportation cost increase of 40 to 80 percent for the 141 rendering facilities that process mammalian protein currently prohibited in ruminant feed. Although most of these renderers do not handle both mammalian protein currently prohibited in ruminant feed and ingredients for feeds for ruminants, they rely on transportation services (most likely contractor services) that transport both materials, and thus would not be in compliance. These transportation cost increases are projected to total $8 to $16 million per year for the rendering industry.

Feed mills would also be expected to incur transportation cost increases due to the prohibition under this option on backhauling ruminant feeds in trucks that are used to deliver feeds with mammalian proteins currently prohibited in ruminant feed. Since backhauling does not occur as often in the delivery of feed due to shorter average distances between feed mills and animal producers than from renderers to feed mills, ERG predicted the transportation cost increases at 25 to 50 percent for feed mills. Based on ERG's calculation of the quantity of feed that would be affected by the proposed rule (4.5 million tons) and the average transportation cost per ton of feed ($12.66), total transportation cost increases for feed mills were estimated to range from $14.2 to $28.4 million per year. These costs would include the amortized cost of capital equipment such as additional trucks, as well as incremental operating and maintenance costs. These costs would be incurred by about 200 feed mills. Again, this number is larger than the number of mills that handle both mammalian proteins currently prohibited in ruminant feed and ruminant feeds due to the additional number of mills that would rely on contract feed haulers that handle both materials. ERG acknowledges uncertainty in these estimates due to possible changes in mill dedication patterns, the analysis of which would have required additional geographic distribution data on feed mills and feed types.

If CMPAFs are banned from use in all animal feeds as proposed in this rule, the agency believes that a provision requiring dedicated facilities or equipment for those handling mammalian proteins currently prohibited in ruminant feed and preparing ruminant feeds would not be necessary because this proposed rule is expected to reduce the number of ID_{50}s available for use in animal feeds by about 90 percent. Requiring separate facilities or equipment for mammalian proteins currently prohibited in ruminant feed and ruminant feeds would not be expected to significantly reduce the risk of feeding prohibited proteins to ruminants, because nearly all of the potentially BSE infective tissues would be unavailable for use in feeds for any animals because of the CMPAF prohibition. Therefore, the risk is minimal that the BSE agent would be present even if cross-contamination occurs between mammalian protein intended for non-ruminant feed and ruminant feeds. The agency requests comment and data on the need for a requirement for dedicated facilities/equipment for those facilities that handle both mammalian proteins currently prohibited in ruminant feed and ruminant feed when a CMPAF ban also exists.

b. *Poultry litter prohibition.* The agency also considered a ban on poultry litter in ruminant feed. Poultry litter contains bedding material, spilled poultry feed, and manure, and is a waste by-product of poultry production. Because poultry feed may contain mammalian meat and bone meal currently prohibited in ruminant feed, there is a risk that cattle fed poultry litter containing spilled poultry feed may be exposed to prohibited meat and bone meal through that spilled poultry feed.

This alternative would ban the use of poultry litter in all ruminant feed. Its costs would be comprised of both substitution costs for the replacement materials needed to provide an equivalent nutritional value, and disposal costs if the poultry litter cannot be used as an alternative product, such as fertilizer. The risk reduction would be the elimination of the possibility of the spread of BSE through the recycling of mammalian proteins currently prohibited in ruminant feed back into cattle feed through poultry litter including the spilled poultry feed containing prohibited mammalian proteins.

A preliminary risk assessment of poultry litter submitted to the agency by an industry member predicted that in its worst-case scenario, under the current ruminant feed ban rule, a cow would need to eat 70.1 tons of litter to be exposed to 1 ID_{50} (Ref. 35). FDA modified some of the assumptions used in this risk assessment and predicted what would happen if there was no mixing during the cleanout process so that the spilled feed remained concentrated in a small portion of the bedding. Under this scenario, a ruminant fed only contaminated litter from under the poultry feeders must consume 3.4 tons to consume 1 ID_{50}. This tonnage is still beyond the volume a stocker steer would realistically consume under normal circumstances due to its relatively short life. Similarly, dairy cows would also not be expected to consume this amount since poultry litter is not generally used in feed for lactating dairy cows. Because it appears to pose only a small baseline risk of BSE for ruminants, FDA currently believes that banning poultry litter from ruminant rations would have little or no affect on the human risk while increasing the environmental risks of its alternative disposal methods. FDA requests comments on this issue.

