Federal Register

Thursday
June 5, 1997

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 589

Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 589

[Docket No. 96N–0135]

RIN 0910–AA91

Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to provide that animal protein derived from mammalian tissues for use in ruminant feed is a food additive subject to certain provisions in the Federal Food, Drug, and Cosmetic Act (the act). The final rule establishes a flexible system of controls designed to ensure that ruminant feed does not contain animal protein derived from mammalian tissues and to encourage innovation in such controls. FDA is taking this action because ruminants have been fed protein derived from animals in which transmissible spongiform encephalopathies (TSE's) have been found. Such proteins may cause TSE's in ruminants. TSE's are progressively degenerative central nervous system diseases of man and other animals that are fatal. Epidemiologic evidence gathered in the United Kingdom suggests an association between an outbreak of a ruminant TSE, specifically bovine spongiform encephalopathy (BSE), and the feeding to cattle of protein derived from sheep infected with scrapie, another TSE. Also, there may be an epidemiologic association between BSE and a form of human TSE known as new variant Creutzfeldt-Jakob disease (nv–CJD) reported in England. BSE has not been diagnosed in the United States, and the final rule is intended to prevent the establishment and amplification of BSE in the United States through feed and thereby minimize any risk to animals and humans.

DATES: This final rule becomes effective on August 4, 1997, except § 589.2000(e)(1)(iv), which contains collection of information provisions subject to review and clearance by the Office of Management and Budget (OMB). FDA is announcing that the proposed collection of information has been submitted to OMB for review and clearance under the Paperwork Reduction Act of 1995. The provision of this section will be effective upon approval. FDA will announce the effective date of § 589.2000(e)(1)(iv) in the **Federal Register**. Submit written comments on the collection of information provisions by July 7, 1997.

FOR FURTHER INFORMATION CONTACT: George A. (Bert) Mitchell, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5587.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of January 3, 1997 (62 FR 552), FDA published a proposed rule that would regulate persons that manufacture, blend, process, and distribute certain animal protein products and ruminant feeds containing such products. The proposed rule would create a new § 589.2000 entitled, ''Animal proteins prohibited in ruminant feed.'' In general, the proposed rule would state that protein derived from ruminant and mink tissues is not generally recognized as safe (GRAS) for use in ruminant feed, but rather a food additive subject to certain requirements under the act. The proposed rule also would require certain cautionary statements on products that contain or may contain such proteins, and establish recordkeeping requirements. These proposed recordkeeping requirements were intended to facilitate compliance with the rule. For example, an invoice obtained from a feed manufacturer for a protein product not labeled with the cautionary statement could be used to trace the product back to the supplier to ensure that the supplier manufactures and distributes animal protein products from nonruminant sources. The proposed rule also would reduce or eliminate certain regulatory requirements upon the development of methods for detecting or deactivating TSE agents, or for verifying product identity.

The preamble to the proposed rule contained information regarding available scientific information about TSE's, industry practices, and regulatory efforts concerning TSE's. The agency refers interested persons to that document for such information. A list of recently published, relevant scientific information also appears later in this document.

The preamble to the proposed rule also contained five alternatives to the proposed restriction on the use of ruminant protein in ruminant feed. These alternatives, which are discussed in greater detail later in this document, included a restriction on the use of all ruminant and mink materials (except those that have not been found to present a risk of transmitting TSE's) in ruminant feed, a restriction on the use of all mammalian protein in ruminant feed, a restriction on the use of materials from domestic species (such as sheep, goats, mink, deer, and elk) diagnosed as having a TSE, a restriction on the use of specified sheep and goat offal in ruminant feed, and a ''no action'' alternative. The final rule restricts the use of protein derived from mammalian tissues, with certain exceptions, in ruminant feed. Thus, the final rule represents a regulatory approach that covers more material and is easier to implement than the proposed restriction on the use of ruminant protein in ruminant feed, but is more flexible and better suited to current industry practices than the alternative restriction on the use of all mammalian protein in ruminant feed.

FDA continues to believe, as it stated in the preamble to the proposed rule, that it is prudent to take action prohibiting the use of certain animal protein products in ruminant feed even though BSE has not been diagnosed in the United States and there is scientific uncertainty as to its origin, transmissibility, etc. This final rule will prevent the establishment and amplification of BSE in the United States through feed, an action the agency believes is necessary to protect animal and public health.

FDA received numerous comments, as discussed below, on its proposed rule. Based on those comments, the agency, in the **Federal Register** of April 17, 1997 (62 FR 18728), published the codified provisions of the draft final rule and provided an opportunity for comment. The codified provisions of the draft final rule were similar to those in the proposed rule, but the draft final rule would prohibit the use of protein derived from mammalian tissue with certain specific exceptions (such as blood, gelatin, inspected and processed meat products that have been cooked and offered for human consumption, and products whose mammalian protein consists entirely of porcine protein). Additionally, the codified provisions of the draft final rule would eliminate the cautionary statements on pet food sold at retail, define the term ''ruminant,'' eliminate certain regulatory requirements if a renderer used exclusively a validated, publicly-available method for controlling the manufacturing process that minimizes the risk of the TSE agent entering the product, and simplify the recordkeeping requirements.

The agency received over 60 comments on the codified provisions of the draft final rule. Most comments supported the draft final rule, although several comments suggested technical changes, additional exemptions, or clarifications. Other comments reiterated their objections to any rulemaking that would declare tissues to be nonGRAS for use in ruminant feed or advocated other alternatives (particularly the use of hazard analysis critical control point programs).

Based on those comments, the agency has made some changes in this final rule. The final rule provides that protein derived from mammalian tissues (with certain exclusions) is a food additive under the act. The act defines a ''food additive'' as ''any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food * * * if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use * * *'' (see section 201(s) of the act (21 U.S.C. 321(s))). Expert opinion that the tissues are GRAS would need to be supported by scientific literature, and other sources of data and information, establishing that there is a reasonable certainty that the material is not harmful under the intended conditions of use. Expert opinion would need to address topics such as whether it is reasonably certain that BSE does not, or will not, occur in the United States; whether it is reasonably certain that the BSE agent will not be transmitted through animal feed, i.e., that the processed tissues are not infected by the agent, are deactivated by the rendering process or are not transmitted orally; and whether it is reasonably certain that the agent will not be transmitted to humans through consumption of ruminant products. ''General recognition'' cannot be based on an absence of studies that demonstrate that a substance is unsafe; there must be studies to establish that the substance is safe. Also, the burden of establishing that a substance is GRAS is on the proponent of the substance (see *U.S.* v. *An Article of Food* * * * *Coco Rico*, 752 F.2d 11 (1st Cir. 1985).

The preamble to the proposed rule included an extensive discussion of the basis of FDA's preliminary conclusion that protein derived from ruminant and mink tissue for use in ruminant feed is not GRAS, but rather is a food additive under the act. As discussed in detail in the agency's responses to the comments received on the proposed rule, FDA did not receive any information that would refute its conclusion that protein derived from ruminant and mink tissue for use in animal feed is not GRAS.

With regard to the scope of the final rule, protein derived from mammalian tissues includes both ruminant and nonruminant tissues. FDA's basis for its nonGRAS determination for ruminant and mink tissue is discussed extensively in the preamble to the proposed rule and no information was submitted to refute that determination. With regard to nonruminant tissue besides mink, such tissues may include animals such as cats, dogs, horses, swine, etc. As the preamble to the proposed rule discussed concerning a mammalian-to-ruminant prohibition (62 FR 552 at 568), industry comments indicated that the usual practice at feed mills and rendering facilities is to commingle ruminant and nonruminant protein products. FDA indicated that regular commingling could provide a basis to determine that protein from mammalian tissues is not GRAS for use in ruminant feed. The description of industry practice received in comments on the proposed rule again indicated that the practice is to commingle ruminant and nonruminant protein. Because of the potential TSE infectivity caused by mixing tissues from ruminant and mink and other mammalian tissues, FDA has determined that protein derived from mammalian tissues (with certain exclusions discussed later in this preamble) is not GRAS for use in ruminant feed. FDA notes that the ruminant-to-ruminant prohibition in the proposed rule also would have prohibited the use in ruminant feed of this commingled tissue because the definition of protein derived from ruminant and mink tissue would apply to pure ruminant or mink tissue as well as other mammalian tissue that could contain ruminant or mink protein due to commingling. This final rule also reduces the risk of cattle and other ruminants being exposed to an agent that causes feline spongiform encephalopathy and acknowledges that feline protein could be a commingled component of mammalian protein products.

The definition of food additive in section 201(s) of the act does not apply to substances used in accordance with a sanction or approval granted prior to enactment of section 201(s) of the act and granted under the act, the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*). The Commissioner of Food and Drugs (the Commissioner) is unaware of any prior sanction applicable to the use of protein derived from mammalian tissue in ruminant feed. No one asserted a prior sanction for the use of protein derived from ruminant and mink tissues in ruminant feed based on the agency's discussion of a possible mammalian-to-ruminant ban in the preamble to the proposed rule (62 FR 552 at 566). In addition, no one asserted a prior sanction for use of protein derived from mammalian tissues in ruminant feed in response to the agency's discussion of a possible mammalian-to-ruminant prohibition in the preamble to the proposed rule. The failure of any person to come forward with proof of an applicable prior sanction is a waiver of the right to assert or rely on a prior sanction at any later time.

The agency notes, that for substances not included in the scope of the definition of protein derived from mammalian tissues, persons may continue to self determine whether such substances are GRAS for use in ruminant feed. FDA's authority to determine substances to be food additives under the act is discussed in further detail below in responses to the comments on the proposed rule.

The final rule also simplifies the cautionary statement for animal feeds containing mammalian-derived proteins, eliminates the labeling requirements for pet food products sold at the retail level and feeds for nonruminant laboratory animals, and elaborates on the information that must be kept and made available for inspection. These changes are further discussed below in the responses to comments received on the proposed rule.

II. Comments on the Proposed Rule and Draft Codified Text

FDA received more than 700 comments on the proposed rule. The comments came from a wide variety of organizations, such as cattlemen, renderers, feed manufacturers, and pharmaceutical firms, Federal agencies, foreign governments, State agriculture departments, trade associations, professional organizations, universities and research institutions, consumer organizations, and individual consumers. Additionally, FDA held two public meetings on the proposed rule. The first meeting was held in St. Louis, MO, on February 4, 1997, and focused on the rule's economic impact and issues of interest to the affected industries. The second meeting was

held in Washington, DC, on February 13, 1997, and focused on the rule's environmental analysis and issues of interest to consumer groups and organizations.

Additionally, in the **Federal Register** of April 17, 1997 (62 FR 18728), FDA published the codified provisions of the draft final rule and provided an opportunity for public comment. FDA received over 60 comments on the draft codified text.

Most comments (including remarks made at the public meetings) agreed that the Federal Government should take action to prevent the establishment and amplification of BSE in the United States through feed. However, many comments disagreed as to whether more or less stringent regulatory efforts were needed. FDA also received comments supporting and opposing each alternative that was described in the preamble to the proposed rule, as well as numerous comments that recommended new alternatives. To simplify the nature of the ideas expressed in the comments, the comments can be divided into two groups. One group would maximize the scope of the regulations, and the other would minimize the scope of regulations.

A large number of comments encouraged FDA to increase the scope of the regulations to include a partial or complete mammalian-to-ruminant prohibition or a mammalian-to-farm animal prohibition, or to apply a feed prohibition on all food-producing animals, either to achieve a greater reduction in the potential risk of human exposure or easier compliance with less need for enforcement actions. For example, a few comments asked that the proposed regulations be expanded to prohibit the feeding of ruminant proteins to felines and zoo animals, and the feeding of proteins from these animals to ruminants. Some comments noted the presence of scrapie and other TSE diseases in the United States and the epidemiological association between scrapie or a modified scrapie agent and BSE in the United Kingdom in support of enlarging the scope of the rule. One comment requested a ban on the feeding of all animal remains to other animals, regardless of species or processing method. Another comment noted that the specifications for tallow allowed for the presence of a small amount of protein and the possibility of a protein-associated infectivity.

Other comments supported a ''minimalist'' approach. For example, a significant number of comments pointed out that BSE has not been diagnosed in the United States despite a most exhaustive surveillance effort by Federal and State veterinary laboratory diagnosticians, veterinarians accredited by the U.S. Department of Agriculture (USDA), and veterinary practitioners who have been specifically trained to diagnose the early clinical signs of BSE in cattle. The USDA through statutes administered by the Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service (FSIS) has taken actions to ensure that the border defenses against importing the BSE agent are as secure as possible. FDA has advised manufacturers of human and animal drugs and devices, human biologics, dietary supplements, and cosmetics to obtain bovine derived ingredients from countries which are free of BSE. Some comments stated that the adoption by industry of voluntary measures to avoid the rendering of fallen sheep or sale of sheep proteins for use in ruminant rations, or to stop the feeding of ruminant proteins to ruminants are sufficient, and no regulation is warranted. Other comments reminded the agency of its public statements that the risk of BSE occurring in the United States is low and getting lower. A comment from a foreign regulatory official observed that zero risk cannot be achieved and that the calculation of risk through a mathematical model is essential; this comment also expressed the view that the agency's proposed regulatory approach exceeded the risk of BSE in the United States.

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

A. General Comments

1. Exclusions for Certain Products

(Comment 1). Several comments, in addressing either the proposed rule or the agency's alternatives to a ruminant-to-ruminant prohibition, suggested exclusions for specific products. The suggested exclusions included proteinaceous tissues (such as meat), nonproteinaceous materials (such as grease, fat, tallow, amino acids, and dicalcium phosphate as a byproduct of the gelatin manufacturing process), and materials that are not considered to be tissues (such as paunch meal, feces, and urine). A few sought exclusions for specific organs, such as hearts and kidneys, or even exclusions for tissues (such as distal ileum) that have been shown to be infective for TSE's in experimental studies.

The agency has carefully considered the various exclusions suggested by the comments and has revised § 589.2000(a)(1) to define ''protein derived from mammalian tissue'' as any protein-containing portion of mammalian animals, excluding blood and blood products, gelatin, inspected and processed meat products which have been cooked and offered for human consumption and further heat processed for feed (such as plate waste and used cellulosic food casings), milk products, and products whose only mammalian protein consists entirely of porcine or equine protein.

FDA excluded these items from the definition because the agency believes that they represent a minimal risk of transmitting TSE's to ruminants through feed. The excluded proteins and other items are materials that the available data suggests do not transmit the TSE agent, or have been inspected by the FSIS or an equivalent State agency at one time and cooked and offered for human food and further heat processed for feed and thus are of lower risk than those products that the agency has determined to be nonGRAS, or current industry practices can provide assurances that certain mammalian products can be produced without becoming commingled with potentially infective materials. Additional information on specific exemptions appears later in this document.

The agency did not revise the definition to exclude nonproteins or items that are not considered tissues. Such products, for example, tallow, fats, oils, grease, amino acids, and dicalcium phosphate as a byproduct of the gelatin manufacturing process, are not covered under this rule and thus do not require a specific exclusion. Moreover, infectivity studies conducted on some of these products (e.g., tallow) have demonstrated that they are at low risk of transmitting the TSE agent. As for those comments suggesting exclusions for specific organs or tissues, FDA declines to exempt such organs or tissues either because of their demonstrated infectivity or because they have not been sufficiently studied to confirm that they cannot transmit TSE disease to ruminants or may present a higher risk of transmitting a TSE to ruminants or because current industry practice does not support separation of these organs or tissues from other higher-risk organs or tissues. For example, under current industry practices, separation of muscle meat from potentially infective nervous tissue from spinal cords or nerve tissue connected to spinal cords cannot be assured. In addition, FDA notes that the origin of these materials is not easily determined when they arrive at a rendering facility.

The agency may revise the rule further to add or delete items from the

list of exclusions and make necessary corresponding changes to the rule when sufficient scientific information becomes available about the ability of those items to transmit TSE disease.

2. Scientific Issues

Numerous comments raised scientific issues regarding BSE, nv–CJD, and the need for additional scientific research.

a. *Causes of BSE.*

(Comment 2). Several comments stated that BSE is unlikely to occur spontaneously in an individual animal.

Although the theory that TSE's occur spontaneously as well as the other theories as to BSE's origins (see 62 FR 552 at 558 and 559) are not proven, FDA has not discounted any theory. The final rule would prevent the establishment and amplification of BSE in ruminants through feed by prohibiting the use of proteins derived from mammalian tissue in ruminant feed regardless of whether BSE may occur spontaneously or enter the United States through imported animals or animal products or may result from a cross-species or intra-species transmission of a TSE agent.

(Comment 3). Many comments claimed that scrapie in sheep was the cause of BSE in the United Kingdom.

FDA agrees that the use of sheep with scrapie which were rendered and fed to cattle as meat and bone meal is a possible cause of BSE in the United Kingdom. This final rule prevents sheep materials from being processed and fed back to cattle and other ruminants. Additionally, some comments stated that the adoption by industry of voluntary measures to avoid rendering of fallen sheep and the sale of sheep proteins to ruminants should provide sufficient safeguards to allow sheep to be excluded from the final rule. FDA disagrees with this statement because sheep are known to have a TSE (scrapie) that has a long incubation period and because of information from an FDA survey conducted in 1992 that clearly showed that a voluntary ban was not fully implemented and that sheep that had died of causes other than slaughter were being rendered and that rendered sheep protein was being sold for use in the manufacture of cattle feed. This survey is discussed in the preamble to the proposed rule (62 FR 552 to 582).

(Comment 4). Several comments argued that, in the United Kingdom, BSE was spread by ruminant-to-ruminant recycling.

FDA agrees that, in the United Kingdom, BSE was spread by the practice of feeding ingredients from processed BSE-infected cattle to other cattle, including young calves. The processes that were used did not completely inactivate the BSE agent. This final rule prevents ruminant-to-ruminant recycling.

(Comment 5). Several comments pointed out that the cause of BSE is unknown.

Even though the exact nature of the cause of BSE and many aspects of its etiology and pathogenesis are unknown, studies indicate that the feeding of BSE-infected material to cattle spread the disease to uninfected animals. The final rule is intended to prevent the establishment and amplification of BSE in the United States through feed even though many details regarding the BSE agent are unknown.

b. *Epidemiology of BSE.*

(Comment 6). Numerous comments expressed concern that transmissible mink encephalopathy (TME) resulted from mink being fed materials derived primarily from downer cattle. These comments suggested that this possible link between cattle and TME may indirectly indicate that BSE is already present in the United States cattle population.

The exact cause of these TME outbreaks, the most recent occurring in 1985, has not been proven, but FDA agrees that there is a possibility that the theory is correct. The final rule, however, would prevent cattle-to-cattle transmission of any undetected BSE in the United States as well as the transmission of TSE's from mink to cattle.

(Comment 7). Several comments claimed that BSE is present in pigs in the United States.

Based on the available evidence, FDA does not believe that BSE is present in pigs in the United States. A naturally-occurring TSE has not been identified in pigs in the United States or elsewhere in the world. FDA is aware that, in a study conducted in the United Kingdom, 1 out of 10 pigs appeared to develop TSE lesions after exposure to BSE (Ref. 1), but this infection occurred through intracerebral, intraperitoneal, and intravenous inoculation rather than under natural conditions (such as feeding). Despite these new inoculations, the other nine pigs did not develop a TSE. In another experiment, newborn pigs fed the BSE agent have remained healthy at 72 months of age (Ref. 2).

(Comment 7a). One comment claimed that a TSE was observed in U.S. pigs in 1979.

The cause of the clinical signs and lesions cannot be affirmed or completely refuted. FDA notes that it has been over 17 years since the incident was reported and that there have been no reports of a recurrence. From FDA's evaluation of this comment, the agency notes that the condition caused by salt toxicity/water deprivation, produces similar clinical signs and lesions as those reported in the 1979 incident.

(Comment 8). Many comments pointed out that TSE's already exist in animals in the United States. These comments usually referred to TSE's in sheep, goats, elk, mink, and deer.

FDA agrees that TSE's already exist in some animals in the United States and identified several such TSE's in the preamble to the proposed rule (see 62 FR 552 at 556 and 557 (describing scrapie, TME, and chronic wasting disease (CWD))). By prohibiting the use of proteins derived from mammalian tissues in ruminant feed, the final rule should prevent the transmission of these diseases to ruminants through feed.

(Comment 9). Several comments cited feline spongiform encephalopathy (FSE) as an example of the BSE agent's ability to cross species barriers.

The epidemiology of FSE supports this theory, but the risk of BSE crossing species barriers is present only in a country where BSE exists. The United States has no BSE, and the final rule provides the necessary feed controls to limit the risk of BSE crossing species barriers and infecting U.S. cattle and other ruminants through feed uses of protein products from infected animals should BSE occur here (i.e., a preventive barrier to the establishment and amplification of BSE through feed).

(Comment 10). Some comments argued that TSE diseases may occur in all animals, and prions have been identified in species as diverse as salmon and fruit flies.

Prions are proteins and are normal constituents of many living organisms ranging from yeast to mammals. The function of prions are unknown. Under one theory, the TSE or BSE agent is an abnormal, infectious protein that changes a normal ''host'' protein or prion in an animal or organism into the causative agent (see 62 FR 552 at 558). At this time, a naturally occurring TSE has not been identified in all animals. For example, although horses, pigs, poultry, salmon, and fruit flies have prions, they are not known to have naturally-occurring TSE's.

(Comment 11). Several comments discussed the possibility of BSE being present in the feces of poultry that consumed cattle meat and bone meal in their diets. These comments expressed concern that the BSE agent would spread to cattle which might consume poultry litter in their feed or to plants to which poultry litter was applied as a fertilizer.

FDA is unaware of any research on this issue that would indicate that the agency should take regulatory action on poultry litter at this time.

c. *Transmission of BSE.*

(Comment 12). Many comments addressed the safety of various tissues (such as blood, bone, and muscle) relative to TSE diseases. For example, some comments asserted that ruminant blood will not transmit TSE whereas others claimed that blood presents some risk of infectivity. Other comments asserted that bone and muscle are safe, but that brain, spinal cord, and eyes are high-risk tissues for TSE. Some comments claimed that oral transmission of TSE is very inefficient.

The research to date on TSE diseases and the infectivity of various tissues from infected animals consists of 2 types. The first consists of extensive research carried out over a long period of time in sheep, using sheep as the model for evaluating scrapie and other TSE diseases. This research has provided valuable information about the nature of the diseases in animals and comparatively little on the infectivity of tissues. The second consists of recent studies that have been carried out in other animals using agents such as BSE in cattle and TSE's in mice. Many of the tissue infectivity studies for scrapie and BSE have been carried out using several different strains of laboratory mice which have various degrees of natural susceptibility to TSE's. Samples of tissues taken from TSE infected animals are inoculated into the brain of these laboratory animals. The assessment of the infectivity of tissues has been based on the outcome of these studies. The results of this research indicate that blood, bone, certain other tissues, and tallow do not transmit TSE to the experimentally exposed mice whereas samples of brain, spinal cord, eyes, and some areas of the intestinal tract from cattle that died of BSE transmit a TSE to the mice.

FDA agrees with the comments regarding the comparative infectivity of oral versus intracerebral routes of exposure and the estimate that the oral route might be as much as 100,000 times less infective than by injection (Ref. 3). However, at this time, research has not provided adequate data on the level of infectivity from oral transmission.

(Comment 13). Other comments pointed to the unproven nature of the rodent bioassay for safety evaluation of various animal tissues. The comments stated that the TSE agent may be in other tissues at amounts below the detection limit of the rodent bioassay. The comments asserted that, if the lowest infectious dose of BSE is very small, undetected small amounts of agent in tissues could theoretically transmit TSE to a new host.

FDA agrees that the infective dose of TSE agents is small and that bioassays have limitations. The results of these assays cannot presently be confirmed by more traditional chemical or microbiological methods. Therefore, while small undetected amounts of the TSE agent could be present in the tissue, at this time, the agency believes these amounts present a minimal risk.

(Comment 14). Several comments discussed recent information describing maternal transmission of BSE. These comments stated that maternal transmission is at a very low rate and would not maintain the epidemic in the United Kingdom. Other comments claimed that lateral transmission (from one animal to another in the same herd) is not detected in BSE, whereas some comments stated that BSE crosses species barriers.

FDA acknowledges these characteristics of BSE, and the preamble to the proposed rule identified possible maternal transmission and BSE's ability to cross species barriers as being among the various factors justifying FDA's regulation of proteins intended for use in ruminant feed in order to prevent the establishment and amplification of BSE in the United States through feed (see 62 FR 552 at 559 and 560). While it may be true that the risk of maternal transmission is very low and will not sustain a significant epidemic as discussed in the preamble to the proposed rule, the possible use of infected protein from mammalian tissues in cattle feed may lead to establishment and amplification of BSE in the United States through feed. Thus, the final rule ensures that, whatever the mode of transmission, the TSE agent will stop with the infected animal.

(Comment 15). One comment suggested that FSE-infected cats transported to the United States from the United Kingdom could introduce BSE into the United States if the carcasses of those cats were permitted to be rendered into meat and bone meal.

