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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending 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 entire carcass of bovine spongiform encephalopathy (BSE)-positive cattle; the brains and spinal cords from cattle 30 months of age and older; the entire carcass of cattle not inspected and passed for human consumption that are 30 months of age or older from which brains and spinal cords were not removed; tallow that is derived from BSE-positive cattle; tallow that is derived from other materials prohibited by this rule that contains more than 0.15 percent insoluble impurities; and mechanically separated beef that is derived from the materials prohibited by this rule. These measures will further strengthen existing safeguards against BSE.

DATES: This final rule is effective April 27, 2009. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in new 21 CFR 589.2001 effective April 27, 2009.

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I. Introduction

BSE is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. However, the distribution of infectivity in the body of the animal and mode of transmission differ according to the species and TSE agent. In addition to BSE, TSEs include, among other diseases, scrapie in sheep and goats, chronic wasting disease in deer and elk, and Creutzfeldt-Jakob disease in humans.

The agent that causes BSE has yet to be fully characterized. The theory that is most accepted in the international scientific community is that the agent is an abnormal form of a normal protein known as cellular prion protein. The BSE agent does not evoke a traditional immune response or inflammatory reaction in host animals. BSE is confirmed by post-mortem microscopic examination of an animal's brain tissue or by detection of the abnormal form of the prion protein in an animal's brain tissues. The pathogenic form of the protein is both less soluble and more resistant to degradation than the normal form. The BSE agent is resistant to heat and to normal sterilization processes.

BSE is not a contagious disease, and therefore is not spread through casual contact between animals. The possibility of maternal transmission (i.e., from a bovine dam directly to her offspring) was suggested by a 1997 study conducted in the United Kingdom. However, subsequent studies have shown that it is unlikely that maternal transmission of BSE occurs at any epidemiologically significant level, if it occurs at all. Scientists believe that the primary route of transmission requires that cattle ingest feed that has been contaminated with a sufficient amount of meat and bone meal (MBM) from an infected animal. This route of transmission can be prevented by excluding potentially contaminated materials from ruminant feed.

Scientific and epidemiological studies have linked variant Creutzfeldt-Jakob disease (vCJD) in humans to exposure to the BSE agent, most likely through human consumption of beef products contaminated with the agent. As of February 2007, 165 probable and confirmed cases of vCJD have been reported in the United Kingdom. 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. As of November 2006, CDC had detected two vCJD cases involving United States residents who were born and raised in the United Kingdom. A third case was confirmed by CDC in November 2006 and involved a United States resident living in Virginia who was born and raised in Saudi Arabia and had lived in the United States since 2005. This individual did not live in Europe at any time, and CDC has determined that this person was most likely infected from contaminated cattle products consumed as a child when living in Saudi Arabia.

On December 23, 2003, the U.S. Department of Agriculture (USDA) diagnosed BSE in an adult cow in the United States that had been imported from Canada. Since then, USDA has confirmed two other cases of BSE in adult cows in the United States. One cow, which was diagnosed on June 24, 2005, was born and raised in Texas. The other cow, which was diagnosed on March 15, 2006, had been on a farm in Alabama for less than a year. The Texas cow was 12 years old and the Alabama cow was determined to be more than 10 years old. Therefore, both cows were born before FDA's 1997 ruminant feed rule (62 FR 30936, June 5, 1997) was in place.

Under USDA's enhanced BSE surveillance program, 787,711 cattle were tested between June 1, 2004, and September 20, 2006. As previously noted, only two animals tested positive for BSE, one in Texas and one in Alabama. In September 2006, USDA transitioned to an ongoing surveillance plan under which approximately 40,000 cattle are tested per year.

In the October 6, 2005, issue of the **Federal Register** (70 FR 58570), FDA published a proposed rule (the October 2005 proposed rule) that would prohibit the use of certain cattle origin materials in the food or feed of all animals. The materials identified in the proposal 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 have not been removed; (4) tallow that is derived from the materials prohibited by the proposed rule that contains more than 0.15 percent insoluble impurities; and (5) mechanically separated beef that is derived from the materials prohibited by the proposed rule.

The preamble to the proposed rule contained information regarding BSE, including a summary of the current animal feed safeguards in the United States and the risk of BSE in North America, other options FDA considered for strengthening animal feed protections, and the reasons for proposing to exclude certain cattle-derived risk materials from all animal food and feed. Also discussed in the preamble to the proposed rule was the Harvard Risk Assessment (referred to in the preamble to the proposed rule as the ''Harvard-Tuskegee Study''), completed for USDA in 2001. The authors released a revised risk assessment in 2003. Among other things, the Harvard-Tuskegee Study identified pathways or practices that, if addressed, could further decrease the already low risk of the spread of BSE if it were introduced into this country.

In mid-July 2006, USDA's Food Safety and Inspection Service (FSIS) released a further revised Harvard Risk Assessment. Conducted in 2005, the risk assessment used an updated model to simulate the impact of measures adopted by USDA and considered by FDA in response to the detection of a BSE-positive cow in Washington State in December 2003. The 2005 study confirmed the original findings in the 2001 Harvard-Tuskegee Study and noted that, with the protective measures in place in the United States in 2003, the introduction of BSE would result in limited spread, and the disease would be eliminated over time. Of the additional feed-related mitigation measures evaluated, the revised model predicted that removal of specified risk materials (SRMs) from all animal feed would result in a substantial reduction of any residual BSE disease agent not eliminated by the 1997 feed ban, because doing so eliminates transmissions resulting from cross-contamination and on-farm misfeeding.

The current U.S. ruminant feed regulation (§ 589.2000 (21 CFR 589.2000)) prohibits the use of certain mammalian-origin proteins in ruminant feed, but allows the use of these materials in feed for non-ruminant animals. While the prevalence of BSE in the United States is very much lower than in European countries with BSE, evidence from the European experience has demonstrated that, in countries with a high level of circulating BSE infectivity, measures on only ruminant feed were not sufficient to eliminate all transmission of BSE; new cases continued to be found in cattle born in the United Kingdom after implementation of a ruminant-to-ruminant feed ban. As stated in the proposed rule, these new cases were attributed to either cross-contamination during feed manufacture and transport, or to intentional or unintentional misfeeding on the farm. FDA believes that the presence of certain cattle-derived risk materials in the non-ruminant feed supply presents a potential source of exposure in the United States. Although in the United States, compliance with the 1997 ruminant feed rule by the U.S. animal feed industry, i.e., renderers, protein blenders, and feed mills, has been very high, inspections of feed manufacturing firms have identified some instances of inadequate cleanout procedures, mislabeling, and recordkeeping deficiencies.

As discussed in the preamble to the proposed rule, data from both naturally infected and experimentally infected cattle indicate that roughly 90 percent of BSE infectivity is contained in the brain and spinal cord, and only about 10 percent of BSE infectivity is present in the retina, dorsal root and trigeminal ganglia, and the distal ileum (Ref. 1). The agency continues to believe that the 1997 ruminant feed rule provides a strong primary line of defense against BSE transmission by prohibiting the use in ruminant feed of all materials with potential BSE infectivity. The additional measures taken in this final rule will further reinforce the existing rule by removing certain cattle-derived risk materials from all animal feed. This action greatly minimizes the residual BSE risks not eliminated by the 1997 feed ban if cross-contamination of ruminant feed with non-ruminant feed, or diversion of non-ruminant feeds to ruminants, were to occur.

As discussed in greater detail in section II of this document, FDA received numerous comments on its proposed rule. Based on these comments, the agency has made some modifications to this final rule. Specifically, a statement has been added setting forth the purpose of the new section, i.e., to prohibit the use of certain cattle origin materials in the food or feed of all animals to further reduce the risk of the spread of BSE within the United States. This change was made to clarify that the cattle materials prohibited by this rule are being prohibited from use in all animal food or feed because of their risk for transmitting BSE. This rule, however, should not be construed to mean that it is legal to use any portion of an animal that is adulterated under the Federal Food, Drug, and Cosmetic Act (the act) in animal food or feed.

Under section 402(a)(5) of the act (21 U.S.C. 342(a)(5)), animal feed and feed ingredients containing material derived from a BSE-positive animal are adulterated because they are in whole or in part the product of a diseased animal. The definition of cattle materials prohibited in animal feed (CMPAF) has been revised to include the entire carcass of BSE-positive cattle. This change was made to be consistent with the agency's previous guidance entitled ''Use of Material from BSE-Positive Cattle in Animal Feed,'' for which a notice of availability was published in the **Federal Register** of September 30, 2004 (69 FR 58448). In that guidance, the agency made clear that it was not going to exercise enforcement discretion with regard to the use of BSE-positive cattle in animal food or feed. Therefore, this rule prohibits the use of BSE-positive cattle in all animal food or feed.

Additional changes have also been made in this final rule to the definition of CMPAF. As defined in the proposed rule, CMPAF included the brains and spinal cords from cattle of any age not inspected and passed for human consumption (or the entire carcass, if brain and spinal cord were not removed). FDA explained in the preamble to the proposed rule its rationale for applying these requirements to cattle of any age. This rationale cited surveillance data showing that cattle not inspected and passed for human consumption were included in the population of cattle at highest risk of BSE, and noted that inspection programs were not in place in the rendering industry for verifying the age of dead cattle. However, given the challenges of removing the brain and spinal cord from this class of cattle, FDA specifically requested comment on this issue.

FDA has revised the definition of CMPAF in the final rule (proposed § 589.2001(a)(iii) and new section 589.2001(b)(iii)) to prohibit the use of the entire carcass of cattle not inspected and passed for human consumption that are 30 months of age or older from which brain and spinal cord have not been effectively removed or otherwise effectively excluded from animal feed. As a result, the rule now prohibits the use of the entire carcass of cattle not inspected and passed for human consumption unless: (1) The cattle are shown to be less than 30 months of age, or (2) the brains and spinal cords were effectively removed or effectively excluded from animal feed use. The final rule was further revised to require renderers to develop and maintain written procedures for determining the age of and/or removing the brain and spinal cord from, dead cattle, and to make the written procedures available for FDA inspection. FDA notes that, for cattle not inspected and passed that are diseased or that died otherwise 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: (1) The remaining material from cattle that are diseased or that die otherwise than by slaughter when the brain and spinal cord are effectively removed or effectively excluded from animal feed use and (2) the entire carcass from cattle that are diseased or that die otherwise than by slaughter if such cattle are shown to be less than 30 months of age.

FDA made these revisions based on comments indicating that it is feasible to put processes in place to age such cattle and that very little risk reduction is gained by excluding material from such cattle. FDA also received many comments that raised concerns about the environmental impacts of disposing of these animals by means other than rendering them for animal feed use.

FDA noted in the preamble to the October 2005 proposed rule (70 FR 58570) that European surveillance data 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. However, FDA considered the level of risk reduction that might potentially be achieved by prohibiting materials from cattle that are not inspected and passed for human consumption and that are less than 30 months of age. 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 established by the final rule represent a secondary level of protection to address failures in compliance that may occur with the existing ruminant feed rule. After considering all of the previously mentioned factors, FDA determined that the proposed measure to prohibit materials from cattle that are not inspected and passed for human consumption and that are less than 30 months of age is not necessary.

Based on comments received, FDA has added a provision to this rule so that the agency may designate a country as not subject to the new requirements in this rule. As explained elsewhere in this document, a country seeking such a designation must submit a written request and include information about the country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other relevant information.

Lastly, for renderers handling cattle materials, this final rule provides, as did the proposed rule, that such renderers must establish and maintain records sufficient to demonstrate that material rendered for animal feed was not manufactured from, processed with, or does not otherwise contain CMPAF. Based on comments received regarding verification of CMPAF segregation in slaughter facilities, this final rule has been revised to clarify that the renderer's records must also include documentation that establishments supplying cattle materials to the renderers have adequate procedures in place to effectively exclude CMPAF. These supplier-related records must include either certification or other documentation from the supplier that material supplied to the renderer does not include CMPAF *or* documentation of another method, acceptable to FDA, such as third-party certification, for verifying that suppliers have effectively excluded CMPAF from animal feed.

II. Comments on the Proposed Rule

FDA received more than 840 comments on the proposed rule. They came from a wide variety of organizations, such as cattlemen, renderers, feed manufacturers, Federal agencies, State agriculture departments, trade associations, professional organizations, universities and research institutions, consumer organizations, and individuals. Many comments questioned the need for additional controls in light of the high compliance with FDA's 1997 feed rule by the U.S. animal feed industry, coupled with the low prevalence of BSE in this country. Some comments took the opposing view, stating that more aggressive steps should be taken by FDA and that all ruminant-derived material should be prohibited in all animal feed. Some comments urged that all exemptions (e.g., plate waste and poultry litter) be removed from the regulations. Other comments asserted that the proposed rule was not scientifically based and should not be finalized.

Many comments from industry raised concerns about the increased burden—financial and otherwise—if the proposed rule is finalized. Some comments discussed the difficulty of ensuring complete removal of brain and spinal cord from dead cattle. Other comments expressed concerns about the increased volume of materials that would have to be disposed of through incineration, landfills, or other means. Potentially adverse environmental effects—and resultant adverse animal and public health consequences—from the increased volume of disposal materials were mentioned by several comments. Comments also expressed concerns about registration, certification, verification of segregation of CMPAF at slaughter establishments, recordkeeping, and record retention time.

A description of the comments and FDA's responses follows.

A. General Comments

1. Need for Additional BSE Safeguards

(Comment 1) Many comments, in addressing the proposed rule generally, said that the current BSE feed regulation does not need to be strengthened. Reasons given for this position were the low prevalence of BSE in this country as shown by USDA's surveillance results, the conclusion of the original Harvard Risk Assessment that the United States is resistant to BSE, and the effectiveness of the current ruminant feed rule (§ 589.2000) as evidenced by the high rate of industry compliance and the absence of BSE cases in cattle born after the 1997 ruminant feed rule. One comment said that FDA should develop a more accurate estimation of BSE risk to U.S. cattle by entering USDA's most recent prevalence data into the Harvard Risk Assessment model.

(Response) FDA agrees that the prevalence of BSE in the United States is very low, and that compliance with the current feed ban by the U.S. animal feed industry is at a high level. Though the situations are not directly

comparable, evidence from the European experience has demonstrated that BSE transmission can continue to occur even with a ruminant feed ban in place. FDA believes that eliminating the highest risk cattle-derived materials from the non-ruminant feed supply will further reduce the potential for cattle exposure to the BSE agent via cross-contamination of ruminant feed during feed manufacturing or transportation, or through on-farm misfeeding. As stated in the preamble to the proposed rule, without fully dedicated equipment, it may not be possible to completely prevent carryover of feed or feed ingredients even when cleanout procedures are in place.

(Comment 2) One comment said that, because the cow found in Texas in June 2005 did not test positive as a typical case of BSE, this case does not support the need for additional regulation.

(Response) FDA is aware that the PrP^{Sc} (disease-specific prion protein) isolates from the Texas and Alabama cases are atypical in that they have characteristics on immunohistochemical and western blot analyses that distinguish them from the typical BSE isolate. Because the significance of these differences, particularly with respect to origin and transmissibility, is not yet clear, the agency believes the atypical nature of these two cases does not diminish the need to strengthen BSE feed controls.

(Comment 3) Several comments said that the proposed rule was not based on the BSE situation in the United States, but rather on the situation in Europe where the incidence of BSE was 500-fold greater and control measures were instituted after BSE cases were identified. One comment also thought FDA might have developed its proposal based on the BSE situation in Japan.

(Response) While the data from Europe and Japan on BSE provided the agency with important information to help develop our response to BSE, the agency based its decision on the BSE situation in the United States and believes that these measures are appropriate to the United States situation. The agency believes, however, that the early firewalls (prohibition on imports of animals and ruminant feed from countries with BSE and the ruminant feed ban) put in place in the United States makes it possible and appropriate to strengthen feed controls with measures that are still less expansive than those that would be appropriate in countries with higher BSE prevalence such as in European countries and Japan. The measures being implemented are commensurate with the BSE prevalence in the United States.

(Comment 4) Several comments declared that the recommendations in the International Review Team's (IRT) February 2005 report are not relevant to the development of this rule because they were not based on science, they do not reflect the difference in BSE risk between Europe and the United States, and they do not present an accurate understanding of the U.S. industry's compliance with the existing BSE feed regulation.

(Response) FDA agrees that not all of the IRT recommendations are appropriate for the U.S. situation. However, FDA is adopting the IRT recommendation to require the removal of certain cattle-derived risk materials from all animal feed. FDA believes that the level of compliance with the current ruminant feed rule by the U.S. animal feed industry is high, but believes that the additional measures provide a secondary level of protection to address failures in compliance that may occur with the existing ruminant feed rule.

(Comment 5) One comment said that cross-contamination is not a problem because the BSE prevalence is so low in the United States. Another comment asked for the data the agency is relying on to show that cross-contamination and feeding errors need to be controlled, especially since the agency's own statistics show the industry is in high compliance with the 1997 ruminant feed rule.

(Response) FDA agrees that overall compliance with the 1997 ruminant feed rule by the U.S. animal feed industry has been high, but there have been instances of noncompliance with the rule that could have resulted in cattle being exposed to prohibited material through cross-contamination, mislabeling, or intentional or unintentional misfeeding. Information describing these instances of noncompliance was set forth in the preamble to the October 2005 proposed rule (70 FR 58570 at 58577). An updated summary of compliance information is provided in the References section of this document (Ref. 2).

(Comment 6) A few comments asked FDA to recognize that the USDA 18-month surveillance snapshot may not be an accurate indication of BSE prevalence in the United States. Specifically, because the BSE cases to date are likely clustered in time and location, USDA's surveillance results may underestimate the true risk.

(Response) FDA stated in the preamble to the proposed rule that the detection of one BSE case in over 418,000 samples analyzed under USDA's enhanced surveillance program at the time of the publication of the proposed rule indicates that the prevalence of BSE is very low in the U.S. cattle population. FDA notes that USDA has conducted surveillance for BSE since 1990. A July 20, 2006, USDA report entitled ''An Estimate of the Prevalence of BSE in the United States'' supports FDA's qualitative statement of a very low prevalence of BSE in the United States (Ref. 3). According to the report, a model developed in Europe was used to calculate U.S. BSE prevalence from two BSE cases detected in 735,213 samples collected over a 7-year period ending in March 2006. Results of this analysis support a conclusion that the prevalence of BSE in the U.S. cattle population is less than one infected animal per million adult cattle.

FDA remains confident in the two models used by USDA. The most likely values calculated by these models for the estimated number of cases were 4 or 7 infected animals out of 42 million adult cattle. USDA's analysis was submitted to the scrutiny of a peer review process, and the expert panel agreed with the appropriateness of USDA's assumptions and the factors it considered, as well as with the estimate of BSE prevalence.

(Comment 7) One comment noted that the effectiveness of the feed ban, especially at the farm level, is not known.

(Response) Inspection results indicate that compliance by U.S. animal feed industry is high. However, FDA agrees that it is very difficult to assess compliance with the ruminant feed rule at the farm level. FDA believes excluding certain cattle-derived risk materials from all animal feed channels will minimize any residual risks from on-farm misfeeding.

(Comment 8) Two comments indicated that the agency's feed control measures for ensuring compliance with the 1997 ruminant feed rule have been inadequate, citing a Government Accountability Office (GAO) study as evidence.

(Response) FDA disagrees with these comments. FDA believes its enforcement activities are adequate for ensuring industry compliance with the 1997 ruminant feed rule. The agency's response to the GAO's study can be found in Appendix VI of the GAO's report (Ref. 4).

(Comment 9) One comment speculated that, in some species, atypical BSE might be more pathogenic than typical BSE.

(Response) FDA is not aware of any scientific evidence that atypical BSE is

more pathogenic than typical BSE. Therefore, the agency believes that the controls in this final rule are appropriate.

(Comment 10) Several comments said the proposed rule will hamper BSE surveillance by reducing the number of cattle available for sampling.

(Response) FDA has conferred with USDA on the development of this rule. Further, USDA's transition from enhanced BSE surveillance to ongoing BSE surveillance places greater importance on collecting samples where clinical histories on sampled animals are more likely to be available, such as on farms and at diagnostic laboratories, and less importance on sampling at rendering plants where clinical histories are usually not available (Ref. 5).

2. Other Approaches for Strengthening Feed Controls

A number of comments recommended ways to strengthen feed controls that they believed would provide better protection than the measures proposed by FDA.

(Comment 11) Several comments stated that the proposed rule does not go far enough, that it still allows materials derived from ruminant species to be fed to other species, and that it does not include any of the actions announced on January 26, 2004. Several comments suggested that no animal or mammalian products be allowed in cattle feed or in feed for any other food-producing animal species. One comment noted that, although the proposed rule is a small step in the right direction, it is inadequate to close the existing loopholes. Two comments stated that the proposal ignores some of the recommendations made by the IRT and other BSE experts. Several comments stated that the proposed rule would leave 10 percent of the potential infectivity in the feeding system. One comment stated that the 10-percent infectivity may represent 780 ID_{50} (ID_{50} is the amount of infective material that would result in a case of BSE in 50 percent of the cattle that consumed it). Another comment remarked that distal ileum should be removed from animal feed, regardless of the disposal problems this could cause. In contrast, several comments were supportive of the agency's reasoning behind the proposed rule. These comments stated that removal of brain and spinal cord from cattle 30 months of age and older is the single most important step that can be taken to prevent the amplification of BSE and thereby shorten the time it takes to eradicate any latent BSE infectivity that might be present but undetected in U.S. cattle. Some comments further noted that the proposal is consistent with the IRT recommendation regarding a staged approach to removing SRM from animal feed.

(Response) The agency does not believe it is necessary, given the low prevalence of BSE in the United States, to prohibit all ruminant material from animal feed, nor is it necessary to prohibit all animal or all mammalian products in cattle feed. Our reasoning for deciding against the measures under consideration by FDA that were announced on January 26, 2004, and choosing instead to focus on certain cattle-derived risk materials was fully explained in the preamble to the October 2005 proposed rule (70 FR 58570 at 58578). In deciding to prohibit brain and spinal cord only from cattle 30 months of age or older, rather than the full list of SRMs, FDA 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 in this rule represent a secondary level of protection to address potential failures in compliance that may occur with the existing ruminant feed rule. FDA believes that the existing ruminant feed rule provides a strong line of defense by prohibiting the use in ruminant feed of protein derived from mammalian tissues. The additional measures in this final rule will further reinforce existing ruminant feed protection measures by removing the highest risk cattle-derived materials from all animal feed.

(Comment 12) One comment stated that the agency's proposal was too broad and asked that the rule be limited to removal of brain and spinal cord from dead and antemortem condemned cattle 30 months of age or older. The comment said this would have captured the two BSE cases in Washington and Texas.

(Response) FDA believes that the rule should apply to cattle slaughtered for human consumption as well as to cattle not inspected and passed for human consumption at antemortem inspection. Infected cattle that are over 30 months of age and in the preclinical stage of disease could pass antemortem inspection, yet still harbor significant levels of BSE infectivity in the brain and spinal cord.