Most poultry litter is not used as cattle feed. As an organic source of nutrients for plants, it has been applied to farmland for years. This practice, however, raised environmental concerns that excess nitrogen and phosphorus could leach from the litter and contaminate waterways. Since rumen microbes can efficiently metabolize poultry litter, feeding litter to cattle provides an alternative use to land application that benefits both poultry growers and cattle producers. Where poultry and cattle operations overlap, poultry growers are willing to sell litter at a price that exceeds the value of any alternative use. Cattle producers obtain a feed ingredient for a lower price than the next best alternative ingredient in the ruminant ration. Banning the use of litter in ruminant feed will likely increase the price of rations for ruminant producers and decrease revenues for poultry producers. Moreover, if poultry producers must dispose of unwanted litter, their operating costs would increase.

To analyze the impact of the ban on poultry litter on ruminant producers, we calculated the per ton price of equivalent cattle rations with and without poultry litter. Based on feed ingredient prices in March 2004 and using equivalent cattle ration formulations recommended by University of Georgia, rations with 38 percent to 53 percent poultry litter average about $65 per ton (Ref. 36). Equivalent rations without poultry litter average about $80 per ton, or about $15 per ton more than the ration with poultry litter. The average cattle fed about 16.5 pounds of feed daily for 200 days consumes a total of 0.6 tons to 0.9 tons of litter, depending on the percentage of litter in the ration. This suggests that the cost of feed will increase by about $25 per head ($15 per ton x 200 days per head x 16.5 pounds per day/2,000 pounds per ton). The annual supply of poultry litter can potentially feed between 1.3 million (1.1 million tons of litter / 0.9 tons of litter

per cow) and 3.2 million cows (2 million tons of litter / 0.6 tons of litter per cow). Thus the total cost of feed could increase from $32 million ($24.75 per cow x 1.3 million cows) to $80 million ($24.75 per cow x 3.2 million cows).

Vertical integration in the poultry industry often results in contract growers' contractual responsibility for litter management. For many reasons, including regional distribution of poultry producers and costly transportation, commodity markets do not handle poultry litter. Some poultry producing states have taken the initiative to promote and develop an infrastructure for litter markets, including programs to match the producers and users of poultry litter; providing transportation subsidies, or encouraging informal ''markets'' where buyers and sellers can contact each other.

Alternative uses for poultry litter are being developed, but are not widely available currently. With technology developed in the United Kingdom, the nation's first poultry litter fired power plant is being constructed in Missouri. Research is underway to convert litter into activated carbons that can absorb environmental pollution.

In areas where cattle and poultry production overlap, banning poultry litter from ruminant feed may require that growers store litter, probably in deep stacking sheds, until alternative uses can be identified. If it is not possible to store litter, however, growers may need to dispose of surplus litter in landfills. To illustrate the cost of a worst-case scenario, disposal of the entire 1.1 million to 2 million tons of litter would range from $44 million to $160 million with disposal fees that range from $40 to $80 per ton.

Without alternative outlets for litter banned from ruminant feed, the total short-run costs might range from $76 million to $240 million. Contract growers and ruminant producers, many of whom are small entities, would incur these costs. Although the poultry litter alternative has not been included in the proposed rule, the agency requests comment on the need for a poultry litter ban in ruminant feed when a CMPAF ban in all animal feed also exists.

c. *Blood and blood products prohibition*. We also considered an alternative that would have prohibited the use of blood and blood products in ruminant feed. We did not include this option in this proposed rule because we could not at this time show any BSE risk reduction as a result of such a prohibition, and these products have beneficial effects in ruminant feed. This option, if adopted, would result in one-time direct costs of about $7 million (annualized at $990,000 over 10 years at 7 percent) for relabeling, reformulation and reregistration, as well as additional revenue losses for the product manufacturers.