The probability that such a scenario would occur appears to be remote since fewer than 100 cats in the United Kingdom have been diagnosed with FSE, and, therefore, the probability that an infected cat would be transported to the United States is small. Furthermore, relatively few domestic cats (those that are considered family pets) are rendered upon their deaths. Rendering of cat carcasses is much more common for feral or stray animals, but in the event that FSE-infected tissues were rendered into meat and bone meal, the final rule prohibits the use of proteins derived from mammalian tissues, including feline tissues, in ruminant feed. Therefore, FSE-infected cats will not cause BSE in the United States through feed.

(Comment 16). Two comments expressed the view that protein derived from cats and zoo animals should be prohibited from use in feeds intended for ruminants, cats, and zoo animals. This recommendation was based on the fact that domestic cats and other members of the family, Felidae, including zoologic specimens are susceptible to TSE.

The agency agrees that the concerns raised in the comments are valid, and the final rule prohibits the use of feline and ruminant protein in ruminant rations including the rations of ruminants maintained in zoological exhibits. The final rule does not prohibit the use of mammalian-derived protein in feeds intended for felids or nonruminant zoo animals because the intent of the rule is to prevent the establishment and amplification of BSE in the United States through feed and thereby minimize risk to animals and humans. The feed use of protein from felids and zoo animals in feed for cats and nonruminant zoo animals should not present a risk of establishing and amplifying BSE in the United States through feeds for ruminants.

d. *New Variant Creutzfeldt-Jakob Disease (nv-CJD).*

(Comment 17). Many comments expressed concern about the emergence of nv-CJD in the United Kingdom and France and that it may have been transmitted to humans through meat consumption. Some comments raised concerns that nv-CJD might occur in the United States.

FDA shares this concern about nv-CJD and, in conjunction with the Centers for Disease Control and Prevention, is monitoring it closely. As stated in the preamble to the proposed rule, the epidemiological studies conducted in the United Kingdom do not directly link nv-CJD to meat consumption, but suggest that the nv-CJD cases are linked to exposure to BSE before the introduction of specified tissue bans in the United Kingdom in 1989 (62 FR 552 at 561). In October 1996, a study using strain typing techniques for TSE's compared nv-CJD's strain characteristics against BSE transmitted to mice and macaques. The results showed nv-CJD's strain characteristics to be consistent with BSE as the source of nv-CJD. This study, which appeared in the October 24, 1996, issue of *Nature* (Ref. 4), provided a suggested link between BSE

and nv-CJD, but was not direct proof of such a link.

The Centers for Disease Control and Prevention completed a survey in 1996 of cases of CJD in the United States and found no cases that fit the characteristics of nv-CJD. Additionally, most meat products consumed by humans are subject to USDA's jurisdiction, and USDA is examining this issue to identify any risk and ways to minimize the risks, if any, to consumers.

e. *Research needs for BSE.*

(Comment 18). Numerous comments expressed concern about the lack of adequate published research on TSE diseases, inactivation of the agents, and public health implications. For example, some comments noted the lack of information about the minimum infective dose for BSE while others expressed a need to develop a process to inactivate or eliminate the BSE agent during rendering or to develop specific and sensitive analytical methods for animal feeds that would detect rendered proteins from various species.

FDA agrees, as discussed in the preamble to the proposed rule, that many scientific issues related to TSE's remain unresolved. The agency encourages research that addresses these needs, specifically (but not limited to): Determination of minimum infective oral dose for establishment of BSE in cattle; development and validation of a process to inactivate or eliminate the BSE agent during rendering; development of specific and sensitive analytical methods for the detection of rendered proteins from various species in animal feeds; development of a highly sensitive bioassay for determination of the TSE agent presence in animal tissues; and development of specific antemortem tests to detect the presence of TSE agents and diseases in animals.

f. *New scientific information.*

Several recently published articles on TSE's, BSE, and nv-CJD are not referenced in the proposed rule. In brief, the most relevant of these scientific publications are listed in the references in section IX of this document.

In one article, the physicochemical properties of the BSE and nv-CJD molecules were characterized to identify strain variations with nv-CJD (Ref. 4). It was found that nv-CJD is distinct from other types of CJD and resembles BSE transmitted to mice, cats, and macaque, which is consistent with BSE being the source of nv-CJD.

In another article, the authors used mathematical models to make assumptions about the incubation period for nv-CJD and the number of exposed people (Ref. 5). Based on these assumptions, they outlined a range of scenarios to estimate the future incidence of nv-CJD in the United Kingdom. A large measure of uncertainty surrounds any modeling that is based on 14 cases of nv-CJD and a lack of reliable information about the incubation period for nv-CJD.

The results of USDA's examination of 5,427 cattle brains were discussed in a recent article (Ref. 6).

Another article discussed the detection of scrapie in peripheral nerves of scrapie-diseased sheep and concluded that mutton of scrapie-diseased animals should not be regarded as being free of the scrapie agent (Ref. 7).

Prion protein was not detected by Western blot analysis in 55 percent of mice inoculated intra-cerebrally with BSE, although it was detected in 100 percent in subsequent passages (Ref. 8).

The hypothesis that BSE is a zoonosis was described and the risk characterized as low (Ref. 9).

TSE's, including clinical signs, gross and microscopic lesions, and ancillary test findings, in wild deer and elk in north-central Colorado from 1981 to 1995 were described (Ref. 10). The disease in wild cervids is indistinguishable from that reported in captive deer and elk.

The articles do not provide entirely new information, but rather add to the basic knowledge about TSE's and the need for this final rule. FDA has placed these articles in the administrative record for the final rule.

3. Enforcement-Related Issues

A number of comments addressed issues related to enforcement of the rule.

(Comment 19). Several comments stated that the proposed rule would be enforceable. However, several others argued that the rule would not be enforceable. The latter comments gave several reasons for their position, including the following: (1) There is no practical analytical test to distinguish ruminant protein from nonruminant protein. Enforcement, therefore, would depend on compliance with the rule's labeling and recordkeeping requirements which could be vulnerable to falsification or other abuse; (2) the rule's reliance on invoices may be inadequate because invoices may not contain sufficient information and may not be kept routinely; and (3) the clean-out procedures for firms that intend to separate ruminant from nonruminant protein (as provided by the proposed rule) would not be readily enforceable. Several comments recommended that the agency adopt a mammalian-to-ruminant prohibition because a practical analytical test (feed microscopy) for distinguishing mammalian from nonmammalian proteins is available.

When the agency issued the proposed rule, it acknowledged that the mammalian-to-ruminant alternative might be more easily enforced than the ruminant-to-ruminant prohibition in the proposed rule. However, the agency intended to commit the resources necessary to enforce the ruminant-to-ruminant option if adopted. The agency believed that the rule which it proposed could be enforced. For example, the establishments that would not separate ruminant from nonruminant protein would be subject to the simple, enforceable requirement that labeling for all outgoing products bear the statement cautioning against use of the product in ruminant feed. The agency estimated that the great majority of affected establishments—independent renderers, blenders, and feedmills—would elect not to separate products. Those that did separate products would be subject to additional scrutiny, such as on-site inspection that would include inspection of incoming product as well as observation of facilities and processes for separation. In addition, the agency has had experience in enforcing the act in other settings in which it was unable to test for violative products.

Limiting the mammalian species exclusion to pure porcine or equine products narrows the number of acceptable mammalian protein sources for ruminant feeds, thus simplifying the agency's records review and trace back efforts. The fact that some comments from regulated industries suggested support for a mammalian-to-ruminant prohibition should foster voluntary compliance.

(Comment 20). Several comments stated that the role of the States in enforcing the rule is unclear, but that State agencies lack the authority to enforce some aspects of the rule. Some comments also asked whether the rule imposed an unfunded mandate upon States.

Because this regulation is a Federal rule, only those State employees that are commissioned by FDA under section 702(a) of the act (21 U.S.C. 372(a)) would have a role in enforcing this rule. For commissioned State employees that have the same enforcement authority as FDA employees, such employees would be able to fully enforce the rule. State employees who are not commissioned do not have authority to enforce this rule. Comments about unfunded mandates imposed on States are discussed elsewhere in this document.

(Comment 21). Several comments suggested additional approaches to enhance the rule's enforceability. One comment suggested that the agency allow firms to substitute commercial contract guarantees (that the product does not contain ruminant material) instead of maintaining and providing sales invoices. The guarantees would be available for FDA inspection and copying. The comment asserted that use of such a guarantee would provide assurance that meat and bone meal containing ruminant or mink protein would not be inadvertently accepted for delivery at commercial feedmills.

FDA agrees that such a provision could enhance enforcement, through both self-regulation within the industry and enforcement of the act which makes the giving of a false guarantee a violation of section 301(h) of the act (21 U.S.C. 331(h)). However, it is unclear from the comments whether the commercial contract guarantees would provide adequate information for FDA to trace back purchases of protein products and feeds. Therefore, it is unclear whether the guarantees would enhance enforcement. In any event, the final rule, as written, provides the necessary tools for enforcement. Therefore, the agency declines to accept the comment's suggestion.

(Comment 22). One comment suggested that the agency revise the rule to require renderers to register with FDA.

Through the use of publicly available sources (such as trade publications), the agency has access to a comprehensive list of renderers, so a registration requirement is, at this time, unnecessary.

(Comment 23). One comment asked FDA to clarify the penalties that would be associated with a violation of the rule. Other comments asked the agency to discuss the consequences of a violation of the regulation and whether a person must knowingly have committed a violation.

The agency notes that it intends to implement a vigorous enforcement program. Although FDA cannot specify the penalty that would be imposed in any given scenario or case, the agency does note that the act provides several possible sanctions, including, but not limited to, injunctions (see section 302 of the act (21 U.S.C. 332)), criminal penalties (see section 303 of the act (21 U.S.C. 333)) and seizure of the adulterated or misbranded product (see section 304 of the act (21 U.S.C. 334)). Seizure and injunction actions generally do not require knowledge on the part of responsible persons, and criminal violations may or may not require such knowledge.

(Comment 24). Some comments asked about the disposition of adulterated feed, animals that have been fed adulterated feed, and products, such as milk, from animals that were fed adulterated feed.

The agency has guidance documents for the disposition of products found to be violative under the act (see for example CPG 675.200). This guidance can be used to facilitate the disposition of products determined to be violative as a result of this final rule. Alternatively, the agency can consider the disposition based upon the unique factors of the situation.

(Comment 25). One comment expressed concern about the adequacy of FDA's enforcement resources, stating a need for more frequent inspections of regulated firms such as feedmills. Another comment stated that an ''unlevel playing field'' would exist in the animal feed industry such that FDA would devote more regulatory attention to a relatively small number of registered (as opposed to unregistered) feedmills.

FDA reiterates its intention to commit adequate resources to enforcing this rule and to implement a vigorous enforcement program. FDA will allocate those resources in such a way that all segments of the industry receive attention commensurate with the risk presented by a violation in each segment.

(Comment 26). Several comments expressed the expectation that a mammalian-to-ruminant prohibition, if adopted by the agency, would also simplify the requirements placed on the affected industries. For example, the comments stated that, under a mammalian-to-ruminant prohibition, no special labeling would be required and that recordkeeping could be simplified.

Because the mammalian-to-ruminant prohibition in this final rule includes certain exceptions, the labeling and recordkeeping requirements are necessary, and the agency has retained them (with some revisions) in the final rule.

(Comment 27). Several comments implied that certain options, other than a ruminant-to-ruminant or mammalian-to-ruminant prohibition, would be enforceable. These options included a partial ruminant-to-ruminant prohibition, a prohibition only of proteins from TSE species, and a plan for ''certified ruminant derived protein'' based on a hazard analysis critical control point (HACCP) program approach. Some comments also stated that the ruminant-to-ruminant prohibition would be unenforceable.

As stated earlier, the final rule adopts a mammalian-to-ruminant prohibition with certain exceptions. The agency agrees that there are alternatives to a ruminant-to-ruminant or a mammalian-to-ruminant prohibition. Each alternative, including a ruminant-to-ruminant or a mammalian-to-ruminant prohibition, presents various enforcement challenges. FDA believes, however, that the final rule is a reasonable approach in terms of enforcement.

(Comment 28). One comment, from a cattle producers' organization, referred to that organization's commitment (along with many others) to ensure enforcement of the final rule. The organization pledged that it would work diligently to inform producers of their role in enforcement. Several other comments advocated use of educational programs, including education to consumers, and guidelines.

The agency appreciates the comment's commitment and intends to work closely with industry associations in educational efforts. The agency also expects to implement an educational program for consumers and the affected industries and will provide guidance documents to the affected industries.

4. Comments on the Alternatives

a. *Background.*

The preamble to the proposed rule listed 6 regulatory alternatives to prevent the establishment and amplification of BSE in the United States through feed (62 FR 552 at 567). The alternatives ranged from a prohibition on the use of mammalian tissue in ruminant feed to a ''no action'' alternative. FDA received comments supporting and opposing each alternative, as well as numerous comments that suggested new alternatives.

The principal alternative was a prohibition on the use of ruminant proteins in ruminant feed; this was the alternative initially selected by the agency and used in the proposed rule. Comments on the ''ruminant-to-ruminant'' prohibition are addressed later in this document. The other alternatives and the comments submitted on those alternatives are described below.

b. *The partial ruminant-to-ruminant prohibition.*

The second alternative was to exclude all ruminant and mink materials, except those that have not been found to present a risk of transmitting TSE's, from ruminant feed. This was commonly known as the ''partial

ruminant-to-ruminant'' ban. The exclusions, in addition to milk products, gelatin, and bovine blood, might have covered products such as bovine byproducts that have been inspected and passed in inspected slaughter facilities (except for the brain, eyes, spinal cord, and distal ileum because these tissues have been shown to transmit TSE's). This alternative had the advantage of having its prohibitions based primarily on scientific information related to the infectivity of specific tissues, yet it also had several important disadvantages. For example it may be impractical in the slaughter and rendering processes to segregate and to exclude the protein tissues that have not been found to present a risk of transmitting TSE disease. USDA expressed reservations that separating the distal ileum from other intestinal offal could jeopardize a slaughter plant's ability to meet pathogen reduction goals required by USDA's HACCP regulations. (The ''ileum'' is the terminal part of the small intestine, from the free edge of the ileocecal fold to the ileocecal orifice, and enters the junction of the cecum and colon obliquely on the medial surface. ''Offal'' refers generally to material left as a byproduct from the preparation of some specific product, less valuable portions and the byproducts of milling.) Enforcement would also be impractical because there is no specific diagnostic method for identifying protein derived from such tissues. Additionally, the alternative would not address the risk that other tissues may present a risk of infectivity (62 FR 552 at 567 and 568).

(Comment 29). Several comments supported this alternative, although most would modify it to cover only some tissues (such as tissues that are known to be infective in sheep, cattle, or other species), conditioned their support on the addition of other requirements (such as a HACCP program and good manufacturing practices (GMP's)), or conditioned their support on the feasibility of enforcing this alternative. A smaller number of comments opposed this alternative; most reiterated the arguments set forth in the preamble to the proposed rule by stating that there is inadequate scientific information to determine whether a particular tissue is or is not safe for use in ruminant feed, that separating certain tissues may be unsafe or impractical, and that the absence of a test to detect the TSE agent warrants rejection of this alternative.

The agency agrees with those comments that oppose a partial ruminant-to-ruminant prohibition. The agency is persuaded that under current industry practice, separating acceptable ruminant tissues from unacceptable ruminant tissue may be impractical, and the current lack of scientific knowledge about the TSE agent and BSE, coupled with the lack of a detection method, makes this alternative less acceptable compared to a mammalian-to-ruminant prohibition which is more enforceable and also endorsed by the most affected industries.

(Comment 30). Two comments raised the concern that the stunning of cattle at slaughter by captive bolt results in the formation of brain emboli which lodge in tissues that are normally considered to be incapable of transmitting TSE diseases. If protein derived from those tissues was permitted for use in ruminant rations, it potentially could transmit TSE diseases to ruminant animals. For this reason, it was argued that a partial ruminant-to-ruminant prohibition may fail to prevent the introduction and amplification of BSE in the United States.

The probability of introducing BSE into the United States from the small amount of nervous tissue that would be expected to result from brain emboli is minimal under a partial ruminant-to-ruminant prohibition; however, the final rule eliminates even this minimal probability because it provides that all mammalian tissues (with certain exceptions) are prohibited from use in ruminant rations.

c. *The mammalian-to-ruminant prohibition.*

The third alternative was to prohibit the use of all mammalian protein in ruminant feed (''mammalian-to-ruminant'' prohibition). The preamble to the proposed rule noted that some rendering and feed associations supported this alternative because separating ruminant from nonruminant materials or proteins might not be feasible due to the routine industry practice of commingling protein products (62 FR 552 at 568). The preamble to the proposed rule also noted that this alternative would provide greater assurance of industry compliance than a partial or total ruminant-to-ruminant prohibition because practical analytical methods exist for distinguishing mammalian from nonmammalian proteins and that this alternative would not require additional or new labeling. Furthermore, the preamble to the proposed rule stated that this alternative would avoid concerns about permitting some products containing meat and bone meal to be used in ruminant feeds while prohibiting others and the effect on financially sensitive commodities markets for animal protein.

The disadvantages to a mammalian-to-ruminant prohibition included the absence of scientific data establishing or suggesting TSE infectivity in nonruminant animals (other than in cats or mink) and claims from some industries that they would prefer or had the ability to separate ruminant from nonruminant tissues.

(Comment 31). The mammalian-to-ruminant alternative received the most support among the alternatives to a ruminant-to-ruminant prohibition discussed in the preamble to the proposed rule. These comments came from the affected industries (although most would prefer alternatives to this rulemaking), consumer groups, other government agencies (including a foreign government), and academia. Most comments supporting this alternative explained that it would provide the same or more protection than the proposed rule, would be both practical and enforceable, would give greater assurance of industry compliance, and would be consistent with international initiatives. However, some comments acknowledged that the current scientific evidence provides more support for a specified tissue prohibition or ruminant-to-ruminant prohibition rather than a mammalian-to-ruminant prohibition.

FDA has revised the rule to prohibit the use of protein derived from mammalian (rather than ruminant) tissues, with certain exclusions. Numerous comments from the rendering and feed industries advocated a mammalian-to-ruminant prohibition. These industries indicated that a mammalian-to-ruminant prohibition would result in easier and greater compliance (because the usual industry practice is to commingle ruminant and nonruminant material rather than separate ruminant from nonruminant material) and provide a higher degree of confidence in the feed or feed ingredients produced and sold. Given this practice of commingling tissues, the possibility of cross-contamination of nonruminant mammalian tissues through contact with ruminant tissues, and reasons explained elsewhere in this document, FDA has determined that protein derived from mammalian tissues (as defined in the rule) is not GRAS for use in ruminant feed and has revised the final rule accordingly. The agency recognizes that, under current industry practices, pigs and horses may be slaughtered at dedicated slaughtering facilities which produce either pure porcine or pure equine material. The exclusion of equine material in addition to porcine material in the final rule is a change from the proposed codified

material. This change was made in response to comments (see comment 44 response) that for mammals which are considered to be major food animals, neither porcine nor equine species have ever been diagnosed with a naturally occurring TSE. For porcine and equine materials, persons may continue to self determine whether their use in ruminant feed is GRAS.

FDA also considered various exclusions to the rule. These exclusions are discussed elsewhere in this document.

(Comment 32). Several comments offered alternatives to a mammalian-to-ruminant prohibition, such as the exclusion of sheep under 12 months of age and cattle under 30 months of age. The comments claimed that animals in these age groups seldom exhibit clinical signs of TSE.

FDA declines to revise the rule as suggested by the comments. Because of the long incubation period for TSE's, an infected animal may not exhibit any clinical signs. Scrapie has been detected in 7-month-old sheep (discussed fully in the preamble to the proposed rule) and results of a BSE maternal transmission study conducted in the United Kingdom suggest that the risk of maternal transmission is approximately 10 percent for BSE infected cows. Additionally, there is little specific knowledge about the infectivity of tissues and organs during this period.

d. *The prohibition of materials from U.S. species diagnosed with TSE's.*

The fourth alternative was to prohibit the use of materials from species in which TSE's have been diagnosed in the United States (sheep, goats, mink, deer, and elk) in ruminant feed. The preamble to the proposed rule noted that this alternative would eliminate the scrapie agent, TME, and CWD from ruminant feed, and thereby reduce the risk of BSE in cattle by TSE transmission from other animal species (62 FR 552 at 568). However, it also noted that this alternative would not prevent the spread of BSE in the United States if BSE occurred for another reason, such as spontaneous mutation in cattle or the importation of animals infected with BSE (when such imported animals are subsequently processed and used in ruminant feed).

(Comment 33). FDA received several comments supporting this alternative and a smaller number opposing it. The comments supporting this alternative stated that it was the most prudent and pragmatic alternative and is supported by current scientific evidence. Comments opposed to this alternative stated that it would not prevent amplification of BSE, would not exclude cattle (because no U.S. cattle have been diagnosed as having BSE or a TSE), and would make it more difficult to exclude potentially infective tissues from ruminant feed. One comment questioned whether this alternative would extend to prohibiting any feed materials to any animal, including nonruminants.

After considering the comments, FDA declines to adopt this alternative. As stated in the preamble to the proposed rule and elsewhere throughout this document, the rule is intended to prevent the establishment and amplification of BSE in the United States through feed. This alternative would restrict some, but not all, routes for the BSE agent to enter ruminant feed. Consequently, FDA is not adopting this alternative.

e. *The sheep-specified offal prohibition.*

The fifth alternative was to prohibit the feeding of specified sheep and goat offal to ruminants. This alternative would eliminate scrapie from ruminant feed, but would not prevent the spread of BSE among cattle if BSE occurred spontaneously or entered the United States (62 FR 552 at 568 and 569).

(Comment 34). Very few comments addressed this alternative. Two comments supported this alternative, stating that no TSE's have been found in the United States or that this alternative would remove much unsafe protein from ruminant feed.

Three comments opposed this alternative. One comment stated that, if BSE is already present in the United States, this alternative would not prevent it from spreading to other cattle. Another comment expressed similar views, but added that the long incubation period for TSE's and the infectivity of tissues from preclinical or asymptomatic animals increased the risk of BSE amplification. Another comment stated that this alternative had limited effectiveness because it did not protect against other known TSE's in other species.

The agency agrees with those comments opposing this alternative. Although it would remove scrapie from ruminant feed, this alternative would be ineffective against BSE and other TSE's. As a result, FDA is not adopting this alternative.

f. *The ''no action'' alternative.*

The sixth alternative was to take no action. The preamble to the proposed rule explained that this alternative is arguably supported by the fact that data and information do not document a recognized immediate threat to the public health in the United States and that any threat may be minimal. Other arguments supporting this alternative included: (1) BSE has not been detected in the United States; (2) surveillance efforts are in place and have not detected BSE; and (3) there is no empirical evidence available to establish that BSE will be transmitted to cattle from another species, will occur spontaneously in cattle, or will be transmitted from imported animals or animal feed (62 FR 552 at 553). The preamble to the proposed rule further noted that: There is no conclusive scientific evidence that BSE would be spread through animal feed (although there is strong epidemiological evidence suggesting that widespread BSE infections in the United Kingdom occurred through contaminated animal feed and that enforced feed control regulations appear to be the reason for BSE's decline in the United Kingdom); the industrial practices in the United Kingdom believed to be associated with the BSE epidemic in the United Kingdom differ from those in the United States; transfer of TSE's from sheep to cattle is suggested by epidemiological evidence, but has not been confirmed by direct scientific data; and while there is an epidemiological association between BSE and the nv-CJD cases in the United Kingdom, the available evidence has not established that BSE causes nv-CJD.

Arguments against a ''no action'' alternative focused on the potentially high cost, in animal and human lives and economics, if BSE appeared in the United States and was transmitted and amplified through the feeding of ruminant protein to cattle. The preamble to the proposed rule noted that TSE transmission from other species, spontaneous occurrence, and transmission from imported animals or animal products was possible. Experimental evidence also indicated that the BSE agent may be more susceptible to oral transmission (such as through animal feed) than other TSE's, thereby increasing the chances that BSE could spread through the United States whether or not the BSE agent developed spontaneously, was transmitted by another species, or was introduced by some other means. Yet the greatest risk factor identified in the preamble to the proposed rule was the potential for unrecognized amplification of the BSE agent given the long incubation period for BSE and the absence of methods for detecting the agent (62 FR 552 at 555).

(Comment 35). Very few comments expressly addressed the ''no action'' alternative. One comment, without any explanation, supported the no action alternative, while another comment claimed that the proposed rule was essentially a ''no action'' alternative

because it would permit the use of tallow and fat in ruminant feed, and the comment opposed the use of tallow. Six comments opposed this alternative, declaring that the Federal Government must act to protect animal and human health and food safety now, that TSE's are known to exist in the United States, and that if TSE's exist in cattle, steps need to be taken to prevent amplification. Other comments opposing a ''no action'' alternative claimed that an undiagnosed TSE may already exist in the United States cattle population (arguing that TME may have originated as an undiagnosed TSE in cattle that was transferred to mink through contaminated feed), that this alternative would not protect against asymptomatic animals infected with a TSE, and that this alternative is not acceptable for purposes of international trade (because other countries will reject U.S. products if they cannot be assured that the products are not infected with BSE or a TSE).

FDA agrees with the comments that oppose a ''no action'' alternative. The most appropriate course of action is to take steps to prevent the establishment and amplification of BSE in the United States through feed before BSE is manifested in the United States. FDA will, as it does for all regulations, amend or modify its regulations to reflect any advances in scientific or industry technology, but the potential consequences to human and animal health are simply too great to justify a ''no action'' alternative at this time.