(Comment 13) Numerous comments suggested that FDA prohibit the use of blood in animal feed. Reasons mentioned were that blood has been shown to contain TSE infectivity in several species, that vCJD has been found to be transmitted through blood, and that emboli created by stunning could carry infectivity. One comment said that, with more sensitive detection methods, BSE infectivity may be confirmed in blood. In contrast, numerous comments said FDA should continue to allow the use of blood in animal feed because there is no scientific basis for prohibiting blood in cattle feed and because calf health is dependent on colostrum supplements, which include blood products. One comment said that the chair of the IRT committee stated that blood does not transmit BSE.

(Response) As explained in the preamble to the proposed rule, FDA is not prohibiting the use of blood and blood products in animal feed because we believe such a prohibition would do very little to reduce the risk of BSE transmission. Although TSE infectivity has been demonstrated experimentally in the blood (Ref. 6) of sheep and rodents (Ref. 7), species differences in the involvement of the lymphoreticular system in TSE diseases suggest that these findings cannot necessarily be extrapolated to cattle (Ref. 8). Studies using mouse and cattle bioassays have so far failed to detect BSE infectivity in bovine blood (Ref. 9). While FDA agrees that more sensitive detection methods might some day demonstrate BSE infectivity in bovine blood, the agency believes that it is highly unlikely that the BSE agent is present in blood of infected cattle at levels sufficient to transmit disease through oral administration of processed blood products. This conclusion is based on the inefficiency of the oral route of transmission relative to the intracerebral route, which was used in unsuccessful attempts to detect BSE infectivity in bovine blood. FDA believes that the prohibitions in this final rule make it unnecessary to also preclude the use of blood in animal feed.

(Comment 14) A number of comments requested that poultry litter not be permitted to be fed to cattle, citing several reasons. One comment asked that FDA determine actual risk before deciding that poultry litter is not a risk factor. One comment stated that feces were infectious in rodents orally challenged with scrapie. Another comment noted that, in the United Kingdom, when cattle are orally challenged, the feces must be treated as medical waste for 1 month post-challenge. Another comment stated that TSE agents may be present in the porcine/poultry intestinal content, while still another comment stated that the 2001 World Health Organization/Food and Agriculture Organization of the United Nations/World Organisation for Animal Health (OIE) Technical

Consultation concluded that digestive contents and fecal material from livestock or poultry being fed meat and bone meal (MBM) potentially contaminated with BSE should not be used as an ingredient in animal feed.

(Response) In the preamble to the October 2005 proposed rule, FDA provided calculations submitted in comments to the advance notice of proposed rulemaking (ANPRM) that published in the **Federal Register** on July 14, 2004 (69 FR 42288), showing that a cow would need to consume a very large volume of poultry litter to ingest an infectious dose of BSE, assuming that the poultry feed spilled into the litter was formulated with MBM derived from a BSE-infected cow. Based on this analysis, FDA believes that the risk of cattle exposure to an infectious dose of BSE through poultry litter is low. The measures contained in this final regulation should reduce that risk even further because removing CMPAF from all animal feed prevents BSE infectivity from reaching poultry in the first place.

(Comment 15) Several comments disagreed with the need for prohibiting poultry litter in cattle feed if FDA finalizes the proposed measures. Two comments said that there is no scientific basis for prohibiting poultry material in ruminant rations. Another comment pointed out that banning poultry litter would create significant disposal issues.

(Response) As discussed in the response to the previous comment, because the rule prohibits the use of the highest risk cattle-derived materials in all animal feed, FDA agrees that it is not necessary to prohibit poultry litter from being fed to cattle.

(Comment 16) Several comments recommended that dedicated facilities and equipment be required in order to prevent cross-contamination. One comment disagreed, stating that requiring dedicated facilities would force some renderers to discontinue operations.

(Response) As explained in the preamble to the October 2005 proposed rule (70 FR 58570 at 58584), FDA fully expects this final rule to reduce substantially the remaining risk associated with cross-contamination, and therefore does not believe that the rule needs to also require dedicated facilities and equipment.

(Comment 17) One comment suggested a ''systems approach'' as a substitute for the measures presented in the proposed rule. This approach, according to the comment, would prohibit the entire carcass (except skeletal muscle) of mature dead cattle and the brain and spinal cord of mature slaughter cattle from all animal feed. It would also prohibit the use of hypobaric (vacuum) rendering for processing inedible ruminant material. The commenter submitted modeling data obtained using the Harvard Risk Assessment model, which showed that this approach is as protective of animal and public health as a complete SRMs ban, while creating a much smaller disposal challenge. According to the modeling results, the ''systems approach'' and the full SRMs approach would reduce cases of BSE by 97 percent and 99 percent, respectively. FDA's proposed measures would reduce new cases by 40 percent to 63 percent, depending on the effectiveness of brain and spinal cord removal. The comment acknowledged that the ''systems approach'' would initially create disposal challenges, especially in the dairy sector, but that cost-effective carcass disposal methods could be implemented.

(Response) The difference between the comment's ''systems approach'' and the approach in this final rule is that the ''systems approach'' would exclude the entire carcass of dead cattle 30 months of age or older rather than only the brain and spinal cord. As the comment acknowledges, eliminating the rendering option (other than disposal rendering) for disposal of all dead cattle 30 months of age or older may create major disposal challenges in some regions of the country (see ''Environmental Assessment'' for this final rule, Docket No. 2002N–0273). Modeling results submitted by the same commenter in response to the ANPRM showed that eliminating vacuum rendering contributed very little to the effectiveness of the ''systems approach.'' The agency believes that excluding brain and spinal cord from all cattle 30 months of age or older, and not the complete list of SRMs, is the most appropriate course of action for the United States where the BSE prevalence is low and strong feed controls are already in place.

(Comment 18) Citing the link of BSE cases in Alberta to hypobaric (or vacuum) rendering, one comment recommended that the use of hypobaric rendering be prohibited because it provides no TSE inactivation.

(Response) FDA agrees that the cluster of BSE cases associated with a vacuum renderer in Alberta underscores the concern about the ability of this process to inactivate BSE infectivity. A major advantage of the measures in this final rule over other options considered is that they prevent the highest risk cattle-derived materials from all animal feed, thereby reducing concerns about vacuum rendering.

(Comment 19) One comment said that FDA should prohibit the use of mammalian protein in feed for food producing animals, and cited the following recent research to support this position:

- Infectious dose may be smaller than previously thought: Attack rate studies in the United Kingdom have demonstrated transmission at a 0.001 gram (g) dose (no reference), 10 times lower than the 0.01 g dose described by FDA in the proposal.
- Repeated low dose exposure: A study in which scrapie was injected into mice (Jacquemot 2005) showed that repeated low doses caused scrapie when a single dose of the same size did not. A second study in which scrapie was administered orally to hamsters (Diringer 1998) showed a higher incidence of scrapie in hamsters receiving repeated doses than in hamsters receiving a single dose.
- Additional organs may be infectious: Disease-specific prion protein (PrP^{sc}) was found in the kidney, pancreas, and liver of scrapie infected mice when inflammation was induced in these organs (Heikenwalder 2005). Another study showed PrP^{sc} in the urine of scrapie infected mice with kidney inflammation. A third study found PrP^{sc} present in mammary glands of sheep with mastitis (Ligios 2005).
- Interspecies barrier may be smaller than previously thought: Some studies have shown interspecies inoculation produced subclinical disease but not clinical disease, suggesting that previously assumed species barriers were not complete (Hill 2000).

(Response) FDA is aware that BSE transmission has been demonstrated at a 0.001 g dose. FDA is also aware of the other recent scientific findings and considered this information as we were developing the final rule. The agency believes that the risks associated with repeated low dose exposure, infectivity in inflamed organs, and unapparent carriers of BSE infectivity are very low. The agency believes the risks of BSE infection are adequately addressed by the 1997 ruminant feed rule and this final rule, and that it is not necessary to prohibit all mammalian protein in feed for food-producing animals.

(Comment 20) One comment noted that species which appear to be resistant may in fact be unapparent carriers and over time could become sources of the BSE agent. Another comment added that failure to detect infectivity in tissues of experimentally infected pigs and chickens might be due to insufficiently sensitive bioassay techniques. Another

comment suggested that because swine and poultry may be silent carriers, materials derived from swine and poultry should not be fed to cattle.

(Response) These concerns were first addressed in the 1997 ruminant feed rule (62 FR 30936 at 30939). The agency has received no new information that would lead us to conclude that the additional measures suggested by these comments are needed to protect against BSE at this time.

(Comment 21) Several comments said that FDA should remove the exemptions in the current feed rule, with the possible exception of the exemption for milk.

(Response) As discussed in the preamble to the October 2005 proposed rule (70 FR 58570 at 58573), the agency considered eliminating certain of the current exemptions in the 1997 ruminant feed rule. However, as further discussed in that preamble, given low levels of BSE prevalence and high compliance with the 1997 ruminant feed ban, the agency determined that prohibiting the highest risk cattle-derived materials from all animal feed would be the most appropriate measure in the United States to further reduce the remaining risk of BSE infection not already addressed by the 1997 feed ban. Other responses to comments in the preamble to this final rule also discuss the agency's reasons for not eliminating certain exemptions in the 1997 ruminant feed rule.

(Comment 22) Numerous comments suggested that the plate waste exemption be eliminated. Reasons cited were that plate waste could contain highly infectious material, FDA has not specified the reheating requirements sufficient to inactivate the agent, it could be a factor in the spread of scrapie, and it confounds feed testing. In contrast, one comment advised against eliminating the exemption, noting that potential infectivity in high risk material has already been removed from meat by USDA regulations.

(Response) The exemption in the 1997 ruminant feed rule is specifically for ''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)'' (§ 589.2000(a)(1)). FDA disagrees that it is necessary to eliminate the plate waste exemption because, since 2004, human food has been required to be free of SRMs by USDA and FDA (69 FR 1862, January 12, 2004 (affirmation of interim rule 72 FR 38699, July 13, 2007), and 69 FR 42256, July 14, 2004, respectively).

3. International Trade Issues

The agency received a number of comments about trade, particularly about international standards related to feed controls for the prevention of BSE.

(Comment 23) One comment stated that FDA should not place more importance on trade considerations than on animal health, while another comment asserted that the proposed rule does not meet international standards, and therefore export markets may remain closed to U.S. products. In contrast, another comment stated that the proposed rule would satisfy trading partners and should help to reopen export markets.

(Response) FDA's mission is to promote and protect public health. The agency's regulations are issued to achieve this mission. FDA is also aware of the international trade obligations of the United States and considers these obligations in rulemaking. FDA believes that this final rule, while based on its mission to promote and protect the public health, is consistent with international trade obligations.

(Comment 24) One comment stated that the OIE recommends that feed and certain other commodities from controlled risk countries should not be traded if they contain protein from brains, eyes, spinal cord, skull, or vertebral column from cattle 30 months of age or older, or contain protein from the distal ileum or tonsils from cattle of any age. The comment added that if these commodities should not be traded internationally, then they should not be used domestically.

(Response) The OIE guidelines described in the comment apply to meat products for human consumption and ruminant feed. They do not apply to all animal feed. FDA also notes that these risk materials are already prohibited from all ruminant feed. As discussed throughout the preamble to this final rule, FDA believes further prohibiting brain and spinal cord from cattle 30 months of age and older in all animal food or feed is appropriate for the U.S. situation.

(Comment 25) Several comments stated that FDA should harmonize its new BSE feed regulations with those proposed by Canada. One comment provided a recommendation on how the United States and Canadian feed regulations should be harmonized, suggesting that both countries prohibit dead and downer cattle and require the removal of brain and spinal cord from cattle 30 months of age and older at slaughter. In contrast, another comment stated that trade with Canada should be restricted because of inadequate feed controls and inadequate surveillance in Canada.

(Response) The governments of the United States and Canada discussed the differences between their proposed regulations and considered options for aligning the two regulations. This led to a better understanding of each country's situation. Having considered the circumstances related to each of the BSE-positive cows and the control systems in place in Canada and the United States, FDA has concluded that measures in the 1997 ruminant feed rule and in this final rule are the most appropriate for the situation in the United States.

(Comment 26) Australia and New Zealand commented that they should not have to meet the proposed FDA requirements for exporting feed products to the United States because both countries have BSE-free status. Further, they stated that such requirements are contrary to World Trade Organization obligations under the Sanitary and Phytosanitary Agreement.

(Response) As stated previously, FDA is aware of the international trade obligations of the United States and has considered these obligations throughout the rulemaking process for this regulation. In the preamble to FDA's interim final rule on prohibiting the use of certain cattle materials in human food and cosmetics (69 FR 42256, July 14, 2004), FDA requested comment on standards to apply when determining another country's BSE status, providing an exemption for ''BSE-free'' countries, and how to determine that countries meet any standards that might be developed. On July 13, 2007, USDA's FSIS published a final rule ''*Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Prohibition on the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter*'' (also referred to as ''the SRM final rule'') (72 FR 38700), which affirmed, with changes, interim measures implemented by FSIS to minimize human exposure to materials that could potentially contain the BSE agent. One change that FSIS made in the SRM final rule was to exclude from the definition of SRMs materials from cattle from a country that can demonstrate that its BSE risk status can reasonably be expected to provide the same level of protection from human exposure to the BSE agent as prohibiting the use of SRMs for human food does in the United States. In the preamble to the SRM final rule, FSIS explained that those countries that believe that they are eligible to have materials from their

cattle excluded from the definition of SRMs should provide sufficient scientific evidence to support their claimed BSE risk status, and FSIS would then develop criteria to evaluate the equivalence request. FDA has decided to adopt a similar approach, and will allow a foreign country to seek a designation from FDA by which the restrictions otherwise applicable to animal feed would not apply to cattle-derived material from that country. Any country seeking such a designation would have to provide sufficient scientific evidence to support its claimed BSE risk status.

B. Comments on Proposed New § 589.2001—Cattle Materials Prohibited in Animal Food or Feed

1. Definition of Cattle Materials Prohibited in Animal Feed (CMPAF)

FDA received numerous comments addressing the definition of ''cattle materials prohibited in animal food or feed'' (CMPAF) as set forth in proposed § 589.2001(a). While some urged that all deads and downers, regardless of age, be included in the definition, others suggested that younger cattle be excluded from the definition because of science showing a lower infectivity risk in this group.

(Comment 27) Numerous comments suggested that FDA exclude all deads and downers, regardless of their age, from the feed chain because they contain the highest level of infectivity and because the Harvard-Tuskegee Study showed reduction of the risk of BSE transmission when these two categories of animals were eliminated from the feed stream. Several comments said that infectivity could be present in tissues other than brain and spinal cord. Specifically mentioned was new research showing infectivity in peripheral nerves, both in one cow using a new bioassay technique (Buschmann and Groschup, 2005 (Ref. 10)), and in a 94-month-old BSE infected cow in Japan using a western blot method. One comment said that subclinical infection could be present in cattle younger than 30 months of age.

(Response) FDA disagrees that it is necessary to prohibit all cattle not inspected and passed for human consumption from all animal feed to prevent BSE infection. BSE has a long incubation period. Epidemiological data from the United Kingdom epidemic have demonstrated that, on average, cattle develop clinical signs 4 to 6 years after infection (Bradley 1991; Anderson 1996 (Ref. 11)), though the incubation period can be longer or shorter than 4 to 6 years. With BSE, as with other TSEs, the total amount of infectivity in an animal increases throughout the incubation period, reaching the highest load at the end, very close to the death of the animal. Infectivity is considered to increase exponentially after exposure, reaching 4.5 logs less than clinical cases by 50 percent of the incubation period, and 3 logs less than a clinical case at 70 percent of the incubation period (Comer and Huntly, 2003 (Ref. 12)). Therefore, FDA assumes that the benefit shown in the Harvard-Tuskegee Study of excluding animals that die on the farm from the animal feed chain (77 percent reduction in mean number of new cases) is primarily attributable to excluding older deadstock.

FDA does not believe that studies showing BSE infectivity in peripheral nerves are sufficient to justify prohibiting all cattle not inspected and passed from use in all animal feed to prevent BSE infection. In the Buschmann and Groschup study, the experimental mice used were approximately 10 times more sensitive than cattle to the BSE agent, and the donor cow was showing severe signs of late-stage clinical BSE. Furthermore, based on end-point titration, incubation time, and transmission rate, the infectivity levels in peripheral nerves are extremely low compared to levels in brain and spinal cord. The mice were injected both intracerebrally and intraperitoneally, which is much more efficient than the oral route of administration. Therefore, the agency believes that very little BSE risk reduction would be realized if this final rule prohibited all cattle not inspected and passed for human consumption from use in all animal feed.

(Comment 28) Several comments suggested that deads and downers under 30 months of age be allowed in non-ruminant feed without brain and spinal cord removal, pointing out that no risk reduction is achieved by this requirement, and that age of deadstock could be verified by dentition, records, animal identification systems, or an onsite inspection. One comment said that FDA should provide guidance to renderers for procedures to verify age of cattle.

(Response). FDA agrees that very little BSE risk reduction would be realized by prohibiting from animal feed all cattle less than 30 months of age that were not inspected and passed for human consumption and from which brain and spinal cord had not been removed. In the preamble to the October 2005 proposed rule, the agency explained the rationale for the 30-month age criterion and stated that it should be applied in the animal feed context. However, the agency also explained that the decision to prohibit all cattle not inspected and passed for human consumption from which the brain and spinal cord were not removed from animal feed was based on the fact that procedures were currently not in place at rendering facilities to verify that firms were determining the age of cattle effectively (70 FR 58570 at 58578). Several comments suggested methods to determine the age of dead cattle, including animal identification systems, dairy herd records, dentition, body weight, or feed lot origin.

Based on the limited scientific basis with regard to BSE risk reduction for prohibiting cattle not inspected and passed for human consumption less than 30 months of age and the comments suggesting ways to determine the age of such cattle, FDA has revised the definition of CMPAF in the final rule. The revised definition of CMPAF includes the entire carcass of cattle not inspected and passed for human consumption that are 30 months of age or older from which brains and spinal cords were not effectively removed or otherwise effectively excluded from animal feed. The final rule requires renderers to maintain written procedures if they remove brain and spinal cord from such cattle, or separate such animals based on whether or not they are 30 months of age or older. As suggested by one comment, FDA will issue separate guidance for industry on methods for determining the age of cattle. FDA will work with USDA to develop methods consistent with those of USDA.

As FDA noted previously (70 FR 58570 at 58579), section 402(a)(5) of the act states that a food shall be deemed to be adulterated if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter. Since the category of cattle defined in this final rule as ''cattle not inspected and passed for human consumption'' are animals that already fall within the category of animals referred to in section 402(a)(5) of the act as ''diseased animals or animals which died otherwise than by slaughter,'' any animal feed derived from such animals would be considered adulterated. However, 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. With the implementation of this final rule, FDA will no longer exercise enforcement discretion over those materials prohibited by this regulation (i.e., CMPAF) that are derived from cattle not inspected and passed for

human consumption. FDA intends to continue exercising such discretion (relative to section 402(a)(5) of the act) for the use in animal feed of material derived from such cattle that are not defined as CMPAF. This includes (1) The remaining material from cattle not inspected and passed for human consumption when the brain and spinal cord are effectively removed or effectively excluded from animal feed use and (2) the entire carcass from cattle not inspected and passed for human consumption if such cattle are shown to be less than 30 months of age.

(Comment 29) One comment asked that downer cattle not be allowed in animal feed.

(Response) Under the final rule, to prevent BSE, cattle not inspected and passed for human consumption are prohibited from use in animal feed unless they are shown to be less than 30 months of age or the brain and spinal cord are effectively removed or effectively excluded from animal feed. FDA originally included cattle of any age that were not inspected and passed for human consumption in the definition of CMPAF because: (1) European surveillance data suggested that cattle not inspected and passed for human consumption posed a higher risk for BSE and (2) we believed that processes were currently not established in the rendering industry for verifying the age of such cattle through inspection. However, FDA received comments on the feasibility of aging such cattle and on the relatively low risk reduction achieved by excluding such cattle if they were less than 30 months of age. FDA considered these comments, surveillance data indicating the current risk of BSE to U.S. cattle is very low, the strong feed protection provided by the existing ruminant feed rule, and the added secondary level of protection provided by the other provisions of this final rule. Based on these factors, FDA concluded that it was not necessary to include in the definition of CMPAF cattle not inspected and passed for human consumption that are under 30 months of age.

(Comment 30) One comment requested that striated muscle from cattle that died otherwise than by slaughter be allowed to be harvested for use in non-ruminant feed.

(Response) This final rule does not prohibit the use of cattle not inspected and passed for human consumption in animal feed if they are shown to be less than 30 months of age or if the brain and spinal cord are effectively removed or otherwise effectively excluded from animal feed. 4–D operations (plants that harvest skeletal muscle from dead, dying, diseased, or disabled cattle) that harvest skeletal muscle for such use as pet and mink food fall within the final rule's definition of renderer and must have written procedures in place describing the aging methods and specifying how brain and spinal cord, or parts of carcasses containing brain and spinal cord, will be effectively removed or effectively excluded from animal feed. As discussed in more detail in the response to Comment 28, FDA notes that the use in animal feed of materials from cattle not inspected and passed for human consumption that are diseased or that die otherwise than by slaughter is the subject of enforcement discretion.

(Comment 31) One comment from a foreign country requested that FDA clarify whether beef recovered by Advanced Meat Recovery (AMR) systems from vertebral column, from which spinal cord has been removed, is permissible in animal feed.

(Response) This final rule does not prohibit in animal feed an AMR product derived from the vertebral column of cattle from which spinal cord has been removed prior to the AMR process, provided that the other requirements of the final rule are also met.

2. Definition of Cattle Not Inspected and Passed for Human Consumption

(Comment 32) Several comments stated that cattle carcasses and parts condemned on post-mortem inspection should not be considered CMPAF because some parts of the condemned carcass may have already been commingled with normal slaughter byproducts. The comments suggested that the definition ''cattle not inspected and passed for human consumption'' be changed to ''cattle that do not pass ante-mortem inspection.''

(Response) The agency did not intend for the purposes of this regulation that the carcasses of cattle condemned on post-mortem inspection be included in the definition of cattle not inspected and passed for human consumption. The agency intended this category of cattle to include cattle that had been presented to a slaughter establishment and rejected (did not pass ante-mortem inspection) as well as cattle that had not been presented to a slaughter establishment and, hence, were not subject to inspection by an appropriate regulatory authority. To clarify this, FDA is modifying the definition of ''cattle not inspected and passed for human consumption'' in this final rule to mean ''cattle that did not pass ante-mortem inspection by the appropriate regulatory authority.

3. Restrictions on Tallow

(Comment 33) One comment stated that the proposal is unclear as to whether the 0.15-percent insoluble impurity standard applies to all tallow or only to tallow derived from CMPAF. The comment requested that the tallow standard only apply to CMPAF-derived tallow.

(Response) The final rule defines tallow as CMPAF if it is derived from: (1) BSE-positive cattle or (2) from other CMPAF material and contains insoluble impurities greater than 0.15 percent. The existing § 589.2000 has been changed to clarify that protein derived from mammalian tissues does not include tallow containing 0.15 percent or less insoluble impurities. The result of these changes is that tallow usage is more restrictive in ruminant feed than in feed for non-ruminants. All tallow that contains more than 0.15 percent insoluble impurities is prohibited in ruminant feed, but only tallow that contains more than 0.15 percent insoluble impurities and that is made from CMPAF is prohibited in the food or feed of all animals.