ERG identified and profiled the various blood and blood products used in animal nutrition. These products include plasma-based therapeutics and feed additives, premium blood-based feed additives and commodity blood meal. The prohibition of blood and blood products would result in some additional administrative costs to feed mills. It would require some mills to reformulate the rations in feeds. Relabeling efforts would also be required for some feeds, depending on whether the current label identifies specific animal proteins or identifies proteins under the broader term ''animal protein products.'' Additionally, some of these feeds would need to be reregistered with state agencies due to their new labeling, resulting in additional administrative cost to the mills.

ERG prepared cost estimates for each of these activities based on FDA database information on feed ban inspections, data from industry-sponsored reports, an industry journal, and Bureau of Labor Statistics data. ERG estimated that about 2,300 feed mills offer some type of blood-meal containing feeds, and that these mills have, on average, about 44 feed mixes that would require reformulation due to their containing blood meal or another ruminant protein that would no longer be offered due to a dedicated facilities/equipment requirement. ERG prepared this estimate assuming that both a blood product prohibition and a dedicated facility/equipment requirement would be proposed. Therefore, to the extent that the estimated 44 feed mixes represent not those containing blood products but rather another ruminant protein that would no longer be available if a dedicated facilities/equipment requirement had been created, these costs will be overestimated. Based on the various labor rates for mill employees, ERG estimated that reformulation efforts would result in a one-time total cost of $2.85 million. Relabeling costs, including both printing plate preparation and additional labor hours, are estimated to result in a one-time cost of $2.77 million. Reregistration costs are projected to add another one-time cost of $1.34 million. In total, these efforts would result in a one-time cost of $6.96 million (average one-time costs per affected mill would be about $3,000). Annualized over 10 years at a 7-percent discount rate, this equates to $990,000 per year (see table 4 of this document).

TABLE 4.—ADMINISTRATIVE COSTS

Cost Element	One-Time Costs (Thousands)	Annualized Costs[1] (Thousands)
Reformulation	$2,853	$406
Relabeling	$2,771	$395
Reregistration	$1,340	$190
Total Costs	$6,963	$990

[1]Over 10 years at a 7 percent discount rate.

Along with the compliance costs mentioned previously, this option would also result in the loss in value of the blood products themselves. ERG's discussions with producers of plasma-based products for therapeutic use led to the following conclusion. Most of these products would not find an acceptable alternative market, or would do so only at a steep price discount, due to their reduced efficacy when used in animals other than cattle. Although ERG projected future market volumes based on industry contacts, current sales of these products are unavailable. Plasma-based feed additives and premium blood-based feed additives are not as species-specific and could be shifted to use in non-ruminant markets assuming a smaller decrease in price than would likely occur with the therapeutic

products. These products, which could be shifted to use in non-ruminant markets, may also incur higher transportation costs because fewer mills would be expected to accept any mammalian proteins currently prohibited in ruminant feed, that is if the dedicated facilities/equipment was also required. Commodity ruminant blood meal, valued at about $41 million in 2003, would also be expected to lose value due to this option. Porcine based blood meal would be expected to increase in value. These losses have not been projected.

At this time, the agency does not have evidence that BSE is transmitted to cattle via blood or blood products. Therefore, the agency has not proposed that these products be banned from use in ruminant feeds in this proposal. The agency requests further comment and scientific information on the need to prohibit the use of blood and blood products in ruminant feed.

d. *Plate waste prohibition*. This alternative would have eliminated the current exemption of inspected meat products which have been cooked and offered for human food, and further heat processed for feed (commonly referred to as plate waste but also including used cellulosic food casings) from the current definition of protein derived from mammalian tissues. It would ban plate waste from use in ruminant feed.

As previously mentioned in the preamble to this proposed rule, the agency requested comment on questions related to the use of plate waste in ruminant feeds in the 2002 ANPRM. These questions focused on the extent of plate waste use in ruminant feeds, the composition of plate waste and its sources, plate waste processing techniques prior to its inclusion in feed, and the adverse and positive impacts for excluding plate waste from feed. Although the agency received many comments to the 2002 ANPRM, they did not include estimates of usage or regulatory impacts that were specific enough to form a foundation for a cost analysis of this option. One comment stated that the amount of plate waste used in ruminant feed was low. Another comment mentioned that substantial tonnages were used in ruminant feed in at least one state. A third comment stated that plate wastes from correctional facilities in another state were used in ruminant feed. No additional data was included to support these statements about the extent of plate waste use in ruminant feed. One comment stated that there were six processors of plate waste in the United States, but did not list these processors or offer any estimate of the use or value of processed plate waste in ruminant feed.