5. Miscellaneous Alternatives Suggested by the Comments

Many comments suggested other regulatory approaches, ranging from more comprehensive prohibitions on the use of animal proteins in feed to less restrictive alternatives that would focus solely on sheep or cattle or certain types of cattle. Other comments suggested alternatives to the nonGRAS status (e.g., issuing a compliance policy guide (CPG), an interim food additive regulation, a GRAS listing with restrictions, temporary ban to suspend the use of ruminant protein in ruminant feed, and HACCP programs). The discussion of these alternatives and the agency's response appears in section I.B.1.b of this document, comments 56 through 60. Few comments offered any detailed rationale or explanation supporting their alternatives.

a. *Alternatives involving ''downer'' animals.*

(Comment 36). FDA received hundreds of comments (in response to write-in campaigns) requesting that ''downer'' (nonambulatory) animals not be used for human food and not processed as ingredients in animal feed. Few comments offered any detailed rationale (scientific or otherwise) for their request, although some comments suggested that downed animals may be unable to walk because they have a TSE agent or suffer from some central nervous system (CNS) disease.

FDA declines to revise the rule as suggested by the comments. The final rule is limited to the use of proteins derived from mammalian tissues in ruminant feed. The rule is intended to prevent the establishment and amplification of BSE in the United States through feed. Because BSE has never been detected in the United States, the agency believes that the actions it has taken in this final rule will accomplish this regulatory objective.

FDA notes that issues involving downer animals actually have two components: (1) Animals that are ''down'' and are condemned on antemortem examination, such as those with clinical signs of CNS disorders; and (2) animals that are ''down'' but which are passed as ''suspects'' pending post-mortem examination, such as those with broken legs, mastitis, paralysis, etc. This final rule will prevent any downed (including CNS-condemned) ruminants from being used in ruminant feed. This final rule does not address issues related to nonruminant feed uses. The agency does not have any information that such uses for nonruminants at this time, present a risk of TSE infection to ruminants. The use of carcasses of downer animals and the offal of animals that are slaughtered as suspect for a CNS disorder in the manufacture of meat and bone meal for use in swine, poultry, and pet rations presents no known risk to humans. The risk to nonruminants other than ruminants appears to be limited to felids and mink and is considered to be extremely small.

Additionally, revising the rule to prohibit the use of all downers in nonruminant feeds would create significant environmental and economic problems. Issues further related to use of meat and poultry for human consumption are outside the scope of this rulemaking since they are regulated by USDA.

b. *Alternatives covering other animals.*

(Comment 37). Several comments advocated more inclusive alternatives, such as prohibiting the use of animals or mammals in mammalian feed, prohibiting the use of animal byproducts in feed for all animals or all farm animals, or prohibiting the use, in any livestock feed, of any potentially infectious tissue from any species known to have a TSE. Few explained their reasons for such alternatives other than to declare that a broader alternative would be more protective, to argue that noncarnivorous animals should eat only plants, or to argue that the practice of feeding animal protein to animals was ''cannibalism'' or ''unnatural.''

In developing this rule, the agency sought to create regulatory requirements that would prevent the establishment and amplification of BSE in the United States through feed while simultaneously considering the impact on the affected industries. The comments did not provide sufficient information to determine that the alternatives suggested by the comments would be equally or more effective in preventing the establishment and amplification of BSE in the United States through feed, and so FDA declines to revise the rule as suggested by the comments.

(Comment 38). Several comments advocated less restrictive alternatives to the rule, such as prohibiting cattle-derived protein from being fed to other cattle, or to sheep and cattle, or to other animals, prohibiting the use of sick and dying animals in human and animal food, or prohibiting the use of spinal cords and heads in animal feed.

FDA declines to revise the rule as suggested by the comments. These less restrictive alternatives would not meet the agency's goals. The comments did not offer any explanation as to how these alternatives would prevent the establishment and amplification of BSE in the United States through feed.

c. *Alternatives covering other subjects.*

(Comment 39). One comment requested that FDA revise the rule to address all food hazards (rather than focus on BSE in ruminants), prohibit the use of all meat protein supplements in all animal feed, prohibit the use of antibiotics in food-producing animals, and concentrate on possible causes of disease.

The agency declines to revise the rule as requested by the comment. The comment does not explain how the suggested change would prevent BSE from being established and amplified in the United States through feed. The comment's requests appear to address issues which are outside the scope of this rulemaking.

B. Comments on Specific Sections in the Proposed Rule

1. Section 589.2000(a)—Definitions

Proposed § 589.2000(a) would define various terms, such as ''protein derived from ruminant and mink tissues,'' ''renderer,'' ''blender,'' ''feed

manufacturer and distributor,'' and ''nonruminant protein.''

All comments addressing proposed § 589.2000(a) focused on the terms ''protein derived from ruminant and mink tissues.'' Proposed § 589.2000(a)(1) would define such proteins as ''any protein-containing portion of ruminant animals or mink, excluding blood from bovines, milk proteins and gelatin.''

As noted earlier in this document, the agency has revised § 589.2000(a)(1) to refer to protein derived from mammalian tissues and has excluded specific items from that definition. In general, the exclusions represent tissues that the available data suggests do not transmit the TSE agent or were, at one time, inspected by FSIS and found fit for human consumption and further heat processed for feed use or tissues from species without TSE's that, under current industry practice, are slaughtered in single species slaughter facilities. Comments on specific tissues are as follows:

(Comment 40). Several comments would exclude plate waste (food that has been inspected, prepared, and/or served to humans) from the rule. Some comments explained that all food products which compose plate waste have already been cooked and inspected several times before being offered for human consumption and later thrown away and that commercial processors of plate waste dehydrate the product at temperatures reaching 290 to 400 °F when converting it to an animal feed ingredient. The comments also asserted that the plate waste comes from institutions (universities, retirement homes, hospitals, prisons, etc.), fast-food establishments, and large restaurants/cafeterias, and does not consist of tissues that have demonstrated infectivity in cattle, e.g., brain, spinal column, eye and distal ileum of cattle. Furthermore, some comments stated that plate waste consists mostly (approximately 98 percent) of nonmeat products and is high in moisture. The high moisture content requires the addition of 50 to 60 percent corn, soybeans, or similar products to aid in the dehydration and the extrusion process. The comments also noted that the feeding of plate waste remains a common practice in many parts of the United States and around the world and that plate waste comprises approximately 8.9 percent of the Municipal Solid Waste stream in the United States.

The draft codified provisions that appeared in the **Federal Register** of April 17, 1997, included as an exclusion from the definition protein derived from mammalian tissue, ''inspected and processed meat products which have been cooked and offered for human consumption (plate waste and used cellulosic food casings).'' The initial decision to exclude plate waste was based on the fact that a small proportion of meat is included in plate waste and that plate waste represents a small proportion of ruminant feed. Additionally, the heat and pressure used to process plate waste should further reduce the risk of transmitting the TSE agent through feed in a product that is of minimal risk prior to the processing as plate waste.

Several comments addressed the reference to ''plate waste,'' and the majority of the comments supported the exclusion of plate waste from the definition of ''protein derived from mammalian tissues.'' However, many of these comments also sought a broader exemption by expanding the rule to include ruminant meat which had passed Federal or state inspection for human consumption. In contrast, one comment, from the USDA/APHIS, opposed an exclusion for plate waste, stating that the exclusion was too broad and could be interpreted to be similar to the USDA definition for garbage at 9 CFR 166.9 and that trimmings (bone and nervous tissue) from TSE-susceptible species might be included under the exclusion.

FDA agrees with the USDA/APHIS that the inclusion of trimmings or high-risk tissue, such as brain and eyes, is inappropriate for use in ruminant feed. FDA declines to expand the exclusion to include all ruminant meat that has passed Federal or state inspection for human consumption. FDA's approach to eliminating trimmings was to describe an acceptable product as one which was ''cooked and offered for human consumption.'' After further consideration FDA has revised the definition of protein derived from mammalian tissues to exclude ''inspected meat products which have been cooked and offered for human food and further heat processed for feed (plate waste and used cellulosic food casings).'' This is to clarify that the high risk tissues USDA/APHIS described in their comment are not covered by this exclusion.

FDA declines to expand the exclusion to include all ruminant meat that has passed Federal or state inspection for human consumption because this would require FDA to remove the safeguard against trimmings and also would allow brains and eyes which have passed inspection to be fed to ruminants.

The agency acknowledges that accurately describing products which are acceptable under this exclusion is difficult. In general, FDA interprets this exclusion as being restricted to food prepared in restaurants or restaurant-like establishments, offered to consumers for consumption on the premises, and then discarded by the consumer. Precooked food items, such as hot dogs, casings from cooked hot dogs, and cooked deli items, would be excluded from regulation under this rule by this exclusion. FDA has revised the definition to better reflect its position that the product must be cooked, offered to the consumer for human food, and then further heat processed before it can be fed to animals.

The Association of American Feed Control Officials, Inc. (AAFCO) is in the process of developing definitions for products described in this section. In general, the ''plate waste'' exclusion is similar to the AAFCO definition of ''restaurant waste.''

(Comment 41). A few comments questioned why meat and meat products inspected by the USDA and found acceptable for human consumption are not acceptable for ruminant consumption.

The risks posed to humans and those posed to animals are different. The significant steps advanced by this rule are supported by public health experts as an effective means to decrease the risk of TSE's in ruminants through feed and the potential risk to humans. To date, the occurrence of nv-CJD in Europe has not been definitively linked to human consumption of meat, and no cases of nv-CJD have been detected in the United States.

(Comment 42). One comment objected to the exclusion of gelatin and blood from the definition of ''protein derived from ruminant and mink tissues.'' The comment argued that gelatin and blood meal may be infectious and that blood meal may not be used as a feed ingredient or a fertilizer in the United Kingdom. The comment further noted that the USDA prohibits the importation of ruminant protein and blood meal from countries with documented BSE cases; the comment stated that if the USDA prohibits such imports because they may be infective, then FDA should not permit the use of domestic gelatin and blood meal.

The agency disagrees with the comment. As the agency discussed in the preamble to the proposed rule (62 FR 552 at 572) available data suggests that gelatin and blood do not transmit the TSE agent and USDA surveillance has not detected BSE in the United States. However, to minimize the risk of infected material being imported into

the United States, USDA has prohibited the importation of such products.

(Comment 43). Several comments addressed the reduction in TSE titer that results from the process that is used to make gelatin. Two comments added that dicalcium phosphate, which is derived from the gelatin manufacturing process, should be excluded from the rule; one described the processes for obtaining dicalcium phosphate. Another comment sought clarification whether amino acids derived from gelatin would be exempt from the rule.

Amino acids and dicalcium phosphate are excluded from the final rule because both products are by-products or the result of further processing of gelatin and do not contain proteins. Dicalcium phosphate is an inorganic mineral source that does not contain protein, and individual amino acids are not proteins. (Instead, proteins consist of amino acids.) Although the codified provision to the draft rule that was published in the **Federal Register** of April 17, 1997, expressly exempted amino acids and dicalcium phosphate derived from gelatin, and one comment sought to revise that language regarding dicalcium phosphate, the agency has reconsidered the need for this express language and decided that, because amino acids and dicalcium phosphate are not proteins, the express language is unnecessary.

(Comment 44). Several comments requested that FDA revise the rule to exclude pure porcine (swine) products. These comments argued that swine are not known to have TSE's and are often slaughtered in dedicated swine slaughter facilities so that pure porcine products can be easily separated from other mammalian products.

Other comments, submitted after the publication of the draft codified provisions in the **Federal Register** of April 17, 1997, suggested that FDA revise the rule to exclude pure equine products. FSIS commented that the rationale for the change from a ruminant-to-mink prohibition in the proposed rule to a mammalian prohibition, with porcine exclusion, is insufficiently supported by scientific fact and suggested that FDA consider an alternative to the draft final.

The agency agrees with the comments and has excluded products whose only mammalian protein consists entirely of porcine or equine protein from the definition of ''protein derived from mammalian tissues.'' This exclusion is scientifically defensible because swine and horses have not been shown or reported to have a condition that can be linked to a TSE and can be accomplished within the current industry structure and practice. Because most swine and horses are slaughtered in dedicated facilities, and the ease of verifying compliance at the source, FDA has excluded products containing pure porcine or pure equine protein from the rule and, where appropriate, revised other provisions in the final rule to reflect an exclusion for pure porcine or equine protein. FSIS is in agreement with these changes.

(Comment 45). A few comments asked the agency to provide a mechanism for exempting animals from flocks or herds that are designated by a Federal agency to be absent from TSE's, such as the USDA's Voluntary Scrapie Flock Certification Program.

The agency supports any initiative such as this which is designed to reduce or eliminate a naturally occurring TSE. However, there appears to be little assurance that the proteins derived from these flocks or herds could be kept separate as pure single-species proteins, and therefore, FDA declines to revise the rule as suggested by the comments.

(Comment 46). Proposed § 589.2000(a)(2) would define ''renderer,'' in part, as ''any firm or individual that processes slaughter byproducts, animals unfit for human consumption, meat scraps or food waste.''

The agency has removed ''food waste'' from the definition. This change is necessary because, as explained above, the agency has excluded plate waste from the definition of ''protein derived from mammalian tissues.'' The agency does note, however, that it interprets the term ''animals unfit for human consumption'' as including parts of animals that are unfit for human consumption.

(Comment 47). Proposed § 589.2000(a)(3) would define the term ''blender.''

The agency received no comments on this definition and has finalized it without change.

(Comment 48). Proposed § 589.2000(a)(4) would define ''feed manufacturer and distributor'' as including manufacturers and distributors of complete and intermediate feeds intended for animals, including on-farm and off-farm feed manufacturing and mixing operations.

FDA has revised the definition to separate ''feed manufacturer'' from ''distributor.'' The agency made this change to clarify that both feed manufacturers and distributors are subject to the rule rather than persons who perform both functions (manufacturing and distributing). Thus, § 589.2000(a)(4) defines ''feed manufacturer'' as including manufacturers of complete and intermediate feeds intended for animals and including on-farm in addition to off-farm feed manufacturing and mixing operations. Section 589.2000(a)(6) defines ''distributor'' as including persons who distribute or transport feeds or feed ingredients intended for animals. The substance of these definitions are similar to the definition in the draft codified provisions that appeared in the **Federal Register** of April 17, 1997. The agency has also made corresponding changes throughout the rule to clarify that feed manufacturers are distinct from distributors and deleted the reference to ''haulers'' from proposed § 589.2000(e) because the definition of ''distributor'' includes persons who transport feed and feed ingredients.

(Comment 49). Proposed § 589.2000(a)(5) would define ''nonruminant protein'' as including protein from nonruminant animals and vegetable sources.

The agency has revised § 589.2000(a)(5) to define ''nonmammalian protein'' as including protein from nonmammalian animals and vegetable sources. This corresponds to the final rule's change to a mammalian-to-ruminant prohibition.

(Comment 50). As stated earlier, FDA has revised the rule to create a new § 589.2000(a)(6) to define ''distributor.'' While the codified provisions of the draft rule that appeared in the **Federal Register** of April 17, 1997, initially defined ''distributor'' as including distributors of complete and intermediate feeds intended for animals, FDA, on its own initiative, has revised the definition further to clarify that persons who transport feed or feed ingredients intended for animals are distributors.

(Comment 51). The agency has also revised the rule to create a new § 589.2000(a)(7) to define ''ruminant'' as including ''any member of the order of animals which has a stomach with four chambers (rumen, reticulum, omasum, and abomasum) through which feed passes in digestion. The order includes, but is not limited to, cattle, buffalo, sheep, goats, deer, elk, and antelopes.'' FDA elected to define the word ''ruminant'' because several comments noted that some people might not know what animals are ''ruminants.''

2. Section 589.2000(b)—Food Additive Status

Proposed § 589.2000(b) would state that protein derived from ruminant and mink tissues is not generally recognized as safe for use in ruminant feed because it may contain TSE's and is a food

additive subject to section 409 of the act (21 U.S.C. 348). Thus, under the proposed rule, the use or intended use of any ruminant or mink-derived protein in ruminant feed would cause the feed to be adulterated and in violation of the act (unless it was the subject of an effective notice of claimed investigational exemption for a food additive or was the subject of a food additive regulation). Proposed § 589.2000(b) would also state that FDA has determined that ruminant and mink-derived protein is not prior sanctioned for use in ruminant feeds.

a. *NonGRAS status.*

At the outset, FDA notes that no comments provided FDA with any published studies, data, or other information or expert opinions upon which FDA could conclude that the material is safe or that there is a reasonable certainty that the material is not harmful under the intended conditions of use. FDA received no scientifically valid information, or expert opinion based on that information, that addressed: (1) Whether it is reasonably certain that BSE does not, or will not, occur in the United States; (2) whether the BSE agent can be detected; (3) whether it is reasonably certain that the BSE agent will not be transmitted to ruminants through animal feed, i.e., that the processed tissues are not infected by the agent, are deactivated by the rendering process or are not transmitted orally; or (4) whether it is reasonably certain that the agent will not be transmitted to humans through consumption of ruminant products. As discussed extensively in the preamble to the proposed rule (see 62 FR 552 at 553 and 564) and herein, these significant safety questions have been raised by credible currently available information about the transmission of BSE and TSE's to ruminants through feed. As a result of these questions, as provided in this final rule, FDA has determined that protein derived from mammalian tissues in ruminant feed is not GRAS.

(Comment 52). Many comments stated that ruminant protein had been safely used as components of animal feed for 100 years as well as before the enactment of the Food Additive Amendments of 1958. These comments seemed to assert that ruminant protein for use in ruminant feed is GRAS based on common use in food prior to 1958, and based on this history of safe use, FDA cannot now declare it to be a food additive.

FDA disagrees. As noted in the preamble to the proposed rule, if a substance was used in food before 1958, general recognition that the use of a feed ingredient is safe can be based on scientific procedures or experience based on common use in food (see 62 FR 552 at 566; section 201(s) of the act (21 U.S.C. 321(s)); and 21 CFR 570.30(a)). General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation, but it nonetheless requires a demonstration of: (1) Safe use based on common use, and (2) an expert consensus of safety, based on that common use (see 21 CFR 570.30). The simple assertion of this safe use thus does not satisfy the burden the proponents of the use bear to establish general recognition. Although FDA agrees that, until recently, this material appears to have had a long history of use without known adverse effects (see 62 FR 552 at 566), FDA has never affirmatively declared the material to be GRAS based on common use in food.

Moreover, even if a substance is GRAS based on common use in food or GRAS based on scientific procedures, FDA may reassess the GRAS status of a food ingredient based on new information (see 21 CFR 530.30(g); see also, e.g., 51 FR 25021, July 9, 1986 (Sulfiting Agents; Revocation of GRAS Status for Use on Fruits and Vegetables to be Served or Sold Raw to Consumers)). Thus, even if ruminant protein for use in ruminant feed were GRAS based on common use in feed prior to 1958, that does not preclude FDA from reassessing it now that there exist new studies, data, or other information that show that the substance is, or may be, no longer safe (this is true whether the studies or data are published or unpublished (see 50 FR 27294 at 27296 (July 2, 1985))) or that there is no longer the basis for an expert consensus that it is safe.

Expert opinion that the substance for use in ruminant feed is GRAS would need to be supported by scientific literature, and other sources of data and information. ''General recognition'' cannot be based on an absence of studies that demonstrate that a substance is unsafe; there must be studies or other information to establish that the substance is safe (see *U.S.* v. *An Article of Food * * * Coco Rico,* 752 F.2d 11 (1st Cir. 1985)). Furthermore, if there are studies and other data or information that raise questions about the safety of the use of the material, this conflict—just like a conflict in expert opinion—may prevent general recognition of the substance.

As the agency explained in the preamble to the proposed rule, research and other information have raised questions regarding the safe use of protein derived from certain animal tissue in ruminant feeds. The agency stated that ''the evidence as discussed in sections I and II.A through II.D of this document, for the development of a new pattern of disease transmission, now indicates that these ingredients can no longer be categorically regarded as safe'' (see 62 FR 552 at 566).

Because the expert opinion must be ''general,'' a substance is not GRAS if there is no recognition among experts, or there is a genuine dispute among the experts, as to whether it is safe. Although there need not be unanimity among qualified experts that a substance is safe for ''general recognition'' of its safety to exist, an ''expert consensus'' is required (see *Weinberger* v. *Hynson, Wescott & Dunning, Inc.*, 412 U.S. 606, 632 (1073)).

Accordingly, there must be no genuine difference of opinion among qualified experts as to the substance's safety (see *Coco Rico*, 752 F.2d at 15 n.6; *United States* v. *Articles of Drug * * * 5,906 Boxes*, 745 F.2d 105, 119 n.22 (1st Cir. 1984)). As the Court of Appeals for the Second Circuit explained in *Premo Pharmaceutical Laboratories, Inc.* v. *United States*, 629 F.2d 795, 803 (2d Cir. 1980), when there is a dispute among experts as to ''general recognition,''

> The * * * issue (of actual safety) is to be determined by the FDA which, as distinguished from a court, possesses superior expertise, usually of a complex scientific nature, for resolving that issue.

See also *5,906 Boxes*, 745 F.2d at 119 n.22; *United States* v. *50 Boxes * * * Cafergot P–B Suppositories*, 721 F.Supp. 1462, 1465 (D. Mass. 1989), *aff'd*, 909 F.2d 24 (1st Cir. 1990); *An Article of Drug * * * Furestrol Vaginal Suppositories*, 251 F.Supp. 1307 (N.D. Ga. 1968), *aff'd*, 415 F.2d 390 (5th Cir. 1969).

The World Health Organization (WHO), in an April 1996 consultation on public health issues related to TSE, recommended that all countries ban the use of ruminant tissues in ruminant feed. This recommendation was intended to minimize the risk associated with exposure to BSE from beef and beef products. The background for WHO recommendation pointed out that the BSE epidemic in the United Kingdom appeared to have been due mainly to the recycling of infected bovine material back to cattle.

In response to the agency's request in the preamble to the proposed rule for comments on a ruminant-to-ruminant prohibition as well as other alternatives including a full mammalian to ruminant

ban, no one submitted or cited published studies to support the contention that the use of protein derived from ruminant tissue or from mammalian tissue in ruminant feed is GRAS. Furthermore, no comments refuted the agency's basis for determining protein derived from ruminant tissue for use in ruminant feed to be nonGRAS as set out in the preamble to the proposed rule. In addition, no one submitted or cited published studies to support a finding that the use of mammalian tissue in ruminant feed is GRAS either in response to the request for comments on the alternative set out in the preamble to the proposed rule or the request for comments on the draft rule, which included the mammalian (with certain exclusions) to ruminant ban. FDA believes that the same research and information set out in the proposed rule and the industry practice of commingling mammalian, including ruminant and mink, tissues, demonstrate that the use of protein derived from mammalian tissues can no longer be categorically regarded as safe. Therefore, this final rule provides that such protein for use in ruminant feed is a food additive subject to section 409 of the act.

(Comment 53). Numerous comments appeared to argue that the agency could not promulgate a rule declaring ruminant protein to be a food additive when intended for ruminant feed because there is no BSE in the United States.

Because these comments did not provide any legal or scientific explanation to support this argument, it is unclear to FDA whether they are arguing: (1) That FDA cannot rely on new information from foreign sources to reassess the GRAS status of a food ingredient, or (2) that FDA cannot take action until BSE actually occurs on United States soil. Whichever argument is meant, FDA disagrees. First, the act does not require evidence of actual harm to exist before a substance can be declared to be not GRAS by FDA; all that is required is information—which exists here—that the use of certain protein in ruminant feed may not be safe or that there is no expert consensus that the use of the substance is safe.

In addition, in response to comments that point out that there is no evidence of BSE in the United States, FDA notes that nothing in the act would support a blanket conclusion that FDA should only rely on data generated or conditions present in the United States when making this reassessment. Indeed, since, under the act, FDA must take into account relevant evidence of foreign use when assessing a claim that a food ingredient is GRAS based on common use in food prior to 1958 (see *Fmali Herb, Inc.* v. *Heckler*, 715 F.2d 1385 (9th Cir. 1985)), FDA believes it should likewise take relevant foreign data and expertise into account when reassessing safety and general recognition. Here, while there have been no reported cases of BSE in the United States, other conditions exist that make the foreign experience relevant, such as the fact that, in the United Kingdom, BSE was spread by the practice of feeding ingredients from processed BSE-infected cattle to other cattle, and the processes that were used failed to inactivate the BSE agent.

Moreover, the act as a whole and the 1958 Food Additives Amendment in particular were intended to give FDA the tools to prevent harm to the public health *before* it occurs (see, e.g., *United States* v. *Ewig Bros Co.*, 502 F.2d 715, 721 & n.24 (7th Cir. 1974), *cert. denied*, 420 U.S. 945 (1975); see also S. Rep. No. 2422, 85th Cong., 2d Sess. 1–3 (1958); H.R. Rep. No. 2284, 85th Cong., 2d Sess. 1 (1958)). As a result of the 1958 amendment, the burden of proof shifted to manufacturers, and the 1958 amendment ''permit(s) FDA to regulate the use of substances affecting foods without first determining that they are in fact dangerous; the method is to require that such substances be established as safe before being used'' (see *Natick Paperboard Corp.* v. *Weinberger*, 525 F.2d 1103, 1106 (1st Cir. 1975), *cert. denied*, 429 U.S. 819 (1976); see also *Ewig Bros.*, 502 F.2d at 721).