(Comment 34) Five comments stated that tallow should be prohibited in animal feed. Two comments said that tallow should be entirely free of protein impurities. In contrast, another comment said that tallow from animals inspected and passed for human consumption with SRM removed should be allowed in animal feed without the 0.15 percent restriction.

(Response) The agency disagrees that all tallow should be prohibited in animal feed or that tallow should be free of impurities to be used in animal feed. The OIE considers tallow with less than 0.15 percent insoluble impurities to be protein-free. Further, OIE guidelines recommend that tallow meeting this standard is safe for use in animal feed, regardless of the exporting country's BSE status. As explained in the proposed rule, the agency is concerned about protein impurities that may be present in tallow particularly now that an attack rate study in the United Kingdom has found that oral administration of a very low dose (1 milligram (mg)) of BSE-infected brain produced disease in 1 of 15 calves receiving the dose. The agency sought comment on its proposed action, but no comments were received that provided a scientific basis for the agency to modify its position. Therefore, FDA has decided to prohibit all tallow containing more than 0.15 percent insoluble impurities from use in ruminant feed, but prohibit only tallow that contains more than 0.15 percent insoluble

impurities and is made from CMPAF from use in food or feed for other animal species.

(Comment 35) Two comments said that, because no BSE risk is associated with the dirt, bone, and sand that comprise the impurities in tallow, the agency does not need to prohibit tallow containing more than 0.15 percent impurities.

(Response) These comments imply that protein is not a component of tallow impurities. A 2001 report from a European Scientific Steering Committee stated that analysis of impurities in six tallow samples found that crude protein levels ranged from 5 percent to 16 percent, assuming that all nitrogen in the impurities was of protein origin (Ref. 13). Since protein may be a component of tallow impurities, FDA believes that limiting tallow impurities to the OIE recommended level of 0.15 percent is appropriate.

4. Feasibility of Removing Brain and Spinal Cord

(Comment 36) Many comments stated that brain and spinal cord cannot be removed completely from some dead cattle, and that the feasibility of removal depends on such things as condition of the carcass, size of the animal, worker skill, weather conditions, and distance between the production site and the rendering facility. Some comments submitted estimates of the percentage of dead animals from which brain and spinal cord could feasibly be removed. Those estimates ranged from as low as 15 percent to as high as 54 percent.

(Response) FDA acknowledges that removing brain and spinal cord from dead cattle may be difficult for the reasons mentioned, and that the agency may have overestimated the number of independent renderers that would choose to remove brain and spinal cord from dead cattle. However, FDA believes that, unless cattle not inspected and passed for human consumption are shown to be less than 30 months of age, the brain and spinal cord must be removed prior to use in animal food or feed to prevent BSE. As discussed in more detail in the response to Comment 28, FDA notes that the use in animal feed of materials from cattle not inspected and passed that are diseased or that die otherwise than by slaughter is the subject of enforcement discretion.

(Comment 37) FDA was asked to define what constitutes an ''acceptable'' level of brain/spinal cord removal. Another comment recommended that renderers maintain written procedures for processes used to remove brain and spinal cord and verify that such processes meet FDA standards for removal.

(Response) During an inspection, FDA will review the adequacy of a firm's written procedures for removal of brain and spinal cord and will verify that the firm is following its procedures and effectively removing all the brain and spinal cord or otherwise excluding it from animal feed use.

(Comment 38) One comment said that custom-slaughter plants (not federally or State inspected) will need to remove the brain and spinal cord of all cattle, regardless of the animal's age.

(Response) Meat from cattle slaughtered under the custom-slaughter exemption is exclusively for the use by the owner of the animal, members of his or her household, and nonpaying guests and employees (Federal Meat Inspection Act, section 623(a)). Because such cattle are slaughtered without inspection by an appropriate regulatory authority, these animals would be considered cattle not inspected and passed for human consumption. The rule prohibits their use in animal feed if they are not shown to be less than 30 months of age or the brain and spinal cord are not effectively removed or effectively excluded from animal feed.

(Comment 39) One comment stated that FDA should require firms that intend to render deadstock for use in animal feed to obtain a special permit and demonstrate to FDA's satisfaction that they have implemented a system that is consistently effective in removing brain and spinal cord.

(Response) This final rule requires that rendering firms maintain written procedures specifying how brain and spinal cord are effectively removed. The agency does not believe that requiring such firms to obtain a permit is necessary at this time. FDA believes that following its current approach of working collaboratively with its State counterparts to ensure compliance with BSE regulations will continue to be effective.

5. Determining the Age of Cattle Not Inspected and Passed for Human Consumption

(Comment 40) Two comments stated that dentition will not work for the process of determining the age of cattle and that an animal identification system is needed.

(Response) The final rule has been revised to emphasize that firms are responsible for having processes in place to ensure cattle not inspected and passed for human consumption from which brain and spinal cord are not removed are shown to be less than 30 months of age. If a firm is unable to determine the age of an animal, the brain and spinal cord must be removed in order for the remaining carcass to be used for animal feed and not violate the prohibitions in this final rule. As discussed in more detail in the response to Comment 28, FDA notes that the use in animal feed of materials from cattle not inspected and passed that are diseased or that die otherwise than by slaughter is the subject of enforcement discretion.

Cattle under 30 months of age may be adequately identified through dentition. Veterinary texts and academic articles indicate that the second set of permanent incisors erupt when cattle are between 24 and 30 months of age. Thus, cattle would be considered to be 30 months of age and older if at least one of the second set of permanent incisors has erupted. However, environmental or operational conditions could make aging by dentition difficult. Therefore, firms' written procedures may need to include other means of age determination or adopt the default assumption that the animal is over 30 months.

6. Disposal of Prohibited Materials

A significant number of comments were submitted pertaining to disposal problems that could be created if the proposed rule is finalized. These problems ranged from the financial burden created by collection fees to State and local regulations that restrict non-feed disposal of prohibited materials.

(Comment 41) Numerous comments said that FDA underestimated the volume of material that will require alternative disposal when FDA's proposed measures force renderers to increase collection fees or discontinue deadstock pickup. One comment said that as a result of the new regulation, pig, horse, and deer mortalities will no longer be picked up on discontinued routes. Another comment stated that farmers and dairymen will probably bury, compost, landfill, or dump carcasses to avoid the increased collection fee that renderers will charge.

(Response) FDA agrees that renderers who continue to collect deadstock will likely increase collection fees to cover the costs of complying with the new requirements, and that we may have underestimated the impact that higher fees will have on deadstock collection. In the October 2005 proposed rule (70 FR 585701 at 58592), we estimated that the 17 percent of dead cattle currently being collected would decrease by 3.5 percent, and did not assume a decrease in the collection of dead animals of other species. The revised economic

impact analysis that accompanies this rule estimates that collection of calves and cattle will decline by 29.4 percent to 44.8 percent, with an additional 10-percent loss in rendering volume throughput to reflect a decrease in collection of dead animals of other species. Dead animals no longer collected should be disposed of in an environmentally and legally acceptable manner.

(Comment 42) Some comments stated that rendering is the best disposal option and that burial, composting, and incineration are undesirable alternatives. One comment said that if SRMs and deadstock are diverted from animal feed use, FDA will no longer have control over this material. Another comment pointed out that it takes 14 months to properly compost a 1500-pound (lb) cow.

(Response) FDA believes this final rule appropriately controls materials to be rendered for animal feed. FDA intends to work with relevant local, State, and other Federal agencies concerning disposal issues.

(Comment 43) Some comments stated that an infrastructure is not in place to provide alternative disposal in all areas of the country. Several comments said the rule will create a disposal crisis. One comment said that landfill operators and solid waste regulators are not prepared to deal with the magnitude of the disposal problem, and that some landfills will not accept dead animals or slaughter byproducts. Another comment said that they found no incinerators in their service area that would accept dead animals. One comment said that disposal rendering is feasible, but may not be locally available or that collection fees may be prohibitive. The last comment also said that alkaline hydrolysis digesters are not feasible, strict air pollution measures might preclude the use of incinerators, composting is prohibited in some areas, and land for burial is unavailable in densely populated areas.

(Response) FDA recognizes that no single method of disposal is available or suitable in all regions of the country and acknowledges that the transition from rendering to other forms of disposal will be challenging in some parts of the country. The regulation will not become effective until 12 months after publication of this final rule, so that livestock producers, meat packers, renderers, and regulators have sufficient time to arrange for disposal of CMPAF using one or more of the alternatives mentioned or any other legal alternative.

(Comment 44) A number of comments stated that, due to disposal restrictions at the State and local levels, a comprehensive disposal plan is needed before the proposed rule is implemented. Several comments said that FDA should consult with Federal, State, and local agencies, and with the affected industries, on environmentally safe disposal of deadstock. One comment said that neither FDA nor USDA has jurisdiction over on-farm disposal. Another comment said that USDA should use its broad animal health authority to lead a Federal agency task force on disposal.

(Response) Non-feed disposal of carcasses and slaughter byproducts is primarily regulated by State and local agencies. Under certain circumstances, Federal agencies, such as the Environmental Protection Agency (EPA), may use their authorities to regulate disposal of this material. FDA consulted with EPA and participated in an industry sponsored roundtable in July 2006 to discuss practical solutions for non-feed disposal throughout the United States. FDA is ready to work with industry and other governmental agencies in identifying appropriate ways to dispose of CMPAF.

(Comment 45) Some comments pointed out that Europe avoided massive disposal problems through government subsidies to the rendering industry for picking up and rendering prohibited material. Subsidies would help with disposal problems in the United States.

(Response) FDA does not have authority to subsidize alternative disposal of CMPAF.

(Comment 46) Several comments urged FDA to explore alternative ways to use CMPAF, such as in the production of biofuel.

(Response) FDA welcomes innovative ways of disposing of animal byproducts, such as using them for the production of biofuels. The agency has participated in industry/government workshops that explored ideas for using deadstock and animal byproducts for the production of energy. The agency encourages environmentally sound, commercial uses of these materials so that the disposal burden is minimized.

(Comment 47) One comment indicated that FDA should not expect a disposal-only rendering industry to develop if the proposed rule is implemented.

(Response) FDA acknowledges that many factors, including the implementation of this final rule, play a role in determining whether facilities dedicated to disposal rendering may emerge in the marketplace.

(Comment 48) One comment stated that prohibited brain and spinal cord material should not be diverted for use as fertilizer because the infectious agent can survive in soil and be recycled to cattle through crops.

(Response) FDA is not aware of any data showing that BSE can be transmitted by this route.

(Comment 49) One comment asked that the U.S. Government focus on research and on supporting the rendering industry's development of alternative uses for animal byproducts.

(Response) FDA agrees that alternative uses for animal byproducts need to be encouraged and studied further.

7. Ensuring Appropriate Handling of Prohibited Material

(Comment 50) Several comments addressed certification/registration of facilities handling cattle materials. One comment suggested that FDA should require annual certification to ensure that every facility handling cattle materials is in compliance with the rule. Another comment suggested registration of entities that handle prohibited cattle material, including renderers, farms that feed or mix feed for ruminants, and other parties that handle prohibited material, except where government inspection is already present (packer-associated renderers).

(Response) The agency does not believe that requiring certification or registration of firms is necessary at this time. FDA believes that continuing its current approach of working collaboratively with its State counterparts to ensure compliance with BSE regulations will continue to be effective.

(Comment 51) One comment asked whether written statements from slaughter and processing establishments would be acceptable to FDA as evidence that offal is free of prohibited material. One comment said that, due to liability concerns, renderers will be reluctant to accept material from plants that are not federally inspected. Two comments said that slaughter plants should be required to verify that raw materials sent for rendering into animal feed are free of prohibited cattle materials.

(Response) The proposed rule provided that renderers that handle cattle materials must establish and maintain records sufficient to demonstrate that materials rendered for animal feed are not manufactured from, processed with, or does not otherwise contain CMPAF. The final rule has been revised to further clarify that renderers' records must also include certification or other documentation from each supplier, or other documentation acceptable to FDA, that CMPAF has been excluded from materials to be

rendered for use in animal feed. Certification or other documentation from the supplier would be considered acceptable provided it includes a description of the supplier's segregation procedures, documentation that the supplier confirms that its segregation procedures are in place prior to supplying any cattle material to the renderer, and records of the renderer's periodic review of the suppliers' certification or other documentation. Other methods acceptable to FDA, such as third-party certification, may also be used by renderers to document that suppliers have excluded CMPAF from material supplied to the renderer.

(Comment 52) One comment asked that FDA clarify whether separate lines of equipment (barrels, room storage, pick-up vehicles) are required for handling SRM material. Another comment said the proposal's requirement that facilities be dedicated may cause renderers to discontinue processing CMPAF. A third comment stated that equipment for processing and transportation of prohibited cattle materials should be specifically designated for such purposes only. A fourth comment suggested that renderers and slaughter plants should have verifiable separation and identification procedures in place.

(Response) Under the final rule, renderers that provide a service to a slaughter plant by disposing of CMPAF must ensure that there is no cross-contamination, either through direct contact or via equipment surfaces, between CMPAF and animal feed or feed ingredients. In addition, CMPAF material is required to be marked and labeled ''Do not feed to animals.'' Renderers are responsible for ensuring that firms collecting such material on their behalf meet these requirements.

8. Enforcement Issues

FDA received many comments that addressed enforcement issues. Specifically, concerns were raised about an increased inspection burden, prohibited materials being illegally transported and dumped, and the need for agency guidance on recordkeeping.

(Comment 53) Several comments said that additional resources will be needed to effectively enforce the new measures. One comment said that additional inspectors may be needed to ensure proper removal and disposal of the CMPAF. Two other comments said that increased inspectional presence will be necessary to ensure that firms comply with aging and brain and spinal cord removal requirements.

(Response) FDA agrees that successful enforcement of the new measures will require an increased inspectional presence at firms that render cattle materials. Any reallocation of inspections needed to enforce this new rule should not affect the inspections of high-risk firms that are already being conducted to enforce the current ruminant feed rule.

(Comment 54) One comment said the proposed rule creates too much of an inspectional burden with an over reliance on the examination of records. Another comment, in contrast, said that visual inspection by investigators ultimately cannot determine the presence or absence of the BSE agent.

(Response) The agency considers both onsite observations of firms' operations and examination of records to be important and valuable components for ensuring compliance with the new rule. Inspections are not intended to detect the presence of the BSE agent, but rather are intended to ensure that CMPAF are not used in animal feed. Records examination is intended to verify that firms maintain and follow written procedures and to facilitate tracking the receipt, processing, and distribution of CMPAF.

(Comment 55) One comment stated that increases in renderer pick-up fees will result in illegal transportation and dumping of deads, downers, and CMPAF.

(Response) FDA intends to vigorously enforce this new rule to ensure that CMPAF is not used in animal feed. FDA believes this final rule appropriately controls materials to be rendered for animal feed. FDA intends to work with relevant local, State, and other Federal agencies concerning disposal issues.

(Comment 56) One comment said the proposal may cause independent renderers to stop accepting offal from red meat slaughter and processing establishments unless assurances are received that prohibited materials have been removed. Another comment cited a statement from a USDA OIG report saying that slaughter establishments are not adequately removing SRMs under current USDA regulations (Ref.14). The comment expressed concern that assurance cannot be provided for the removal of CMPAF from slaughter cattle under the proposed FDA regulation.

(Response) As stated in the proposed rule, this final rule requires renderers to establish and maintain records sufficient to demonstrate that raw materials to be rendered for animal feed are free of CMPAF. The agency expects that, as a condition of collection, renderers will require beef slaughter establishments to provide sufficient documentation to enable the renderers to meet their obligation for establishing and maintaining records demonstrating CMPAF removal. As discussed above, this final rule clarifies that renderers' records must include documentation, such as certification or other documentation from the supplier that material supplied to the renderer does not include CMPAF, or documentation of another method acceptable to FDA to verify that CMPAF has been segregated from slaughter byproducts that are to be rendered for animal feed use.

(Comment 57) Several comments stated that renderers might not collect offal from 4–D plants and custom slaughter establishments because there is not routine government inspection of these operations to ensure removal of CMPAF. Several comments suggested that FDA require written certification of CMPAF removal.

(Response) Because 4–D plants meet the definition of renderer, these firms are subject to the requirements of this rule. The final rule requires that renderers maintain written procedures for how they will remove brain and spinal cord from cattle not inspected and passed for human consumption and, if such cattle are to be rendered without brain and spinal cord removal, written procedures for how they will verify that such cattle are less than 30 months of age. Rendering firms that collect material from a 4–D operation would have the responsibility of showing that CMPAF had been removed by the 4–D plant prior to collection, or that any CMPAF-containing material collected is not introduced into animal feed.

With respect to custom slaughter, the final rule defines CMPAF to include certain cattle not inspected and passed for human consumption by the appropriate regulatory authority. Since the slaughter and processing of cattle in custom slaughter operations are not subject to inspection, the cattle handled by custom slaughter facilities would be considered not inspected and passed for human consumption. Therefore, cattle materials from custom slaughter establishments cannot be rendered for use in animal feed if the brain and spinal cord are not effectively removed from cattle that are 30 months of age or older. It is the renderer's responsibility to establish and maintain records sufficient to demonstrate that material rendered for use in animal feed does not contain CMPAF. The final rule clarifies that these records must include certification or other documentation from the supplier demonstrating that adequate segregation procedures are in place at slaughter establishments, including custom slaughter

establishments, that supply cattle materials to the renderers.

If renderers receive CMPAF for disposal, they are responsible for ensuring that it is excluded from animal feed. As discussed in more detail in the response to Comment 29, FDA notes that the use in animal feed of materials from cattle not inspected and passed for human consumption that are diseased or that die otherwise than by slaughter is the subject of enforcement discretion.

(Comment 58) Numerous comments asked that FDA provide guidance on several aspects of the rule, such as proper recordkeeping, acceptable processes for removing brain and spinal cord from cattle not inspected and passed for human consumption, and separation and dedication of processing areas.

(Response) FDA has specified in the final rule the recordkeeping requirement for renderers receiving raw materials from slaughter facilities. FDA will provide guidance as needed for meeting other requirements of the new rule.

(Comment 59) One comment suggested that FDA require firms handling prohibited material to be registered.

(Response) Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, facilities that manufacture, process, pack, or hold food for consumption in the United States must register with FDA. The agency does not believe that requiring additional registration of all firms handling prohibited material is necessary at this time. FDA believes that following its current approach of working collaboratively with its State counterparts to ensure compliance with BSE regulations will continue to be effective.

(Comment 60) One comment suggested that FDA license firms handling prohibited cattle material just as it licenses feed mills that use Category II drugs as Type A medicated articles.

(Response) The agency does not believe that requiring that firms be licensed is necessary at this time. FDA believes that continuing its current approach of working collaboratively with its state counterparts to ensure compliance with BSE regulations will continue to be effective.

(Comment 61) Two comments questioned whether FDA has jurisdiction to inspect slaughter establishments to verify proper segregation of CMPAF. Another comment said it strongly opposes new FSIS inspectional activity to oversee CMPAF removal from animal feed. In addition, two comments said that the proposed rule amounts to an unfunded mandate requiring States to conduct additional inspections at slaughter establishments to ensure proper removal of CMPAF.

(Response) Under this final rule, it is the responsibility of the renderer to ensure that material rendered for use in animal feed is free of CMPAF. FDA acknowledges that it does not conduct inspections in USDA-regulated slaughter establishments. Nevertheless, the agency believes that ensuring the segregation of CMPAF from other slaughter byproducts is pivotal to enhancing the safety of all animal feed. During inspections at rendering facilities, FDA intends to verify that renderers maintain records sufficient to demonstrate that material rendered for use in animal feed does not contain CMPAF. In response to comments regarding recordkeeping and the need for verification of the raw materials, the final rule has been revised to clarify that a renderer's records must either include certification or other documentation from the supplier that material supplied to the renderer does not include CMPAF, or documentation of another method acceptable to FDA, such as third party certification, for verifying that suppliers have effectively excluded CMPAF.

(Comment 62) Two comments stated that distribution records should be sufficiently detailed to allow for conducting trace forward and trace back investigations of prohibited cattle materials.

(Response) As finalized herein, § 589.2001(c)(2)(vi) (21 CFR 589.2001(c)(2)(vi)) requires renderers that handle CMPAF to establish and maintain records sufficient to track CMPAF to ensure such material is not introduced into animal feed, and make the records available for inspection and copying by FDA. And under § 589.2001(c)(3)(i), renderers that handle any cattle materials must 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, CMPAF, and make the copies available for inspection and copying by FDA. FDA expects to provide guidance, as needed.

(Comment 63) One comment stated that renderers should maintain records on how they dispose of prohibited cattle material.

(Response) The final rule requires renderers to maintain records sufficient to track CMPAF to ensure that the material was not introduced into animal feed.

(Comment 64) Several comments suggested that instead of requiring that records be kept for 1 year, FDA should require that records be maintained for a longer time period. Suggestions ranged from 3 to 12 years.

(Response) FDA does not consider it necessary to extend the recordkeeping requirement. As discussed in greater detail in the preamble to the October 2005 proposed rule (70 FR 58570 at 58582), FDA believes 1 year is appropriate, considering the amount of time the products will be in the animal feed production and distribution systems.

9. Implementation of New Requirements

(Comment 65) Several comments pointed out that time may be needed for implementation of the rule. Two comments suggested that it would take more than a year for renderers to develop dedicated rendering facilities or other types of disposal in California. Two other comments suggested a staged approach.

(Response) FDA received numerous comments regarding the impacts of the proposed new requirements, particularly with respect to the separation and appropriate disposal of CMPAF. The analysis of economic impacts completed for this final rule estimates that slaughter and rendering facilities will incur substantial one-time capital costs in order to comply with the new requirements. Furthermore, this analysis indicates that a substantial component of the total cost of this rule is associated with the disposal of CMPAF. Based on comments received on the proposed rule and on FDA's impact analysis completed for this final rule, FDA agrees that sufficient time will be needed to effectively implement the new requirements of this final rule including the development of alternate methods for disposing of CMPAF. FDA believes that 12 months should be a sufficient amount of time for the U.S. animal feed industry to come into compliance with this final rule.

(Comment 66) Several comments said that instead of implementing new measures, FDA should provide additional resources to support compliance and enforcement of the current ban. Two comments stated that implementation of the new rule should not lessen enforcement of the current rule.

(Response) The basis for the measures in this final rule was discussed in the preamble to the October 2005 proposed rule (70 FR 58570 at 58578). Implementation of this new rule should not diminish inspection and enforcement of the 1997 ruminant feed

rule at firms that handle prohibited mammalian protein. Current resources should allow for effective enforcement of both rules.

(Comment 67) One comment said that rendering plants will need time to modify equipment and procedures before the rule is implemented.

(Response) FDA understands that rendering plants will have to make a variety of modifications to comply with the final rule. For this reason, FDA has made the new rule effective 12 months from the date of publication.