We tried to collect more information on the use of plate waste in ruminant feed and any expected impacts from its ban in ruminant feed, by contacting all those who commented to the ANPRM about plate wastes. The comment that mentioned the use of plate waste from correctional facilities offered additional anecdotal data about this practice in one state, stating this practice was common in areas that had cattle or hog farms located near correctional facilities. It is likely, though, that because most or all of this plate waste is not currently further heat processed for feed, it would not be exempt from the current feed ban as defined in the 1997 ruminant feed final rule. No additional data on actual volumes of plate waste was offered. Another state agriculture agency that responded to the ANPRM, when contacted for further information, also stated that very little, if any, plate waste was further heat processed and used in ruminant feeds. Further, earlier estimates of significant tonnages of plate waste being used in feeds could not be verified by this agency through its investigators in the field. The other comments did not respond to our attempts at further contact.

We also requested the assistance of agency personnel with knowledge of the ruminant feed industry in estimating the extent of use of plate waste in ruminant feeds. Although these agency sources acknowledge that the practice exists, we do not have any estimate of its prevalence on a national level. According to these agency sources, since plate waste (including used cellulosic food casings) is expected to have a relatively low nutritional value when used as a supplement in ruminant feeds, it would not be used in ruminant feed as a general rule. While the agency acknowledges that some plate waste is currently used in ruminant feeds, it cannot offer an estimate of this plate waste volume. The agency acknowledges there would be incremental disposal costs and alternative feed costs, due to a ban on the use of plate wastes in ruminant feeds. However, the agency cannot reliably estimate these costs at this time.

The agency has concluded that this additional measure would be unnecessary given that measures already implemented by USDA and FDA to prohibit SRMs from human food effectively eliminate BSE infectivity from plate wastes. The agency requests further public comment on the extent of plate waste use in ruminant feeds and the costs such a prohibition would impose on any industry members.

e. *SRM prohibition*. A final alternative would prohibit the use of a more extensive list of cattle materials in any animal feed. These materials would include the following: (1) SRMs, (2) The small intestine of all cattle, (3) material from cattle not inspected and passed for human consumption (including nonambulatory disabled cattle), (4) tallow containing more than 0.15 percent insoluble impurities if derived from prohibited material, and (5) MS beef. SRMs would be defined as the skull, brain, eyes, spinal cord, trigeminal ganglia, vertebral column, (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) and dorsal root ganglia of all cattle 30 months of age or older, plus the tonsils and distal ileum of all cattle regardless of age.

FDA stated in July 2004 that it was considering this alternative, and ERG completed a cost analysis of this option. It is available at the Division of Dockets Management (see **ADDRESSES**).

This alternative would require slaughterers to separate SRMs from slaughter cattle, and require renderers and firms that process dead, down, disabled, and diseased cattle (cattle not inspected and passed for human consumption) to separate all material from such animals from the remaining cattle offal produced for eventual use as animal feed. We estimate that the separation of these SRMs and material from cattle not inspected and passed for human consumption would require about $26.5 million in one-time capital costs (or $3.8 million annualized at 7 percent and $3.1 million annualized at 3 percent, over 10 years). We estimate that the annual cost of the additional labor to separate SRMs from other cattle offal is estimated to cost about $9.2 million annually. The analysis projected that SRMs, instead of being rendered for animal feed, would most likely be rendered for disposal, based on the large amount of banned material this option would generate. To the extent that some states would allow landfilling (another relatively low cost disposal option), this analysis may overestimate compliance costs. Although compliance costs for these activities would be borne initially by slaughterers, and are presented as such by ERG, a portion of the costs are likely to be passed through to cattle producers and consumers. Annual rendering costs, which would include the value of the MBM net of the value of the recovered tallow, would range from $24 million to $88 million at the low estimate of the number of cattle not inspected and passed for human consumption that are currently rendered

