converting a facility back to SRM-free rendering.

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

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

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

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

II. Proposed Measures to Strengthen Animal Feed Safeguards

A. FDA Response to Comments to the 2004 ANPRM

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

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

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

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

B. Additional Measures to Further Strengthen Feed Protection

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2. Cattle Not Inspected and Passed for Human Consumption

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

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

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

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

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

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

3. Mechanically-Separated Beef (MS)

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

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

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

4. Tallow

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

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

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

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

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

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

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

E. Disposal of Cattle Materials Prohibited in Animal Feed

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

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

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

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

III. Description of Proposed Rule and Legal Authority

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

A. Definitions

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

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

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

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

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

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

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

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

B. Proposed Requirements

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

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

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

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

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

C. Proposed Recordkeeping and Access Requirements

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

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

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

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

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

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

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

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

E. Legal Authority

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV. Analysis of Economic Impacts

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

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

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

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

A. Summary of Proposed Regulatory Impact Analysis

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

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

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

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