C. Comments on Proposed Amendments to § 589.2000—Animal Proteins Prohibited in Ruminant Feed

The final rule amends § 589.2000 to exclude 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 § 589.2001(b)(6). FDA also received several comments related to other requirements in § 589.2000.

(Comment 68) Three comments stated that salvaged pet foods, including distressed pet food, should be prohibited in cattle feed.

(Response) Pet food containing prohibited mammalian protein is prohibited from use in ruminant feed by the 1997 ruminant feed rule. Pet food products sold or intended for sale as distressed or salvage items must be labeled with the statement ''Do not feed to cattle or other ruminants'' if they contain or may contain prohibited mammalian protein (see § 589.2000(d)(4)). This final rule further reduces the risk that cattle could be exposed to the BSE agent through pet food because it requires the removal of certain cattle-derived risk materials from all animal feed.

(Comment 69) Two comments requested that the current feed rule be revised to exempt firms that handle retail pet food from recordkeeping requirements.

(Response) The 1997 ruminant feed rule requires firms to maintain records sufficient to track products containing prohibited mammalian protein. Exempting retail pet food distributors from recordkeeping requirements would diminish the ability of the agency to trace feed or feed ingredients that are adulterated under the 1997 ruminant feed rule. The agency intends to issue guidance that addresses what constitutes records sufficient to track prohibited protein associated with the sale of retail pet food.

(Comment 70) One comment suggested that the current rule be revised to require feed labels that clearly, concisely, and accurately inform users about the source of animal protein ingredients in feeds. The comment said that requiring new feed ingredient definitions such as ''non-ruminant derived animal proteins,'' ''ruminant derived animal proteins,'' and ''non-mammalian derived animal proteins'' would be helpful.

(Response) Section 589.2000 requires that feed products that contain or may contain prohibited mammalian protein be labeled with the caution statement ''Do not feed to cattle or other ruminants.'' Part 501 (21 CFR part 501) contains most of the labeling requirements for animal feed. Under § 501.4, ingredients must be listed on the product label by their common or usual name. Section 501.110 provides for the use of collective terms, such as ''animal protein products,'' in lieu of listing each ingredient by its common or usual name. For FDA recommendations regarding the common or usual names for animal feed ingredients, see Compliance Policy Guide 7126.08. In response to the FDA Amendments Act of 2007, FDA intends to develop new regulations on processing and ingredient standards and ingredient definitions for all animal feed, and updated labeling standards for pet food.

III. Description of the Final Rule

A. Definitions

Section 589.2001(a)(1) is being added to the final rule, and it sets forth the purpose of new § 589.2001, which is to prohibit the use of certain cattle origin materials in the food or feed of all animals to further reduce the risk of the spread of BSE within the United States.

To address the BSE risk, § 589.2001(b)(1) defines cattle materials prohibited in animal feed (CMPAF) to include the following: (1) The entire carcass of BSE-positive cattle; (2) the brains and spinal cords of cattle 30 months of age and older; (3) the entire carcass of cattle not inspected and passed for human consumption that are 30 months of age or older from which brains and spinal cords were not effectively removed or otherwise effectively excluded from animal feed; and (4) mechanically separated beef and certain tallow that is derived from materials prohibited by this rule. The definition of CMPAF does not include tallow derivatives or certain tallow that contains no more than 0.15 percent insoluble impurities. This definition differs from the proposed rule in that the entire carcass from BSE-positive cattle has been added to the definition. This was done to clarify that all materials from such animals are prohibited from use in animal feed. Further, the regulations were revised to exclude from the definition of CMPAF certain cattle that have not been inspected and passed for human consumption. Under the proposed rule, cattle that were not inspected and passed for human consumption were excluded from the definition of CMPAF if their brains and spinal cords were removed. The final rule was revised to indicate that such cattle are not considered CMPAF if the animals were shown to be less than 30 months of age, regardless of whether the brain and spinal cord have been removed. The regulations have also been revised to exclude from the definition of CMPAF certain cattle materials that originate from a country that has been designated by FDA as exempt from the requirements of this rule based on its BSE risk status. This exclusion is being added in response to comments and because the agency has determined that it is not necessary for all BSE-related restrictions to apply to animal feed regardless of a country's BSE status. Epidemiological evidence indicates that the BSE epidemic in the United Kingdom (U.K.) was a result of consumption of animal feed contaminated by the BSE agent. The spread of BSE outside the U.K. has been attributed to the export of BSE-contaminated feed from the U.K. to other countries prior to the realization of the role of feed in transmitting the disease and the subsequent restrictions on such trade. FDA acknowledges that a country may not have engaged in commercial trade in animal feed with the U.K. or other affected countries, and it may have had preventive measures in place for a length of time adequate to make remote the chance that BSE is present in that country.

Such a country may be able to demonstrate to FDA that its BSE case history, risk factors, and measures to prevent the introduction and transmission of BSE make certain BSE-related restrictions unnecessary with respect to cattle materials from that country. Allowing cattle materials from such a country to be used in non-ruminant animal feed manufactured from, processed with, or otherwise containing CMPAF is consistent with OIE's recommendation that other prohibited materials from negligible risk countries not be restricted. The process for seeking designation to be covered by this exclusion is set forth in § 589.2001(f).

In its application, the requesting country will be expected to provide information to FDA on its BSE case history, including whether cattle in that

country have tested positive for BSE, and, if so, the circumstances and the country's response. In addition, FDA will review information that addresses the extent to which the requesting country has identified and taken into account relevant risk factors such as the following:

- Possible presence of BSE in indigenous and/or imported cattle;
- Geographic origin of imported cattle;
- Materials used in the production of ruminant feed and feed ingredients; and
- Importation of ruminant feed and feed ingredients.

FDA will consider information relating to the possible presence of BSE in indigenous and imported cattle in the requesting country as well as the requesting country's production and importation of ruminant feed and feed ingredients. With respect to imported cattle, relevant information includes the identification of any countries where imported cattle were born or raised and the dates any cattle were imported. With regard to ruminant feed, FDA will consider, among other things, how ruminant feed was produced in the requesting country, including what animal origin materials were allowed to be included. FDA will also consider whether ruminant feed and feed ingredients were imported, and if so, the source countries and dates of import.

In addition to reviewing risk factors such as those identified previously, FDA will assess how the requesting country has addressed and managed any identified BSE risks through the implementation of appropriate measures to prevent the introduction and transmission of BSE. FDA will consider how long such preventive measures have been in place and whether they have been effectively carried out. Examples of preventive measures include the following:

- A prohibition on the use of ruminant feed that might carry a risk of transmitting the BSE agent;
- A prohibition on the import of cattle and cattle-derived products that might carry a risk of transmitting the BSE agent;
- Surveillance systems for BSE in cattle populations with appropriate examination of brain or other tissues collected for surveillance in approved laboratories;
- Mandatory notification and examination of all cattle showing signs consistent with BSE; and
- Protocols or other written procedures for investigating potential cases of BSE, including ability to trace former herdmates of BSE-positive animals.

As part of its evaluation of a requesting country's feed restrictions, FDA will consider factors including whether appropriate feed restrictions are in place and the adequacy of enforcement of those restrictions (e.g., the frequency of facility inspections and level of compliance). FDA also will consider a requesting country's import controls for cattle material. Such consideration will include whether the country effectively monitors and controls potential pathways of cattle materials and other potentially infective materials into its country from other countries for which such controls are necessary.

In addition, FDA will consider the requesting country's surveillance and monitoring efforts with respect to BSE. For example, FDA will evaluate the level at which the country performs surveillance and monitoring, whether tissue samples are collected and examined at approved laboratories, and whether recognized diagnostic procedures and methods are used, such as those procedures and methods provided in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Ref. 15).

FDA also will consider whether the requesting country has an ongoing program for notification and investigation of all cattle showing signs consistent with BSE. In evaluating such a program, FDA will consider, among other factors, whether notification and investigation is mandated, whether veterinarians, producers, and others involved in cattle production have been provided sufficient information about BSE, such as through an awareness program, and whether there are additional measures in place to stimulate reporting of suspect cattle, such as compensation or penalties.

FDA also will consider a requesting country's written procedures for investigating potential cases of BSE. Such a consideration will include whether the country has written procedures for the investigation of suspect animals and whether the country has the investigative capability to follow up positive findings by tracing former herdmates of animals determined to be BSE positive. Finally, FDA also will consider any other information relevant to determining whether the country should be designated under § 589.2001(f).

FDA and the USDA agencies, APHIS and FSIS, have different regulatory responsibilities with respect to preventing BSE and ensuring food safety. Therefore, FDA cannot rely on the evaluations of APHIS and FSIS in making a determination on country designations. FDA will, however, consult with APHIS and FSIS as part of its evaluation process. In addition, FDA will take into consideration available risk assessments of other competent authorities in conducting its evaluation. Although it is not required, a previous BSE evaluation by USDA, OIE, or by another government or another competent authority, will be helpful to FDA in its review and may decrease the time needed for FDA to make a determination.

Upon completion of its review, FDA will provide written notification of its decision to the requesting country, including the basis for the decision. FDA may impose conditions in granting a request for designation. Further, any designation granted under § 589.2001(f) will be subject to future review by FDA to ensure that the designation remains appropriate. As part of this process, FDA may ask designated countries to confirm that their BSE situation and the information submitted by them in support of their original application remain unchanged. Further, FDA may revoke a country's designation if FDA determines that it is no longer appropriate.

FDA will provide further information on its evaluation process, the scope of the review, and the types of supporting information that it would find helpful in reviewing a country's submission at the time of the request.

Section 589.2001(b)(2) defines cattle not inspected and passed for human consumption as cattle that did not pass antemortem inspection 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. The definition of cattle not inspected and passed for human consumption was revised to add the word ''ante-mortem'' to clarify that cattle referred to in this definition are those that did not pass (or were not subjected to) antemortem inspection.

Section 589.2001(b)(3) defines mechanically separated beef as 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.

Section 589.2001(b)(4) defines renderer to mean 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.

Section 589.2001(b)(5) defines tallow to mean 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.

Section 589.2001(b)(6) defines tallow derivative to mean any product obtained through initial hydrolysis, saponification, or transesterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or transesterification may be applied to obtain the desired product.

The definitions in § 589.2001(b)(3), (b)(4), (b)(5), and (b)(6) are unchanged from the proposed rule.

B. Requirements

Section 589.2001(c)(1) provides that no animal food or feed ingredient shall be manufactured from, processed with, or otherwise contain CMPAF. Section 589.2001(c)(2) provides new requirements for renderers that handle CMPAF. Section 589.2001(c)(3) provides new requirements for renderers that handle any cattle material.

1. Requirements for Renderers That Receive, Manufacture, Process, Blend, or Distribute CMPAF

Section 589.2001(c)(2) of the final rule has been revised to include requirements for renderers that intend to render for use in animal feed cattle not inspected and passed for human consumption. If such cattle are to be rendered for animal feed, the renderer must ensure that the brain and spinal cord are effectively removed or otherwise effectively excluded from material rendered for use in animal feed. If such cattle are to be rendered without brain and spinal cord removal, the renderer must ensure that such animals are less than 30 months of age. In addition, written procedures must be maintained specifying the procedures used to ensure compliance with these requirements.

As provided in the proposed rule, § 589.2001(c)(2) of the final rule also requires that renderers that handle CMPAF 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 CMPAF or products that contain or may contain CMPAF do not serve as a source of cross-contamination.

In addition, § 589.2001(c)(2) requires renderers that handle CMPAF or products that contain or may contain CMPAF to: (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 requirements are intended to ensure that CMPAF 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 other cattle materials. 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 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. Requirements for Renderers That Receive, Manufacture, Process, Blend, or Distribute Any Cattle Materials

Section 589.2001(c)(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, CMPAF; (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. These requirements are unchanged from the proposed rule.

C. Recordkeeping and Access Requirements

Section 589.2001(c)(2)(v) requires that renderers that receive, manufacture, process, blend, or distribute CMPAF establish and maintain records sufficient to demonstrate that such material was not introduced into animal feed and make them available to FDA for inspection and copying. Furthermore, § 589.2001(c)(3) requires that renderers that receive, manufacture, process, blend, or distribute any 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 CMPAF. Such records shall be considered sufficient to meet this requirement if they include documentation that establishments supplying cattle materials to the renderers have adequate procedures in place to effectively exclude cattle materials prohibited in animal feed. The exclusion of CMPAF by establishments supplying cattle materials to renderers must be demonstrated either by certification or other documentation provided by the supplier or by another method acceptable to FDA such as third-party certification. Certification or other documentation provided by the supplier is acceptable provided such records include a description of the supplier's segregation procedures, documentation that the supplier confirms that such procedures are in place prior to supplying any cattle material to the renderer, and records of the renderer's periodic review of its suppliers' certification or other documentation. Copies of all records established and maintained by renderers must be made available for inspection and copying by FDA.

In the preamble to the October 2005 proposed rule (70 FR 58570 at 58581), FDA explained that these recordkeeping requirements were intended to ensure that no CMPAF would enter the feed channel. At that time, the agency explained that it did not believe it was 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 CMPAF. The agency went on to state its belief 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, however, sought comments on the need to require that records be maintained by persons other than renderers. The agency did not receive any comments on this point. Therefore, FDA is requiring that such records be established and maintained by renderers for the reasons explained in the preamble to the proposed rule.

FDA also sought specific comments on what types of records would be appropriate for satisfying the recordkeeping requirements and whether further detail would be needed

in the regulation regarding specific record requirements. FDA received one comment asking whether written statements from slaughter and processing establishments would be acceptable to FDA as evidence that CMPAF has been removed. Several comments stated that slaughter plants should be required to verify that raw materials sent for rendering into animal feed are free of CMPAF. In addition, a few comments stated that the records should be detailed enough to allow trace forward and trace back as part of any investigation of prohibited cattle materials and asked that FDA provide guidance on proper recordkeeping. As discussed above, FDA has provided additional details about the recordkeeping requirements for renderers. Furthermore, as discussed in section II of the preamble, the agency plans to issue guidance, as needed, to assist renderers in complying with the recordkeeping and other requirements.

Section 589.2001(e) provides that the records required by this final 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. In reaching this conclusion, the agency considered 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.

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

Section 589.2000(a)(1) has been amended 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 § 589.2001(b)(1)(v). As discussed in the preamble to the proposed rule, § 589.2000 previously did not include tallow in the definition of protein derived from mammalian tissues. However, in light of concerns about protein impurities present in tallow, FDA has included tallow in the definition of protein derived from mammalian tissues unless it contains no more than 0.15 percent insoluble impurities.

IV. Analysis of Economic Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 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). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities.

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 finalizing ''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 $122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product.

FDA finds that the final rule constitutes an economically significant regulatory action as defined in section 3(f)(1) of Executive Order 12866 because the sum of the recurring costs and capital costs that could be incurred in 1 year rounds to $100 million. We base this conclusion on both a study of the impacts on industry of the final rule (conducted for FDA by the Eastern Research Group (ERG), a private consulting firm (Ref. 16)) and the discussion in the remainder of this section. Under the requirements of the Regulatory Flexibility Act (RFA), the agency has determined that the regulation will have a significant impact on a substantial number of small entities. Therefore, the agency has prepared a final regulatory flexibility analysis in accordance with the RFA (5 U.S.C. 604). The analysis can be located in section IV.H of this document. This final rule imposes no mandates on government entities, and does not require the expenditure of over $122 million in any 1 year by the private sector. As such, further analysis of anticipated costs and benefits is not required by the Unfunded Mandates Reform Act.

A. Summary of Final Regulatory Impact Analysis

The existing rule, which provides the baseline for this analysis, prohibits the use of certain protein derived from mammalian tissues in ruminant feeds. This final rule expands this restriction to prohibit certain cattle-derived risk materials in all animal feeds. The final rule, which is very similar to the proposed rule, would define those CMPAF to include the brain and spinal cord of all cattle 30 months of age or older slaughtered for human consumption, as well as the brain and spinal cord of cattle not inspected and passed for human consumption 30 months of age or older, the entire carcass of cattle not inspected and passed for human consumption 30 months of age or older unless the brain and spinal cord have been effectively removed or effectively excluded from animal feed, as well as other materials. The final rule makes a notable change from the proposed rule by not defining as CMPAF the brain and spinal cord from cattle under 30 months of age that are not inspected and passed for human consumption. FDA has also revised the final rule to clarify that the records established and maintained by renderers that receive cattle materials to be rendered for use in animal feed must include certification or other documentation from the supplier, or other documentation acceptable to FDA, that material supplied to the renderer does not include CMPAF. For the purposes of this final rule, the term ''cattle not inspected and passed for human consumption'' includes non-ambulatory disabled cattle. The final rule prohibits tallow derived from BSE-positive cattle from use in animal feed and prohibits tallow derived from other CMPAF from use in animal feed unless it contains no more than 0.15 percent insoluble impurities. The final rule also prohibits mechanically separated (MS) beef derived from any of the CMPAF from use in animal feed. Additional provisions of the final rule would require renderers that handle CMPAF to use separate equipment or containers to handle this material once it has been separated from other cattle materials. Such renderers would also be required to follow certain procedures for labeling and marking CMPAF and recordkeeping and records access.

The benefits of the final rule include the elimination of the vast majority of the risk not addressed by the 1997 ruminant feed ban 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. The final rule would effectively remove from use in non-ruminant feeds those cattle tissues that account for approximately 90 percent of potential BSE infectivity (Ref. 17). Although the animal and public health benefit associated with the additional BSE risk reduction is paramount, the U.S. economy may also benefit from regained market access in countries that remain fully or partially closed to U.S. beef and beef products to the extent that the final rule persuades foreign governments that more U.S. beef products are safe to import. Although we are unable to quantify the effects of this final rule on removing restrictions to foreign markets, the benefits are potentially large because the economy as a whole loses an annual surplus equal to about $58 million from the remaining restrictions.

This final rule that prohibits the use of these materials in animal food or feed would impose four types of costs: Disposal costs, the opportunity cost of the MBM and tallow not produced, direct costs of new equipment and re-allocated labor, and feed substitution costs. Total compliance costs of the final rule are estimated to range from about $64.4 to $80.9 million per year annualized over 10 years assuming a 7-percent discount rate; at a 3-percent discount rate, total compliance costs are estimated at $64.0 to $80.5 million per year.

Compliance costs include those imposed by the rule's prohibition on the use of certain tissues from cattle 30 months of age or older slaughtered for human food and cattle 30 months of age and older not inspected and passed for human consumption in any animal feed as well as the cost to substitute other feed ingredients for those foregone from further processing of CMPAF. First, we discuss the brain and spinal cord ban as direct costs to the affected firms (including disposal costs, where applicable) and the social cost of the ban on the raw materials used in feed product inputs. Then, we discuss the feed substitution costs. Table 1 of this document shows a summary of these costs.

The ban on the use of certain cattle materials in all animal feed from cattle 30 months of age and older slaughtered for human consumption and cattle 30 months of age and older not inspected and passed for human consumption would require renderers that process either materials from cattle 30 months of age and older slaughtered for human consumption or cattle not inspected and passed for human consumption 30 months of age and older to separate the CMPAF from the remaining offal. Renderers may require slaughter facilities to separate such materials as a condition of collection. We estimate the one-time capital costs of such a requirement for slaughterers at about $2.1 million (Table 1, line 2) (or $299,000 annualized at 7 percent over 10 years and $246,000 annualized at 3 percent over 10 years). We estimate that the annual cost of the additional labor to separate this CMPAF from other cattle offal at about $972,000 (Table 1, line 3) (including maintenance on new equipment). Although compliance costs of these activities will be borne initially by slaughterers, a portion of the costs are likely to be passed along to cattle producers and consumers. For renderers, average annualized capital investment and labor costs for CMPAF separation and segregation are estimated at about $7.0 million (Table 1, lines 9 and 10).

Our analysis does not project a specific disposal route for CMPAF due to the variability of State and municipal laws for disposal of organic wastes. As it did for the proposed rule, our analysis of the final rule estimates a $12 per 100 lbs (hundredweight (cwt)) of CMPAF disposal cost (including any transportation costs) from slaughter and rendering establishments. We estimate annual disposal costs for CMPAF from independent renderers at about $11.3 million (Table 1, line 11) and from slaughterers at about $3.4 million (Table 1, line 23). We expect that the disposal costs for slaughter CMPAF are immediately passed on to animal producers as lower prices for animals delivered to slaughter. Additional disposal costs to animal producers for other animals that would no longer be rendered as a result of this rule will range from $24.7 million to $35.7 (Table 1, line 22) million annually. We estimate the social cost of the loss of MBM sales to range from $0.8 to $1.0 (Table 1, lines 4 and 14) million and the social cost from lost tallow sales to range from $0.7 to $0.8 million (Table 1, lines 5 and 15). These costs include the lost value from CMPAF from cattle 30 months of age and older slaughtered for human consumption, cattle not inspected and passed for human consumption 30 months of age and older, as well as calves, cattle under 30 months not inspected and passed for human consumption and other species that would no longer be rendered as a result of this rule. We judge the social cost of the loss of hide value resulting from this rule to range from $9.2 million to $13.7 million (Table 1, line 12) annually. The estimated cost of both creating and executing procedures for the aging of animals at greater or less than 30 months of age is $2.4 million (Table 1, lines 6 and 13) annually. To the extent some slaughter establishments already have aging procedures in place to comply with FSIS' SRM rule, this amount may be an overestimate.

The final rule, as in the proposed rule, requires that tallow derived from certain CMPAF contain no more than 0.15 percent insoluble impurities. Even though the estimate of CMPAF is much larger in the final rule, because the amount handled directly by independent renderers would remain relatively small, we concluded that it would not be economical for renderers or tallow manufacturers to further process into tallow the brains and spinal cords from all cattle that have their brains and spinal cords removed while complying with the additional equipment separation and tallow testing and purification requirements. We therefore did not include any additional cost for this provision.

TABLE 1.—TOTAL COSTS ($ MILLIONS) [1]

Line	Cost item	One-time cost	Annual costs	Annualized costs [2]
1	Slaughter Facilities			
2	Capital investments	$2.1		$0.30
3	Labor		$0.97	0.97
4	Social cost of lost MBM		0.04	0.04
5	Social cost of lost tallow		0.03	0.03
6	Creating/Performing cattle aging procedures		1.10	1.10
7	Subtotal—Slaughter Facilities	2.1	2.14	2.44
8	Renderer Facilities			

TABLE 1.—TOTAL COSTS ($ MILLIONS) [1]—Continued

Line	Cost item	One-time cost	Annual costs	Annualized costs [2]
9	Capital investments	20.25	3.04	5.92
10	Labor		1.09	1.09
11	Disposal of CMPAF from cattle > 30 months		11.30	11.30
12	Value of cattle hides		9.16–13.69	9.16–13.69
13	Creating/Performing cattle aging procedures		1.28	1.28
14	Social cost of lost MBM		0.80–0.98	0.80–0.98
15	Social cost of lost tallow		0.64–0.78	0.64–0.78
16	Plant modification for tallow purification			
17	Slaughter and renderer marking of CMPAF		0.02–0.06	0.02–0.06
18	Slaughter and renderer recordkeeping/labeling	0.30	0.21	0.27
19	Subtotal—Renderer Facilities	20.55	28.20–33.09	31.14–36.04
20	Animal Producer			
21	Disposal of cattle > 30 months not inspected and passed, all other animals		24.70–35.70	24.70–35.70
22	Disposal of slaughter cattle CMPAF		3.38	3.38
23	Feed substitution		2.92–3.51	2.92–3.51
24	Subtotal—Animal Producers		31.0–42.59	31.0–42.59
25	Final Rule Total Costs	22.65	61.34–77.82	64.58–81.06

[1] Totals may not sum due to rounding.
[2] Annualized cost equal to annual cost plus one-time costs at 7 percent over 10 years. Using a 3-percent rate, annualized costs equal $63.99–$80.48 million.