Thus, to claim that FDA cannot declare a substance to be a food additive until it has actually done damage in the United States and FDA can prove that actual harm has occurred would eviscerate the act. It would be contrary to the public health if FDA could not use this authority—based data and other relevant information from other countries—to prevent harm from occurring through the use of certain ingredients in feed.

FDA notes that section 801 of the act (21 U.S.C. 381), which gives the agency the authority to prevent the import into the United States of food that violate the act unless such items are intended for export rather than domestic distribution, underscores the weakness of the comments' arguments. If the act did not allow FDA to consider conditions that exist in, or evidence from, other countries when determining whether an article violates the provisions of the act, FDA would not be able to implement section 801 of the act and keep violative food from entering the country. Furthermore, if the comments' interpretation of the act is correct—that FDA can only look at conditions in this country—then FDA would not be able to declare animal protein from other countries to be an unsafe food additive, even if there had been cases of BSE reported in the country in which the animal protein originated.

(Comment 54). Several comments argued that more research is needed before FDA can take action and that the agency must establish that all feed components affected by this rulemaking may transmit TSE's.

These comments misunderstand the structure of the food safety provisions of the act. As noted above and in the preamble to the proposed rule (62 FR 552 at 566), the act places the burden to establish safety of a feed component on the proponent of the substance, not on the government to prove actual harm. Research of the type suggested by the comments could take years to complete. The agency believes that it is neither required nor appropriate to delay regulatory action to prevent transmission of BSE pending the completion of research.

The information presented in the preamble to the proposed rule set out the basis for the agency's nonGRAS determination for the use of protein derived from ruminant and mink tissue in ruminant feed. As discussed earlier in this preamble to the final rule, after evaluating the issues and information presented in the comments on the proposal and all other evidence, the agency has determined that a consensus does not exist that the use of protein derived from mammalian tissues is safe for use in ruminant feed. The agency finds that the potential remains for ruminants to be exposed to TSE agents in ruminant feed. When a ruminant is fed protein derived from mammalian tissues, TSE's may be transmitted. Therefore, FDA concludes that the use of protein derived from mammalian tissues in ruminant feed can no longer be considered GRAS.

(Comment 55). The draft rule that appeared in the **Federal Register** of April 17, 1997, revised § 589.2000(b) to eliminate unnecessary phrases that were included in proposed § 589.2000(b). These phrases were statements referring to FDA's determination that these proteins are nonGRAS, the absence of a regulation providing for safe use, and FDA's determination that these proteins are not prior sanctioned for use in ruminant feeds. A small number of comments questioned why the language was removed (because it did not alter the fact that proteins derived from

mammalian tissues for use in ruminant feed are food additives subject to section 409 of the act), and one comment asked FDA to restore the nonGRAS language.

FDA eliminated the text described above from § 589.2000(b) because the language was unnecessary. These revisions are solely editorial in nature and do not affect the substance of the agency's rulemaking or its determination that protein derived from mammalian tissues is not GRAS for use in ruminant feed and is not prior sanctioned for use in ruminant feeds.

b. *Alternatives to nonGRAS status and other legal comments.*

Several comments advocated alternatives to declaring proteins derived from ruminant tissues to be nonGRAS.

(Comment 56). Several comments suggested that FDA refrain from issuing the rule and instead issue a CPG. Some comments stated that a CPG could be used to determine that certain proteins are adulterants when added to ruminant feed and that use of a CPG would meet FDA's goal of increasing prevention of BSE. Some comments stated that a CPG would prevent the loss of GRAS status for the protein products and claimed that this loss will have serious ramifications, such as stigmatizing the protein products, as well as affecting the companies' ability to compete in the global market. One comment advocated the use of a CPG because it would allow the agency additional time to do a reasoned analysis of the scientific information before taking a final action. Some comments stated that use of a CPG would allow the agency to respond more quickly to scientific and technical changes than the use of notice and comment rulemaking.

FDA disagrees with these comments. Contrary to the arguments presented in the comments, FDA cannot use CPG's to impose any requirement. CPG's are guidance documents issued by the agency. These documents are not binding on the agency or any person. As the agency explained in its ''Good Guidance Practice'' document published in the **Federal Register** of February 27, 1997 (62 FR 8961), guidance documents ''represent the agency's current thinking on (a) subject'' and ''do not themselves establish legally enforceable rights or responsibilities and are not legally binding on the public or the agency.'' To issue a binding prohibition, the agency must follow an appropriate rulemaking procedure (see *Community Nutrition Institute* v. *Young*, 818 F.2d 943 (D.C. Cir. 1987)). Therefore, if the agency issues a CPG, it would not be binding and, as such, would be an ineffective means of banning the use of protein derived from certain tissues in ruminant feed. Furthermore, a CPG that states that certain proteins used in ruminant feed are adulterants under the act would require the agency, on a case-by-case basis, to bring enforcement actions for violations of section 402(a)(1) or section 402(a)(2)(C) of the act. Again, the agency does not believe this is an effective approach to preventing the establishment and amplification of BSE through feed. The agency believes it has made a reasoned analysis of the scientific information available and based on this analysis, the agency is taking the approach set out in this final rule.

(Comment 57). Several comments urged FDA to use an interim food additive regulation rather than declare certain proteins for use in ruminant feed are not GRAS. These comments explained that an interim food additive regulation would prevent their products from being stigmatized by a not GRAS determination. These comments also explained that the interim food additive regulation would keep the administrative record open to new evidence, permit FDA and the industry to react to new research findings, and permit FDA to require the industry to conduct planned research. Some comments cited the regulations in part 180 (21 CFR part 180) and the interim selenium rule as precedent for FDA issuing an interim food additive regulation.

FDA disagrees with these comments. The regulations in part 180, issued under section 409 of the act, apply to ''substances having a history of use in food for human consumption or in food contact surfaces'' (see § 180.1(a)). The definition of ''food'' for the subchapter (which includes part 180) includes ''human food, substances migrating to food from food-contact articles, pet food, and animal feed'' (see 21 CFR 170.3(m)). The language of § 180.1, however, only refers to human food and substances migrating to food from food contact surfaces. The limiting language in § 180.1 makes it clear that it does not apply to pet food or animal feed. The agency recognizes that § 570.38(c)(2) (21 CFR 570.38(e)(2)), applicable to animal feeds, provides that an interim food additive regulation may be issued. This provision was carried over when the rules at part 121 (21 CFR part 121 (1976)), which addressed both human food and animal feed additives, were reorganized to separate the human food and animal feed provisions. Section 121.41 of FDA's regulations, which included the reference to interim food additive regulations, was republished as § 570.38. The provisions governing promulgation of interim food additive regulations at § 121.4000 (now § 180.1) were not republished in part 570 (21 CFR part 570) governing animal feed (41 FR 38618, September 10, 1976). A decision to extend the use of interim food additive regulations to animal feeds and the creation of a procedure for doing so would likely require rulemaking under the Administrative Procedure Act (5 U.S.C. 501 *et seq.*)

Furthermore, even if this procedure were available to the agency here, it would not prevent the stigma that the comments state is created by the agency's determination that protein derived from certain tissues for use in ruminant feed is not GRAS since the same determination must be made to issue an interim food additive regulation (see, e.g., 61 FR 7990 March 1, 1996) (interim food additive for mannitol). Any determination by the agency that a substance is a food additive is also a determination that the substance is not GRAS. This is true regardless of whether the agency takes an action as in this final rule or the agency issues an interim food additive regulation.

With regard to the interim rule on selenium cited by some comments as an interim food additive regulation, the agency disagrees that the interim rule on selenium is an interim food additive regulation like those for human food issued under part 180. The selenium regulation at 21 CFR 573.920 was initially based on an approved food additive petition submitted under section 409 of the act. The interim final rule on selenium that appeared in the **Federal Register** of October 17, 1995 (60 FR 53702) was issued as an interim rule under the Administrative Procedure Act (5 U.S.C. 501 *et seq.*), not as an interim food additive regulation under section 409 of the act. The interim selenium rule implements Pub. L. 103–354 regarding the allowable levels of selenium in certain animal feeds. The rule is designated as an interim rule because it was issued under an exception in the Administrative Procedure Act (5 U.S.C. 553(b)(B)). This exception allows a final rule to be issued without prior notice and public comment if use of the procedures is impracticable, unnecessary, or contrary to the public interest. As stated in the preamble to the selenium rule, the agency determined that prior notice and public comment was unnecessary because the rule merely repeated the terms of Pub. L. 103–354 (see 60 FR 53702 and 53703). As stated above, an interim food additive regulation would be issued under section 409 of the act. Therefore, the interim selenium rule is

not precedent for the agency to issue an interim food additive regulation in this case.

(Comment 58). One comment stated that, instead of publishing a regulation under part 589 (21 CFR part 589) which lists substances prohibited in animal feed, the agency should do a GRAS listing with restrictions similar to the action taken in the propylene glycol rule that was published in the **Federal Register** of May 10, 1995 (60 FR 24808). The comment asserted that the GRAS listing (which is referred to as a ''GRAS affirmation'') would reduce the possible taint from listing the protein in part 589 as a prohibited substance. The comment explained that the GRAS listing could limit the animal feed that could contain the protein as it is listed in the proposed rule and include an exemption for use of approved deactivation and detection methods. The comment stated that the preamble to the rule should state the agency's view that all uses excepted from GRAS status must be subject to a food additive provision.

FDA does not agree with this comment. The action on propylene glycol that the comment cites was a proposed rule that would exclude from GRAS status propylene glycol used in or on cat food. The final rule was published in the **Federal Register** of May 2, 1996 (61 FR 19542). The proposed rule cited by the comment, as well as the final rule, included two provisions. One provision amended § 582.1666 (21 CFR 582.1666), which sets out the GRAS status of propylene glycol, to except its use in cat food. The second provision was a new § 589.1001 which lists propylene glycol in or on cat food as a substance prohibited from use in animal food or feed. In this case, no regulation exists that sets out a FDA determination of GRAS for protein derived from certain tissues for use in animal feed. Therefore, there is no GRAS regulation to amend as in the case with propylene glycol. Furthermore, this final rule, like the propylene glycol regulation, will list the substances as prohibited from use in animal feed in part 589.

The current regulations at §§ 570.30 and 570.35 (21 CFR 570.30 and 570.35) describe the information necessary to determine a substance as GRAS or to affirm GRAS status. The comment did not include or cite any information that would provide a basis for the agency to determine that the other feed uses of protein derived from certain tissues is GRAS or to affirm it as GRAS. FDA notes, however, that the act does not preclude manufacturers from making their own decisions on the GRAS status of uses not covered by this final rule. If FDA disagrees with this self-determination, FDA may take action, as it has done in this final rule or by enforcement action, to end that self-determined GRAS status (see FDA's proposed rule, Substances Generally Recognized as Safe, published on April 17, 1997 (62 FR 18938), for proposed revisions to the GRAS affirmation process.

(Comment 59). Several comments suggested that FDA adopt a ''temporary ban'' or a ''temporary moratorium'' to suspend the use of the ruminant protein in ruminant feed. The comments claimed that such temporary measures, unlike a formal rule, would be quickly modified or rescinded based on new information. The comments also stated that FDA should consider other alternative, yet effective, approaches and that FDA has the ability to use other available regulatory options.

The agency declines to adopt the comments' suggestions. The comments did not indicate what legal authority FDA should use or how ''temporary'' a ban or moratorium should be. While the agency has several authorities related to the regulation of animal feed, they are not applicable or would not be the most effective means of accomplishing the rule's goals. The agency believes that the approach used in this final rule is the most effective approach to accomplish the agency's objective of preventing the establishment and amplification of BSE in the United States through feed.

As stated in a response to an earlier comment, the agency could bring adulteration charges under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)) or section 402(a)(2)(C) on a case-by-case basis. The agency does not believe this is a viable, efficient solution to preventing BSE because it would require FDA to prove, on a case-by-case basis, that mammalian protein is not GRAS when intended for use in ruminant feed. In addition, the burden of proof would be on the agency in such enforcement actions.

Under section 404 of the act (21 U.S.C. 344), the agency may issue regulations providing for the issuance of permits governing the manufacture, processing, or packaging of any class of food which the agency has found may be injurious to health due to contamination with micro-organism during such manufacture, processing, or packing. However, in this case, the agency may be unable to determine adequately whether a food may be injurious after the food has entered interstate commerce. The lack of information required to establish necessary conditions, coupled with the fact that the incubation period for BSE may range from 2 to 8 years, effectively precludes use of section 404 of the act.

Section 406 of the act (21 U.S.C. 346) authorizes the agency to set tolerances for food additives that are required for the production of a food or cannot be avoided by good manufacturing practice. However, in this case, section 406 of the act is inapplicable because protein derived from certain tissues is not required to produce ruminant feed nor is the protein an unavoidable contaminant. Even if section 406 of the act were applicable, FDA does not have sufficient information to set a tolerance because the quantity of the BSE agent necessary to product infection is currently unknown.

Finally, the agency has the authority to make and enforce regulations to prevent the spread of communicable diseases under section 361 of the Public Health Service Act (42 U.S.C. 264). This authority is available to the agency to address issues related to TSE's. FDA, however, has determined that, at this time, use of its authority under the food additive provisions of the act is appropriate.

(Comment 60). Comments from several individuals and organizations strongly opposed the agency's proposal to declare certain animal-derived feedstuffs as nonGRAS. As an alternative, the comments suggested that adequate methods could be instituted which would reduce to an acceptable level the risk that these feeds could transmit TSE's to ruminants. Such methods included, *inter alia,* eliminating high risk sources of raw materials (e.g., downer animals, specified ovine tissues) from processing into feedstuffs intended for ruminant rations, processing (rendering) conditions specifically designed to reduce the infectivity of the raw materials if TSE agents were present in such materials, and adequate clean-out, transport, and storage practices which would minimize the risk from carryover or contamination of feeds or feedstuffs with potentially infective materials.

Many comments, including some from the industries directly affected by this rule, suggested that the agency issue regulations to require risk reduction processes. These comments suggested that regulatory oversight would be facilitated through GMP's, HACCP programs, or similar instruments, and commercial firms determined by the agency to be in compliance with such regulations would be permitted to label feedstuffs produced under those conditions as ''Certified Ruminant Derived Protein.'' Feed bearing such labeling would be permitted for use in

all animal feed, including ruminant feed. One comment even provided a detailed example of an HACCP program applicable to rendering facilities, including a quantitative risk analysis specifying the reduction in BSE infectivity at each critical control point. A comment from the rendering trade association provided a detailed generic HACCP plan which could be adapted by individual rendering establishments to their specific operation. This comment also contained proposed codified language for implementing HACCP. Several other comments provided examples of practices intended to prevent high risk animals from entering rendering channels.

In the preamble to the proposed rule, the agency agreed that the need for mandatory HACCP, supported by GMP's for animal-derived proteins, could be considered in future rulemaking (62 FR 552 at 567). The agency continues to encourage the voluntary adoption of HACCP on a plant-by-plant basis in both the rendering and feed industries. To the extent that HACCP is adopted, FDA will be able to examine whether safe conditions of use for some or all of the prohibited protein in ruminant feed, using an HACCP plan, can be established under a food additive regulation or whether such uses using an HACCP plan are GRAS. However, a regulatory action to make HACCP mandatory for all manufacturers in these industries is outside the scope of this final rule.

The agency agrees, in concept, that procedures which inactivate TSE agents in feedstuffs or methods that detect the presence of TSE agents in feedstuffs could form the basis for determining whether HACCP, GMP, or similar process validation programs were sufficient to ensure that TSE's could not be transmitted to ruminants through consumption of feedstuffs produced under those programs. Additionally, under the final rule, renderers are exempt from labeling and certain recordkeeping requirements under this rule if they use routinely a test method that FDA has validated to detect the presence of the agent that causes TSE's and whose design has been made available to the public; or use exclusively a method for controlling the manufacturing process that minimizes the risk of the TSE entering the product and whose design has been made available to the public and validated by FDA.

Presently, the agency has not validated any methods to detect the TSE agent or any methods for controlling the manufacturing process that would minimize the risk of the TSE agent entering the product. Although some comments argued that rendering systems used widely in the United States have been shown by European researchers to inactivate BSE under specific parameters, such that products produced using these rendering systems should be exempted from the rule, it should be noted that mammalian meat and bone meal produced under the European system is not permitted to be fed to ruminants in the European Union (Ref. 11).

The agency believes that the information provided is insufficient to validate specific rendering processes. Although these rendering processes appear to reduce the infectivity of materials in the mouse model, the infective dose of a TSE agent remains unknown. The assay method used to measure reduction of infectivity has been questioned as to whether it is the appropriate assay for determining the infectivity of tissues under natural conditions. When the mouse bioassay has been used, there remain questions whether the test materials (tissues from BSE-infected cattle) contained sufficient titres of the TSE agent to ensure that materials produced under these rendering systems will not transmit TSE's to ruminants (see comment 41 of this document and the agency response). When sufficient data are available for the agency to validate a process for inactivating TSE agents in processed feedstuffs, a method for controlling the manufacturing process, or a test for detecting the TSE agent in feed, FDA will be able to examine whether safe conditions of use for mammalian protein in ruminant feed, using such validated processes or tests, can be established under a food additive regulation or whether such uses using the validated process or test are GRAS.

3. Section 589.2000(c)—Requirements for Renderers That Are Not Included in Paragraph (e) of This Section

Proposed § 589.2000(c) would set forth the requirements for most renderers. Proposed § 589.2000(c)(1)(i) would require renderers whose products contain or may contain protein derived from ruminant and mink tissues and intended for use in animal feed to label the materials as follows: Contains (or may contain) protein derived from ruminant and mink tissues. Do not feed to ruminant animals, and do not use to manufacture feed intended for ruminant animals. Proposed § 589.2000(c)(1)(ii) would require renderers to maintain copies of sales invoices and to make them available to FDA for inspection and copying. Proposed § 589.2000(c)(2) would exempt renderers from the labeling and recordkeeping requirements if they use exclusively a manufacturing method that FDA has validated to deactivate the TSE agent and make that method available to the public or routinely use a test method, also validated by FDA, for detecting the TSE agent, under proposed § 589.2000(c)(2)(ii), would be labeled ''Not for Use in Animal Feed,'' and records of test results would be made available for FDA inspection. Proposed § 589.2000(c)(3) would exempt renderers from recordkeeping requirements if they use a permanent method, approved by FDA, to mark the presence of protein derived from ruminant and mink tissues. If the marking method could not be seen on visual inspection, the proposed rule would require the method to be validated by FDA and made available to the public.

a. *Cautionary statement.*

Several comments addressed the statement in proposed § 589.2000(c)(1)(i).

(Comment 61). Several comments requested that FDA revise the rule to make the labeling statement simpler and more concise. Many suggested that the statement simply say, ''Do Not Feed to Ruminants.''

FDA agrees and has revised the cautionary statement in § 589.2000(c)(1)(i) to read, ''Do not feed to cattle or other ruminants.'' This statement has the advantages of being simple and concise, and it refers to cattle as an example of a ruminant animal.

(Comment 62). In contrast, some comments asked FDA to revise § 589.2000(c)(1)(i) by placing the word ''warning'' or ''caution'' in the heading; requiring the use of bold type; referring to FDA regulations or some other statement to indicate a legal prohibition; and specifying the type, size, color or location of the label to ensure it is noticeable.

The agency agrees in part and disagrees in part with the comments. Section 403(f) of the act (21 U.S.C. 343(f)) requires that any word, statement, or other information required to appear on food labels or labeling to be ''prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.'' Here, the essential point of the cautionary statement is that the product should not be fed to cattle and other ruminants; thus, citing FDA regulations to indicate

a legal prohibition would provide little useful information to the vast majority of consumers and would be contrary to keeping the statement simple and concise.

The agency does agree that the cautionary statement should be noticeable. The statement should appear on product labels (such as those attached to or are part of a bag or other container) and other labeling for the product. For bulk products, the statement should appear on the placard and invoice that accompany the shipment and on any other labeling for the product. The agency does not have a regulation that provides additional direction, beyond the statutory language quoted above, regarding the prominence of the cautionary statement and does not believe it is necessary to do so in this final rule. However, the agency suggests that the statement be distinguished by different type size or color or other means of highlighting the statement so that it is easily noticed by a purchaser. Additional information on animal food labeling may be found at part 501 (21 CFR part 501).

(Comment 63). One comment indicated a need for clear end user labeling of any and all human foods containing the specified offal (eye, spinal column, tonsil, thymus, spleen, and intestine) and/or mechanically recovered meat.

The USDA is responsible for labeling most meat products destined for human consumption as food. Thus, the comment's suggestion is outside the scope of this rule.

b. *Records.*

Proposed § 589.2000(c)(1)(ii) would require renderers to maintain copies of sales invoices and to make copies available for inspection and copying by FDA. The preamble to the proposed rule indicated that such records are a usual and customary part of normal business activities (see 62 FR 552 at 570 and 579) and that FDA would use such records to verify compliance with the rule.

(Comment 64). FDA received several comments concerning records. Several comments supported the use of such records for compliance purposes. However, a few comments suggested that sales invoices may not always accompany products, that persons may not retain sales invoices or records, or that sales invoices may not contain sufficient information for enforcing the regulation.

In considering these comments, the agency reviewed several Establishment Inspection Reports (EIR's) and supporting material that had been collected as part of routine inspections or surveys of feed ingredient manufacturers and feedmills. The supporting material for the EIR's confirmed that some invoices contained detailed information (regarding the items being sold and the identities of the seller and purchaser) while others contained only a vague description of the product and the name (without any address) of the company or person receiving the product. Given the diversity in the sales invoices, and the concerns expressed in some comments, FDA revised § 589.2000(c)(1)(ii) to require renderers to maintain records sufficient to track the materials throughout their receipt, processing, and distribution (rather than refer to sales invoices only), and to make the copies available for inspection and copying by FDA. The final rule enables renderers (and other parties that must comply with the record requirement in § 589.2000(c)(1)(ii)) to use sales invoices or other records or a combination of such information so long as they provide sufficient information to enable FDA to determine the receipt, processing, and distribution of materials.

The recordkeeping requirement can be satisfied by an invoice or other similar document reflecting receipt or purchase, and sale or delivery of the product by the renderer. The information normally expected to be included in these documents includes: (1) Date of the receipt or purchase, or sale or delivery; (2) seller's name and address; (3) consignee's name and address; (4) identification of the product; and (5) quantity. Regarding an identification of the product, FDA notes that invoices or similar sales documents may serve as labels for bulk rendered products.

The act generally requires that the label of a regulated product contain the product's customary or usual name. The common or usual names of rendered products typically are those included in the definitions published by AAFCO, such as ''meat and bone meal.'' Thus, the use of the common or usual name on the invoice or similar sales document will satisfy, in part, the ''records'' requirement in § 589.2000(c)(1)(ii) as well as the ''common or usual name'' requirement in the act. As discussed later in this document, the records must be made available for FDA inspection and copying. They should be kept so they are legible and readily retrievable.

c. *Exemptions for manufacturing and test methods.*

As stated earlier, proposed § 589.2000(c)(2)(i) would exempt renderers from the labeling and recordkeeping requirements if they use exclusively a manufacturing method for deactivating the TSE agent that has been validated by FDA and made available to the public. Proposed § 589.2000(c)(1)(ii) would exempt renderers from the label and recordkeeping requirements if they routinely use a test method, validated by FDA, for detecting the TSE agent and make that method available to the public. Products found to contain a TSE agent would be labeled ''Not for Use in Animal Feed,'' and records of test results would be made available for FDA inspection.

Several comments strongly supported this provision because it would provide flexibility to the industry or would make methods available to the public where they could be discussed and analyzed. Other comments suggested amendments or clarification.

(Comment 65). One comment concerning proposed § 589.2000(c)(2)(i) suggested that ruminant protein rendered by an FDA-validated procedure should be labeled as ''Contains inactivated bovine protein.''

FDA declines to revise the rule as suggested by the comment. The agency will make any necessary changes to the labeling requirements by rulemaking when it validates the first rendering process.

(Comment 66). One comment claimed that, in proposed § 589.2000(c)(2)(ii), the label statement for products found to contain the TSE agent did not go far enough. The comment stated that such products should be destroyed and positive tests reported to FDA.

FDA declines to revise the rule as suggested by the comment at this time. However, as explained below, FDA has revised the labeling requirement so that products that are found to have a TSE agent must be labeled ''Do not feed to cattle or other ruminants.'' Products intended for use in ruminant feed that are found to contain a TSE agent are violative under the act, and the agency has guidance documents pertaining to the disposition of violative products.

(Comment 67). Several comments raised issues related to the concept of acceptable risk. One comment stressed that a definition of ''acceptable risk'' was necessary in order to develop a regulatory program with a targeted end point. Other comments indicated that regulatory programs should be based on some acceptable level of risk reduction rather than defining a finite level of acceptable risk. One comment suggested that FDA establish working groups comprised of members from industry and consumer organizations to establish the necessary level of risk reduction. Several comments cautioned that establishing a zero level of risk could unnecessarily destroy certain industries

and adversely impact the environment through the disposal of dead animals and animal tissues by means other than rendering.