to $31 million to $117 million at the high estimate. Additional SRM transportation costs would be incurred to move SRMs and cattle not inspected and passed for human consumption from slaughterers to disposal renderers, and to move nonSRM offal a further distance to another renderer due to their current renderer becoming a for-disposal-only renderer. We estimate these to range from $22 million to $39 million at the low estimate of cattle not inspected and passed for human consumption that are rendered to $33 million—$58 million at the high estimate annually. Additionally, the estimated cost to dispose of the resulting MBM is estimated at $8 million—$16 million at the low estimate and $12 million -$24 million annually at the high estimate. Total annualized costs of the prohibition of SRM, cattle not inspected and passed for human consumption (as shown in table 4 of this document) are estimated to range from $76 million to $161 million at the low end of the estimates of cattle not inspected and passed for human consumption that are rendered. Using the high estimate, annualized costs would range from $102 million to $225 million. FDA expects MBM disposal costs to decrease in the future with the development of alternative markets for MBM of SRM-origin, but can offer no projections of these cost reductions.

These cost estimates assume the development of a rendering industry dedicated entirely to disposal. This industry would earn no fees from selling rendered material, but would instead charge slaughterers and cattle owners for the disposal of prohibited materials. Information submitted to the agency implies that some independent rendering establishments would be used as rendering for disposal, contingent upon a volume of SRM products that would make disposal rendering profitable. It may be possible that some geographic areas would be underserved by disposal renderers due to the lack of availability of SRMs and cattle not inspected and passed for human consumption, necessary to provide the service at a charge that is lower than the cattle producers' indirect cost of on-farm disposal of cattle not inspected and passed for human consumption. Neither FDA nor ERG has the geographic data on renderer locations and offal suppliers, or the financial data on individual renderers necessary to predict the number or geographic location of rendering establishments that will undertake SRM rendering for disposal. Further discussion of the implications for the development of a disposal rendering industry is available in the environmental assessment of this proposed rule. We request comments and data concerning the development of a rendering industry dedicated to rendering for disposal only of SRM and cattle not inspected and passed for human consumption.

ERG determined that the prohibition on the use of tallow derived from the list of cattle materials prohibited under this alternative option that contains more than 0.15 percent hexane-insoluble impurities would result in annualized costs estimated at $2. million. These costs consist of capital and operating costs for polishing centrifuges that would be needed by a small segment of independent renderers (further analysis of this provision led ERG to reduce the estimated cost, as it reported in its analysis of the proposed rule, to $1.78 million annually). The loss in market value of both MS beef and muscle tissue from cattle not inspected and passed for human consumption used in animal feeds is projected at about $75 million. FDA acknowledges that this last estimate is speculative because these sales cannot be distinguished from other renderer sales in U.S. Census data. FDA invites public comments and data on the impacts of the provisions that would prohibit all tallow derived from the prohibited materials that contains more than 0.15 percent insoluble impurities and all MS beef from use in animal feeds. Total costs of this alternative are estimated to range from $154.0 million to $242.6 million annually for the low estimate of cattle not inspected and passed for human consumption. Using the high estimate, total annualized costs are projected at $178 million to $302 million Table 5 of this document displays the costs associated with this alternative.

TABLE 5.—TOTAL COSTS ($ MILLIONS)[1]

Cost Item	One-Time Cost	Annual Costs	Annualized Costs
Capital Investments	$27	N/A	$4
Labor		$9	$9
Net Rendering Costs[2]		($25–$88) to ($31–$117)	($25–$88) to ($31–$117)
SRM Transportation		($22–$39) to ($33–$58)	($22–$39) to ($33–$58)
Disposal Costs		($10–$18) to ($17–$29)	($10–$18 to ($17–$29)
SRM Marking		($0.02–$0.15) to ($0.03–$0.23)	($0.02–$0.15) to ($0.03–$0.23)
Recordkeeping/Labeling		$0.05 to $0.06	$0.05 to $0.06
Feed Substitution		$6–$7	$6–$7
Subtotal—Codified SRM, Dead, Downer Ban		($72–$161) to ($96–$220)	($76–$165) to ($100–$224)
Tallow Restriction	$11	$1	$2
MS Beef Ban		$75	$75
SRM Alternative Total Costs			($153.0–$242) to ($178–$302)

[1] Low cost estimate ranges reflect lower estimate of cattle not inspected and passed for human consumption. High cost estimate range reflect high end of estimates of cattle not inspected and passed for human inspection.