B. Cost Effectiveness of Final Rule and Alternatives

Compared with the final rule, we do not offer any alternative that would impose greatly lower costs. The only feasible lower-cost alternative that would reduce the risk of cross contamination would be to require separate facilities or equipment to produce ruminant and non-ruminant feed.

Alternative 1—Dedicated Facilities and Equipment

This alternative would strengthen FDA's 1997 feed rule by preventing cross contamination of feed ingredients for ruminants with mammalian proteins currently prohibited from ruminant feed. To prevent cross contamination, this alternative would require dedicated equipment in those facilities producing or handling feed or feed ingredients for ruminants and mammalian proteins currently prohibited from ruminant feed. In the analysis of the alternatives to the proposed rule, ERG estimated that only independent renderers and feed mills would incur compliance costs for this dedicated facilities or equipment (70 FR 58593). It should be noted, however, that this requirement for dedicated facilities and equipment differs from the dedicated equipment requirement of the SRM ban (Alternative 3 in this document). Since the dedicated facilities and equipment option is analyzed here as a separate alternative (i.e. not as part of the SRM ban), the tonnage of rendered ruminants would not be reduced (without the SRM ban), and the resulting transportation costs would be larger than had the SRM ban been included as part of this alternative.

To dedicate facilities, independent renderers would invest about $8 million in one-time costs and feed mills would invest about $43.2 million in one-time costs. Annualized over 10 years at 7 percent, capital investment for dedicated facilities would equal about $7.3 million, or about $1.1 million for independent renderers and about $6.2 million for feed mills. ERG forecast that this alternative would have little effect on MBM production, but would force firms to spend more to transport MBM because they could no longer backhaul ruminant feed in trucks used to transport feed containing mammalian proteins currently prohibited in ruminant feed (70 FR 58593 to 58594). In the analysis for the proposed rule, ERG estimated that dedicated equipment would increase transportation costs by $8 million to $16 million for renderers and $14.2 million to $28.4 million for feed mills (70 FR 58594). Accounting for ERG's revised fuel costs (Ref. 16), the estimated costs for dedicated transportation equipment range from $14.6 million to $29.3 million annually for renderers and from $22.5 million to $45.0 million annually for feed mills. The total estimated annualized compliance costs of this alternative range from $44.4 million to $81.6 million.

This alternative addresses the problem of animal feed being cross-contaminated with prohibited mammalian protein in firms that manufacture animal feeds and also handle prohibited mammalian protein by requiring such firms to have dedicated facilities or equipment for animal feeds. The compliance costs of this alternative are similar to the costs of the final rule. In contrast to the final rule, however, this alternative would allow CMPAF with the highest BSE infectivity to remain in the animal feed supply, allowing potential exposure to BSE infectivity when cattle consume feed intended for other species through cross-contamination or misfeeding. We conclude, therefore, that the final rule more effectively reduces the risk from cross-contamination and misfeeding than this alternative to require dedicated facilities or equipment. Given the general similarity in compliance costs, we therefore judge this alternative to be less cost-effective than the final rule.

Alternative 2—The Proposed Rule

The proposed rule would require that the brain and spinal cord from all cattle 30 months of age or older slaughtered for human consumption, and from all cattle not inspected and passed for human consumption of any age to be defined as CMPAF. The main difference between the proposed rule and the final rule is that the proposed rule would also define as CMPAF the brain and spinal cord of cattle under 30 months of age that were not inspected and passed for human consumption. Compared with the final rule, this alternative produces more tissue for disposal by deadstock renderers, increasing the compliance costs for independent renderers.

However, these costs would be offset somewhat because, under the proposed rule, deadstock renderers would not need to determine the age of the animal. The annualized compliance costs for independent renderers would range from $34.9 million to $41.5 million. Similar to the final rule, livestock producers would likely pay higher prices for feed substitutes and on-farm disposal of deadstock. Annualized compliance costs for livestock producers would range from $36.4 million to $51.9 million. Slaughterers would incur about $2.5 million in annualized costs. Table 2 of this document shows that, in total, the estimated annualized compliance costs for this alternative range from $73.8 million to $95.9 million and exceed the annualized compliance costs of the final rule.

Although this regulatory action would prohibit more material from animal feed than would the final rule, it would only add the brain and spinal cord of cattle not inspected and passed for human consumption under 30 months of age to the list of prohibited cattle material. Scientific evidence indicates that the probability that the brain and spinal cord from cattle under 30 months of age contains BSE infectivity is extremely low (Ref. 18). Consequently, this alternative is less cost-effective than the final rule because it cost $9.2 to $14.8 million more without a commensurate reduction of risk.

TABLE 2.—SUMMARY OF THE COMPLIANCE COSTS OF THE PROPOSED RULE [1]

Cost item	One-time costs ($ million)	Annual costs ($ million)		Annualized costs [2] ($ million)	
		Low estimate	High estimate	Low estimate	High estimate
Capital investments	26.2	.....	.....	3.7	3.7
Labor	.....	8.4	8.4	8.4	8.4
Loss of net revenue	.....	12.8	19.4	12.8	19.4
Disposal costs	.....	44.9	59.9	44.9	59.9
Marking	.....	0.0	0.1	0.0	0.1
Recordkeeping/Labeling	0.2	0.1	0.1	0.1	0.1
Feed substitution	.....	3.8	4.4	3.8	4.4
Total costs	26.3	70.0	92.1	73.8	95.9

[1] Numbers may not sum due to rounding.
[2] Costs are annualized over 10 years at 7 percent.

Alternative 3—The SRM Ban

The third alternative we considered would prohibit the use of the full list of specified risk material (SRM) from animal feed and require the use of dedicated equipment by renderers. The scope of this alternative is similar to Canada's 2006 enhanced feed rule and is the most restrictive regulatory action we considered.[1] This alternative expands the list of prohibited material and would substantially increase the amount of prohibited material generated by regulatory action. It also requires that renderers have dedicated equipment used to process or transport protein prohibited from being fed to ruminants and to process or transport protein not prohibited from being fed to ruminants.

In practice, some tissues that are not defined as SRM would be difficult to separate and are treated as SRM. Canada made a similar distinction in its enhanced feed rule. Thus, in addition to the material prohibited in the final rule, this alternative would prohibit from all animal feed: The skull, eyes, 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 cattle 30 months of age and older, and the tonsils and distal ileum of all cattle.

As shown in Table 3 of this document, the estimated annualized costs of this alternative range from $332.0 million to $344.7 million. Slaughterers would incur annualized costs of about $19.5 million in lost revenues and increased labor and capital costs. Independent renderers would incur from $42.9 million to $55.6 million in annualized costs of lost revenues and increased labor and capital costs. Animal producers would incur about $12.7 million annually in feed substitution costs. Disposal costs for animals that would no longer be rendered as a result of the SRM ban and the disposal costs for slaughter SRM would account for the majority of the estimated annualized costs and equal about $257 million. Because most slaughterers can immediately pass disposal costs back to cattle producers by adjusting the prices they pay for slaughter animals, cattle producers would likely incur the entire cost of SRM disposal in the short run. ERG estimated that over time, markets would adjust to the impacts of an SRM ban and about 50 percent of the total incremental costs of this alternative would be passed on to consumers as higher beef prices, 38 percent of the total incremental costs would be passed back to cattle producers as lower cattle prices and 12 percent of the total incremental costs would be incurred by processors.

Although this option would increase the material removed from animal feed when compared with the first alternative, the incremental reduction in the potential risk would not be commensurate with the costs as shown in Table 3 of this document. Thus, this regulatory alternative would be much less cost-effective than either the final rule or the proposed rule.

[1] The enhanced Canadian feed ban exempts feed mills from the requirement for dedicated equipment. Although ERG included feed mills in its analysis of the SRM ban, we have excluded these costs from our analysis.

TABLE 3.—COMPLIANCE COSTS OF A FULL SRM BAN [1]

Cost item	One-time costs ($ million)	Annual costs ($ million)		Annualized costs [2] ($ million)	
		Low estimate	High estimate	Low estimate	High estimate
Capital investments	37.8			5.4	5.4
Labor		12.7	12.7	12.7	12.7
Loss of net revenue		35.8	35.8	35.8	35.8
Transportation		7.9	20.5	7.9	20.5
Disposal costs		257.0	257.0	257.0	257.0
Marking		0.6	0.6	0.6	0.6
Recordkeeping/Labeling	0.2	0.1	0.1	0.1	0.1
Feed substitution		12.7	12.7	12.7	12.7
Total compliance costs	38.0	326.6	339.3	332.0	344.7

[1] Numbers may not sum due to rounding.
[2] Costs are annualized over 10 years at 7 percent.

Summary of Regulatory Alternatives

Table 4 of this document shows the annualized and incremental costs of each regulatory alternative considered. The safeguards put in place by the 1997 ruminant feed rule have substantially reduced the potential risk that tissues infected with the agent that causes BSE could get into ruminant feed. The final rule further reduces the possible risk of cross contamination of ruminant feed with prohibited material. As explained previously, we have determined that the final rule is the most cost-effective action for reducing the potential risk that animal feed or feed ingredients intended for ruminants could contain the agent that causes BSE.

TABLE 4.—COSTS OF ALTERNATIVE POLICIES

Alternative	Annualized costs [1] ($ million)		Incremental annualized costs (from previous alternative) ($ million)	
	Low estimate	High estimate	Low estimate	High estimate
Separate facilities and equipment for renderers and feed mills	44.4	81.6		
Final rule	64.6	81.1	20.2	(0.5)
Proposed rule	73.8	95.9	9.2	14.8
Full SRM ban; separate facilities and equipment for renderers	332	344.7	258.2	248.8

[1] Costs are annualized over 10 years at 7 percent.

C. Need for Regulation

Executive Order 12866 directs agencies to assess the need for any significant regulatory action and to provide an explanation of how the regulation will meet that need. Comments on the October 2005 proposed rule did not address the accuracy of the theoretical argument FDA put forth in the preamble to the October 2005 proposed rule related to private incentives and market failure (70 FR 58570 at 58587). Therefore, FDA retains this argument here in the final rule. In this instance, FDA 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 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 final rule would eliminate are the same as described in the 1997 ruminant feed 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 processed CMPAF. Feed purchasers, however, are unlikely to obtain the information they need due to the long incubation period for BSE, which could lead to a suboptimal level of risk prevention by purchasers during the incubation period. Moreover, ruminant producers have no way of knowing whether a particular batch of feed or feed ingredients intended for ruminants is free of potentially infective proteins due to the possibility of CMPAF being introduced through cross-contamination with feed or feed ingredients intended for non-ruminants.

D. Benefits

FDA received few comments on the proposed rule that focused on the benefits section. One comment stated that the proposal was unnecessary because it addressed only a very small risk. FDA agrees that the risk is low but reiterates, as in the proposed rule, that by requiring removal of the highest risk cattle-derived materials from use in any animal feed, the final rule further reduces BSE risks not already addressed by the 1997 feed ban.

The purpose of the final rule is to further strengthen existing safeguards against BSE in the United States. Reduced risk of BSE among cattle also reduces human risk of vCJD, which is believed to be caused by consumption

of beef products contaminated with the BSE agent. The final rule also increases the potential for exports by reducing foreign governments' concerns about the safety 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 final rule on U.S. exports of beef and other livestock products.

1. Risk Reduction

FDA estimates that banning CMPAF 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 ban on CMPAF, 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 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. This rule would prohibit use in all animal feed of these tissues from all cattle 30 months of age or older. Brain and spinal cord taken from cattle under 30 months of age would not be defined as CMPAF, however, because the probability is extremely low that tissues from cattle of this age would contain BSE infectivity. Thus, banning CMPAF from animal feed 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 are exposed to infected material.

The potential human exposure to infectious materials from consuming beef is already small, because USDA and FDA prohibit the use of certain cattle materials, including SRMs, from human food. The 2005 Harvard Risk Assessment that USDA's Food Safety and Inspection Service made available to the public in July 2006 estimates that interim measures implemented by FSIS on January 12, 2004, and finalized on July 13, 2007, reduce potential human exposure to BSE infectivity by 99.6 percent (see 69 FR 1862 and 72 FR 38700).

Assessing the public health implications from estimates of the human exposure to the BSE agent is difficult because there is no agreed-upon relationship between human exposure to cattle ID_{50}s (ID_{50} is the amount of infective material that would result in a case of BSE in 50 percent of the cattle that consumed it) and vCJD cases. During the 1980s and 1990s, in the absence of preventive control measures, millions of ID_{50}s may have been available for consumption by residents of the United Kingdom, because each cow with clinical symptoms of BSE contains an average of about 7,800 ID_{50}s. While the United Kingdom totaled over 183,000 cases of BSE (Ref. 19) through January 21, 2007, the cumulative number of definitive or probable vCJD cases identified in the United Kingdom as of February 2007 was 165 (Ref. 20). Thus, the experience of the United Kingdom suggests that the BSE agent is many times less infective in humans than in cattle.

2. Increased Export Potential

A second major category of benefits largely accrues to U.S. cattle producers and reflects the potential for increased exports of U.S. beef and beef products to countries that have acted to curtail exports since the discovery of the infected cow in Washington State in December 2003. USDA assessed this category of benefits in the FSIS SRM interim final rule that it issued in January 2004. In its assessment, USDA concluded that ''the 2004 beef export demand forecast has been reduced by 90 percent'' (Ref. 21). Foreign trade data shows that from 2003 to 2004, the quantity of beef, veal, and beef variety meat exported by the United States decreased by about 75 percent, whereas the value of these exports declined by about 80 percent (Ref. 22). According to USDA data, total U.S. exports of beef, veal, and variety meats amounted to $3.9 billion in sales in 2003, and exports of live cattle resulted in an additional $63 million. USDA reports that the value of total beef and veal exports for 2006 amounted to $2 billion. In 2006 prices, the decline in export value comes to $2.2 billion (= ($3.85 billion * 1.09 [price adjustment]) − $2 billion). The quantity exported fell from 1,274,110 metric tons in 2003 to 653,205 metric tons in 2006. Some export markets disappeared almost overnight: Exports of U.S. beef to Japan fell from 375,452 metric tons in 2003 to 517 metric tons in 2004; exports to South Korea fell from 246,595 metric tons in 2003 to 144 metric tons in 2004. Exports have increased since 2006 but remain below 2003 levels.

Numerous foreign governments have cited perceived weaknesses in the 1997 feed ban as a justification for not fully opening their markets to U.S. beef and beef products. The preventive measures contained in this final rule may increase the likelihood that foreign governments ease some restrictions on imports of U.S. beef products and cattle.

We cannot estimate the trade benefits of this final rule. We can estimate the net effect on social surplus of the continuing restrictions on beef exports, as well as the potential gain from removing those restrictions. To do so, we use a standard economic model of the effects of export restrictions on consumer and producer surplus. The closing of export markets, all else being the same, leads to a fall in exports and a rise in domestic consumption as more beef is sold on the domestic market (Ref. 23). The forced sale to U.S. consumers increases consumer surplus and decreases producer surplus. Over time, the quantity produced in the domestic economy falls as well, as producers respond to the restrictions. If the trade restrictions on U.S. beef are removed, beef exports will increase, domestic consumption will decrease, and domestic production will increase. Once all adjustments are made to the withdrawal of the restrictions, we estimate the gain in social surplus to be about $105 million per year, with a range of $80 million to $120 million.

We estimate the effects of the export restrictions using changes in beef prices and exports. Price changes in the U.S. market, however, are dominated by seasonal and trend effects, fluctuations in feed costs, and a host of other factors. These complications make it difficult to use actual beef price changes to estimate the effect of diminished exports on price. As an alternative to direct estimates of price changes, we impute the price effect by estimating the decline in domestic price needed to clear the market if beef intended for export is instead sold on the domestic market. Again, we do not estimate the actual change in price but the imputed contribution of the increased quantity of beef on average price. Our imputed price change draws on the price elasticity of demand for beef, which is the percentage change in the quantity of beef demanded divided by the percentage change in price. The estimates in the literature show the mean price elasticity of demand for beef is about −1.086, although the variance of the estimates is high (Ref. 24).

To estimate the continued effect of the export restrictions and the potential gains from their removal, we assume that in their absence, the proportion of U.S. production exported would return to the 2003 level, 9.6 percent (Ref. 25). In 2006, the shortfall in beef exports compared with 2003 accounted for

about 5.2 (= 0.096 − 0.044) percent of 2003 beef production (Ref. 25). If we assume that the price elasticity of U.S. beef supply is about 0.5, removing the trade restriction would lead to responses on the supply about one-half as large as on the demand side, so domestic consumption would decline by 3.7 percent (= 0.035/(1 − 0.044 − 0.017)). With a price elasticity of −1.086 and a 3.7 percent decline in quantity demanded, we estimate the imputed price effect to be a rise of about 3.4 percent (= 3.7 percent/1.086).

The rise in social surplus can be approximated using the rise in price and the average value of exports in 2003 and 2006. We estimate this gain to be about $105 million (= ½ * ($4.2 billion + $2.0 billion) * 3.4 percent). This social surplus represents the continuing annual loss from the restrictions and the annual gain from their removal.

The estimated gain in social surplus is highly sensitive to the assumptions made about the responses of domestic beef consumers and producers to the removal of export restrictions. Our base estimate of the gain in social surplus assumes that in the long-run, the changes in consumption are about twice as large as the change in production (the price elasticity of supply is about half as large as the price elasticity of demand in absolute value). If increased U.S. beef production accounts for one-half of the response to the removal of trade restrictions (the price elasticity of supply is about the same as the price elasticity of demand in absolute value), the gain in social surplus is about $80 million per year. By contrast, if reduced consumption of beef in the United States accounts for three-fourths of the response to the removal of trade restrictions (the price elasticity of supply is about one-third the price elasticity of demand in absolute value), the gain in social surplus is about $120 million per year.

The estimates we present here are all based on a simplified model of the effects of trade restrictions. The estimates represent the gains from removing all remaining restrictions on beef exports, which will increase the world demand for U.S. beef. The estimates do not represent the gains from this final rule. The gains from this final rule would be estimated based on any relaxation of trade restrictions resulting from the rule. If other public and private policies reduce trade restrictions, then the potential gains from this rule would be correspondingly reduced. New safety events, such as more BSE cases, would also reduce the potential effects of this final rule on trade. We also expect that as time passes, the effects measured here will dissipate to be dominated by other changes in the world and domestic markets for beef. The social surplus estimated here would only be the short-term benefit of this final rule if publication of this rule leads directly to the return of U.S. beef to its status in world markets before the discovery of the infected cow in Washington State in December 2003, assuming that no other policies or events intervene.

E. Costs

FDA has examined the numerous public comments that addressed the analysis of impacts section published with the proposed rule. Furthermore, FDA contracted with ERG to update the analysis it prepared for the proposed rule, taking into account the comments and data provided during the public comment period, as well as any other new or amended provisions that FDA made to the final rule. This section summarizes the ERG report on the final rule, responds to comments on the costs of the proposed rule, and describes the composition, size, and scale of economic activity for the various affected industry sectors that would be impacted by the final rule.

The feasible regulatory alternatives to the final rule include the following: (1) Separate facilities and equipment for renderers and feed mills; (2) the proposed rule, which would prohibit the use of brain and spinal cord from cattle 30 months of age and older slaughtered for human consumption as well as from all cattle not inspected and passed for human consumption from animal feed; and (3) a full SRM ban in animal feed and separate facilities and equipment for renderers. The ERG report also includes estimates of impacts on small entities in the sectors that are impacted to a significant degree to fulfill requirements of a regulatory flexibility analysis.

In the development of its final report on the brain and spinal cord prohibition, ERG reviewed the public comments to the rule that concerned the economic impacts of the proposed rule, focusing closely on the data and analysis included in a report prepared for and submitted by the National Renderers Association. ERG utilized the services of industry consultants and other contractors for their technical expertise, including contracting with an agricultural engineering firm to generate capital cost estimates for independent rendering operations. Additionally, ERG prepared and administered a small survey to independent renderers with additional questions about their operations, including logistics of animal pick-up services, days of operation, decomposition of deadstock, and their ability to comply with the rule.

1. Public Comments on Costs

One of the most comprehensive comments to the proposed rule was prepared by Informa Economics for the National Renderers Association entitled ''Economic Impacts of Proposed Changes to Livestock Feed Regulations'' (Ref. 26). It concluded that the economic impact on renderers would far exceed the impacts that FDA estimated in the proposed rule, resulting in a significant economic burden of $127.7 million annually in direct economic impacts. Many of the individual comments or criticisms of our analysis of the proposed rule contained in the Informa report reflected other public comments from other individuals, companies, associations, and State governments. We have assembled similar comments together and will address them throughout the summary of the latest ERG analysis.

Approximately $113 million of the $127.7 million (about 88 percent) of the direct costs in the 2005 Informa report represent the estimated deadstock collection fees that would be paid by livestock producers for picking up those deadstock that would still be rendered under the proposed rule. The Informa analysis assumes that the average individual pick-up fees that would be charged across the four cattle categories represent the costs that renderers would incur to remove the CMPAF from cattle not inspected and passed for human consumption, as well as costs to handle, process, and dispose of the material. The assumption, however, leads to an estimate of costs that represents not the expected marginal fee increases from the proposed rule, but rather the total pick-up fee that the animal producer would pay. Using only the marginal pick-up fee per cwt that would be imposed by this rule reduces the total cost from $112.7 million to $62.9 million. The remainder of the original $112.7 million in fees ($49.8 million) represents costs that are currently incurred by the animal producers and are therefore not compliance costs of this rule. Further, the other 12 percent of the total direct costs represent the market value of the tallow and MBM that would be foregone due to this rule. Accounting for only the social costs of these lost revenues, estimated at the renderer's net income rate of 5.65 percent (use of net income as social cost is explained later in this document), reduces the $15.7 million to only about $0.89 million, a reduction of about $14.81 million.

This adjustment in estimated pick-up fee and MBM and tallow social cost losses reduces Informa's total direct costs to about $63.1 million. This figure is actually below our final rule estimate of $64 million to $81 million, which includes a cost reduction from the exemption from the definition of CMPAF for cattle under 30 months not inspected and passed for human consumption. If, however, we were to include the upper end of the range of marginal fee increases from the Informa report (Informa's $112.7 million cost represents only the lower bound of the data it presented), the range of the total direct costs from the Informa report (after accounting for the changes mentioned previously) would be $63.1 million to $113.53 million.