The agency determines the safety of substances intended to become a part of food by approval of a food additive petition or by general recognition of safety. In either case, it must be established that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. Reasonable certainty of no harm does not imply a zero level of risk (see 21 CFR 570.3(i)). Congress, when enacting the Food Additive Amendments of 1958, recognized that it is impossible to establish with complete certainty that any substance is absolutely safe for use.

For the agency to determine that protein derived from mammalian tissue would be safe for use in ruminant rations, it must be demonstrated by scientific procedures that there is a reasonable certainty that such feedstuffs could not transmit TSE's to ruminants. The agency has determined that there is insufficient research on TSE diseases to determine a minimum infective dose of the TSE agents in ruminant rations, dose and age-related susceptibility factors, methods for inactivation of the TSE agents, or methods for reliably detecting the TSE agent in animal feeds. Such information is fundamental to the establishment of any safe use of protein derived from mammalian tissue in ruminant feed, and, under FDA's current statutory and regulatory requirements, questions regarding the safe use of the tissues are to be answered and presented to the agency in a food additive petition submitted under section 409 of the act. Alternatively, consistent with section 201(s) of the act (21 U.S.C. 321(s)) and § 570.30, the agency may be able to determine that the tissues are generally recognized as safe based on scientific procedure. The provisions of § 589.2000(c)(2)(i), (c)(2)(ii), and (c)(2)(iii) of this final rule provide that products containing protein derived from mammalian tissues are exempt from the labeling and recordkeeping requirements if a method for inactivation of the TSE agents is presented to and validated by the agency, a test method to detect the presence of the agent that causes TSE's is presented to and validated by the agency, or if validated methods for controlling the manufacturing process that minimizes the risk of the TSE entering the product are presented to and validated by the agency. These developments and their validation by FDA should provide relevant information on the establishment of safe conditions of use for protein derived from mammalian tissues.

(Comment 68). Proposed § 589.2000(c)(2)(ii) would require, in part, products that are found, through the use of validated test method to detect the presence of a TSE agent, to be labeled, ''Not for Use in Animal Feed.''

Upon further reflection, FDA realized that the proposed labeling in § 589.2000(c)(2)(ii) was not consistent with the agency's objective to prevent the establishment and amplification of BSE in the United States through ruminant feed. Because products found to contain the TSE agent are high risk FDA has revised the regulation to provide that for renders using validated test methods, such renders must continue to comply with the labeling and recordkeeping requirements in § 589.2000(c)(1) for products that test positive for the TSE agents.

(Comment 69). FDA, on its own initiative, has created a new § 589.2000(c)(2)(iii) to provide an exemption from the rule's labeling and recordkeeping requirements if a renderer uses exclusively a validated method for controlling the manufacturing process that minimizes the risk of the TSE entering the product. Under § 589.2000(c)(2)(iii), the method must be made available to the public and validated by the agency. The agency added this provision to complement § 589.2000 (c)(2)(i) and (c)(2)(ii) and because an exemption from the labeling and recordkeeping requirements would be appropriate if such a method were developed, validated, and used.

d. *Exemptions for marking methods.*

Proposed § 589.2000(c)(3) would exempt renderers from the recordkeeping requirement if they use a permanent method, approved by FDA, to mark the presence of protein derived from ruminant and mink tissues.

(Comment 70). FDA received very few comments on this provision. Two comments supported the provision, although one comment conceded that it was unaware of any permanent marking methods. Another comment suggested that, for used cellulosic food casings, the casings themselves act as a marker for ruminant proteins inside the casing.

As stated elsewhere in this document, FDA has revised the definition of ''protein derived from mammalian tissues'' to exclude used cellulosic food casings. As a result, it is unnecessary to consider whether used cellulosic food casings are a permanent method of marking.

FDA has made minor changes to this provision. The final rule omits the reference to renderers ''who are not exempted under paragraph (c)(2)(i) or paragraph (c)(2)(ii) of this section.'' FDA deleted this language because it is unnecessary. A second minor change consists of revising the phrase ''to mark the presence of the materials'' to ''to make a mark indicating the presence of the materials.'' This change reflects the fact that the presence of a material cannot be marked, but that the product can be marked to show that it contains or may contain protein derived from mammalian tissues.

4. Section 589.2000(d)—Requirements for Protein Blenders, Feed Manufacturers, and Distributors That Are Not Included in Paragraph (e) of This Section

Proposed § 589.2000(d)(1) would require protein blenders and feed manufacturers and distributors to comply with labeling and recordkeeping requirements. Proposed § 589.2000(d)(2) would provide exemptions if a protein blender or feed manufacturer and distributor purchased animal protein products from renderers that certified compliance with the requirements for deactivating or detecting the TSE agent or complied with such requirements itself. Proposed § 589.2000(d)(3) would exempt a protein blender or feed manufacturer and distributor from the recordkeeping requirement if it purchased animal protein products that had been marked or complied with the marking requirement itself. Proposed § 589.2000(d)(4) would require copies of the certified compliance statements to be made available to FDA for inspection and copying.

a. *Cautionary statement.*

Under proposed § 589.2000(d)(1)(i), protein blenders and feed manufacturers and distributors that manufacture, blend, process, and distribute products containing protein derived from ruminant and mink tissue would have to label the product to state, ''Contains (or may contain) protein derived from ruminant and mink tissues. Do not feed to ruminant animals, and do not use to manufacture feed intended for ruminant animals.''

(Comment 71). Several comments would exempt pet food from the rule's labeling requirement. One comment provided results from interviews of 350 pet owners in 5 cities. These interviews examined consumer reaction to the proposed rule's statement ''Contains (or may contain) protein derived from ruminant and mink tissues. Do not feed to ruminant animals, and do not use to manufacture feed intended for ruminant animals.'' Sixty-eight percent of pet owners said they would be concerned

about the safety of feeding any food to their pets with the proposed statement, and more than 71 percent said that they would buy some other pet food the first time they encountered the proposed statement on the label of the pet food they generally buy. Other comments argued that the statement was unnecessary on pet food because pet food is not used for ruminant feed (due to its smaller quantity and higher price when compared to ruminant feed). These comments did, however, suggest that the cautionary statement would be appropriate for pet food products that are salvaged or distressed and sold for possible use in animal feed.

Another comment, submitted in response to the draft codified provisions that appeared in the **Federal Register** of April 17, 1997, suggested that FDA also exempt feeds for nonruminant laboratory animals from the labeling requirement.

FDA agrees that the cautionary statement serves no useful purpose on pet food and feed for nonruminant laboratory animals and has amended the rule by creating a new § 589.2000(d)(4) to exclude pet food products that are sold or intended for sale at retail to non-food-producing animals and feeds for nonruminant laboratory animals. These products typically cost substantially more per ton than most complete feeds intended for food-producing animals. Therefore, there is little, if any, risk that pet foods or feeds for nonruminant laboratory animals will be purchased at full price for use in ruminant rations. However, if the pet food products are sold or are intended for sale as distressed or salvage items, then, under § 589.2000(d)(4), such products must state, ''Do not feed to cattle or other ruminants.''

In addressing the labeling requirement for salvaged or distressed pet food, the draft codified provisions that were published in the **Federal Register** of April 17, 1997, initially included the phrase ''for possible use'' in ruminant feed. FDA has deleted the phrase ''for possible use'' because it is unnecessary.

(Comment 72). One comment, responding to the draft rule that appeared in the **Federal Register** of April 17, 1997, sought clarification as to what ''pet food'' meant.

FDA interprets pet food as the food product fed to pet animals. A pet animal is any domesticated animal normally maintained in or near the household(s) of the owner(s) thereof. Examples include dogs, cats, rats, mice, hamsters, gerbils, rabbits, ferrets, nonhuman primates, canaries, psittacine birds, mynahs, finches, tropical fish, goldfish, snakes, and turtles. FDA does not consider horses or other equids to be pets because they are routinely slaughtered for human food. Furthermore, FDA believes that, since feed for horses can be readily utilized in ruminant rations and is often priced comparably to ruminant feed, horse feed must be labeled ''Do not feed to cattle or other ruminants.''

(Comment 73). Some comments suggested revising the rule to require feeds destined for use in nonruminant livestock to carry the cautionary statement. In contrast, other comments argued that the cautionary statement was unnecessary for nonruminant livestock feed.

FDA acknowledges the possibility that very little feed labeled for use in nonruminant livestock is diverted to ruminant rations and that which is diverted would likely have to be markedly diluted to be nutritionally balanced for maximum benefit by the ruminant. Nevertheless, FDA agrees that a cautionary statement should be required. Complete feeds for nonruminant livestock typically cost only slightly more per ton and often contain more protein than complete ruminant feeds. Therefore, because nonruminant livestock feed may be diverted to ruminant feed, the final rule requires the cautionary statement on all animal feed, including nonruminant livestock feeds (with the exception for pet food products).

(Comment 74). Other comments suggested that the agency revise the collective terms in § 501.110 (21 CFR 501.110) because, as a result of the final rule, some feed ingredients would be prohibited in ruminant rations.

The agency disagrees with the comments. At this time, no revision to § 501.110 is necessary because there will still be a collective name/term known as animal protein products and this collective name/term will include animal products, marine products, and milk products. The final rule merely prohibits animal protein products containing protein derived from mammalian tissues from being used in ruminant feeds. Because of the final rule, however, AAFCO may need to amend its definition of the collective term ''animal protein products'' to identify those feed ingredients that are prohibited from use in ruminant rations. FDA intends to work with AAFCO to accomplish this change. Although manufacturers of ruminant feeds that use this collective term may need to reformulate their rations to exclude the protein derived from mammalian tissue, the ingredients list on the label for any ruminant feed can continue to use the ''animal protein products'' collective term.

(Comment 75). Several comments suggested that a mammalian to ruminant ban would eliminate the need to change the AAFCO definitions.

Except for some current AAFCO ingredients listed under animal protein products in the collective terms section, FDA agrees with the comments. AAFCO definitions currently allow the species of origin to be listed in the name of the product (e.g., swine meat and bone meal). These AAFCO definitions are flexible enough to allow positive certification on invoices and convey adequate information to consumers who are concerned about the presence of mammalian proteins in their feeds.

b. *Records.*

Proposed § 589.2000(d)(1)(ii) would require protein blenders and feed manufacturers and distributors to maintain copies of invoices for purchases of animal protein products or feeds containing such products and to make those records available for inspection and copying by FDA.

(Comment 76). One comment stated that this proposal was redundant to the GMP recordkeeping requirements although, under the proposal, the retention period would be 1 year longer than those required under the GMP regulations.

FDA disagrees, in part, with the comment. The GMP recordkeeping requirement at § 225.202 (21 CFR 225.202) requires records to be maintained that identify ''the formulation, date of mixing, and if not for own use, date of shipment'' and that the records be ''adequate to facilitate the recall of specific batches of medicated feed that have been distributed. Yet § 225.202, and the regulations in part 225, (21 CFR part 225) generally, only apply to persons manufacturing, processing, packing, or holding medicated feed, and it is unlikely that all protein blenders, feed manufacturers and distributors subject to § 589.2000 will be manufacturing, processing, packing, or holding medicated feed. However, because most persons subject to § 589.2000(d)(1)(ii) may be subject to the GMP recordkeeping requirement for medicated feed and because § 225.202 only requires records to be kept for 1-year after the date of last distribution, the agency has evaluated the relative benefit of a 2-year recordkeeping requirement and concluded that a 1-year recordkeeping requirement is adequate. Thus, FDA has revised § 589.2000(h) to adopt a 1-year record retention period.

FDA advises protein blenders, feed manufacturers, and distributors that the recordkeeping requirement can be

satisfied by an invoice or other similar document reflecting receipt or purchase, and sale or delivery of the product. The information normally expected to be included in these documents includes: (1) Date of the receipt or purchase, or sale or delivery; (2) seller's name and address; (3) consignee's name and address; (4) identification of the product; and (5) quantity. Regarding an identification of the product, FDA notes that invoices or similar sales documents may serve as labels for bulk rendered products, including blended protein products and feeds. The act generally requires that the label of a regulated product contain the product's customary or usual name. The common or usual names of blended protein products and feed ingredients typically are those included in the AAFCO definitions, such as ''meat and bone meal.'' Thus, the use of the common or usual name on the invoice or similar sales document will satisfy, in part, the ''records'' requirement in § 589.2000(d)(1)(ii) as well as the ''common or usual name'' requirement in the act. As discussed later in this document, the records must be made available for FDA inspection and copying. They should be kept so they are legible and readily retrievable.

(Comment 77). One comment stated that the recordkeeping requirement, as applied to feed containing ruminant tissue, places an unnecessary burden on all manufacturers of nonruminant feeds and pet foods.

Because the final rule now prohibits the use of protein derived from mammalian tissues in ruminant feed, FDA has revised § 589.2000(d)(1) to state that protein blenders, feed manufacturers, and distributors that manufacture, blend, process, and distribute products that contain or may contain protein derived from mammalian tissues shall comply with the requirements in § 589.2000(c)(1). This means that the provision does not apply to protein blenders, feed manufacturers, and distributors who do not manufacture, blend, process or distribute products that contain or may contain proteins derived from mammalian tissues.

(Comment 78). A small number of comments would revise this provision of the proposed rule so that commercial contract guarantees could be used as evidence of compliance by feed manufacturers. These comments explained that feed manufacturers should be able to rely on a guarantee because FDA, itself, would rely on commercial records for enforcement purposes.

The agency declines to revise the rule as suggested by the comments. Section 303 (c)(2) and (c)(3) of the act (21 U.S.C. 333 (c)(2) and (c)(3)) and FDA regulations at 21 CFR 7.12 and 7.13 already establish the statutory and regulatory requirements for a guaranty. Thus, the change suggested by the comments is unnecessary (see response to comment 21).

c. *Exemptions for purchases from renderers certifying compliance.*

Proposed § 589.2000(d)(2)(i) would exempt protein blenders, feed manufacturers, and distributors from the requirements in § 589.2000 (d)(1)(i) and (d)(1)(ii) if they purchased animal protein products from renderers certifying that they used methods to deactivate or detect the presence of the TSE agent. Alternatively, under proposed § 589.2000(d)(2)(ii), a protein blender, feed manufacturer, or distributor could obtain the exemption if it complied with the requirements regarding methods to deactivate or detect the presence of the TSE agent.

(Comment 79). One comment stated that, insofar as methods for deactivating the BSE agent are concerned, FDA must examine the accuracy of the infectivity assessment and the sensitivity and reliability of the methods used and consider the relationship between the quantity of material tested and the total quantity in a particular batch. The comment stated that FDA must use or develop this expertise.

The agency agrees with the comment and intends to carefully examine, when a claimed method for inactivating a TSE agent is presented to FDA for validation, whether the method is effective. At this time, the agency is unaware of any such methods.

(Comment 80). One comment, submitted in response to the draft provision that appeared in the **Federal Register** of April 17, 1997, requested clarification of the type of certification required under § 589.2000 (d)(2) and (d)(3) if the qualifications for exemption identified in § 589.2000(c)(2) were met.

FDA has not validated any methods that would meet the requirements for any of the exemptions in this rule. If and when the agency does so, it will provide guidance as needed for the implementation of such exemptions, including certification under § 589.2000 (d)(2) and (d)(3).

d. *Exemptions for purchases of marked protein products.*

Proposed § 589.2000(d)(3) would exempt protein blenders, and feed manufacturers and distributors from recordkeeping requirements if they purchased animal protein products that had been marked to indicate the presence of animal protein derived from ruminant or mink tissues complied with the marking requirement itself.

(Comment 81). One comment would revise this provision to include products that are ''labeled'' as being in compliance. The comment contemplated a system whereby persons could certify that their products did not contain ruminant protein and complied with the rule.

The agency declines to revise the rule as suggested by the comment. The permanent mark described in § 589.2000(c)(3) serves as a visual cue or other detectable signal that protein derived from mammalian tissue may be present. Labeling is not equivalent to a permanent mark because it may be separated from the product.

e. *Copies of certifications.*

Proposed § 589.2000(d)(4) would require copies of the certifications described in § 589.2000 (d)(2) and (d)(3) to be made available for inspection and copying by FDA.

(Comment 82). FDA received no comments on this provision. However, because the agency has added a new paragraph (d)(4) to exempt pet food products and feeds for nonruminant laboratory animals from the labeling requirement, FDA has renumbered proposed paragraph (d)(4) as paragraph (d)(5).

5. Section 589.2000(e)—Requirements for Persons That Intend To Separate Mammalian From Nonmammalian Materials

Proposed § 589.2000(e) would require persons that intend to separate ruminant and mink materials from nonruminant material to comply with the labeling requirement for products derived from ruminant and mink tissues or feeds containing such products, would require renderers to obtain nonruminant (excluding mink) materials only from single-species facilities, and would require these persons to provide for measures to avoid commingling and cross-contamination. Additionally, the proposal would exempt renderers, blenders, and feed manufacturers and distributors from these requirements if they met certain exemption criteria.

a. *Cautionary statement.*

Proposed § 589.2000(e)(1)(i) would require persons who intend to separate ruminant/mink and nonruminant/mink materials to comply with the labeling requirement in § 589.2000 (c)(1) or (d)(1) for products derived from ruminant and mink tissues or feeds containing such products.

(Comment 83). One comment would revise this provision to add equine materials.

Because the final rule now pertains to protein derived from mammalian tissues, the agency has revised § 589.2000(e)(1)(i) so that the labeling requirement only applies to products containing protein derived from mammalian tissues or feeds containing such products. Additionally, FDA, on its own initiative, has made two revisions to this provision. The agency has deleted ''haulers'' from the § 589.2000(e)(1) because such persons are considered to be ''distributors'' as defined in § 589.2000(a)(6). The final rule also refers to ''products containing protein derived from mammalian tissues'' rather than ''products derived from mammalian (other than pure porcine)'' tissues as used in the codified (62 FR 18728), to be consistent with the definition of ''protein derived from mammalian tissues'' in § 589.2000(a)(1).

b. *Nonmammalian or pure porcine or equine materials only from single-species facilities.*

Proposed § 589.2000(e)(1)(ii) would require renderers who intend to separate ruminant/mink and nonruminant/mink materials to obtain nonruminant (excluding mink) materials only from single-species facilities.

(Comment 84). FDA received no comments on this provision. However, because the final rule now pertains to protein derived from mammalian tissues, the agency has revised § 589.2000(e)(1)(ii) so that the renderer must obtain nonmammalian or pure porcine or equine materials only from single-species slaughter facilities. The insertion of the word ''slaughter'' is intended to clarify the type of facility involved in this provision. Additionally, FDA interprets the term ''single-species slaughter facilities'' to mean dedicated slaughter facilities that only slaughter one type of animal; the term does not include facilities that slaughter different types of animals on different days or work shifts.

c. *Measures to avoid commingling and cross-contamination.*

Proposed § 589.2000(e)(1)(iii) would require persons that intend to separate ruminant/mink from nonruminant (excluding mink) materials to provide for measures to avoid commingling or cross-contamination. This could be achieved through separate equipment or facilities for the manufacture, processing, or blending of such materials or through ''clean-out procedures or other means adequate to prevent carry-over'' of ruminant and mink derived protein into animal protein products or feeds intended for use in ruminants.

(Comment 85). No comments focused on the concept of maintaining separate equipment or facilities for the manufacture, processing, or blending of materials (although one comment presumed that separate facilities and equipment could be costly). Nevertheless, FDA advises interested persons that it interprets this provision as extending to separate storage of such materials.

(Comment 86). Most comments on proposed § 589.2000(e)(1)(iii) addressed issues concerning ''adequate'' clean-out and carry-over. Oral comments from the public meetings and written comments to the proposed rule requested that FDA define what constitutes ''adequate'' clean-out. Comments from industry and consumer groups expressed concern that it would be difficult to verify if adequate clean-out procedures were used because there is no test that readily differentiates between ruminant and nonruminant protein. Other comments suggested that firms handling prohibited and nonprohibited products obtain prior approval from FDA, that FDA consider the clean-out provisions of GMP's currently used by the feed industry for medicated feeds to be ''adequate,'' that FDA require clean-out procedures only where raw-product is co-mingled (i.e., equipment is shared), and that the agency publish procedures for ''adequate'' clean-out and solicit public comment. Additionally, one comment noted that much rendering equipment is not designed to be readily opened, so washing the equipment is not a viable option, while a comment from the rendering industry detailed clean-out procedures for the various rendering systems. The procedures varied depending on the system used and the point at which materials shared the same processing steps or equipment.

FDA agrees that only equipment and storage facilities that are shared by proteins derived from mammalian and nonmammalian tissues are subject to the clean-out requirement.

With regard to the word ''adequate,'' the agency realizes that equipment utilized by the feed and rendering industries has certain limitations relating to cleanout. In the feed industry, the medicated feed GMP's for sequencing and cleanout have proved to be effective in preventing unsafe drug carry over into feed and thereby preventing unsafe tissue residues in foods of animal origin intended for human consumption. For renderers, blenders, feed manufacturers, and distributors (including haulers), FDA will consider the use of clean-out procedures described immediately below to be ''adequate'' for purposes of § 589.2000(e)(1)(iii)(B). The procedures for blenders, feed manufacturers, and distributors are based on the equipment clean-out procedures in § 225.65 (21 CFR 225.65). The procedures for renderers are based on comments from the rendering industry on the proposed rule, suggesting clean-out procedures for the four types of rendering systems currently used in the United States. FDA will consider renderers who can document that they are using the clean-out protocol applicable to their system to be using ''adequate'' clean-out procedures under § 589.2000(e)(1)(iii)(B). The clean-out procedures for renderers appear in section II.B.5.c.i of this document.

i. *Separating and processing options for renderers.*

These options are based on what should work in most actual operational conditions that renderers face day-to-day in their plants.

(1). *A single plant with two or more totally segregated processing lines. This includes all process functions from raw material receiving through and including finished product load-out*

BILLING CODE 4160–01–P

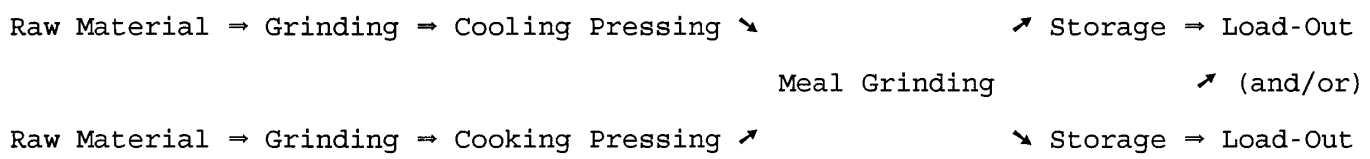
Raw Material ⇒ Grinding ⇒ Cooking ⇒ Pressing ⇒ Meal Grinding ⇒ Storage Load-Out

BILLING CODE 4160–01–C

Suggested Clean-out Procedures for Processing Option 1—No clean-out procedures are necessary for this processing situation, as the lines are completely separate. This type of plant should have the ability to process prohibited and nonprohibited products from the same plant so long as procedures are in place to assure total segregation. These procedures may be part of the plant's written procedures specifying the clean-out procedures utilized and would be available for inspection and subject to FDA review for compliance purposes.

(2). *Single plant with two or more segregated raw material receiving, grinding, cooking, and pressing lines but sharing finished product conveying, grinding, and load-out systems*

BILLING CODE 4160–01–P



BILLING CODE 4160–01–C

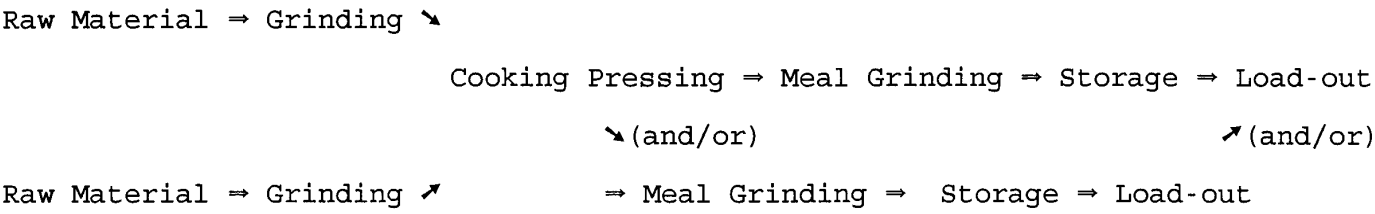
Suggested Clean-out Procedures for Processing Line Option 2—The clean-out and flushing guidelines for this type of plant deal specifically with the meal grinding (and screening), storage, and load-out systems. It is assumed that this type of plant would have separate storage facilities for prohibited versus nonprohibited product. It may have separate or common load-out facilities.

The first step in the clean-out and flushing procedure should be to empty all transport and process equipment from the first point of commonality of products to the final load-out device. The system should then be flushed with a sufficient volume of nonprohibited product to accomplish one complete change of operating volume of the entire system (exclusive of separate meal storage facilities). The flush material would be considered as prohibited meal and treated as such.

Once the system has been flushed, all subsequent material processed would be nonprohibited meal. Specific operating procedures would be documented and verified and would be part of the plant's written procedures specifying the clean-out procedures utilized and would be available for inspection and subject to FDA review for compliance purposes.