[2] Has been reduced by the value of the tallow products recovered.

To assess the risk reduction from the SRM alternative in this proposed rule, we use two distinct approaches. In the first approach, we assume that the number of new BSE cases is proportional to the amount of all infectious material included in feed. Given this assumption, we can estimate the percentage reduction in risk as the percentage reduction in infectious material.A report by the Scientific Steering Committee of the European Union suggests that the tissues designated as SRM (brain, spinal cord, trigeminal ganglia, dorsal root ganglia, distal ileum, eyes) constitute at least 99.44 percent of the total infective load (Ref. 29). These tissues (SRMs) from cattle 30 months of age and older, the tonsils and distal ileum of all cattle, and all material from cattle not inspected and passed for human consumption, would be prohibited from use in any animal feed under this alternative. SRMs (except for tonsils and distal ileum which are prohibited regardless of age of cattle), when taken from cattle less than 30 months of age, would not be prohibited from use in all animal feed because the probability is very low that tissues from cattle of this age would contain BSE infectivity. FDA estimates, therefore, that banning SRMs from use in any animal feed would effectively remove about 99 percent of any remaining infectivity from possible spread through the feed system.

The second approach uses the Harvard-Tuskegee risk assessment model, making adjustments to the infectivity pathways for cattle and humans that would still be available even after the USDA interim final rules concerning SRMs in human food and Advanced Meat Recovery (AMR) systems became effective. FDA has updated the model to simulate the introduction of five infected cattle into the United States. The model was also updated to further reduction in the spread of BSE among cattle and reduction in human exposure to cattle oral ID_{50}s that would result from a ban on SRMs in animal feeds. The USDA rule, prohibiting the use of SRMs in human food as well as the FDA interim final rule prohibiting the use of SRMs in human food and cosmetics, may cause some offsetting increases in the amount of SRMs that enter non-ruminant feeds; the proposed SRM ban would address this increase in SRMs in animal feed. Under this second approach, we define risk reduction as the reduction in human exposure that would result from the ban on the use of SRM in any animal feed using the HCRA model. These results show that prohibiting the use of SRMs in all animal feed would effectively negate about 95 percent of the remaining risk of human exposure to cattle oral ID_{50}s. When considered as a complementary measure to the USDA and FDA SRM bans for human food, the estimate of overall human exposure reduction from those bans and the SRM alternative is more than 99 percent.

The model does not take into account any additional risk reduction from the restrictions on the use of tallow or MS beef in animal feeds. While we believe these additional restrictions would likely further reduce the risk to human health from BSE to a small degree, we cannot quantify this risk reduction.

Compared to the proposed rule, this alternative would impose an additional $171 million to $226 million in annual compliance costs. As discussed earlier, we believe that this proposed rule provides the appropriate level of protection against the spread of BSE in a cost-effective manner.

V. Paperwork Reduction Act

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Substances prohibited from use in animal food or feed.

Description: We are proposing to amend our regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals. These materials include the following: (1) The brains and spinal cords from cattle 30 months of age and older (2) the brains and spinal cords from cattle of any age not inspected and passed for human consumption, (3) the entire carcass of cattle not inspected and passed for human consumption if the brains and spinal cords were not removed, (4) MS beef that is derived from cattle from which prohibited materials were not previously removed; and (5) tallow that is derived from cattle materials prohibited in animal feed unless such tallow contains no more than 0.15 percent insoluble impurities. These measures will further strengthen existing safeguards designed to help prevent the spread of BSE in U.S. cattle.

Description of Respondents: Rendering facilities, Medicated feed manufacturers and distributors, livestock feeders.