The Informa report also concludes that additional indirect costs for slaughter facilities to handle and dispose of CMPAF (which is not calculated separately in the report) and capital investments made by renderers to handle, process and dispose of CMPAF would likely result in a total cost exceeding $150 million annually. We agree that slaughtering facilities will incur additional capital costs, and ERG has increased its estimate from $676,000 in the proposal to about $1.27 million annually in the final rule. The capital investments for renderers that are detailed in the Informa report (amounting to an annualized total of $11.3 million) are based on an assumption that 26 renderers would actually install additional equipment to render the CMPAF for disposal, which is 50 percent of the number that replied that they might consider installing such equipment. Those 26 rendering operations in question, however, would also have been included in the survey's question on the expected increase in pick-up fees. The increase in pick-up fees, therefore, would account for these additional capital costs if they were indeed anticipated. The previously mentioned modifications to Informa's calculations result in a significantly lower total cost for the final rule. Additionally, we disagree with Informa's conclusion that, due to State and local prohibitions against its disposal in landfills, there is a high likelihood that all CMPAF would need to be rendered prior to disposal, although we agree that there is some uncertainty about the disposal methods that will be used throughout the United States.

Various other comments focused on the general subject of increased costs to slaughterers and other meat processors for disposal of byproducts, the reduction in the value of the slaughtered animals, and the reduction in the profitability of renderers. Although almost none of these comments contained additional data to support these conclusions, ERG performed additional analyses of the relevant industries that largely support the main concerns expressed in these comments.

Other comments stated that increased costs would be passed on to farmers. We agree that some compliance costs will be immediately passed on to farmers; ERG therefore concluded that animal producers would incur $28.1 million to $39.1 million in annual costs for alternative disposal of CMPAF from cattle slaughtered for human consumption and cattle not inspected and passed for human consumption (Table 1, lines 21 and 22). Other comments requested that we offer other economic incentives or remuneration in order to compensate renderers for converting operations to alternative disposal methods or for the cost of disposal, as has occurred in Europe. We did not consider subsidies as a policy option because FDA does not have this authority. Furthermore, the use of subsidies would not change the total social costs of the final rule, but rather transfer the costs to others. Likewise, the social cost does not change, as one comment suggested, if the number of cattle available for USDA's BSE testing program decreases because the renderer refuses to waive pick-up fees. In this case, the social cost is transferred to the general public.

We also received some comments that made claims about costs to individual States, such as the claim that the proposed rule would impose $10 million in costs on California dairy farmers, feedlots, and beef cattle producers. While we cannot verify this estimate without additional data necessary to support such claims, we agree that the costs of this final rule will be proportionally heavier in states with large populations of affected cattle.

One comment stated that removal of brain and spinal cord would reduce processing ability by 40 percent to 50 percent, without providing supporting information. Another comment stated that FDA should focus on removal of SRMs from 4D and antemortem condemned animals greater than 30 months, the cost of which would be from $64 million to $76 million, according to some industry estimates that were not disclosed. Without supporting information, we cannot respond directly to these comments. The ERG report, however, takes into account a number of public comments and changed many of its assumptions due to these public comments.

In general, this final rule, which prohibits certain cattle-derived risk materials from all animal food or feed, would impose four types of costs: Disposal costs, lost revenue measuring the value of the MBM and tallow not produced, direct costs of new equipment and re-allocated labor, and feed substitution costs.

2. Disposal Costs

For the proposed rule, ERG identified and discussed five options for disposal of CMPAF. These included landfilling of the CMPAF without rendering, rendering for disposal, disposal through alkaline hydrolysis digesters, incineration, and composting. The analysis concluded that landfilling would likely be one of the methods used to dispose of CMPAF, and that rendering for disposal would be unlikely due to the relatively small amount of CMPAF. The disposal cost estimate of the proposal was set at $12/cwt, based on discussions with industry members and ERG's other report on alternative regulatory options, including a full SRM prohibition. ERG concluded that the per cwt disposal cost would be higher than the full SRM prohibition disposal cost due to the lower volume of CMPAF for the brain and spinal cord prohibition as well as the uncertainty in disposal methods and unfamiliarity with some of the disposal methods in the industry. At this $12/cwt rate, disposal costs of the proposed rule for CMPAF from slaughter and render facilities were estimated at $7.72 million.

ERG also calculated the disposal costs of cattle not inspected and passed for human consumption that would no longer be rendered as a result of the proposed rule. This ban was expected to result in an increase in the number of on-farm disposals. For its analysis of the proposed rule, ERG estimated that 17 percent of cattle not inspected and passed for human consumption were currently rendered. In addition, ERG had predicted that an additional 0.6 percent of all cattle not inspected and passed for human consumption (or 3.5 percent of all cattle not inspected and passed for human consumption that are currently rendered) would no longer be rendered due to the proposed rule. These animals were estimated to result in an increase in capital and labor costs for on-farm burial of about $1.02 million.

We received numerous public comments concerning the estimates on the rendering of cattle not inspected and passed for human consumption. Some were more specific than others, but the prevailing theme was that we had

significantly underestimated the number of cattle not inspected for human consumption that are currently rendered. In particular, the Informa report questioned the accuracy of the estimate that only 17 percent of cattle not inspected and passed for human consumption are currently rendered. In fact, FDA had included in the proposal a discussion of the uncertainty of its own estimate along with Informa's previous estimate of this number at about 42 percent, and also incorporated this 42-percent estimate as the high end of the range of cost estimates for the proposal, where appropriate. Accepting Informa's 2004 estimate that 42 percent of cattle not inspected and passed for human consumption were rendered, we modified the proposal's disposal cost estimate for CMPAF from cattle slaughtered for human consumption and cattle not inspected and passed for human consumption that would continue to be rendered, from $7.72 million to a range of $7.72 million to $9.97 million. Similarly, we modified the proposal's disposal cost estimate for cattle not inspected and passed for human consumption that would no longer be rendered as a result of the proposed rule from $1.02 million to a range of $1.02 million to $2.5 million.

In its analysis of the final rule, the ERG report uses the Informa survey data of renderers (conducted for its November 2005 report) and USDA data, which show that about 45 percent of cattle not inspected and passed for human consumption are currently rendered. We therefore base our cost estimates for the final rule solely on the 45 percent figure, and do not include those based on the former range of 17 percent to 42 percent.

We also received many comments concerning the ERG estimate that about 26,000 cattle not inspected and passed for human consumption (or 0.6 percent of all cattle not inspected and passed for human consumption) would no longer be rendered as a result of the rule. Informa's 2005 results showed that renderers replied that, in total, about 67 percent of cattle not inspected and passed for human consumption that are currently rendered would no longer be rendered due to the proposed rule. That is, 45 percent times 67 percent = 30 percent of all cattle not inspected and passed for human consumption due to either renderer refusal to accept the animal or the producer's refusal to pay a higher pick-up fee, would no longer be rendered. The final ERG report, relying on estimates it received from deadstock renderers and estimated price elasticities of deadstock to renderers, projects that pick-up charge increases would range from 25 percent to 50 percent for all cattle under 30 months and 100 percent to 150 percent for cattle 30 months of age or older. We note that one comment stated that California renderers would increase their pick-up fees by 50 percent. These higher pick-up fees, coupled with expected closures of rendering plants handling about 10 percent of these cattle, support ERG's revised estimate that 29.4 percent to 44.8 percent of currently rendered cattle not inspected and passed for human consumption will no longer be rendered as a result of this rule. We accept this estimate as well and include it in this analysis. The Informa estimate of 67 percent may overstate the probability of an animal no longer being rendered because some of the carcasses that one renderer says will no longer be picked up by his company may still be picked up by another renderer. As a result of this and other changes in the final report, we estimate that the total amount of CMPAF would range from 610 million to 733 million lbs, a significant increase from the 64 million lbs estimated in the proposed rule.

Due to many public comments that FDA underestimated disposal costs in the proposed rule, ERG re-analyzed its methodology and assumptions concerning disposal in its report for the final rule. It reviewed various disposal technologies and a range of estimated costs for each based on literature compiled by researchers at Kansas State University, National Agricultural Biosecurity Center Consortium. The Kansas State University report presents a most likely representative estimate of costs, although it was derived from a graphic figure in the source document and thus contains some uncertainty. It also identified another disposal method that ERG had not considered in the proposed rule, namely that cattle would be left to decompose in the field or range without any additional treatment of the carcass. Some comments reflected the overall conclusions of the Kansas State University report, stating that incineration and composting are currently prohibitively expensive or complicated. One comment stated that burying CMPAF could be very expensive if a minimum of 4 hours rent for a backhoe is required, giving further support to the conclusion that when possible, these cattle would likely be left to decompose in the field. Several other comments questioned the availability of landfills for disposal of CMPAF. Another comment asked that we consult cost data in the 2004 publication on carcass disposal technologies by the National Agricultural Biosecurity Center Consortium. Table 7 in that publication shows disposal costs per ton for various carcass disposal methods. For both burial and landfilling, it presents cost estimates that are below the estimates ERG uses in its analysis of this final rule (Ref. 27).

Although many other comments questioned what they perceived to be low total disposal costs published in the proposed rule, the 2005 Informa survey reported an average disposal cost estimate of $11.51/cwt among those firms that indicated they would accept the CMPAF. Additionally, the Kansas State study reported 7 disposal options greater than $12/cwt and 4 options lower than $12/cwt. Accordingly, ERG has retained the overall average of $12/cwt disposal cost for CMPAF (from brain and spinal cord removal) from independent rendering operations for the final rule. Some comments questioned the economic feasibility of using dedicated trucks to transport CMPAF to disposal or for further processing. We have in fact included these costs in our totals because in its analyses of disposal costs, ERG included the transportation costs in the $12 per cwt estimate. Further, the Informa survey of renderers (reporting that renderers expect disposal costs would average $11.51 per cwt.) based its questions on CMPAF as defined by the proposed rule, which would require separate transportation trucks or compartments. Based on this $12/cwt rate, we estimate that CMPAF disposal costs of the final rule for slaughter facilities will be $3.4 million (Table 1, line 22).

Disposal costs for CMPAF removed at independent renderers are estimated using the same $12/cwt estimate used in the proposal (we explained the $12/cwt figure and public comments in detail earlier in the document). The Informa report and many other comments remarked that much more than just the brain and spinal cord would need to be removed from those cattle not inspected and passed for human consumption that were not too decomposed to undergo separation. Furthermore, comments stated that a significant number of them would be too decomposed to separate the brain and spinal cord. For both the proposed and final rule, ERG judged that from 1.3 lbs to 53.0 lbs of CMPAF would be removed from cattle 30 months of age or older, but for the final rule it also included an allowance for the number of cattle 30 months of age or older not inspected and passed for human consumption that are picked up but that are too decomposed to undergo tissue separation. The Informa claim

that 54 percent of these animals being too decomposed to undergo tissue separation added significant weight to the volume of CMPAF that would be prohibited. Based on the aggregate weight of CMPAF removed, ERG estimated disposal costs at $11.3 million for the CMPAF that is removed by independent renderers and for the cattle not inspected and passed for human consumption that are picked up by renderers but are too decomposed to undergo tissue separation.

For the disposal of the additional cattle not inspected and passed for human consumption that are no longer picked up for rendering, ERG adjusted the $12/cwt disposal cost for those carcasses that are likely to be buried on the farm. For on-farm burial, the most likely representative cost listed in the Kansas State University report was $6/cwt. ERG increased this to an estimated $8/cwt to account for those farms where burial is less economical or less viable due to the absence of available land. The cattle carcasses were then distributed among the following four types: Calves, feedlot, cattle 30 months of age or older, and cattle under 30 months. For its disposal cost calculations, ERG used only the incremental social cost, which is the difference between the disposal method and the existing charge for renderer pick-up cost (per cwt) as developed in the Informa report. For cattle 30 months of age or older not inspected and passed for human consumption, ERG calculated the incremental cost per cwt at $4.65 ($8.00/cwt minus the current $3.35/cwt); for cattle under 30 months ERG calculated the incremental cost at $5.49 ($8.00/cwt minus the current $2.51/cwt). For feedlot cattle, whose full disposal cost remains at $12/cwt because it is unlikely they would be buried at the producer site, ERG calculated the incremental cost at $10.24/cwt ($12.00/cwt minus the current $1.76/cwt). For calves, ERG assumed current pick-up charges to increase by $4.00/cwt, noting that their current reported pick-up fee exceeds $12/cwt. As a result, we estimate total disposal costs for the additional cattle not inspected and passed for human consumption to range from $22.0 million to $33.0 million annually.

To account for the additional tonnage of non-cattle species that died at the animal producer establishment and would no longer be rendered as a result of this rule as suggested by some comments, ERG added an additional 10 percent of the cost of the midpoint in the range of total disposal costs for the combined calves, feedlot, cattle 30 months of age or older, and cattle under 30 months ($2.7 million) (Table 1, line 21 adds $2.7 million to the disposal cost range of $22.0 to $33.0 million). We acknowledge additional uncertainty in this 10-percent estimate as we lack the data to present a more robust estimate. In sum, we find that the total disposal costs for slaughter establishments ($3.4 million), renderers ($11.3 million), cattle not inspected and passed for human consumption that would no longer be picked up by renderers ($22.0 million to $33.0 million), and other non-cattle species ($2.7 million) will range from $39.4 million to $50.4 million.

3. Lost Value of CMPAF and Hides

For the proposed rule, ERG had calculated that the 64 million lbs. of CMPAF from both slaughter operations and from those cattle not inspected and passed for human consumption that would no longer be rendered would have yielded about 10,800 lbs. of MBM and 4,400 lbs. of tallow. Using historical byproduct prices, ERG had estimated the value of the MBM and tallow at $1.0 million and $0.8 million. Accepting the 2004 Informa estimate of a larger number of cattle currently rendered, we had included in the proposed rule an upper estimate of lost revenues of MBM at $1.7 million and tallow at $1.2 million.

The final rule differs from the proposed rule in that it exempts certain cattle-derived risk materials (brain and spinal cord from cattle under 30 months not inspected and passed for human consumption) from the definition of CMPAF. The final rule continues to prohibit the use of CMPAF in all animal feeds to prevent BSE.

Both ERG's 2004 report (relied upon for our analysis of the proposed rule) and the Informa report included the foregone revenues from MBM and tallow that would have been produced from the CMPAF as costs of the rule. This approach, however, overstates the true social cost of the rule because it includes value added from the use of capital and labor at rendering facilities that would not be used if the CMPAF goes to disposal without further rendering. A better estimate of social cost would include only the lost value attributable to the now-prohibited raw materials, or the difference in total cost between final products made with MBM or tallow from the CMPAF and the total cost of final products made with alternative raw materials. A more accurate estimate of the social cost of the rule would be the net income that would otherwise have been generated from the processing of CMPAF into MBM and tallow. For the final rule, ERG has estimated renderer average net income for both MBM and tallow at 5.65 percent of their foregone sales, based on 2002 Census of Manufacturers data. Marginal net income may be more appropriate because it takes into account the existence of fixed costs. The lack of detailed revenue and cost data for those independent renderers affected by the rule, however, prevents us from estimating the cost functions necessary for a measure of marginal net income. The significance of the difference between marginal and average net income is not likely to be large in this case, since the supplies of raw materials are highly elastic and the amount affected is a small fraction of all ingredients. Industry data show that 18 percent of cattle 30 months of age or older are slaughtered for human consumption, thus requiring CMPAF removal. Consequently, ERG estimated the CMPAF removed at slaughterhouses to be about 28 million lbs. Using industry data on byproduct yields as well as historical averages prices for MBM and tallow of $180/ton and $360/ton, ERG estimated the value of this foregone MBM at $0.6 million and tallow at $0.5 million. Using a 5.65 percent net income rate, ERG estimated the social cost of the foregone MBM and tallow from slaughtered cattle at $64,000 per year (Table 1, lines 4 and 5).

Additionally, ERG estimated the value of the MBM and tallow foregone from the carcasses of the cattle not inspected and passed for human consumption that would no longer be collected by renderers as a result of this rule (and would likely be disposed of on the farm or elsewhere). This reduction in rendering would include those cattle not rendered due to the reduced quantity demanded for rendering services of cattle not inspected and passed for human consumption caused by the substantial expected increase in pick-up charges. In addition, fewer cattle will be rendered due to a number of rendering plant closures. Using various price elasticities of demand, ERG's calculations forecast a 29.4 percent to 44.8 percent reduction in the number of cattle not inspected and passed for human consumption that are picked up for rendering. Using industry averages of animal weights for cattle of different ages, ERG calculated the total weight of animals that would no longer be picked up for rendering at 489 million lbs to 719 million lbs. Applying the yield rates of MBM and tallow for whole carcasses (25 percent for MBM, 10 percent for tallow) results in MBM revenue losses ranging from $11.0 million to $16.2 million, and tallow

revenue losses from $8.8 million to $12.9 million. Additional MBM and tallow revenue losses are estimated at $3.1 million and $2.5 million, respectively, for animals that were picked up by the renderer but were too decomposed to undergo tissue separation. Based on a 5.65 percent annual net income rate for both MBM and tallow, the resulting net income losses would range from $1.4 million to $1.8 million (Table 1, lines 14 and 15). Adding these losses to the net income loss from CMPAF derived from slaughterhouses results in total net income losses of $1.5 million to $1.8 million annually.

ERG also calculated the social cost of the hides that would be lost due to an increase in the number of cattle not inspected and passed for human consumption that would no longer be rendered as a result of this rule. The same assumptions and calculations that form the basis for the 29.4-percent to 44.8-percent increase in cattle not inspected and passed for human consumption that would no longer be rendered as a result of this rule apply to loss of cattle hide value as well. ERG has taken the reduction in each of the four individual cattle categories (the total reduction ranges from 29.4 percent to 44.8 percent over all calves, feedlot, cattle 30 months of age or older, and cattle under 30 months), and applied the average market value of the hide for each to estimate the total hide value lost due to this rule at $9.16 million to $13.69 million. In this case, ERG concludes that the social cost would include almost the entire market value of the hide because the only value added to the process is a very small amount of labor required for hide removal. Because this value was not calculated and subtracted from the average market values, the previously mentioned total may slightly overestimate the social costs.

4. Direct Costs

In the proposed rule we reported five categories of direct costs, including: (1) Capital and labor costs for slaughtering and rendering, (2) the tallow restriction, (3) MS beef restriction, (4) marking costs, and (5) labeling and recordkeeping costs. For the final rule, we address these same costs as well as the cost of (6) creating procedures for training on, and actual administration of, the age determination process for cattle.

a. *Capital and labor costs for slaughtering and rendering.* This final rule will result in cattle slaughter operations that separate CMPAF and arrange for its disposal separate from other cattle offal. FSIS' regulations at 9 CFR 310.22 prohibit SRMs for use as human food but do not prohibit these materials from being rendered into MBM and tallow for use in feed for non-ruminant animals. Under this final rule, CMPAF from slaughterhouses (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-prohibited material-origin and offal of CMPAF-origin.

For the proposed rule, we relied on the previous ERG report to project that slaughterers would incur annualized capital and labor costs that totaled $676,000 ($597,000 in annual labor costs plus $555,000 in capital costs annualized at 7 percent over 10 years). These costs included the additional offal bins that all slaughterers were expected to require, the modified procedures and processes for the larger slaughterers, and additional labor to segregate the CMPAF. Comments on the proposed rule did not offer specific costs for slaughterers but generally maintained that slaughterers would be affected.

For the final rule, ERG revised its estimated number of USDA-inspected plants upward to 1,545 from 689, but revised the estimated number of cattle having CMPAF removed at slaughterers down from 100 percent to about 18 percent due to the change in approach whereby only cattle 30 months of age or older would have CMPAF removed at slaughter. ERG estimated the resulting one-time capital expenditures of the final rule at $2.10 million (or $299,000 annualized at 7 percent over 10 years). With the addition of maintenance costs of about $315,000 and labor costs of $656,000, ERG estimated the total annualized slaughter costs for capital and labor at about $1.27 million (Table 1, lines 2 and 3), representing a small increase from the proposed rule.

In the proposed rule, we concluded that renderers would also incur additional capital and labor costs to handle CMPAF segregation from cattle not inspected and passed for human consumption. ERG projected equipment purchases and installation at a one-time cost of $3.1 million (or $442,000 at 7 percent over 10 years), as well as additional labor costs of $1.4 million annually. We used this cost as the low end of the range of costs, and used a figure 2.46 times greater as the upper end based on the 2004 Informa assertion that 42 percent of cattle not inspected and passed for human consumption were currently rendered, compared with ERG's previous finding of this number at 17 percent. The proposed rule's estimate for both renderer capital and labor costs was $1.9 million to $4.6 million annually. Numerous public comments addressed the capital and labor costs to renderers. In general, the comments stated that FDA greatly underestimated the cost to renderers of removing brain and spinal cord from cattle not inspected and passed for human consumption.

For the final rule, ERG reassessed the conclusions in its analysis of the proposed rule using the information provided in the 2005 Informa Economics report and presents final rule estimates that are substantially larger. ERG now estimates that there are 70 deadstock renderers, including 25 very small renderers that were likely not included in the Informa survey's result of 45 deadstock renderers. The estimated number is, however, a decrease from the proposed rule's estimate of 141 independent renderers because it is now accepted that deadstock renderers are a small subset of independent renderers, and non-deadstock renderers would not incur these additional capital and labor costs.

ERG contracted with an engineering firm to estimate the renovation of deadstock rendering facilities in order to remove CMPAF. The engineering firm created a detailed capital cost estimate for a deadstock renderer handling 150 animals per day at about $600,000. ERG used this estimate as well as results of its discussions with other deadstock renderers to produce capital cost estimates across the range of deadstock renderers by size. The capital costs on a per plant basis have increased substantially for this final rule, most notably to account for the planning and construction of a separate structure for the removal of CMPAF. Whereas ERG had estimated one-time costs for capital improvements for renderers at $3.1 million for the proposed rule (or $442,000 annualized at 7 percent over 10 years), it estimated if all renderers initiated such renovations, the one-time costs for capital improvements for the final rule would be $32.2 million (or $4.6 million annualized at 7 percent over 10 years). The engineering estimates did not include a specific cost for construction permits, as one comment suggested would be needed, but the cost of construction permits would likely amount to a small part of the separate contingency costs that were included at $54,000 per rendering facility.

ERG also increased its estimate of deadstock renderer labor costs on a per plant basis, due to further discussions with rendering facility managers. Whereas ERG estimated the additional

labor required for the proposed rule to range from 0.04 to 2.21 employees, it estimated the range for the final rule at 0.17 to 8.00 employees. Due to the estimated reduction in the number of rendering plants that would undertake such renovations and additional hiring, ERG concluded that total labor costs would only increase by $1.4 million to $1.7 million. ERG also found that an additional maintenance cost estimated at 15 percent of aggregate capital costs would add another $4.8 million annually. Several comments on the proposed rule mentioned efficiency losses for renderers due to slower line speeds. We agree with the comment that this may be a possibility and have included additional labor costs, which would tend to offset those efficiency losses.