(3). *Single plant with separate raw material receiving and grinding, common cooking and pressing, common or separate finished product handling.*

BILLING CODE 4160–01–P



BILLING CODE 4160–01–C

Suggested Clean-out Procedures for Processing Option 3—The clean-out and flushing guidance for this type of plant deal specifically with the cooking and pressing systems. The meal grinding, storage, and load-out systems should be cleaned and flushed according to the guidance in processing option 2 above. It is also assumed that this type of plant would have separate storage facilities for prohibited versus nonprohibited finished meal. It may have separate or common load-out facilities.

The first step in the clean-out and flushing procedure should be to empty all transport and process equipment (including the cooker) from the first point of commonality of raw material to the meal grinding system. The system should then be flushed with sufficient prohibited raw material to accomplish the following changes of the operating volume of the cooker:

In the case of a continuous cooker with a bottom discharge (to provide positive cooker clean-out), raw material equal to at least one-half the operating volume of the cooker;

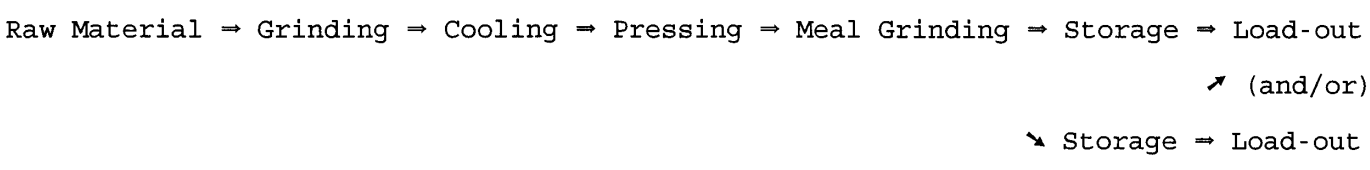
In the case of a continuous cooker without a bottom discharge, raw material equal to at least the operating volume of the cooker; or

In the case of a batch cooker system, raw material equal to at least one half the operating volume of the cooker for each batch cooker.

In general, the volume of material required to flush the cooking system should provide an adequate flush of the meal grinding, storage and load-out system, as well. The flush material should be considered prohibited product and treated as such. All subsequent material processed should be considered nonprohibited product. Specific operating procedures should be documented and verified, should be part of the plant's written procedures specifying the clean-out procedures utilized, and would be available for inspection and subject to FDA review for compliance purposes.

(4). *A single plant with one processing line. This includes all process functions from raw material receiving through and including product load-out.*

BILLING CODE 4160–01–P



BILLING CODE 4160–01–C

Suggested Clean-Out Procedures for Processing Option 4—The clean-out and flushing guidelines for this type of plant deal with the complete plant process. It is assumed that this type of plant would have adequate storage facilities to separate prohibited from nonprohibited finished product. It may have separate or common load-out facilities.

The first step in the clean-out and flushing procedure should be to empty all transport and process equipment including the raw material receiving hoppers, conveyors, grinders, and cooker from the first point of commonality of raw material through the load-out system. As a guideline, the volume of flushing material should be equal to the operating volume of the process and transport equipment, including the cookers.

The flush material should be considered prohibited product and

treated as such. All subsequent material processed would be considered nonprohibited product. Specific operating procedures should be documented and verified, be part of the plant's written procedures specifying the clean-out procedures utilized, and be available for inspection and subject to FDA review for compliance purposes.

(5). *Summary for clean-out procedures.*

Due to the degree of variability among rendering systems, HACCP would be helpful in implementing any of the above clean-out procedures and could enable differences to be addressed on a site-specific basis. Renderers could follow the above clean-out procedures by determining their plant's individual characteristics and apply appropriate time and volume requirements for flushing material to accomplish the intent of the procedures. Individual clean-out procedures, including time and volume calculations, should be part of the plant's written procedures specifying the clean-out procedures utilized and would be available for inspection and subject to FDA review for compliance purposes.

ii. *Separating and processing options for blenders, manufacturers, and distributors.*

FDA is providing the following practical guidance based on what should work in most actual operational conditions that blenders, feedmills, distributors, and haulers face day-to-day in their operations and for complying with § 589.2000(e)(1)(iii)(B). This guidance was adapted from the medicated feed GMP's in § 225.65. The medicated feed GMP's for clean-out were chosen as a model because they have proved to be effective in preventing unsafe drug carry-over into feed and thereby preventing tissue residue in products intended for human food. The medicated feed GMP's are not an entirely appropriate model for clean-out procedures for the rendering industry because of the difference in equipment and operating procedures. The agency will consider firms using the clean-out procedures at least as stringent as those detailed below to be of ''adequate'' as used in § 589.2000(e)(1)(iii)(B).

Adequate clean-out procedures for all equipment used in the manufacture and distribution of feeds containing mammalian and nonmammalian protein are essential to avoid unsafe contamination of ruminant feeds. Such procedures may consist of cleaning by physical means, e.g., vacuuming, sweeping, washing, etc. Alternatively, flushing or sequencing or other equally effective techniques may be used whereby the equipment is cleaned through use of a nonprohibited product. After cleaning, the non-prohibited product used in the cleaning should be handled and stored in an appropriate manner.

FDA suggests that all equipment, including that used for storage, processing, mixing, conveying, and distribution that comes in contact with feeds containing mammalian and nonmammalian protein, follow all reasonable and effective procedures to prevent contamination of manufactured feed. The steps used to prevent contamination of feeds often include one or more of the following, or other equally effective procedures: (1) Physical means (vacuuming, sweeping, or washing), flushing, and/or sequential production of feeds; (2) if flushing is utilized, FDA recommends that the flush material be properly identified, stored, and used in a manner to prevent contamination of other feeds. The volume of the flushed material should be sufficient to equal the operating volume of the shared equipment; (3) if sequential production is utilized, FDA recommends that it be on a predetermined basis designed to prevent unsafe contamination of ruminant feeds. An example of appropriate sequencing would be producing a swine feed containing mammalian protein, followed by a swine or poultry feed not using mammalian protein, followed by a ruminant feed containing nonmammalian protein.

Due to the degree of variability among feedmill systems, an HACCP-based approach of process controls would be helpful in implementing any of the above clean-out procedures. This will enable differences to be addressed on a site-specific basis. Feedmills could follow the clean-out procedures by determining their plant's individual characteristics and apply appropriate time and volume requirements for flushing material to accomplish the intent of the procedures. Individual clean-out procedures, including time and volume calculations, may be part of the plant's written procedures specifying the clean-out procedures utilized, and the written procedures are subject to FDA review for compliance purposes.

d. *Written procedures.*

Proposed § 589.2000(e)(1)(iv) would require persons to maintain written procedures specifying the clean-out procedures or other means for separating ruminant and mink materials from nonruminant (excluding mink) materials from the time of receipt until the time of shipment.

(Comment 87). One comment suggested that firms that intend to separate ruminant from nonruminant protein be required to notify FDA of their intent.

As applied to the final rule, such a notification requirement could result in a more efficient use of FDA enforcement resources. However, because it would impose an additional burden on the regulated industry, the agency has decided against imposing a notification requirement.

(Comment 88). FDA, on its own initiative, has revised § 589.2000(e)(1)(iv) to replace ''ruminant and mink materials from nonruminant (excluding mink) materials'' with ''mammalian (other than pure porcine or equine) materials from nonmammalian materials.'' This change was necessary because the final rule now prohibits the use of protein derived from mammalian tissues in ruminant feed.

FDA also advises persons subject to § 589.2000(e)(1)(iv) to draft their written procedures in sufficient detail to give an FDA investigator a general understanding of the procedures being used to satisfy the regulations. The written procedures should also enable the investigator to take the written procedures into the plant and easily identify operations and procedures stated in the written procedures. In other words, the written procedures should correspond to the facility's actual operations.

e. *Exemptions.*

Proposed § 589.2000(e)(2) would, under certain conditions, exempt renderers, blenders, feed manufacturers, and distributors that intend to separate ruminant/mink from nonruminant/mink materials from the requirements in § 589.2000(e)(1).

(Comment 89). One comment stated that an exemption should be available for facilities using validated separation and clean-out procedures.

The agency believes that the comment misinterprets § 589.2000(e)(2). If a person separates materials and uses clean-out procedures or other means adequate to prevent carry-over of protein derived from mammalian tissues, then that person is, in effect, complying with § 589.2000(e)(1). Thus, no revision to § 589.2000(e)(2) is necessary.

6. Section 589.2000(f)—Requirements for Establishments and Individuals That Are Responsible for Feeding Ruminant Animals

Proposed § 589.2000(f) would require establishments and individuals that are responsible for feeding ruminants to

maintain copies of purchase invoices and labeling for all feeds received and to make copies available for inspection and copying by FDA.

(Comment 90). One comment stated that it was neither practical nor necessary to require establishments and individuals responsible for feeding ruminant animals to maintain copies of purchase invoices and labeling for all feed received. The comment stated that the recordkeeping requirement should apply only to feed and feed ingredients containing animal protein.

FDA agrees with the comment and has revised the rule to clarify that the recordkeeping requirement applies only to feed and feed ingredients containing animal protein products. The recordkeeping requirement does not apply to other feed and feed ingredients such as roughage, feed grains, etc.

The agency recognizes that bulk shipments of feed are commonplace, and that labeling information typically is contained in the invoices for bulk shipments. In those instances, maintenance of the invoice is sufficient. If the only labeling for a bulk product is on a placard, the placard for each shipment should be retained. Feed may also be received in bags or other containers that have attached labeling. In those instances, the labeling should be removed and retained. However, maintenance of only one such labeling piece from each shipment that represents a different product is necessary. Finally, if the labeling cannot be removed from the bag or other container, maintenance of a representative bag or a transposed copy of the labeling information from a container that cannot feasibly be stored will suffice.

7. Section 589.2000(g)—Adulteration and Misbranding

Proposed § 589.2000(g) would declare that animal protein products and feeds containing such products that do not comply with the requirements in § 589.2000 (c) through (f) may be deemed adulterated under section 402 (a)(2)(C) or (a)(4) of the act. Products that do not comply with the labeling requirements would be misbranded under section 403(a)(1) of the act.

(Comment 91). FDA received no comments on this paragraph. However, the agency, on its own initiative, has revised § 589.2000(g) to include a reference to section 403(f) of the act. Section 403(f) of the act (21 U.S.C. 343(f)) considers a food to be misbranded if any word, statement, or other information required by the 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 conditions of purchase and use.'' Here, a reference to section 403(f) of the act is appropriate because the final rule contains a required cautionary statement.

8. Section 589.2000(h)—Inspection and Records Retention

Proposed § 589.2000(h)(1) would require records to be made available for inspection and copying and to be kept for at least 2 years. Under proposed § 589.2000(h)(2), written procedures required by § 589.2000 would have to be made available for FDA inspection and copying.

(Comment 92). A small number of comments would revise proposed § 589.2000(h)(1) to extend the time period. Some comments explained that TSE's have a long incubation period so, in the event of a TSE outbreak, the records may no longer exist. These comments suggested lengthening the amount of time records would be retained.

FDA declines to revise the rule as suggested by the comments. The rule is intended to help prevent the establishment and amplification of TSE's in ruminants through feed, and the records to be retained under the rule are to help FDA determine compliance with the rule. FDA acknowledges that TSE's may have long incubation periods exceeding 2 years, but, for purposes of determining whether a person is currently complying with the rule and for reasons expressed earlier in this document, the agency has revised § 589.2000(h)(1) to adopt a 1 year record retention period.

Additionally, extending the record retention period would have little practical value in determining the source of a TSE in an animal, considering the potentially long time period from ingestion of the TSE agent in feed to manifestation of clinical signs and lesions and the lack of a reliable estimate for the latency period.

FDA does suggest, however, that records be kept in a clean and orderly manner to facilitate prompt retrieval and be legible.

C. Comments on the Effective Date

(Comment 93). Two comments endorsed implementation of the final rule 60 days after date of publication in the **Federal Register**. However, one comment suggested that printed packaging materials, labels, and labeling on hand or under production contract be exempt from compliance with the implementation date. The other comment requested an exemption for the finished products on hand or in channels of distribution.

Another comment, submitted in response to the codified provisions (62 FR 18728), requested a 1-year effective date.

FDA does not believe that an effective date of 1 year after publication of this final rule is consistent with the agency's objectives. Therefore, the final rule is effective on August 4, 1997. With regard to printed packaging, labels, labeling, and finished products manufactured before the publication of the rule, such materials and products may continue to be used until those supplies are exhausted, but such period should not exceed October 3, 1997. The agency believes this is a reasonable period to exhaust existing supplies during the 60 days before the rule takes effect and within 60 days after the rule becomes effective.

D. Miscellaneous Comments

(Comment 94). One comment asserted that the absence of reported BSE cases in the United States can only support the assumption of BSE-free status with an acceptable level of uncertainty if there exists an effective epidemiological surveillance program, and an acceptable reduction in exposure of sensitive animals, based on supportable risk assessment studies, has been achieved. The comment further described an effective epidemiological surveillance system to include an information network among veterinary practitioners, breeders, and the government veterinary services. The comment would also require all suspect animals, including downer cattle, to undergo an histological diagnostic examination for TSE's.

There is no evidence to date to show that BSE exists in the United States. As stated in the preamble to the proposed rule, APHIS has a comprehensive surveillance program in the United States to ensure timely detection and swift response should BSE occur in the United States (see 62 FR 552 at 562 and 563). The APHIS surveillance program incorporates both the location of imports from the United Kingdom and targeted active and general surveillance for either BSE or any other TSE in cattle. APHIS has not found any evidence of BSE in any British cattle imported into the United States between January 1, 1981, and July 1989 (at which time the United States prohibited the importation of ruminants from countries affected with BSE).

In May 1990, a targeted active surveillance program for BSE began. BSE is a notifiable disease, and more

than 250 Federal and State regulatory veterinarians are specially trained to diagnose foreign animal diseases, including BSE. This surveillance effort, which involves APHIS, FSIS, and the Centers for Disease Control and Prevention, examines cases of cattle exhibiting signs of neurological disease, cattle condemned at slaughter for neurological reasons, neurological cases submitted to veterinary diagnostic laboratories and teaching hospitals, and a random sampling of cattle which are nonambulatory at slaughter. The targeted active surveillance program focuses on these animals because they are the highest risk population. As of March 31, 1997, 5,552 brains had been examined for BSE or another TSE in cattle, and no evidence of either condition has been found.

Additionally, the USDA has a general surveillance program that uses existing data sources, such as a database of diagnoses from 27 veterinary schools in the United States, CNS antemortem condemnation data from FSIS, necropsies performed at zoos on various species, and a veterinary diagnostic laboratory reporting system. Referrals of unusual cases by private practitioners to veterinary schools and diagnostic laboratories adds to this surveillance. Through these sources, there has been no reported incidence of a new neurologic disease in cattle and no increase in the number of neurologic diagnoses or referrals.

Based on these programs, there is no evidence to date to show that BSE exists in the United States. FDA's final rule adds to these programs by preventing the establishment and amplification of BSE in the United States through feed, thereby minimizing the health risk to animals and humans.

As for the comment that would require all suspect animals to undergo a histological diagnostic examination for TSE's, such examinations are conducted by the USDA and therefore are outside the scope of this rule.

(Comment 95). One comment objected to a sentence in the preamble to the proposed rule which stated that there is ''no immediate threat to the U.S. public health'' (62 FR 552 at 554). The comment argued that the sentence should say that there is no ''recognized'' immediate threat to public health and claimed that over 10,000 people would eventually die from nv-CJD.

FDA agrees that there is no recognized immediate threat of BSE or nv-CJD in the United States because neither BSE nor nv-CJD have been diagnosed in the United States. There is a very small probability that undiagnosed cases of BSE and/or nv-CJD might exist.

(Comment 96). One comment objected to a sentence in the preamble to the proposed rule which stated that ''The agency recognizes that processed ruminant byproducts have a long history of use in animal feeds without known adverse effects'' (62 FR 552 at 566). The comment interpreted this sentence as meaning that an animal fed a high-fat diet will have a body fat composition that is a reflection of the degree of saturation of the fats in the diet.

FDA does not dispute this dietary interpretation, but the agency's intent was to state that correctly processed and handled ruminant byproducts used in feeds have not previously been implicated as a vector for diseases in animals. BSE is the first instance in which the safe use of these processed products in ruminant feed has been questioned as a possible vector for disease.

(Comment 97). The same comment also questioned the role of overall food animal management practices (diet, housing, breeding, etc.) and the role these practices have in animal diseases.

FDA is unaware of any food management practices, other than the use of mammalian protein in ruminant feeds, that presents a risk of contributing to the establishment and amplification of BSE in the United States through feed. FDA is opposed to management practices that result in physical or nutritional harm to animals. A correctly formulated feed containing animal protein should be safe both from a nutritional and animal disease standpoint. BSE has prompted FDA to question the safety, from an animal disease perspective, of feeding mammalian protein products to ruminants, but has not led FDA to question the nutritional value of rendered ruminant products.

(Comment 98). One comment questioned whether the final rule applies to imported animal feeds and feed ingredients.

The act does not impose different requirements for imported animal feeds and feed ingredients intended for use in the United States. Such products are subject to the same statutory and regulatory requirements as domestically produced animal feeds and feed ingredients. Thus, under the final rule, protein derived from mammalian tissues is not generally recognized as safe for use in ruminant feed in the United States regardless of whether the feed is domestic or imported.

(Comment 99). Two comments referred to additional surveillance data which were available from other State and Federal sources but not used in the proposed rule. These comments stated that more complete data are available from accredited and certified State and Federal diagnostic laboratories to supplement surveillance and risk assessments, and the comments requested that FDA assemble, evaluate, and publish the data before issuing a final rule.

When FDA drafted the proposed rule, it used the most recent data available from the USDA. FDA is aware of the recent data which was published in 1997 (Ref. 12) but the data do not warrant a change to the rule.

Additionally, contrary to the comments' assertion, there are no State surveillance data.

(Comment 100). Several comments addressed issues related to surveillance activities. These comments called for: increased import restrictions, including the acceptance of imported products from only BSE-free countries that have active monitoring and surveillance programs and with similar controls on rendering practices; the testing of all downer cows or all animals exhibiting neurological disorders and of beef and dairy herds by using a bovine urine test; the eradication of all TSE's in food animals; examination of the brains of pigs and poultry for CNS disorders; a separate, significant epidemiological study to determine the incidence of TSE in downer cattle through a mandatory inspection program; a mandatory certification program for Suffolk sheep breeders, and for all infected flocks and for all flocks to which infected sheep have been traced back, for all breeds; a mandated scrapie and TSE eradication program with full producer indemnification; and monitoring, surveillance and education regarding all TSE diseases in animals, including veterinary and producer education programs, and the establishment of a national database of TSE monitoring with information from all state veterinarians. Another comment requested that the agency inform consumers of the risk associated with eating meat from animals fed animal byproducts. Several comments addressed the adequacy of United States surveillance efforts. An additional comment questioned the impact that the proposed rule will have on existing and potential animal disease control programs. Another comment suggested that farmers should be reimbursed for the ''pre-disease full market value'' for any BSE-infected cattle, which must be killed and carefully disposed of, to prevent farmers from hiding or selling BSE-infected cattle.

These animal disease monitoring matters are covered by laws which are

administered by the USDA, and are therefore outside the scope of this rule. FDA intends to work with the USDA to coordinate respective educational programs.

(Comment 101). One comment argued that the rule was unnecessary because, according to the comment, the heat used in rendering processes reaches 270 °F and therefore would kill infectious organisms.

FDA disagrees, in part, with the comment. While rendering does eliminate conventional infectious organisms such as bacteria and viruses, the TSE agent does not appear to be a conventional living organism. As noted in the preamble to the proposed rule, the TSE agent is resistant to various methods for inactivation, including high temperatures (see 62 FR 552 at 560). Research has shown that some rendering processes may reduce the amount of the TSE agent present, but may not eliminate it completely. FDA is also aware that not all rendering processes reach 270 °F; some reach lower temperatures.

(Comment 102). Two comments pertained to the risk to humans who consume mechanically deboned meat including meat obtained from Advanced Meat Recovery systems. The comments indicated that meat from such systems contains central nervous tissue in the form of the brain stem and spinal cord, thus exposing the public to tissues that potentially contain TSE agents. One comment stated that FDA should work with the FSIS to ensure that the animal population and the human population are protected by minimizing the possibility of BSE reaching the United States.

FDA does not have jurisdiction over mechanically deboned meat and, therefore, cannot address issues related to mechanically deboned meat in the final rule. Because the rule is intended to prevent the establishment and amplification of BSE within the United States through feed, cattle presented for slaughter should remain free of TSE agents, and any potential risk of transmitting TSE's to humans from consuming of mechanically deboned meat should be reduced substantially.

(Comment 103). One comment asserted that the comment period on the proposed rule was not adequate in light of the far reaching and complicated issues involved in this rulemaking. The comment stated that the agency should publish an interim final rule to give industry additional time to comment.

The agency does not agree with this comment. The agency believes it has provided a more than adequate comment period to address the issues presented in this rulemaking. Because of the complex issues involved in this rulemaking, in addition to the 45-day comment period for the proposed rule, the agency has provided four other opportunities for public comment. The advanced notice of proposed rulemaking that was published in the **Federal Register** on May 14, 1996 (61 FR 24253), provided a 30-day public comment period. In addition, the agency held two open forums to discuss the notice of proposed rulemaking (see 62 FR 3848, January 27, 1997). Finally, the agency made available a draft rule and provided a 10-day public comment period (see 62 FR 18728).

The Administrative Procedure Act (APA) requires only that an agency ''give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments * * *'' (5 U.S.C. 553(c)). This is all the APA requires; there is no statutory requirement concerning how many days an agency must allow, nor is there a requirement that an agency must extend the period at the request of an interested person (see *Phillips Petroleum Co.* v. *EPA*, 803 F.2d 545, 559 (10th Cir. 1986)).

FDA's own regulations generally afford the public 60 days to comment on a proposed rule, unless the Commissioner of Food and Drugs shortens or lengthens the period for good cause (21 CFR 10.40(b)(2)). Executive Order 12889 implementing the North American Free Trade Agreement prescribes a minimum comment period of 75 days on certain proposed rules, except when good cause is shown for a shorter comment period (see 58 FR 69681, December 30, 1993).

Here, the agency provided the public with 87 days to participate in this rulemaking including 85 days to provide written comments and 2 days to present views at the open public forums. The agency does not believe that any interested person has not been provided an adequate opportunity to participate in this rulemaking. The agency received over 600 comments on the advanced notice of proposed rulemaking, more than 700 comments on the notice of proposed rulemaking. In addition, the agency received oral views at the public forums and over 60 comments on the draft codified provisions that the agency made available pursuant to 21 CFR 10.40(f) and 10.80(d)(2). Given the number of comments the agency received on the proposed rule, at the public forums, and on the draft codified text, the agency does not agree that it should issue an interim final rule under the APA to give the regulated industry additional time to comment on the final rule.

(*Comment 104).* FDA, on its own initiative, has revised the ''authority'' citation for the rule to include section 403 of the act. Section 403 of the act applies to misbranded foods and is relevant to this rule because of the required cautionary statement.

III. Description of the Final Rule

As mentioned earlier, the final rule states that proteins derived from mammalian tissues are a food additive subject to section 409 of the act. Consistent with the definition of ''food additive'' in section 201(s) of the act, FDA's determination that protein derived from mammalian tissues for use in ruminant feed is a food additive also is a determination that this use is not GRAS. Section 589.2000(a)(1) defines ''protein derived from mammalian tissues'' as being any protein-containing portion of mammalian animals, excluding blood and blood products, gelatin, inspected meat products which have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings), milk products, and products whose mammalian protein consists entirely of porcine or equine products. In general, the exclusions represent tissues that the available data suggests do not transmit the TSE agent or were, at one time, inspected by the FSIS and found fit for human consumption and further heat processed for feed use or tissues from pigs and horses that are slaughtered in single species slaughter facilities.

Section 589.2000(a)(2) defines ''renderer,'' in part, as any firm or individual that processes slaughter byproducts, animals unfit for human consumption, or meat scraps.

Section 589.2000 (a)(3) and (a)(4) define the terms ''blender'' and ''feed manufacturer'' respectively. These definitions are essentially unchanged in the final rule.

Section 589.2000(a)(5) defines ''nonmammalian protein'' as including proteins from nonmammalian sources. This definition corresponds to the final rule's mammalian-to-ruminant prohibition.

Section 589.2000(a)(6) defines ''distributor.'' This term was initially part of § 589.2000(a)(4) but is now a separate definition to clarify that a distributor does not have to be a feed manufacturer and that persons who transport feed and feed ingredients intended for animals are distributors.

Section 589.2000(a)(7) defines ''ruminant'' to provide an

understanding as to what animals are ruminants.

Section 589.2000(b) declares that protein derived from mammalian tissues for use in ruminant feed is a food additive under section 409 of the act. While not stated in the rule itself, FDA's food additive determination is a determination that this use is not GRAS. The final rule states that use of such proteins in ruminant feed will cause the feed to be adulterated and in violation of the act unless it is the subject of an effective notice of claimed investigational exemption for a food additive.