TABLE 6.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Recordkeeper	Total Hours	Operation and Maintenance Cost
589.2001(b)(2)(iv) and (b)(3)(i)	141	1	141	20	2,820	$47,940
Total					2,820	

The estimated recordkeeping burden is derived from agency resources and discussions with affected industry. The recordkeeping requirement in proposed § 589.2001(b)(2)(iv) will apply to the limited number of renderers who will handle prohibited bovine material. We estimate that no more than 50 rendering firms will be involved in the handling

of this material. Although we may consider the distribution records needed to comply with this proposed regulation ''usual and customary'' and thus not subject to PRA, we believe there will be burden associated with setting up a system to assure such records are sufficient to address the proposed recordkeeping requirement. Likewise, although we may consider the records necessary to comply with proposed § 589.2001(b)(3)(i) as ''usual and customary'' and not subject to PRA burden accounting, we are including a burden estimate to cover establishment of a system to assure existing receipt and manufacturing records adequately address this proposed requirement.

In compliance with the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB).

OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

VI. Environmental Impact

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

VII. Federalism

We have analyzed this proposed rule in accordance with the principles in Executive Order 13132. We have determined that the proposed rule does not contain policies that have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have tentatively concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.

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11. U.S. Department of Agriculture, Animal and Plant Health Inspection Service, USDA's BSE Testing Program, USDA/APHIS Internet Page (*http://www.aphis.usda.gov/lpa/issues/bse_testing/index.html*).

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13. Overview of the BSE risk assessments of the European's Commission Scientific Steering Committee (SSC) and its TSE/BSE ad hoc group, Adopted between September 1997 and April 2003, June 5, 2003, Europa Internet Page (*http://europa.eu.int/comm/food/fs/sc/ssc/out364_en.pdf*).

14. U.S. Food and Drug Administration, Center for Veterinary Medicine, Summary of FDA Inspectional Findings and Recalls Involving the Ruminant Feed Ban Regulation (21 CFR 589.2000) Conducted in Fiscal Year 2004 and First Half of Fiscal Year 2005, September 2005.

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25. ''Economic Impacts of Proposed FDA Regulatory Changes to Regulations of Animal Feeds Due to Risk of Bovine Spongiform Encephalopathy,'' Contract No. 223–03–8500, Task Order 3, Eastern Research Group, Lexington, MA, July 25, 2005.

26. ''Preliminary Analysis of Interim Final Rules and an Interpretive Rule to Prevent the BSE Agent from Entering the U.S. Food Supply,'' USDA, April 7, 2004, FSIS/USDA Internet Page (*http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=/oppde/rdad/frpubs/03–025n/bse_analysis.pdf*).

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List of Subjects in 21 CFR Part 589

Animal feeds, Animal foods, Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the Food and Drug Administration, it is proposed that 21 CFR part 589 be amended to read as follows:

PART 589—SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

1. The authority citation for 21 CFR part 589 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 371.

2. Section 589.2000 is amended by revising paragraph (a)(1) and by adding paragraphs (c)(4) and (e)(3) to read as follows:

§ 589.2000 Animal proteins prohibited in ruminant feed.

(a) * * *

(1) *Protein derived from mammalian tissues* means any protein-containing portion of mammalian animals, excluding: Blood and blood products; gelatin; tallow containing no more than 0.15 percent insoluble impurities and tallow derivatives as specified in § 589.2001; 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); milk products (milk and milk proteins); and any product whose only mammalian protein consists entirely of porcine or equine protein.

* * * * *

(c) * * *

(4) Renderers shall comply with all applicable requirements under § 589.2001.

* * * * *

(e) * * *

(3) Renderers shall comply with all applicable requirements under § 589.2001.

* * * * *

3. Section 589.2001 is added to read as follows:

§ 589.2001 Cattle materials prohibited in animal food or feed.

(a) *Definitions*—(1) *Cattle materials prohibited in animal feed include*:

(i) The brains and spinal cords of cattle 30 months of age and older;

(ii) The brains and spinal cords of cattle not inspected and passed for human consumption as defined in paragraph (a)(2) of this section;

(iii) The entire carcass of cattle not inspected and passed for human consumption from which brains and spinal cords were not removed;

(iv) Mechanically separated beef as defined in paragraph (a)(3) of this section that is derived from materials specified in paragraphs (a)(1)(i), (a)(1)(ii), and (a)(1)(iii) of this section; and

(v) Tallow as defined in paragraph (a)(5) of this section that is derived from materials specified in paragraphs (a)(1)(i), (a)(1)(ii), and (a)(1)(iii) of this section. Cattle materials prohibited in animal feed do not include:

(A) Tallow derivatives as defined in paragraph (a)(6) of this section and;

(B) Tallow as defined in paragraph (a)(5) of this section that is derived from materials specified in paragraphs (a)(1)(i), (a)(1)(ii), and (a)(1)(iii) of this section and that contains no more than 0.15 percent insoluble impurities. Insoluble impurities must be measured by the method entitled ''Insoluble Impurities'' of the American Oil Chemists' Society (Official Method Ca 3a–46), or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a–46. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies of the method from the AOCS (*http://www.aocs.org*). Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(2) *Cattle not inspected and passed for human consumption* means cattle of any age that were not inspected and passed for human consumption by the appropriate regulatory authority. This term includes nonambulatory disabled cattle. Nonambulatory disabled cattle are cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or

ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

(3) *Mechanically separated beef* means a finely comminuted meat food product, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses.

(4) *Renderer* means any firm or individual that processes slaughter byproducts, animals unfit for human consumption, or meat scraps. The term includes persons who collect such materials and subject them to minimal processing, or distribute them to firms other than renderers (as defined in this paragraph) whose intended use for the products may include animal feed, industrial use, or other uses. The term includes renderers that also blend animal protein products.

(5) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues.

(6) *Tallow derivative* means any product obtained through initial hydrolysis, saponification, or trans-esterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or trans-esterification may be applied to obtain the desired product.

(b) *Requirements.* (1) No animal feed or feed ingredient shall be manufactured from, processed with, or otherwise contain, cattle materials prohibited in animal feed as defined in paragraph (a)(1) of this section.

(2) Renderers that manufacture, process, blend, or distribute cattle materials prohibited in animal feed as defined in paragraph (a)(1) of this section, or products that contain or may contain cattle materials prohibited in animal feed, shall take the following measures to ensure that materials identified in paragraph (b)(1) of this section are not introduced into animal feed:

(i) Once cattle materials prohibited in animal feed have been separated from other cattle materials, provide for measures to avoid cross-contamination;

(A) Use separate equipment while handling cattle materials prohibited in animal feed; or

(B) Use separate containers that adequately prevent contact with animal feed, animal feed ingredients, or equipment surfaces;

(ii) Label the cattle materials prohibited in animal feed and products that contain or may contain cattle materials prohibited in animal feed in a conspicuous manner as follows: ''Do not feed to animals'';

(iii) Mark the cattle materials prohibited in animal feed and products that contain or may contain cattle materials prohibited in animal feed with an agent that can be readily detected on visual inspection; and

(iv) Establish and maintain records sufficient to track cattle materials prohibited in animal feed to ensure such material is not introduced into animal feed, and make the records available for inspection and copying by the Food and Drug Administration.

(3) Renderers that manufacture, process, blend, or distribute any cattle materials shall take the following measures to ensure that materials identified in paragraph (b)(1) of this section are not used in animal feed:

(i) Establish and maintain records sufficient to demonstrate that material rendered for use in animal feed was not manufactured from, processed with, or does not otherwise contain, cattle materials prohibited in animal feed, and make the copies available for inspection and copying by the Food and Drug Administration; and

(ii) Comply with all applicable requirements under § 589.2000 regarding animal proteins prohibited in ruminant feed.

(c) *Adulteration and misbranding.* (1) Failure of a renderer to comply with the requirements in paragraphs (b)(2)(i), (b)(2)(iii), (b)(2)(iv), or (b)(3)(i) of this section will render the animal feed or feed ingredients adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the act).

(2) Animal feed or feed ingredients that are not in compliance with paragraph (b)(1) of this section are adulterated under section 402(a)(2), 402(a)(3), or 402(a)(5) of the act.

(3) Animal feed or feed ingredients that are not in compliance with the labeling requirements of paragraph (b)(2)(ii) of this section are misbranded under section 403(a)(1) or 403(f) of the act.

(4) Failure of a renderer to comply with the requirements in paragraph (d) of this section will render the animal feed or feed ingredients adulterated under section 402(a)(4) of the act.

(d) *Inspection; records retention.* Records required to be made available for inspection and copying by the Food and Drug Administration, as required by this section, shall be kept for a minimum of 1 year.

Dated: July 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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