Public comments and industry discussions with ERG indicate that many facilities would not undertake the capital improvements and additional labor necessary to renovate facilities and change their operating procedures. In its analysis of the final rule, ERG adjusted the total costs to account for the number of deadstock renderers that would not undergo these renovations, assuming that the expected decline in the percentage of renderers would equal the percentage reduction in material sent to rendering. To do this, ERG relied on renderers' predictions (through direct discussions with renderers as well as in public comments) that they would require very large increases in pick-up fees. Some predicted that the pick-up fees would more than double. As a result, ERG estimated that the increase in fees would range from 100 percent to 150 percent for cattle 30 months of age or older, and 25 percent to 50 percent for all other cattle. Using estimated price elasticities ranging from 0.25 for feedlot cattle to 0.6 for calves (Informa also suggests an inelastic demand for rendering services by many livestock producers), ERG calculated the total reduction in raw material going to rendering at 29.4 percent to 44.8 percent, including an additional 10 percent reduction for facilities that abandon deadstock rendering. The 29.4 percent reduction in raw material going to rendering represent a decrease of 549,000 from the current total number of 1,870,000 cattle rendered (549,000/1,870,000 = 29.4 percent). This decrease is the combined decrease in numbers of calves, feedlot cattle, cattle 30 months or older, and cattle under 30 months. The number of calves going to rendering will decrease by 216,000, or 25 percent from the current number, 865,000 calves (865,000 times 25 percent = 216,000). The 25 percent decrease includes a 15 percent decrease due to increased pick-up fees (0.6 elasticity times 25 percent increased pick-up fees) plus a 10 percent further reduction in non-cattle rendering due to plant closures. The number of feedlot cattle going to rendering will decrease by 27,000, or 6.3 percent from the current number, 424,000 feedlot cattle (424,000 times 6.3 percent = 27,000). The 6.3 percent is the result of a 0.25 elasticity times a 25 percent increase in pick-up fees. The number of cattle 30 months of age or older going to rendering will decrease by 281,000, or 60 percent from the current number, 469,000 cattle 30 months of age or older (469,000 times 60 percent = 281,000). The 60 percent decrease includes a 50 percent decrease due to increased pick-up fees (0.5 elasticity times 100 percent increased pick-up fees) plus a 10 percent further reduction in non-cattle rendering due to plant closures. The number of cattle under 30 months of age going to rendering will decrease by 25,000, or 22.5 percent from the current number, 111,000 cattle under 30 months of age (111,000 times 22.5 percent = 25,000). The 22.5 percent decrease includes a 12.5 percent decrease due to increased pick-up fees (0.5 elasticity times 25 percent increased pick-up fees) plus a 10 percent further reduction in non-cattle rendering due to plant closures.

The total reduction in cattle equals 29.4 percent of the currently rendered number of cattle (549,000/1,870,000 = 29.4 percent). The upper end of the range (44.8 percent) was calculated by the same method using the upper end range of factors. Using the midpoint of this 29.4-percent to 44.8-percent range, ERG predicted that about 37.1 percent of the renderers will not undergo these necessary capital renovations, thereby reducing the $32.2 million one-time cost to $20.25 million and the $11.2 million in annualized capital, maintenance, and labor costs to $7.0 million (Table 1, lines 9 and 10). Additionally, the number of cattle 30 months of age or older going to rendering would be reduced by 60 percent to 85 percent, thereby reducing the disposal costs to $11.3 million. Without the adjustment for these two factors, the annualized capital, operating, maintenance, and disposal costs for deadstock operators would be estimated at $52.4 million, not $18.4 million.

b. *Tallow restriction.* The final rule would prohibit entirely the use of tallow derived from BSE-positive cattle and prohibit the use of certain other CMPAF-derived tallow unless it contains less than 0.15 percent insoluble impurities, as did the proposed rule. For the proposed rule, we concluded that it would not be economical for renderers or tallow manufacturers to further process the separated brains and spinal cords and other tissues from those cattle undergoing tissue separation into tallow while complying with the additional equipment separation and tallow testing and purification requirements. We therefore did not include any additional cost for this provision. We received one comment that stated that the capital investment for dedicated equipment to be used to produce tallow (that would then need to meet the purity requirements) would be substantial. We agree with this comment. The final rule contains an estimate of a much larger volume of CMPAF than the original estimate for the proposed rule. However, the amount of CMPAF that is handled directly by renderers is still a relatively small amount (because most is either on-farm disposal or other disposal of cattle not inspected and passed for human consumption), which would still not be economical to further process, due to the same equipment separation and tallow testing/purification requirements in this final rule. We have, therefore, not included additional costs for this provision. This analysis previously accounted for the net income lost on the value of this tallow and MBM.

c. *MS beef restriction.* In the proposed rule, we predicted that there would not be any costs for the provision that would prohibit the use of MS beef in animal feeds if the brain and spinal cord of cattle 30 months of age or older or the brain and spinal cord of all cattle not inspected and passed for human consumption has not been previously removed from the cattle material used to make MS beef. ERG's previous analysis concluded that the brain and spinal cord are already removed from the carcasses of dead cattle at the ''4D'' plants (independent renderers that collect dead and downer cattle and process the carcasses for red meat to be used for pet food manufacturers, zoos, and other animal feeding operations) that process them.

The ERG report maintains that all or almost all 4D plants already remove the brain and spinal cord. To the extent that a small percentage of 4D plants might not remove these materials, we agree that there could be some additional compliance costs to this final rule but believe them to be small due to the small number of establishments. As such, we have slightly revised our previous conclusion that there would not be additional compliance costs as a

result of the MS beef provision of the final rule.

d. *Marking costs.* The final rule, like 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. For the proposed rule, ERG used various assumptions to characterize the cost of adding marker dyes to this material. It concluded with an estimate ranging from $1,700 to $13,000 annually for total industry compliance. Public comments on the proposed rule did not address the marking cost estimate.

For the final rule, ERG used the same assumptions to calculate its estimate of marking costs, resulting in the same marking ranging from $0.11 to $0.78 per ton of CMPAF. In this case, though, ERG included as an upper bound estimate of marking costs the tonnage of MBM and tallow from cattle not inspected and passed for human consumption that would not be rendered for non-ruminant feed as a result of this rule. In effect, ERG has allowed for the possibility that the additional cattle that would not be rendered for feed as a result of this rule would be rendered for disposal instead. Taking this possibility into account provides for a worst-case scenario for marking costs. We now estimate the final rule marking costs to range from $18,000 to $64,000 annually, a relatively large increase from those of the proposal but a very small part of total compliance costs.

e. *Labeling, recordkeeping, certification, and access costs.* The proposed rule would require that renderers that handle CMPAF or products that contain CMPAF ensure that the CMPAF are not used in animal feed. The proposed requirements included labeling for products with CMPAF that states ''Do not feed to animals,'' the establishment and maintenance of records sufficient to track CMPAF to ensure the materials are not introduced into animal feed, and making such records available to FDA. ERG judged that the proposed labeling requirements would impose only modest compliance costs since the labeling requirements (applying primarily to bulk shipments) could be incorporated into current labeling practices. ERG estimated total industry costs 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 did not receive any substantive public comments concerning the labeling and recordkeeping costs.

For the final rule, ERG increased the hours needed for label design, production, and review, but did not revise hourly estimates for recordkeeping modification and review. In total, we estimate this labeling and recordkeeping provision to cost industry about $90,000 annually (a $165,000 one-time cost annualized at 7 percent over 10 years plus $67,000 in annual costs). Additionally, the final rule has been revised to clarify that a renderer's records must either include (1) certification or other documentation from the supplier that material supplied to the renderer does not include CMPAF, provided that it includes a description of the segregation procedures used, documentation that the supplier confirms that its segregation procedures are in place prior to supplying any cattle material to the renderer, and records of the renderer's periodic review of the suppliers' certification or other documentation; or (2) documentation of another method, acceptable to FDA, such as third party certification, for verifying that suppliers have effectively excluded CMPAF.

Based on the levels of effort estimated for the 2007 dietary supplement cGMP final rule (72 FR 34752) requiring certification of procedures, FDA projects that the initial certification or other documentation of the suppliers' procedures will require a 20-hour effort by a management level employee of an independent renderer. The Bureau of Labor Statistics (BLS) provides data on employee costs for management occupations classified within the North American Industrial Classification System (NAICS) code 311600—the animal slaughtering and processing industry (BLS data on individual occupations within NAICS code 311613—rendering and meat product processing, is not available). We have adjusted the BLS wage data, including a 40 percent increase for benefits and adjusting for inflation in employment costs. FDA estimates the initial certification or other documentation of suppliers to an independent renderer to cost about $1,030 (annualized at $250 per year over 10 years at a 7 percent discount rate). FDA estimates that the periodic review of the certification or other documentation to take 8 hours annually, resulting in a $412 annual cost. FDA expects daily recordkeeping to amount to 5 minutes per day for an administrative support employee. Using the BLS data, this recordkeeping cost is estimated at about $460 annually. Total annualized certification or other documentation costs per independent renderer establishment are estimated at about $1,125.

FDA projects that the initial certification or other documentation of the internal system of a packer/renderer will require 6 hours for a management level employee. An additional 3 hours is expected to be expended each year for periodic review of the internal certification or other documentation. Packer/renderers will also be expected to incur recordkeeping costs estimated at about 5 minutes per day. Using the same BLS wage data as above, FDA projects annualized certification or other documentation costs per packer/renderer establishment to be about $690. The total annualized costs of the new recordkeeping costs associated with the certification or other documentation of suppliers (slaughterers) for the estimated 125 independent renderers and 50 packer/renderers handling CMPAF is estimated at about $175,000.

f. *Animal age determination.* The final rule does not include in the definition of CMPAF cattle not inspected and passed for human consumption under 30 months of age. FDA originally included these cattle in the definition of CMPAF because of European surveillance data suggesting that cattle not inspected and passed for human consumption pose a higher risk for BSE, and due to concerns that processes were currently not established in the rendering industry for verifying the age of such cattle through inspection. However, FDA received comments on the feasibility of aging such cattle and on the relatively low risk reduction achieved by excluding such cattle. FDA considered these comments, surveillance data indicating the current risk of BSE to U.S. cattle is very low, the strong feed protection provided by the existing ruminant feed rule, and the added secondary level of protection provided by the other provisions of this final rule. Based on these factors, FDA concluded that it was not necessary to include in the definition of CMPAF cattle not inspected and passed for human consumption that are under 30 months of age.

The ERG report concludes that, in the absence of a national cattle identification system, deadstock renderers will need to make the judgments regarding age on an animal-by-animal basis. Compliance costs for such a system would include administrative costs for the creation of procedures for employees to judge the age of animals, and training costs for educating employees on these procedures, as well as annual labor costs for the employees that administer the age determination process.

ERG assumed that the cost of procedure development, normally a

one-time cost, would likely be revised annually as the industry moves toward a national cattle identification system. Additionally, ERG estimates that annual training times for non-clerical workers will be 4 hours for deadstock renderers and 2 hours for non-deadstock independent renderers. In addition, 1 hour per year of supervisor time for employee training will be required for deadstock renderers and 0.5 hour for non-deadstock independent renderers. The total estimated costs to renderers of annual procedure development and updating and annual employee training will amount to about $491,000. For large slaughterers that also perform their own rendering, ERG estimated the costs of procedure development and employee training for slaughter animal age identification at $1.10 million annually. To the extent some slaughterers already have aging procedures in place to comply with FSIS' SRM rule, this may be an overestimate.

For the age determinations, ERG judged that the rendering truck drivers would make the actual age determinations at the animal producer site by reviewing the paperwork or using the dentition method. ERG judged that this procedure would not add to the total time an employee spends at each pick-up site. It therefore did not include additional compliance costs for the rendering truck driver. Review of these determinations and paperwork would be made at the rendering facility by supervisory personnel. ERG estimated total annual labor costs for the in-plant reviews of the age determination at about $790,000. Total annual costs for renderer age determination efforts are estimated at $1.28 million ($491,000 plus $790,000).

5. Feed Substitution Costs

For the proposed rule, we included in the compliance costs the incremental cost for the feed ingredients that would be needed to replace the MBM in non-ruminant animal feeds. Animal feed producers would be expected to substitute more costly protein sources for the MBM that was previously manufactured from CMPAF. In the analysis of the 1997 final rule prohibiting the use of mammalian proteins (with exceptions) from use in ruminant feeds, we calculated the cost to substitute MBM in a typical cattle ration. Assuming a $20 per ton price difference between MBM and a substitute feed ingredient, in this case soybean meal, we estimated that the reformulated cattle ration would cost an additional $31.76 per ton (including other ingredients). However, the prices of MBM and equivalent substitutes vary constantly based on weather, global markets, slaughter rates, and other factors. We have no other information on the types of rations or feed formulations that will be affected by this final rule. Consequently, we accept the cattle ration example as a conservative estimate of the long-term cost of feed substitution.

Accordingly, for the October 2005 proposed rule, we inflated the unit cost from $31.76 per ton to $38.33 per ton to account for inflation through 2005 and determined the tonnage of MBM that would no longer be processed from the CMPAF. Multiplying this total, 15.6 million lbs, by $38.33 per ton resulted in about $300,000 in feed substitution costs for the proposed rule. Accounting for the high end of the range of animals currently rendered (as noted in the 2004 Informa report) led to an upper end cost of about $450,000.

We received one comment that the removal of ruminant proteins from non-ruminant feed may increase the price of other protein sources, but it did not address the method used to account for feed substitution costs. We received many comments concerning the total amount of cattle byproducts that would no longer be made available for further processing for use in non-ruminant feeds. As noted previously in the section on disposal costs, ERG concluded that a much larger amount of cattle byproducts would no longer be available for this use. In total, the ERG calculations imply that the amount of MBM foregone from slaughterer and renderer CMPAF, as well as MBM that could have been produced from cattle not inspected and passed for human consumption that will no longer be rendered due to this rule, will range from 76,100 tons to 91,500 tons; a significant increase from the 7,800 tons estimated for the proposed rule. Based on the incremental feed substitution cost of $38.33 per ton of MBM, we estimate that long-term total feed substitution costs for the final rule will range from $2.92 million to $3.51 million annually.

F. Government Costs

For the proposed rule, we concluded that there may be an increase in Federal fund expenditures for inspection activities, but did not expect it to be significant. The total number of establishments inspected was not expected to change substantially, as all establishments that would be inspected for compliance under § 589.2001 are already subject to § 589.2000 or other Federal rules. The additional materials that would be included as CMPAF may result in an increase in the number of inspections or the length of time necessary to inspect an establishment. We did not estimate the additional costs that would be required because we judged that the additional resources would not be substantial. ERG judged that no new rendering facilities would be constructed or dedicated to rendering for disposal due to the proposed rule, and thus our inspection activities would not noticeably increase.

Country Designation

The final rule contains a provision that was not included in the proposed rule. This provision exempts CMPAF from designated countries from the prohibition on its use in animal feed. A foreign country seeking this designation will submit a written request to FDA that includes (1) information about the country's BSE case history, (2) risk factors, (3) measures to prevent the introduction and transmission of BSE, and (4) any other information relevant to determine how cattle materials from the country will be defined under 21 CFR 589.2001(b)(1). FDA will respond to a country's request in writing and may specify certain conditions when granting a request. Country designations will be subject to future review by FDA and can be revoked if a review shows that BSE-related restrictions are necessary.

a. *Number of countries affected.* Although we do not know how many countries will submit a request to FDA for a designation under § 589.2001(f), we can use information from OIE and USDA to estimate the number of requests that might be submitted to the Center for Veterinary Medicine. According to the requirements of the OIE Terrestrial Animal Health Code (16th edition 2007), OIE officially recognizes five countries as having a ''negligible BSE risk,'' including Australia, Argentina, New Zealand, Singapore, and Uruguay. In addition, OIE recognizes Iceland and Paraguay as ''provisionally free'' from BSE. According to OIE recommendations, SRM removal is not a condition for importing fresh meat or meat products from a negligible risk country. Allowing animal feeds or animal feed ingredients containing CMPAF to be imported from designated countries is consistent with the lack of any restrictions on SRMs from negligible risk countries in the OIE guidelines.

In addition to the countries recognized by OIE, a country exporting a large quantity of cattle products into the United States may submit a request for country designation to FDA. Table 1 presents data from USDA's Foreign Agricultural Service showing countries

that exported cattle products to the United States in 2006. Comparing the seven countries officially recognized by OIE as having a negligible BSE risk or being provisionally free of BSE and the countries listed in Table 5, approximately nine countries might submit a request. Because we are uncertain about the actual number of requests, for this analysis we estimate that 10 countries could submit a request to FDA to be exempted from CMPAF restrictions applicable to animal feed. Our estimate is not intended to suggest that all of these countries would qualify for a designation under § 589.2001(f).

TABLE 5.—BOVINE PRODUCT IMPORTS TO THE UNITED STATES (2006)

Exporting country	Percentage of imported bovine products
Canada	31
Australia	28
New Zealand	17
Uruguay	9
Brazil	7
Argentina	2
Nicaragua	2
Mexico	1
Costa Rica	1
Other Countries	2

Source: USDA, Foreign Agricultural Service, HS 6-Digit Imports. Report for bovine product codes generated January 28, 2008 at *http://www.fas.usda.gov/ustrdscripts/USReport.exe*.

b. *Cost of designation provision.* We make certain assumptions concerning the effort to prepare and submit a request for country designation in preparation of these costs estimates. Because a country that submits a request to be designated as exempt from certain BSE-related restrictions for animal feed may also petition USDA for exclusion from USDA's BSE-related requirements, we assume that a country wishing to submit a request to FDA to be designated as exempt from CMPAF restrictions has already completed a risk assessment and put risk management strategies into place. Whether these risk assessment and mitigation strategies are sufficient for a country to be so designated by FDA will be determined on a case-by-case basis. Moreover, we assume a request would include other technical information on the country's BSE status, a detailed outline of risk mitigation strategies, and information on the country's cattle-derived products that are exported to the United States. We assume that a foreign government employee earning the wage equivalent of a GS–14 step 1 would spend about 80 hours to collect and prepare this information for each country submitting a request for country designation at an estimated cost of $5,395.20 (80 hours × $67.44 per hour including overhead). The request will also be reviewed by government managers before being submitted to the FDA. Assuming it takes a foreign government executive 40 hours to review the request, at a wage equivalent to a GS–15 step 3, it would cost approximately $3,384.80 (40 hours × $84.62 per hour including overhead) to review the request. Thus, the total cost to each country to prepare and submit a request to FDA to be considered for this designation would be about $8,780. Once the request is received by FDA, we estimate that it will take approximately 80 hours to review each request, at a cost of approximately $3,700 (80 hours × $45.65 per hour for an employee rated as a GS–13 step 7). Thus, as shown in Table 6, the total cost of an initial request is approximately $12,480. The estimated annual total for 10 requests would be $124,800, with FDA incurring about 29 percent of these costs and foreign governments incurring the remaining 71 percent.

TABLE 6.—TOTAL COST OF THE INITIAL REQUEST AND REVIEW

Collect information, Prepare and Submit the Request to FDA	$8,780
FDA Review per Request	3,700
Cost per Country	12,480
Total Cost for 10 Countries	124,800

Countries that successfully request to be designated as exempt from CMPAF restrictions applicable to animal feed will be subject to annual review by FDA to ensure that their designation remains appropriate. As part of this process, FDA may ask designated countries to confirm that both their BSE status and the information submitted by them in support of their original application remain unchanged. FDA may revoke a country's designation if FDA determines that it is no longer appropriate.

FDA has not yet determined the method by which the agency will conduct these annual reviews. One possible method would be for FDA to send a letter to designated countries asking whether there has been a change in their status or circumstances relative to their BSE history, surveillance, import activities, or other relevant criteria, and then compare any changed information with the information in the original submission. The OIE requires that countries whose BSE status has been officially recognized ''should annually confirm during the month of November whether their status and the criteria by which their status was recognized have remained unchanged.'' In some cases, the FDA reviewer might rely on this information, if available, in conducting a future review of the country's designation.

For this analysis, we assume it will take FDA and the designated country about one-third the time and effort as the original request for country designation. Thus, if the total cost to submit the request and have it reviewed by FDA was $12,480, the annual review of the country designation by FDA and the submitting country will cost about $4,200 (see Table 7).

TABLE 7.—COST OF ANNUAL REVIEW OF COUNTRY DESIGNATION

Submission of Additional Information by the Designated Country	$3,000
FDA Review of Information	1,200
Cost per Designated Country	4,200
Total Cost for Review (10 Countries)	42,000

It is likely that those countries that currently export to the United States a significant amount of cattle-derived material that contains CMPAF will be most interested in submitting a request for country designation. It is also possible that new markets for cattle-derived products containing CMPAF could develop, providing an incentive for other countries to submit a request to FDA to be designated as exempt from CMPAF restrictions in animal feed. For this analysis, we do not attempt to forecast either new markets for cattle-derived products containing CMPAF or the frequency and costs of future requests for country designations.

G. Sensitivity Analysis

For the proposed rule, we presented alternative ranges of costs that could be expected due to the uncertainty in certain cost factors. Specifically, we showed that total compliance costs would increase substantially (from a range of $14 million to $24 million to a range of $20 million to $36 million) if the number of cattle not inspected and passed for human consumption that would no longer be rendered as a result of this rule (or 3.4 percent of all cattle not inspected and passed for human consumption) increased to about 11.6 percent of all cattle not inspected and passed for human consumption. This increase would be due to the much greater weight of the entire cattle carcass that would be disposed of compared with the weight of CMPAF from an

average cow slaughtered for human consumption or cow not inspected and passed for human consumption that had its CMPAF separated at the deadstock rendering facility.

Public comments on the method used by both ERG and FDA have previously been presented. The common perception in comments, summarized here again, is that the analysis of the proposed rule considerably underestimated the number of cattle not inspected and passed for human consumption that would no longer be rendered. We have also previously shown that additional data, public comments, and discussion with industry and association members have led to an updated analysis that presents a significantly greater number of those animals that would no longer be rendered due to this final rule. The sensitivity analysis included in the ERG report on the final rule attempts to identify the most influential factors of the analysis, and the range of costs associated with varying the key assumptions. ERG finds the disposal cost rate for CMPAF to be particularly influential because it represents a large fraction of total costs. Specifically, its analysis shows that a 33-percent increase or decrease in the disposal cost per cwt of CMPAF results in a respective $18.1 million increase or decrease in the lower bound of total costs and a $23.7 million increase or decrease in the upper bound of total costs. The price of MBM and tallow does not have much effect on total costs. Similarly, the level of renderer capital costs do not appear to be significant because the amortization over 10 years results in a small annual cost compared to disposal costs. The elasticity estimates appear to have a more significant effect on total costs. A reduction in price elasticity of 50 percent from the low estimate for each ruminant category would reduce the lower bound of total compliance costs by about 22 percent, while an increase in elasticity by 50 percent from the high estimate for each ruminant category would result in a 15 percent increase in the upper bound of total compliance costs.

H. Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires an agency 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 of the final rule, as well as data and analysis contained in this rule's regulatory impact analysis, and section three of the ERG report, constitutes our final regulatory impact analysis in compliance with section 604 of the Regulatory Flexibility Act.

The Regulatory Flexibility Act requires that we present a succinct statement of a rule's objectives. As stated previously in this analysis and unchanged from the proposed rule, the intent of this rule is to strengthen the safeguards designed to prevent the spread of BSE in U.S. cattle, as well as to reduce further any risk posed to humans from the agent that causes BSE.