Section 589.2000(c) describes the principal requirements for renderers. The provision differs from the proposed rule in two principal respects. First, § 589.2000(c)(1)(i) requires products that contain or may contain mammalian proteins to bear a label stating, ''Do not feed to cattle or other ruminants.'' This statement is more concise than the statement in the proposed rule and identifies cattle as ruminants. Second, § 589.2000(c)(1)(ii) requires renderers to maintain records sufficient to track the receipt, processing, and distribution of materials. This provision differs from the proposed rule by addressing the type of information FDA requires rather than referring to a specific type of record. The remaining paragraphs in § 589.2000(c) provide for exemptions from the labeling and recordkeeping requirements if the renderer uses a manufacturing method validated by FDA for deactivating or detecting the TSE agent or a process that minimizes the risk of the TSE agent entering the product or if the renderer uses a permanent method, approved by FDA, to mark the feed to indicate that it contains or may contain protein derived from mammalian tissue.

Section 589.2000(d) describes the principal requirements for protein blenders, feed manufacturers, and distributors. These persons are subject to the same labeling and recordkeeping requirements as renderers, except that, under § 589.2000(d)(4), pet food products that are sold or intended for sale at retail and feeds for nonruminant laboratory animals do not have to be labeled with the statement, ''Do not feed to cattle or other ruminants.'' Pet food products and feeds for nonruminant laboratory animals that are sold as distressed goods or salvaged are, however, subject to the labeling requirement. Section 589.2000(d) also provides exemptions if animal products are purchased from renderers that certified compliance with the requirements pertaining to methods for deactivating or detecting the TSE agent or if the protein blender, feed manufacturer, or distributor complies with such requirements itself. Another exemption exists if protein blenders, feed manufacturers, and distributors purchase animal protein products that are marked in accordance with the regulations or mark such products themselves.

Section 589.2000(e)(1) sets forth requirements for persons that intend to separate mammalian and nonmammalian materials. This requires compliance with the labeling and recordkeeping requirements, requires renderers that intend to separate these materials to obtain nonmammalian or pure porcine or equine materials only from single-species slaughter facilities, and requires persons to avoid commingling and cross-contamination with mammalian materials. The provision further requires persons to maintain written procedures specifying the clean-out procedures to prevent carry-over of mammalian protein into ruminant feed and the procedures for separating materials from the time of receipt to the time of shipment. Section 589.2000(e)(2) provides for persons to be exempt from applicable requirements in paragraph (e)(1) if they meet the exemption criteria in paragraph (c)(2), (c)(3), (d)(2), or (d)(3). Persons meeting the exemption criteria in paragraph (c)(3) or (d)(3) are exempt only from the recordkeeping requirements in paragraph (e)(1). Such persons must continue to comply with the labeling requirement in paragraph (e)(1).

Section 589.2000(f) contains recordkeeping requirements for establishments and individuals that feed ruminant animals. Under the final rule, these requirements would apply only for feed or feed ingredients containing animal protein products.

Section 589.2000(g) states that animal protein products and feeds containing such products that do not comply with the regulation will be deemed adulterated or misbranded under the act.

Section 589.2000(h) contains the inspection and record retention requirements. The record retention period is 1 year under the final rule.

IV. Environmental Impact

The ''Environmental Impact'' discussion in the preamble to the proposed rule summarized the agency's environmental assessment (EA) and its analysis of the 6 regulatory alternatives (see 62 FR 552 at 571). The agency considered each alternative under 2 different scenarios; under one scenario, BSE does not occur in the United States, and, under the other scenario, BSE does occur in the United States. The discussion described the range of environmental impacts for the alternatives, including environmental effects from on-farm disposal of animals and landfill use, and concluded that the proposed rule would not have a significant impact on the human environment.

FDA received several comments on its environmental analysis.

(Comment 105). One comment questioned the safety of burial as a method for disposal of TSE- infective animals and whether burial should be allowed as a method for disposal of dead stock (as discussed in the agency's EA).

There is no current disposal method for TSE-infected tissues shown to completely remove all infectivity. FDA recognizes that one report (Brown and Gajdusek, 1991) found that buried scrapie-infected tissue may still be infective after 3 years, although infectivity was reduced by 2 to 3 logs by this exposure.

Migration of prions from burial sites is expected to be minimal. Prions, as proteinaceous materials carrying electrostatic charges, are unlikely to move with water through soil media, but are apt to be adsorbed to clay particles. This is supported by the Brown and Gajdusek (1991) (Ref. 13) observation that ''no infectivity was detectable in the lower layer of soil 4–8 cm beneath the bottom of the dish.'' In other words, little leaching of the scrapie infective agent was found. This method of disposal, burial, is the method accepted by APHIS for disposing of scrapie infected sheep and goats in the United States.

Secondly, most on-farm dead stock die from causes other than TSE's, and FDA does not expect that cattle dead stock will include significant numbers of cattle that died from BSE. BSE has not been found in the United States, and this final rule puts into place procedures that will limit the spread of any cases that might occur undiagnosed in the ruminant population.

Third, States and localities regulate burial of animals, and, in areas where burial is inappropriate due, for example, to high water table or inappropriate soil type, these laws would prohibit burials. The final rule does not require burial of dead stock. Burial is merely an option to be considered where State and local authorities permit it.

Burial of dead stock has limitations in that it requires resources to dispose of dead stock as a waste rather than to produce useful products. However, at this time, there is no evidence that burial of animals that are susceptible to

TSE's, in accordance with existing State and local controls, is inherently more environmentally unsafe than incineration, composting, or rendering.

(Comment 106). Several comments requested that the agency prepare a formal environmental impact statement (EIS) under the National Environmental Policy Act in addition to the Finding of No Significant Impact and Environmental Assessment (FONSI/EA) that was prepared in support of the proposed action.

A primary difference between the EA prepared in this instance and an EIS is the administrative process that was followed. Both documents are objective analyses that focus on significant environmental issues associated with the proposed action and possible alternative actions. The EIS process, however, is a more formal process that includes issuance of a notice of intent describing the proposed action and possible alternatives, convening of optional public forums to identify (''scope'') environmental issues of concern to the public, preparation of a draft EIS that is filed with the Environmental Protection Agency and distributed to the public for comment, preparation of a final EIS describing how the comments were considered, and preparation of a concise public record of decision describing the weight that environmental effects were given in the decision making.

As part of the Advanced Notice of Proposed Rulemaking on May 14, 1996, FDA requested environmental information to assist the agency in determining the scope of issues to be addressed and the significance of environmental issues related to the full spectrum of possible actions being considered by the agency. FDA then solicited comments on the FONSI/EA as part of the proposed rule that appeared in the **Federal Register** on January 3, 1997. At the same time, FDA made the FONSI/EA available on the Center for Veterinary Medicine's (CVM's) ''Home Page,'' in addition to the traditional means of availability, in order to facilitate submission of additional information through comments to the docket established for the proposed rule. Furthermore, FDA held public meetings on February 4 and 13, 1997, where comments on the FONSI/EA were solicited, and placed transcripts from those meetings on the CVM Home Page, as well as in the docket, to facilitate commenting. The preamble to the proposed rule and this preamble to the final rule, like the record of decision prepared for an EIS, discuss how environmental issues were weighed in the decision.

Consistent with the National Environmental Policy Act and the Council on Environmental Quality's regulations, FDA discussed in its EA and FONSI the need for action, significant environmental issues, and alternative actions, and carefully listed the sources of information and methods used in preparing the EA. The agency took a hard look at the environmental consequences of its proposed action and the alternatives before deciding that an EIS was not required. FDA encouraged and facilitated public involvement, requesting information and soliciting public comment on all issues involved with this rulemaking, including environmental issues. Given the rigor of FDA's EA and the steps taken to involve the public and the limited benefits from a more searching evaluation, the time and expense of preparing an EIS are not commensurate with the likely benefits of preparing such a document (see *River Road Alliance* v. *Corps of Engineers*, 764 F.2d 445, 449 (7th Cir. 1985) (''The statutory concept of 'significant' impact has no determinate meaning, and to interpret it sensibly in particular cases requires a comparison that is also a prediction; whether the time and expense of preparing an environmental impact statement are commensurate with the likely benefits from a more searching evaluation than an [EA] provides.''), *cert. denied*, 475 U.S. 1055, (1986).

(Comment 107). Several comments made FDA aware of some potential environmental impacts that could be mitigated, and these mitigations were integrated, where consistent with other factors, in the final action. The final rule excludes certain items, such as blood and gelatin, from the definition of ''protein derived from mammalian tissues'' and these excluded materials may be used in ruminant feed as well as feed for other species. Thus, materials excluded from the final rule have a reduced potential to become wastes. Plate wastes, used cellulosic food casings, and pure porcine or equine products are all examples of materials that are allowed in cattle feed that would not have been allowed under the mammalian-to-ruminant ban described in the proposed rule which was broader than the mammalian to ruminant ban in this final rule. These materials should now be fully utilized instead of presenting potential environmental issues relating to disposal.

As a result of comments on the proposed rule, the final rule does not require a cautionary statement on labeling of pet foods at the retail level. Thus, there is no longer the potential for consumers to misinterpret the cautionary statement and incorrectly deduce from the labeling a safety problem for pets. In the absence of the potentially confusing cautionary statement on pet food at the retail level, it is now not expected that meat and bone meal would be dropped from pet food formulations. Consequently, the demand for meat and bone meal derived from ruminants should not be significantly decreased in the pet food industry.

Therefore, certain anticipated environmental issues will not be realized because of the changes to the action that appear in this final rule, compared to both the proposed rule and the mammalian-to-ruminant alternative originally described. These changes are the consequence of comments received on the proposed action.

(Comment 108). Comments from the rendering industry, in particular, desired a more quantified environmental analysis of the potential impacts of the actions covered in the EA. These comments were especially concerned about the amounts of dead stock that might no longer be rendered due to an anticipated decrease in the value of meat and bone meal derived from ruminants and, consequently, in the value of raw materials used to make the meat and bone meal.

Some quantities of dead stock were estimated in a report (the Sparks Report) presented in the comment from the National Renderers Association; however, other comments only spoke in generalities about the issue without providing information that could be used in the requested quantification.

The Sparks Report (Table III–1, p. 10) estimated that 1.1 billion pounds (lb) of dead cattle are collected from all sources and rendered each year. Presumably, dead sheep, goats, and deer are included in the 190 million (m) lb that are collected from ''Other'' species in the Sparks Report. It is not known with certainty whether these estimates represent a large percentage of all ruminant dead stock, as such information is not reported and was not submitted in comments despite requests from FDA. However, some rough calculations can be used to make an estimate. There are approximately 100 m cattle of all ages in the United States at any time. If the overall mortality rate on the farm (i.e., for reasons other than slaughter) is 5 percent per year, then this would result in 5 m dead cattle of all ages available for pick up by renderers each year. If the average weight for a dead cattle carcass (across all age groups) is 650 lb, then the total weight of dead cattle that could be potentially retrieved by renderers each

year is 3.25 billion lb. Based on this estimate, then renderers are currently retrieving about one-third (by weight) of the available dead cattle that could be rendered. This also indicates that about two-thirds of the available dead cattle are currently being disposed of by means other than rendering. If one assumed a mortality rate higher than 5 percent or a larger standing population of cattle, then renderers would be picking up a smaller proportion.

FDA did not receive any comments containing first hand information indicating that the current unretrieved dead stock are being disposed of in an unsafe manner, and the agency has no independent information to this effect. Methods that are available in some, but not all locations include burial, as discussed above, landfilling, and composting (often for animals smaller than 300 lb). In some locations (such as on range land), animals that die may be left exposed. A small number of farms may own or have access to an appropriately designed incinerator. State and local regulation affects the availability of disposal options. While rendering is a desirable option for disposal of dead stock, it is not the only acceptable option.

The comments provided no basis to estimate the final rule's effect on the retrieval of dead stock by renderers. The agency's economic analysis (which appears later in this document) accepts estimates that the value of meat and bone meal may decrease by $68 per ton. While this price is still profitable, it is possible that there may be some disruption in dead stock retrieval from small producers while the rendering industry adjusts to the new prices. For the sake of discussion, FDA assumes that the upper limit on this temporary decrease in dead stock retrieval could be 20 percent. Twenty percent of 1.1 billion lb is 220 m lb, or at an estimated 650 lb per carcass, about 340,000 fewer cattle picked up, against a background of 5 m dead cattle per year.

The estimated, temporary, 20 percent decrease from the current level of dead stock retrieval is probably an overestimate. First, the final rule takes steps different from the proposal to encourage the continued use of ruminant products in acceptable animal feed applications. For example, the final rule eliminates potentially confusing labeling in pet foods at retail. Second, protein supplements manufactured from dead stock are expected to remain in strong demand, especially from countries that remain BSE free and have taken precautionary steps to minimize the potential for its amplification through the food chain. (In other words, a strong market will exist because foreign buyers will be confident in the safety of rendered products from the United States.) Meat and bone meal today in the United States is worth more than before FDA published the advanced notice of proposed rulemaking in May 1996. Third, trends in feedlots and dairies in the United States have been towards larger facilities. Large facilities, because of the larger population of animals, generate the most dead stock. This centralized location is efficient for renderers to retrieve dead stock, as opposed to traveling a collection route among smaller farms. In many locations, owners of large feedlots and dairies are currently being paid by renderers for their dead stock. Even if the credit for dead stock were erased, large facilities would likely still find it convenient to use rendering as the disposal option for their dead stock. Fourth, cattle producers would still demand protein and mineral supplements derived from animal sources, for example blood meal, poultry meal, and pure porcine or equine meat and bone meal. Therefore, continued demand for animal protein products by ruminant producers will contribute to overall demand for animal protein products, including those affected by the final rule, for use in feed of all species of animals. Lastly, mammalian-derived protein affected by this rule is still expected to be profitable to produce and to sell. Adjustments by renderers to buy additional equipment and incorporate new procedures are expected to proceed rapidly during the delayed effective date for this rule.

For the reasons stated above, any decreases in dead stock retrieval from farms that occurs as a result of disruptions caused by this final rule should be short term and small in magnitude. Long term trends will continue to encourage use of dead stock as a feed ingredient raw material.

Outside of these types of estimations, quantifications of the environmental benefits and costs of any of the regulatory alternatives including ''No Action,'' are not feasible with the quality of information currently available. Much needed information, for example the dead stock issue above, appears to be unavailable. Other environmental benefits and costs rely on chains of events occurring where there is considerable uncertainty. These uncertainties are detailed in the EA, consistent with the guidance in 40 CFR 1502.22 of the Council on Environmental Quality's regulations.

FDA will continue to be receptive to information that could assist in a better quantification of impacts and will use such information in considering what amendments, if any, should be made to the final rule in the future. FDA has a continuing interest in this matter, as environmental costs of disposal alternatives for dead stock will be a major consideration in the event that BSE is ever found to be established in the U.S. cattle population. Remedial actions by FDA, alone and in concert with other agencies, at such a time will be considered separately for potential environmental impacts.

The potential long term and short term environmental effects of the final rule are qualitatively similar, perhaps intermediate in magnitude when compared with the proposed ruminant-to-ruminant ban and the alternative mammalian-to-ruminant ban described in the EA. These potential effects were compared at Table 1 of the EA, pages 63 and 64. Because the potential environmental impacts of the final rule are bracketed by these two alternative actions that were considered equally in the EA, because a hard look at the consequences of both alternatives led to a finding of no significant impact, and because additional information was not submitted or identified that would improve the quantification of the EA, FDA does not believe that it is necessary to further amend the EA apart from the clarifications to the analysis found in this Environmental Issues section of the preamble to the final rule.

(Comment 109). Several comments asserted that there would be large increases in the quantity of dead stock and offal requiring disposal and questioned the environmental safety of landfilling as a disposal method. One comment stated that landfilling of dead stock was not permitted in some areas. Another comment objected to the use of landfills for the disposal of offal or carcasses. No comment provided supporting details or other information on this issue.

Similar to the situation with burial of dead stock as a disposal method, landfilling is not available as a disposal method where State or local authorities do not permit it. This final rule, however, does not require disposal of dead stock or offal by landfilling, although it may be an option in some areas. Where landfilling is an option, there is no reason to suspect that this means of disposal is unsafe. FDA did not receive any comments from a State environmental office or local landfill or waste control authority on this issue or any related issue.

FDA expects that, to the extent that landfilling occurs due to a decrease in the retrieval of dead ruminant stock by renderers, the increased use of landfill

space for disposal of dead stock would be small and temporary. In any event, as discussed above, it is evident that the majority of dead ruminant stock is currently being disposed of by means other than retrieval by renderers and that such means includes landfilling.

As for offal, the agency does not anticipate that there will be any significant reduction in the collection of offal by renderers. Thus, there should be no significant increases in landfilled offal resulting from this rule. Hide and tallow provide significant economic incentive for continued collection and rendering of offal and carcasses whether or not the protein products have greater or lesser value.

(Comment 110). Some comments claimed that there will be adverse effects to the environment because of changes in disposal practices at small locker plants and grocers.

As markets adjust to the rule, FDA believes that there may be a temporary, small decrease in the pickup by renderers at small locker plants that process ruminants (i.e., there will be a corresponding small increase in material disposed of by composting, by on-site burial, by incineration and in local landfills). Additionally, because the rule should enhance the value of rendered ruminant products from the United States on the world market, FDA believes that most of the anticipated increase in disposal by means other than rendering at small locker plants will be temporary (see also discussion relating to retrieval of dead stock, above, for a discussion of additional factors that, in the long term should support the value of raw materials used to make animal protein feed ingredients).

FDA believes that fat trimmings and out-of-date meat are the major products picked up by renderers at most small grocers. Because fat, tallow, and grease are not affected by this rule and most out-of-date meat is collected with these materials at grocers, renderers will continue to pickup virtually all material from small grocers. Thus, FDA foresees minimal, if any, adverse environmental effects from this rule on small grocers.

(Comment 111). Other comments inquired as to the environmental effects when feeds containing ruminant proteins must be disposed because they cannot be sold. This would primarily involve feed formulated especially for ruminants.

This final rule becomes effective on August 4, 1997. Furthermore, as stated earlier in this document, FDA intends to permit persons to exhaust existing supplies of products that were manufactured before June 5, 1997, but this period should not exceed October 3, 1997. Thus, at this time, FDA foresees minimal, if any, disposal or reconditioning of feed required by this rule.

(Comment 112). Several comments raised concern that poultry, as consumers of ruminant-derived meat and bone meal, may excrete intact prions in chicken litter. This litter could later be spread on crops, causing an unexpected contamination of vegetables. Some comments also noted that chicken litter is sometimes recycled as a cattle feed and could therefore serve as a source of TSE for ruminants. The source of this concern appears to be a hypothesis offered by Clarence Gibbs in his testimony to the House of Representatives' Subcommittee on Human Resources and Intergovernmental Relations on January 29, 1997.

FDA has no evidence, other than Clarence Gibbs' statement, that would indicate that infective ruminant prions survive the chicken intestinal tract and/or the composting process. Such a hypothetical route of transmission would appear to be of more immediate importance in countries where BSE has been diagnosed.

To FDA's knowledge, none of the countries where BSE is present have reported the presence of prions in poultry litter. FDA is not aware of any epidemiologic evidence that associates BSE with the incorporation of poultry litter in cattle rations or on crop land. In Suffolk sheep with scrapie, there is no detectable infectivity in the feces (see Bulletin of the World Health Organization, 70(2):183–190 (1992)). This is the only report, to FDA's knowledge, of testing of TSE infectivity in feces of any species. FDA will continue to monitor scientific developments in this area for findings clarifying this issue.

(Comment 113). One comment, with little explanation, disagreed with the agency's environmental analysis and suggested that FDA consult the Environmental Protection Agency (EPA) ''to accurately assess the impact.''

Consistent with the National Environmental Policy Act and the Council on Environmental Quality's regulations, FDA maintains an interdisciplinary staff of scientists with broad expertise in EA methodology, animal disease and nutrition, the feed industry, and animal and agricultural waste management. FDA used this expertise in preparing the EA for this action. FDA is not required to involve EPA in the preparation of an EA.

Nonetheless, FDA has extensive, long-standing contact with EPA at scientific and managerial levels. The agencies cooperate in many areas where there is a common mission or complementary expertise. The development of the action described here began in the work leading up to the 1994 proposed rule on scrapie in sheep and goats. FDA coordinated its efforts with many groups in the USDA and the Centers for Disease Control and Prevention to obtain the best expertise available. FDA carefully considered whether EPA, by virtue of its expertise or mission, needed to be involved in developing the EA or other aspects of this action, and concluded that, because FDA already uses EPA's environmental risk assessment paradigm, EPA's involvement would not yield additional benefits to the analysis.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (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, and distributive impacts and equity). The Regulatory Flexibility Act requires agencies to examine the economic impact of a rule on small entities. The Unfunded Mandates Reform Act requires agencies to prepare an assessment of anticipated costs and benefits before enacting any rule that may result in an expenditure in any one year by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation).

FDA concludes that this final rule is consistent with the principles set forth in the Executive Order and in these two statutes. FDA's analysis, as presented in the remainder of this section, demonstrates that the final rule constitutes an economically significant rule, as described in Executive Order 12866. The agency has further determined that the final rule may have a significant economic impact on a substantial number of small entities. This analysis, therefore, along with the other relevant sections of this preamble and the two reports of FDA's economics contractor, the Eastern Research Group (ERG), constitute the agency's final regulatory flexibility analysis as required under the Regulatory Flexibility Act. Because this rule makes no mandates on government entities and will result in expenditures of less than $100,000,000 in any one year, FDA need

not prepare additional analyses pursuant to the Unfunded Mandates Reform Act.

FDA presented a summary of its preliminary economic analysis in the preamble to the proposed rule (62 FR 552 at 572). The summary discussed the potential benefits of the proposed rule and described an industry impact analysis conducted by FDA's contractor, ERG. In response, the agency received many comments, both oral and written, which addressed economic issues and concerns. Many industry comments criticized FDA's analysis for underestimating the burden that the rule would impose and for counting the economic gains as well as the costs in aggregating the net impacts of the rule. Only a few comments spoke to the estimates included in the benefits discussion. Although most industry comments presented little quantitative information, a report prepared by the Sparks Companies Inc. for the National Renderers Association, Inc., and the Animal Protein Producers Industry provided detailed industry data and alternative estimates of the regulatory burdens. FDA has examined and evaluated the reasoning and data presented in all these comments and has incorporated many of these elements into this revised analysis of the final rule. (An addendum to ERG's preliminary cost analysis presents the industry impact estimates in even greater detail.)

A. Need for Regulation

In its analysis of the proposed rule, FDA explained that the need for regulatory action is based on the risk that BSE will be established and proliferate in the United States. In its guidelines for the preparation of Economic Impact Analyses, OMB directs Federal regulatory agencies to determine whether a market failure exists, and if so, whether that market failure could be resolved by measures other than new Federal regulation. In this instance, FDA determined that private incentive systems for both suppliers and purchasers in markets for cattle, rendering, and ruminant feed may inadequately address the risk of BSE. The potential for market failure among suppliers in these sectors results from the externality that could be created by individual suppliers imposing economic hardships on other suppliers within the industry. The potential for market failure among purchasers results from the inadequate information that would be available to purchasers of potentially infective products.

With respect to suppliers, any renderer, feed manufacturer, or cattle producer that permits animal protein derived from at-risk mammals to be placed in ruminant feed increases the risk that other renderers, feed manufacturers, or cattle producers will suffer the severe economic consequences that would follow an outbreak of BSE in the United States. Although the benefits of voluntary programs designed to reduce or eliminate this risk accrue to all members of these industries, compliance with these measures is incomplete, because individual noncomplying members can avoid the costs of risk reduction measures while still enjoying the benefits of compliance by others in the industry.

If purchasers could easily identify the risk of the infective agent associated with products from specific suppliers, they could more easily take defensive actions to reduce these risks (e.g., refusing products from cattle known to have consumed specified ruminant proteins). Purchasers are unlikely to obtain the information they need, however, for several reasons. First, the long incubation period for BSE creates a lag between the actual onset and the recognition of the disease and could lead to a suboptimal level of risk prevention by the concerned parties during the incubation period. By the time the first signs of disease are observed, many animals may have been exposed. Moreover, renderers sell their product to feed manufacturers who frequently combine proteins from many different sources and animal species to produce cattle feed. Ruminant producers, therefore, have no sure way of knowing whether a particular batch of feed is free from potentially infective proteins and cannot easily avoid purchasing risky feed. Finally, if renderers or feed manufacturers do not believe that BSE is an important threat, they may choose not to take preventive action, regardless of the risk levels perceived by epidemiological experts or consumers. FDA received no comments that directly questioned the existence of this market failure.

B. Benefits

The primary benefits of this regulation are the costs that would be averted by reducing the risk that BSE will become established and proliferate in the United States through feed. As described in FDA's analysis of the proposed rule, a quantitative measure of these benefits must consider three distinct factors: (1) The probability that, in the absence of this rule, BSE would be established and amplified in the United States through feed, (2) the costs, both direct and indirect, that would be associated with the spread of BSE in the United States, and (3) the extent to which this rule would reduce the likelihood of these costs. FDA explained that it could not develop an overall quantitative estimate of these benefits, primarily because it could not adequately measure the first of these factors, the probability that BSE would otherwise occur in the United States. While the agency determined that the risk was positive, the available data were inadequate to develop a quantitative risk assessment. The agency did, however, derive a partial estimate of the potential direct costs that would result from the proliferation of BSE in the United States (the second factor), and present a strong qualitative assessment of the probable effectiveness of the proposed rule (the third factor).