Other requirements of the Regulatory Flexibility Act are a description of the small entities that would be impacted by the final rule, an estimate of the number of small entities to which the rule would apply, a description of the projected reporting, recordkeeping (see Section VI. Paperwork Reduction Act of 1995) and other compliance costs of the rule and the reason why any other significant alternatives considered by the agency were rejected.

The ERG analysis concentrates on the effects of the rule on small renderers and small slaughterers, and to a lesser extent on small dairy farms. Slaughterers are classified in the North American Industrial Classification System (NAICS) under code 311611—Animal (Except Poultry) Slaughtering, and renderers are classified under NAICS code 311613—Rendering and Meat Byproduct Processing (see Table 8). The Small Business Administration (SBA) classifies both slaughterers and renderers with less than 500 employees as small businesses.

TABLE 8.—TOTAL AND NUMBER OF AFFECTED ESTABLISHMENTS, BY SIZE IN SLAUGHTERING AND RENDERING

Employment size group	NAICS 311611 (slaughterers and renderers)		NAICS 311613 (rendering)	
	Total number of establishments	Estimated number of cattle slaughtering establishments [a]	Total number of establishments in 2002 census	Establishments affected by principal deadstock restrictions [b]
1 to 4	1,132	1,132	30	0
5 to 9	229	229	25	0
10 to 19	131	124	41	25
20 to 49	134	7	72	22
50 to 99	64	14	46	19
100 to 249	66	6	13	3
250 to 499	40	13	4	1
500 to 999	20	7	0	0
More than 1,000	53	13	0	0
Total	1,869	1,545	231	70

[a] Cattle slaughterer distribution derived from federal and state slaughterer establishment count in USDA/NASS (2006). Establishments arrayed across size classes assuming that slaughter rates coincide with employment sizes. State slaughterers were assumed to be small and were added to the small size categories to match but not exceed the Census count of establishments. The distribution should be considered approximate.

[b] The employment size class of deadstock renderers was estimated by ERG and should be considered to be approximate.

Source: ERG Report, Table 3–1, Page 3–2.

The number of cattle slaughtering and rendering establishments expected to be impacted by the CMPAF ban is 1,545 and 231, respectively. The majority of the impacts on renderers are expected to be incurred by the 70 deadstock renderers. Using both Census and USDA data, ERG distributed the slaughtering establishments across the size classes of establishments using the same proportions as those presented in the total number of establishments. This distribution shows that almost 99 percent of slaughtering establishments would qualify as small businesses.

According to SBA data, over 97 percent of all slaughtering firms would be considered small businesses, which would take into account multi-establishment firms. The SBA data also reports that 83 percent of all rendering firms would be considered small businesses. ERG concluded that it is likely that all 70 deadstock renderers have less than 500 employees and thus are considered small businesses. In summary, the number of affected small businesses in both sectors would be substantial.

As in its analysis of the proposed rule, ERG used its Small Business Impact Model (SBIM) to predict net income and closure impacts on both slaughtering and rendering firms (Appendix A of the ERG report contains a technical explanation of the SBIM). The model, which assumes a partial cost pass-through of costs for slaughterers (animal producers would incur the disposal costs), predicts modest impacts on cattle slaughtering due to the small minority of cattle slaughtered for human consumption that are 30 months of age or older. The model predicts costs for the small slaughterers to range from under $100 for the smallest establishments slaughtering less than 1,000 animals per year to about $7,100 per establishment for those slaughtering 300,000 to 500,000 cattle annually. Compliance costs as a percent of net income would range from less than 0.1 percent to 2.1 percent for the small slaughter businesses. For all slaughterers, regardless of size, costs are expected to be significantly below 1 percent of revenues.

Costs for the deadstock renderers were estimated through the SBIM with two separate scenarios: One in which disposal costs are included and one in which they are not included. Disposal costs are not included under one scenario to reflect the likelihood that increased pick-up charges to animal producers will mostly offset the additional disposal costs. In this case, compliance costs for the smallest establishment ranged from an estimate of $97,000 to $122,000 ($153,000 to $180,000 including disposal costs). Compliance costs for the larger establishments ranged from $2.01 million to $2.57 million ($3.23 million to $3.79 million including disposal costs). Compliance costs as a percent of net income ranged from 41 percent to 81 percent across all deadstock renderer sizes (from 65 percent to 100 percent including disposal costs). The total number of rendering establishments expected to close (assuming only disposal costs are transferred to animal producers), using a net income assumption of 5.65 percent, ranged from 12 to 16 facilities. If these disposal costs are not transferred, the model forecasts 23 to 28 closures. Although all renderers contacted by ERG that were contemplating investing in capital to remove brain and spinal cord expected to charge substantially more in pick-up fees to recover these costs, some rendering plant closures are likely to result from this rule (Ref. 16, Section 3.3).

Small farms will incur compliance costs for the disposal of those animals that are no longer rendered due to either the increase in renderer pick-up fees or the termination of deadstock rendering services. ERG prepared a baseline enterprise dairy budget to demonstrate the relative size of the impacts of the final rule on a small (120-cow) dairy farm with about $300,000 in revenues. The SBA defines small dairy and beef cattle producers as those with revenues under $750,000, and USDA data shows the average dairy farm has about 110 dairy cows (Ref. 28). The expected incremental compliance costs (from the ERG model) for disposal of the annual number of dead dairy cows and calves (assumed to be disposed of off-site at $12/cwt and $4/cwt, respectively) on an operation of this size is about $700, using the individual disposal rates for over 30-month cattle and calves. Compliance costs of an operation of this size are estimated at 0.25 percent of revenues and 2.63 percent of net income.

The effect of the annual feed substitution costs on small non-ruminant animal operations is also expected to be minimal. The $2.9 to $3.5 million in additional costs would not be significant when spread over the thousands of non-ruminant animal producers that currently use ruminant protein in animal feeds.

The Regulatory Flexibility Act requires agencies to analyze regulatory alternatives that would minimize any significant impact of a rule on small entities. For an analysis of the regulatory alternatives to this final rule, see section IV.B of this document.

V. The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)

SBREFA (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with SBREFA, OMB has determined that this final rule is a major rule for the purpose of congressional review.

VI. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that were submitted to OMB for review under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520).

The title, description, and the respondent description of the information collection provisions are shown 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.

Title: Substances Prohibited From Use in Animal Food or Feed

Description: This final rule (§ 589.2001) prohibits the use of certain cattle origin materials in the food or feed of all animals. These materials include the following: (1) The entire carcass of BSE-positive cattle; (2) the brains and spinal cords from cattle 30 months of age and older; (3) the entire carcass of cattle not inspected and passed for human consumption that are 30 months of age or older from which the brains and spinal cords were not effectively removed or otherwise effectively excluded from animal feed; (4) mechanically separated beef that is derived from cattle materials prohibited by the rule; and (5) tallow that is derived from BSE-positive cattle and tallow that is derived from certain other materials prohibited by the rule 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. FDA has revised the final rule to include a statement of this purpose (§ 589.2001(1)).

As discussed in section I of this document, FDA has revised the final rule to include a statement of purpose for the rule, specifically, to prohibit the use of certain cattle origin materials in the food or feed of all animals to help prevent the spread of BSE in U.S. cattle. The final rule was also revised to require renderers to establish and maintain written procedures on aging animals to ensure that such animals are less than 30 months old if they are to be rendered for use in animal feed without brain and spinal cord removal.

Further, in response to concerns about ensuring effective removal of brain and spinal cord from animals 30 months of age or older, FDA has revised the final rule to require the establishment and maintenance of written procedures for ensuring that brain and spinal cord are effectively removed or effectively excluded from animal feed. As discussed in section I of this document, FDA has determined that it is the responsibility of the renderer to ensure that materials rendered for use in animal feed do not contain CMPAF. Therefore, the agency has explained in the final rule that a renderer's records must either include certification or other documentation from the supplier that material supplied to the renderer does not include CMPAF, or documentation of another method, acceptable to FDA, such as third-party certification, for verifying that suppliers have effectively excluded CMPAF. Also, FDA is adding a provision to this rule so that it may designate a country as not subject to the CMPAF requirements of this rule (§ 589.2001(b)(1)(vi)). A country seeking such a designation must submit a written request and include information about the country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether the country should be subject to the requirements regarding CMPAF as discussed in greater detail in section I of this document. These are new collection of information requirements that have been added to the previous burden estimate set forth in the proposed rule.

FDA believes that it has maximized the practical utility of this collection of information by not prohibiting certain cattle materials in animal food or feed, as long as the agency can be assured, through the establishment of written procedures, that brain and spinal cord were effectively removed or effectively excluded from animal feed or that the material was from cattle less than 30 months of age. FDA believes it has minimized the burden to the rendering industry by not specifying the procedures to be followed so as to provide the latitude to establish procedures that can most efficiently be incorporated into rendering operations.

Description of Recordkeeping for Respondents: Rendering facilities, medicated feed manufacturers and distributors, livestock feeders.

TABLE 9.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR section	Number of recordkeepers	Annual frequency per record-keeper	Total annual records	Hours per recordkeeper	Total hours	Operation and maint. costs
589.2001(c)(2)(vi) and (c)(3)(i)	175	1	175	20	3,500	$59,500
589.2001(c)(2)(ii)	50	1	50	20	1,000	17,000
589.2001(c)(3)(i)(A)	175	1	175	26	4,550	80,580
Total					9,050	157,080

The estimated recordkeeping burden is derived from agency resources and discussions with affected industry. As discussed in the Paperwork Reduction Act section of the October 2005 proposed rule (70 FR 58570 at 58598), the recordkeeping requirement in § 589.2001(c)(2)(vi) will apply to the limited number of renderers that will handle CMPAF. FDA estimates that no more than 50 of the approximately 175 (based on current data) total independent rendering firms will be involved in the handling of this material. Although the agency may consider the distribution records needed to comply with this regulation ''usual and customary'' and thus not subject to the PRA, FDA believes there will be a burden associated with setting up a system to ensure such records are sufficient to address the recordkeeping requirement. Likewise, although FDA may consider the records necessary to comply with § 589.2001(c)(3)(i) as ''usual and customary'' and not subject to PRA burden accounting, FDA is including a burden estimate to cover establishment of a system to ensure that existing receipt, manufacturing, and certification records adequately address this requirement. FDA estimates that the recordkeeping burden associated with § 589.2001(c)(3)(i) would apply to the balance of the rendering firms not handling CMPAF. FDA solicited public comment on the estimated recordkeeping burden associated with § 589.2001(b)(2)(iv) (§ 589.2001(c)(2)(vi) in the final rule) and § 589.2001(b)(3)(i) (§ 589.2001(c)(3)(i) in the final rule) of the proposed rule, but no comments were received. It was estimated that the operation and maintenance cost per renderer for complying with the records requirements of either of these sections would be $340.

As discussed previously, FDA has revised the final rule to require the maintenance of certain written procedures if cattle not inspected and passed for human consumption are to be rendered for use in animal feed. The recordkeeping burden associated with the requirement to maintain written procedures (§ 589.2001(c)(2)(ii)) will apply to only those renderers that choose to render for use in animal feed cattle not inspected and passed for human consumption. Based on the expertise of FDA's compliance staff who are knowledgeable about industry practices, FDA estimates that no more than 50 of the approximately 175 total independent rendering firms will be involved in the handling of this material. Furthermore, FDA estimates that the recordkeeping burden for this new requirement is similar to the burden that was previously estimated for § 589.2001(c)(2)(vi) and § 589.2001(c)(3)(i). Therefore, FDA estimates that the cost per renderer for compliance with the new requirement for establishing and maintaining written procedures will be $340 per renderer, hence the new figure of $17,000 as shown in Table 9 of this document. Table 9 also reflects the estimated 26 hours each renderer will need to satisfy the requirement under which renderers must maintain records from their supplier, certifying that materials provided were free of CMPAF.

Description of Respondents for Reporting: As discussed earlier, the final rule includes a new provision that exempts CMPAF from designated countries from the prohibition on its use in animal feed (§ 589.2001(b)(1)(vi)). A foreign country seeking this designation will submit a written request to FDA that includes a variety of information about the country's BSE status (§ 589.2001(f)). As discussed in section IV, FDA estimates that 10 countries could submit a request to FDA to be exempted from the CMPAF restrictions. FDA estimates the burden for this

information collection as shown in Table 10:

TABLE 10.—ESTIMATED ONE-TIME AND RECURRING REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
§ 589.2001(b)(1) [2]	10	1	10	80	800
§ 589.2001(f)	10	1	10	26.4	264
Total one time burden					800
Total recurring burden					264

[1] There are no capital costs or operating costs associated with the collection of information under this final rule.
[2] One-time burden.

One-Time Reporting Burden

There will be a one-time burden to countries that apply to FDA seeking to be designated as not subject to restrictions applicable to CMPAF. We estimate that each country that applies for an exclusion will spend 80 hours putting information together to submit to FDA. Table 10 row 1 of this document presents the one-time burden expected for countries that apply for the exclusion.

Recurring Burden

Countries that successfully petition FDA to be designated as exempt from certain BSE-related restrictions applicable to animal feed will be subject to future review by FDA to ensure that their designation remains appropriate. As part of this process, FDA may ask designated countries from time-to-time to confirm that their BSE situation and the information submitted by them in support of their original application remains unchanged. We assume it will take FDA and the designated country undergoing a review in the future about one third the time and effort it did when the information was submitted. Table 10 row 2 of this document presents the expected recurring burden.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register**, announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information, unless that agency displays a currently valid OMB control number.

VII. Environmental Impact

In the ''Environmental Impact'' section of the preamble to the October 6, 2005, proposed rule (70 FR 58570), FDA stated that it had carefully considered the potential environmental impact of this action and had determined that the proposed action would not have a significant impact on the human environment and that an environmental impact statement was not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, were placed on display in the public docket (Docket No. 2002N–0273).

As discussed in section IV of the preamble to this final rule, the agency received many comments to the proposed rule that addressed the environmental effects of the proposed action, noting that the volume of material that would not be allowed in animal feed was much larger than originally estimated. As a result, FDA decided to perform a new environmental assessment that took into account the new information submitted in response to the proposed rule. Following a review of this new assessment, FDA again has made a finding of no significant impact. The evidence supporting that finding, contained in the new environmental assessment, may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. For ease of reference, the ''Summary of Environmental Consequences'' is reproduced below:

''The EA has examined the environmental consequences of prohibiting the use in animal feed of brain and spinal cord from cattle over 30 months of age, and the carcasses of dead stock cattle that were either not age verified or from which brain and spinal cord were not removed. Our assessment indicates that, under this final rule, approximately 670 million pounds of cattle byproducts that would normally be recycled in animal feed will be diverted to other forms of disposal. In most areas of the country, this change in disposal patterns is not expected to have a large impact on the environment. In some areas of the country, however, adverse environmental impacts could be expected unless new disposal capacity is developed. To allow time for development of new methods of disposal, the agency is delaying implementation of this regulation for 12 months. We assume that disposal of the materials prohibited in animal feed by the final rule will be disposed of in accordance with local, State, and Federal laws and regulations.''

FDA received several comments on the proposed rule that addressed environmental concerns surrounding the residual effects of disposal of cattle byproducts. The comments and the agency's responses are set forth in the following paragraphs.

(Comment 71) Several comments said that FDA did not conduct an adequate environmental impact analysis for the proposed rule and improperly made a finding of no significant impact. Another comment said that the environmental assessment failed to consider alternative methods of disposal other than landfilling and rendering. A number of comments said that FDA underestimated the environmental impact resulting from improper composting and landfilling.

(Response) In comments to the proposed rule, FDA received new information indicating that some of the assumptions used in the economic analysis may have been incorrect, especially those assumptions related to disposal of deadstock. The agency modified the assumptions based on this new information and considered all other relevant comments in completing a re-analysis of both the economic and environmental impacts of the proposed rule. After completing a new environmental assessment, the agency still concludes that the environmental

impact is not significant, see revised environmental assessment in the public docket (Docket No. 2002N–0273).

(Comment 72) Several comments said that animal and human health risks from non-feed disposal of deadstock are greater than the risks reduced by the proposed regulation. In contrast, one comment stated that, since the majority of cattle mortalities today are disposed of by means other than rendering and since this disposal does not appear to be causing disease outbreaks, the comment questioned the assertion by some that on-farm and alternative disposal will degrade public and animal health. Another comment stated that health concerns resulting from the proposed rule are being exaggerated for the purpose of preventing the rule from being finalized.

(Response) The agency received no data in support of either position on the effects of non-feed disposal of CMPAF on animal or human health.

(Comment 73) Several comments asked why FDA is not concerned about environmental exposure to the BSE agent through indiscriminant disposal of deadstock if the BSE infectious dose is really 10 mg or less and the agent remains infectious in soil.

(Response) The agency believes that, based on the extremely low prevalence of BSE in this country and the absence of evidence that BSE is transmitted through soil and water, the risk of BSE transmission through exposure to the BSE agent in the environment is very low.

(Comment 74) Several comments said that landfilling and burial will create problems of odor control, ground and surface water contamination, and disease caused by conventional pathogens. Other comments stated that the soil and geologic conditions in certain states are particularly unsuitable for carcass burial.

(Response) FDA believes that odors and pathogens should not be significant problems when carcasses are properly buried, and in particular, when carcasses are landfilled. The agency acknowledges, however, that soil or geologic conditions in some parts of the country may not permit carcasses to be properly buried. In such areas, alternative disposal methods should be identified. The agency intends to allow sufficient time before the rule becomes effective to allow for the arrangement of disposal methods that are appropriate for local conditions.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles in Executive Order 13132. FDA has determined that the final 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, the agency has concluded that the 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.

IX. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 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 addresses after this document publishes in the **Federal Register**.)

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4. GAO Report No. 05–101, ''Mad Cow Disease: FDA's Management of the Feed Ban Has Improved, but Oversight Weaknesses Continue to Limit Program Effectiveness,'' February 2005.
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13. Scientific Steering Committee, European Commission, report of March 26 and 27, 1998, updated June 24 and 25, 2001, ''Safety of Tallow Derived from Ruminant Tissues.''
14. OIG Report No. 50601–10–KC [Bovine Spongiform Encephalopathy (BSE) Surveillance Program (Phase II) and Controls Over BSE Sampling, Specified Risk Materials, and Advanced Meat Recovery Products (Phase III)], January 2006.
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16. ''Economic Impacts of FDA Regulatory Changes Due to Risk of Bovine Spongiform Encephalopathy'' (Final Report), Contract No. 223–03–8500, Task Order Number 8, Eastern Research Group, Inc., Lexington, MA, March 15, 2007.
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Scientific Steering Committee at its meeting of 10–11 January 2002 and amended at its meeting of 7–8 November 2002),'' *http://ec.europa.eu/food/fs/sc/ssc/out296_en.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, 21 CFR part 589 is 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 to prevent the transmission of bovine spongiform encephalopathy.

(a) *Purpose*—The purpose of this section is to prohibit the use of certain cattle origin materials in the food or feed of all animals to further reduce the risk of the spread of bovine spongiform encephalopathy (BSE) within the United States.

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

(i) The entire carcass of BSE-positive cattle;

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

(iii) The entire carcass of cattle not inspected and passed for human consumption as defined in paragraph (b)(2) of this section that are 30 months of age or older from which brains and spinal cords were not effectively removed or otherwise effectively excluded from animal feed;

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

(v) Tallow as defined in paragraph (b)(5) of this section that is derived from materials specified in paragraphs (b)(1)(i), (b)(1)(ii), and (b)(1)(iii) of this section.

(vi) Cattle materials prohibited in animal feed do not include:

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

(B) Tallow as defined in paragraph (b)(5) of this section that is derived from materials specified in paragraphs (b)(1)(ii) and (b)(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'' (AOCS Method Ca 3a–46), American Oil Chemists' Society (AOCS), 5th Edition, 1997, 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 AOCS Official Method Ca 3a–46. You may obtain copies of the method from the AOCS (*http://www.aocs.org*), 2211 W. Bradley Ave., Champaign, IL 61821. 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.*

(C) Materials as defined in paragraphs (b)(1)(ii), (b)(1)(iii), (b)(1)(iv) (other than mechanically separated beef from the carcass of a BSE-positive cattle), and (b)(1)(v) of this section from cattle from a country that has been designated under paragraph (f) of this section.

(2) *Cattle not inspected and passed for human consumption* means cattle that did not pass antemortem inspection 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.

(c) *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 (b)(1) of this section.

(2) Renderers that receive, manufacture, process, blend, or distribute cattle materials prohibited in animal feed as defined in paragraph (b)(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 prohibited as defined in paragraph (b)(1) of this section are not introduced into animal feed:

(i) Exclude from use in animal feed the entire carcass of cattle not inspected and passed for human consumption as defined in paragraph (b)(2) of this section if:

(A) The brain and spinal cord are not effectively removed from such cattle or the brain and spinal cord from such cattle are not otherwise effectively excluded from animal feed; and

(B) Such cattle are 30 months of age or older.

(ii) If renderers remove brain and spinal cord from cattle not inspected and passed for human consumption, or separate such animals based on whether or not they are 30 months of age or older, renderers must maintain adequate written procedures specifying how these processes are carried out.

(iii) 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;

(iv) 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'';

(v) 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

(vi) 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 receive, manufacture, process, blend, or distribute any cattle materials shall take the following measures to ensure that materials prohibited as defined 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 copies of all records available for inspection and copying by the Food and Drug Administration. With respect to cattle materials obtained from establishments which have segregated cattle materials prohibited in animal feed, such records must demonstrate that establishments supplying cattle materials to the renderers have adequate procedures in place to effectively exclude cattle materials prohibited in animal feed; and these records shall be considered sufficient to meet this requirement if they include either:

(A) Certification or other documentation from the supplier that material supplied to the renderer does not include cattle materials prohibited in animal feed; such certification or documentation is acceptable, provided that it includes a description of the segregation procedures used, documentation that the supplier confirms that its segregation procedures are in place prior to supplying any cattle material to the renderer, and records of the renderer's periodic review of the suppliers' certification or other documentation; or

(B) Documentation of another method acceptable to FDA, such as third-party certification, for verifying that suppliers have effectively excluded cattle materials prohibited in animal feed.

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

(d) *Adulteration and misbranding.* (1) Failure of a renderer to comply with the requirements in paragraphs (c)(2)(i) through (c)(2)(iii), (c)(2)(v) and (c)(2)(vi), or (c)(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 (c)(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 (c)(2)(iv) 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 (e) of this section will render the animal feed or feed ingredients adulterated under section 402(a)(4) of the act.

(e) *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.

(f) *Process for designating countries.* A country seeking designation must send a written request to the Director, Office of the Center Director, Center for Veterinary Medicine, at the address designated in § 5.1100 of this chapter. The request shall include information about that country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether the cattle materials from the requesting country do or do not meet the definitions set forth in paragraph (b)(1) of this section. FDA shall respond in writing to any such request and may impose conditions in granting any such request. Any grant by FDA of such a request under this paragraph will be subject to future review by FDA and may be revoked if FDA determines that the granted request is no longer appropriate.

Dated: April 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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