For its estimate of the potential direct costs associated with the outbreak and spread of BSE in the United States, FDA extrapolated from the experience of the United Kingdom, but adjusted for certain differences between the United States and the United Kingdom. The relevant United Kingdom variables included the number of cattle that had died from BSE (despite the implementation of a feed ban in that country after BSE was identified) and the slaughter and destruction of additional cattle considered to be at risk of BSE. Based on these projections, FDA estimated that, if BSE were to occur in this country, the disease would be associated with approximately $3.8 billion in losses due to the destruction of BSE-exposed livestock and the taking of other measures needed to prevent continued BSE proliferation. While FDA could not quantify the expected additional costs to consumers and producers in the United States that would result from the loss of consumer confidence following a BSE outbreak, the agency found that plausible scenarios indicated that the likely drop in the demand for cattle and beef products could cause billions of dollars in lost market values. In addition, FDA noted, but did not attempt to quantify, the value of the human lives that might be lost or the associated medical treatment costs that might follow a domestic outbreak of BSE.

(Comment 114). One comment on the proposed rule stated that FDA should modify its projection of the potential amplification and subsequent proliferation of BSE in the United States, because FDA's use of the United Kingdom's experience as a model is misleading and exaggerates the real risk. The comment suggested that an

extensive epidemiological study be conducted instead, based on use of ruminant proteins in ruminant feed over the past 50 years, to produce a more accurate risk assessment.

FDA does not believe that its projection was invalid or misleading, because although the United Kingdom's and United States' cattle industries are not identical, the United Kingdom experience provides the most detailed and least speculative basis available for understanding the potential impact of BSE on this nation's cattle industry. FDA's methodology incorporated adjustments to reflect the younger average age of United States cattle and the later age of first exposure of United States dairy cattle to meat and bone meal. The analysis concurred that, compared to the United Kingdom, a much lower proportion of cattle in the United States would be at risk of contracting BSE if an outbreak occurred. Nonetheless, because of the delay between infection and identification, it found that a substantial number of cattle in the United States could become infected before the disease was contained.

Although further epidemiological study on the use of mammalian protein in ruminant feed (with exclusions) could provide useful information, FDA believes that such a study would not significantly alter the agency's conclusions, because the degree of infectivity at various exposures to mammalian protein is not known. Moreover, only a small part of the overall cost to industry of a BSE outbreak would depend on the number of cattle actually infected. The greatest costs would be associated with the measures that would be needed to restore consumer confidence in beef and dairy products, and these measures would be undertaken irrespective of the precise level of infectivity.

FDA has, however, updated its estimates of the projected costs of a BSE outbreak, based on: (1) The more recent estimates of the number of United Kingdom cattle diagnosed with BSE (projected here at approximately 169,600 cumulative BSE deaths through 1997); (2) the current United Kingdom estimates of 1.3 m cattle culled by the end of 1996 to end the epidemic; (3) the more recent estimates of the size of the United States cattle population (now estimated at approximately 101 m cattle); (4) the assumption that cattle at risk of BSE would require disposal at a cost of $33 per animal, and that cattle with known BSE could require medical-waste level incineration at a cost of $100 per animal; and (5) the updated estimates of the costs of implementing a feed ban at the time of a BSE outbreak (currently estimated, as described below, at $52.9 m per year).

FDA's revised calculation again addresses only three of the costs that would be associated with the proliferation of BSE in the United States: (1) The cost of direct livestock losses due to BSE infection, (2) the costs associated with slaughtering at-risk cattle culled to prevent BSE spread and restore consumer confidence, and (3) the costs associated with imposing feed regulations at the time BSE was detected. Recalculating BSE-related costs using the updated figures yields an estimated present value for these three components of $93 m, $4.7 billion, and $593 m, respectively. In sum, these updated projections yield an estimated present value of $5.3 billion in costs that would be associated with the establishment and proliferation of BSE in the United States through feed.

Additional costs that could not be quantified include the lost human lives and medical treatment costs that could result from BSE-related disease, as well as the consumer and producer losses that would result from the expected decrease in the sales and consumption of beef. Sales of medical products and cosmetics containing cattle-derived components could also be affected.

(Comment 114a). One comment stated that a single case of BSE in the United States would have an enormous impact on the American cattle industry and that a 1 percent change in consumer purchases of cattle products results in a $350 m impact on farm and ranch income. Other comments stated that action must be taken to maintain consumer confidence in meat products, and one estimated that, if BSE were detected, first year costs to the economy would total $64 billion.

Nevertheless, FDA is still unable to quantify the expected benefits of this rule, because the agency cannot estimate the probability that, in the absence of this regulation, BSE would occur and proliferate in the United States.

Moreover, to the extent that the rule will not completely eliminate all chance of a BSE outbreak, the expected value of the potential benefits is less than the expected value of the potential BSE-related costs. Several comments pointed out that a lack of enforcement of the proposed rule would greatly reduce its efficacy. FDA agrees that adequate enforcement is critical to achieving the full potential benefit of the rule, and, as discussed elsewhere, has attempted to craft the rule in a way that will maximize its enforceability. Thus, FDA believes that the vigorous implementation of this rule will very nearly eliminate the risk of the widespread proliferation of BSE in the United States.

C. Industry Impacts

FDA has carefully examined numerous public comments that addressed industry impacts of the proposed rule. In addition, FDA asked ERG to prepare an addendum to its earlier impact analysis. This section summarizes the ERG reports, responds to public comments related to the analysis of industry impacts, describes the composition, size, and scale of economic activity for the various affected industry sectors, and presents FDA's estimates of the cost and market impacts of the final rule and six other regulatory alternatives (see Table 1).

TABLE 1.—ESTIMATED ANNUAL AFFECTED PROTEIN AND ANNUAL COSTS OF ALTERNATIVE REGULATORY PROHIBITIONS [1]

Annualized impacts	Mammalian-to-ruminant	Mammalian-to-ruminant, with exceptions [2] (final rule)	Partial ruminant-to-ruminant	Sheep/mink-to-ruminant	Sheep/goat-to-ruminant
Quantity of restricted meat and bone meal (m lb)	6,086	5,031	2,283	16.9	0.6
Capital costs ($ m)	7.1	7.1	4.9	NA	NA
Plant Operating costs ($ m)	20	20	26.9	NA	NA
Transportation costs ($ m)	10.7	7.5	5.3	NA	NA
Documentation costs ($ m)	0.3	0.3	0.2	0	0
Reformulation, reregistration and relabeling costs ($ m)	2.1	1.3	0	NA	NA
Feed substitution costs ($ m)	9.7	8	3.6	NA	NA
Disposal costs ($ m)	NA	NA	NA	5.1	0.2

TABLE 1.—ESTIMATED ANNUAL AFFECTED PROTEIN AND ANNUAL COSTS OF ALTERNATIVE REGULATORY PROHIBITIONS [1]—Continued

Annualized impacts	Mammalian-to-ruminant	Mammalian-to-ruminant, with exceptions [2] (final rule)	Partial ruminant-to-ruminant	Sheep/mink-to-ruminant	Sheep/goat-to-ruminant
Subtotal ($ m)	49.9	44.3	41.1	5.1	0.2
Meat and bone meal revenue losses [3] ($ m)	206.9	171	77.6	4.2	0.2
Nonruminant sector gains ($ m)	(196.6)	(162.5)	(73.7)	NA	NA
Aggregate net costs ($ m)	60.2	52.9	44.9	9.3	0.4

[1] Totals may not match text due to rounding error.
[2] Also reflects costs of proposed ruminant-to-ruminant rule.
[3] Assumes $68 per ton decrease in price of affected meat and bone meal.

1. Summary of Impacts of Final Rule

The final regulation prohibits the use of mammalian protein (excluding pure porcine or equine protein and certain other materials) in ruminant feeds. FDA estimates that the direct compliance costs of the rule, including annualized capital and operating costs, will be about $44.3 m per year. In addition, FDA has accepted an industry forecast that the regulatory prohibition will lower the price of the affected meat-and-bone-meal (MBM) by as much as $68 per ton, reducing the initial value of this product to the rendering industry by $171.0 m annually. In contrast, nonruminant animal producers may gain up to $162.5 m in lower feed costs. Thus, FDA estimates that the aggregated net annualized costs of this rule, accounting for both losses and gains, will total $52.9 m. Renderers will pass much of the economic burden of the new regulations upstream to meat packing operations, which will incur increases in renderer charges (or declines in renderer payments) of up to 1 percent of revenues. In turn, meat packers will raise slaughtering fees and lower the price paid for slaughter cattle. In the long run, these actions will result in a modest reduction in the size of the affected animal herds.

2. Market Impacts

a. *Introduction to regulatory alternatives.*

The regulatory action selected by FDA is one of seven regulatory alternatives examined by the agency, of which six would prohibit some type of animal protein in ruminant feed, generating compliance costs and revenue impacts on industry. The seven alternatives are, in order of their regulatory stringency: (1) A prohibition on mammalian-derived protein in ruminant feed; (2) the final rule, a prohibition of mammalian proteins in ruminant feed, excluding protein exclusively from porcine and equine sources, and selected other materials; (3) the proposed rule, a prohibition on ruminant protein in ruminant feed; (4) a prohibition on selected ruminant tissues, i.e., those believed most likely to be infectious, in ruminant feed; (5) a prohibition on protein from those species in which TSE has been identified, including sheep, goat, deer, and mink in ruminant feed; (6) a prohibition on sheep and goat protein in ruminant feed; and (7) a no action alternative, or an agency position of watchful waiting. The estimated costs for five of the alternatives are displayed in Table 1 of this section. (Estimates for the third and seventh alternative as described above, are not displayed, because the estimated costs for the third alternative (the proposed rule) are almost identical to those of the second alternative (the final rule), and the seventh alternative generates no regulatory costs.)

b. *Quantities of offal and meat and bone meal affected.*

The regulatory alternatives are differentiated by the types of animal protein prohibited in ruminant feed. The final rule will affect the sale of protein generated from the annual slaughter or processing of about 50 m animals. An estimated 5 billion lb of protein (see Table 1 of this section) is rendered from the animals and other protein sources covered by the final rule. This rule is less inclusive than Alternative 1, which would prohibit all mammalian protein in ruminant feed and therefore restricts the sale of pure porcine or pure equine protein as well. The final rule is similar in coverage to the ruminant-to-ruminant alternative, which FDA had first proposed and most industry comments addressed. The least restrictive regulatory alternative would target only sales of sheep and goat offal, affecting minor quantities of animal offal and protein. Alternative 7, under which the agency takes no action but continues to monitor the health of U.S. herds, does not affect the processing of animals.

c. *Affect on meat and bone meal prices.*

There was little disagreement within the public comments that the first four regulatory alternatives, by prohibiting the sale of certain types of meat and bone meal for use in ruminant feed, would cause declines in the long-run equilibrium price of this product. The other three alternatives were believed to have negligible effects on the market for meat and bone meal.

In its economic assessment of the proposed rule, FDA accepted the estimate of its contractor (ERG) that the more restrictive alternatives would cause a price decline for meat and bone meal of $25 to $100 per ton. The size of the estimated range reflected considerable uncertainty over the reaction of the affected markets to the new restrictions. Nevertheless, even under the high market impact scenario, ERG forecast that the market for meat and bone meal would reach an equilibrium (i.e., quantity demanded would equal quantity supplied) at a positive market price.

A number of comments on the proposed rule addressed the estimated decline in the price of ruminant-containing meat and bone meal. The National Renderers Association commissioned a comprehensive study by Sparks Companies, Inc. (SCI) to assess the regulatory impact on the meat and bone meal markets. SCI developed an independent estimate of the size and breadth of the agricultural markets affected by the proposed regulation and estimated that 15 percent of meat and bone meal is consumed by ruminant animals, compared to the 10 percent presented in the ERG study. SCI considered questions relating to the disposition and price of ruminant-containing meat and bone meal under the proposed rule by analyzing the historical statistical relationship between meat and bone meal and soybean meal and by conducting telephone interviews with 30 executives

of affected industries. For its most likely scenario, SCI concluded that ''all raw materials would continue to be rendered, and all ruminant-containing meat and bone meal would be consumed by nonruminant operations, though a price discount would be necessary to induce these operations to purchase the additional quantities that otherwise would have been used in ruminant feed.'' For this scenario, SCI estimated that meat and bone meal prices would decline by $68.27 per ton, or almost the midpoint of the $25 to $100 per ton range previously estimated by ERG ($62.50 per ton).

(Comment 115). A comment by a federation of American farm bureaus predicted that the proposed ruminant-to-ruminant prohibition would cause a fairly small price effect, but many other comments suggested that the price of meat and bone meal would fall sharply due to the perceived stigma that would be placed on the product. Most of these comments, however, expressed strong opposition to the proposed rule's labeling requirement, asserting that the proposed labels would generate unwarranted public concern over the safety of meat and bone meal in pet foods and, in turn, would significantly reduce the demand for meat and bone meal by pet food manufacturers.

FDA believes that it has alleviated this concern by exempting retail pet food packaging from the labeling requirements of the final rule.

(Comment 116). One major feed industry association had initially argued that meat and bone meal prices would fall to zero, triggering large-scale disposal of the material and other economic impacts. These comments, however, contained no market analysis for their forecast of meat and bone meal prices. This association later acknowledged that its forecasted price decline was an assumption.

(Comment 117). One comment disagreed with FDA's position that a lower meat and bone meal price would increase sales of meat and bone meal to the nonruminant sector (62 FR 552 at 576). The comment claimed that the poultry and swine industries cannot absorb 450,000 tons of meat and bone meal (which would otherwise have been used for ruminant feed) and that substituting meat and bone meal for other meal (such as soybean meal) would adversely affect animal production.

FDA disagrees with the comment because it failed to provide information to demonstrate that the poultry and swine industries were at their maximum use level for meat and bone meal. Moreover, the comment did not consider the ability of the pet food industry to include more meat and bone meal in its products. Given the expected price reductions, the agency believes that these industries will find it cost-effective to absorb the additional meat and bone meal.

The comment also misconstrues FDA's position. The agency does not expect meat and bone meal to serve as a total substitute for soybean meal. Instead, FDA finds that the nonruminant sector will be able to include more meat and bone meal in its formulations without the negative effects predicted by the comment. For example, just a 1.5 percent increase of meat and bone meal in the diets of all swine in the United States would absorb the entire excess.

In the addendum to its final report, ERG explained that because meat and bone meal can be readily substituted for other protein sources in many uses, the resulting price decline for meat and bone meal could be towards the lower end of its previously estimated $25 to $100 per ton range. ERG acknowledged, however, that the price decrease could be greater if large buyers of meat and bone meal for poultry feed or pet food react adversely to public uncertainty or concerns about BSE dangers. ERG also noted that such reactions could occur irrespective of this rule in response to fears triggered by the presence of BSE in Europe, or to new research findings of greater health risk. Since the industry has not presented any data suggesting price declines outside of the projected range of $25 to $100 per ton, ERG revised its analysis to maintain the range, but used the approximate midpoint of $68 per ton, as suggested by the SCI study, to project the probable industry impacts.

FDA has similarly adopted SCI's forecast of a $68 per ton decline in the price of affected meat and bone meal as a basis for calculating reasonable estimates of regulatory impacts. This estimate was derived directly from discussions with industry representatives, is fully consistent with the earlier analysis prepared by ERG, and no other industry comment offered more persuasive, alternative data.

3. Costs of Compliance

a. *Direct costs.*

i. *Documentation and relabeling costs*

The final rule requires renderers, feed manufacturers, and other affected parties to perform specific recordkeeping and labeling activities to demonstrate compliance. For its analysis of the proposed rule, FDA had estimated that added recordkeeping, including relabeling, would cost $1.5 m to $1.8 m per year. These estimates generated a number of comments.

(Comment 118). A representative of the AAFCO commented in public hearings that relabeling costs had been underestimated because necessary changes in the AAFCO definitions for certain collective terms would involve more animal feed mixes than simply those containing meat and bone meal. Specifically, the comment claimed that the proposed rule would have necessitated a change in the AAFCO collective term ''animal protein products'' which is used on bag labels and tags for products containing proteins other than ruminant protein.

Under the final rule, AAFCO will need to amend its definition of the collective term ''animal protein products'' to identify those feed ingredients that are prohibited from use in ruminant rations. FDA intends to work with AAFCO on this matter. Although manufacturers of ruminant feeds that use this collective term may need to reformulate their rations, there should be no change required in the ingredient list on the labels for any feed manufacturer that uses the ''animal protein products'' collective term.

(Comment 119). A number of industry associations expressed concern about the market impact of the proposed labeling requirement, particularly as it was potentially applicable to retail sales of pet food that contain ruminant meat and bone meal.

FDA agrees that the cautionary statement is not necessary on pet food intended for retail sale, and the final rule eliminates the requirement for pet food for retail sale.

(Comment 120). Other comments expressed general concerns or made suggestions about documentation and labeling requirements, but did not provide specific information on costs.

As shown in the addendum to its final report, ERG revised its earlier estimates by distinguishing between relabeling and documentation costs and changing its method of estimating relabeling costs from per facility to per label costs. As shown in its addendum, ERG also increased the projected number of feed mix reformulations that would be necessary under the final rule. Although ERG determined that it had previously undercounted the number of affected labels, the net result of these changes yielded an annualized incremental cost for relabeling, reregistration and reformulation of $1.3 m and an annualized feedmill documentation cost of $0.3 m. FDA has included these adjustments in its revised estimates of capital and operating costs.

ii. *Plant and equipment costs.*

FDA does not expect renderers to invest in separate processing lines for mammalian and nonmammalian tissues. ERG reported that large packer/renderers process only a single animal species and will have no incentive or use for separate processing lines. Independent renderers were assumed to be too dependent upon mammalian animals and dead stock to have sufficient economic rationale to invest in a separate processing line for nonmammalian protein. The SCI report confirmed this view by presenting a financial assessment of the investment that would be needed by independent renderers to construct separate processing lines for nonmammalian protein. This analysis concluded that renderers would lose money by operating separate lines.

ERG determined, however, that the rule is likely to prompt new capital expenditures by certain feedmills. Many feedmills, including some in areas with both cattle and hog production, now have storage bin capacity for only one type of meat and bone meal. If the price of affected meat and bone meal falls substantially, a number of feedmills will choose to add storage bin capacity in order to carry both types of meat and bone meal (i.e., containing protein from pure porcine and mixed mammalian sources), so that the price discount for meat and bone meal containing mammalian protein can be passed on to their hog-producing customers. No comments questioned ERG's initial estimate that 1,000 major commercial feedmill operations would install a second meat and bone meal storage tank to handle both restricted and unrestricted meat and bone meal.

(Comment 121). One comment from a major feed industry association suggested that the ERG capital cost estimate of $50,000 per feedmill for capacity expansion was too low.

ERG had noted that this expenditure would be sufficient to add a storage tank capable of receiving one and one-half truckloads of meat and bone meal. This size (representing approximately 30 to 40 tons) is economically efficient because it would allow a feedmill to receive a full truckload of new product before exhausting the previous shipment. Also, the National Grain and Feed Association (NGFA) estimated the cost of capacity expansion at feedmills at $25,000 to $30,000. As such, FDA has retained ERG's $50,000 estimate for feedmill expansion costs and estimates the annualized capital costs of the final rule (discounting over 10 years at 7 percent) to be $7.1 m.

iii. *Plant operating costs.*

ERG initially estimated the incremental operating costs of adding new clean up procedures at each feedmill that handles both ruminant and nonruminant protein to be $10,000 per year. FDA received no comments on the accuracy of this estimate, which ERG derived from data provided in the NGFA comments to the advance notice of proposed rulemaking. Thus, FDA has retained this figure as the best available measure of the incremental operating costs for these feedmills. Additionally, further analysis contained in ERG's addendum concludes that the $10,000 annual cost estimate should also be applied to the 1,000 major feedmills which already have the excess capacity to handle both types of meat and bone meal. This adds $10 m to the annual clean out cost estimate for feedmills for a total of $20 m.

iv. *Transportation costs.*

In its analysis of the proposed rule, ERG had found that renderers would incur incremental transportation costs to sell meat and bone meal to new customers, many of whom might be in more distant regions, and that feedmills and animal producers would purchase substitute feed inputs, which sometimes would come from more distant suppliers. Renderers were not assumed to incur incremental transportation costs for the collection of animal tissue because, as noted, they were not expected to separate animal offal and, therefore, would not change their sources of animal tissue.

ERG had allocated an average incremental transportation cost of $25 per ton for that portion of meat and bone meal (estimated at approximately 500 m lb in ERG's initial cost analysis) that would be displaced by the restrictions on ruminant feed. ERG had also allocated $5 per ton of meat and bone meal to address incremental transportation costs for feed substitutes. While these data were limited, these amounts were considered overall averages sufficient to represent this element of the regulatory impact.

(Comment 122). A few comments noted that transportation costs could be significant, but no comments provided specific estimates of expected increases in transportation costs. One comment criticized the ERG study for lacking analysis of specific regional transportation difficulties.

FDA recognizes that ERG did not present a regional transportation analysis and that renderers in regions most distant from prospective new markets might incur relatively high transportation costs. Nevertheless, no industry comment provided quantitative data on this point or sufficient analysis to indicate that transportation costs would be higher than that predicted. Therefore, FDA has accepted ERG's methodology. Table 1 indicates that these compliance costs are estimated at $7.5 m per year.

v. *Disposal costs.*

(Comment 123). A number of comments stated that renderers or meatpackers would incur additional disposal costs if economic conditions deteriorate to the point where animal offal or dead stock is no longer rendered.

As discussed above, FDA believes that these costs will be small, because essentially all animal offal will continue to be rendered. The agency agrees, however, that some incremental on-farm disposal of dead stock may occur in response to increases in renderer pickup charges. As explained below in the discussion of market adjustments, these activities would not raise the agency's overall cost estimates.

b. *Indirect costs.*

i. *Initial revenue losses.*

Table 1 summarizes the initial decline in meat and bone meal revenues under the various regulatory alternatives. These estimates were derived by multiplying the quantity of meat and bone meal affected by the forecasted $68 per ton meat and bone meal price decline. As shown, the final rule is expected to generate an initial revenue decline for renderers of $171 m per year. The industry-sponsored SCI study used essentially the same methodology and estimated the most likely loss to renderers from the ruminant-to-ruminant prohibition at $160 m. Both ERG and SCI predicted that most of these losses will be passed back to suppliers of the raw materials.

ii. *Feed costs in ruminant sectors.*

The restriction on the use of mammalian protein (with exceptions) in ruminant feed will require existing purchasers of this material to substitute new feed ingredients. FDA's estimate of the cost of this substitution effect was derived from an American Feed Industry Association (AFIA)-sponsored analysis of feed price impacts. In this analysis, Dr. Thomas Lenard calculated the costs of substituting soybean and replacement minerals for ruminant meat and bone meal and estimated a unit price increase of $0.01588 per pound of ruminant-containing meat and bone meal replaced. Because Dr. Lenard assumed that no meat and bone meal would be sold once the rule was in place, his analysis applied this incremental feed substitution cost to all current meat and bone meal consumption. Both the ERG and the SCI analyses, however, concluded that it is

much more likely that meat and bone meal will continue to be sold for nonruminant feed. Thus, FDA has rejected the assumption that additional feed substitution costs will be incurred to replace all meat and bone meal and has extrapolated the unit cost over only the 10 to 15 percent share of mammalian meat and bone meal now consumed by cattle to calculate an expected cost increase of $8.0 m per year.

(Comment 124). Some comments expressed additional concern about the cost of feed. Some mentioned higher prices for new dairy cattle feeds than are derived using Dr. Lenard's unit cost estimates.

These comments, however, did not provide sufficient data for FDA to evaluate their assumptions and calculation methodologies. ERG attempted to confirm the validity of one very high estimate of feed substitution costs, but that comment could not verify the factors used in the estimate. Thus, FDA has retained the AFIA unit cost increment to support its $8.0 m estimate for feed substitution costs.

iii. *Feed costs in nonruminant sectors.*

The forecasted decline in the price of restricted meat and bone meal will reduce feed costs for those sectors, such as poultry and hog producers and pet food manufacturers, that will continue to use the product. As shown in Table 1, FDA forecasts that these feed cost savings will be $162.5 m per year under the final rule. The estimated savings to these purchasers are slightly less than the estimated revenue decline for producers of ruminant meat and bone meal, because the meat and bone meal will be somewhat less efficient in these uses.

(Comment 125). Only a few comments noted that the nonruminant sectors would gain from the decrease in ruminant-derived meat and bone meal prices, and no quantitative estimates of such savings were provided to the agency. A number of comments, however, suggested that these cost savings not be used to offset costs to other sectors.

As discussed below, FDA believes that the societal perspective appropriate for agency analyses of federal regulations must consider significant impacts on all affected sectors. FDA is fully aware, however, that any gains to the nonruminant sectors will not reduce the regulatory burden imposed on the rendering, livestock feed, and cattle industries. These sectors will experience significant costs and revenue reductions.

iv. *Distribution of costs and revenue losses by sector.*

(1) *Initial impacts.*

(Comment 126). Many comments raised questions about the distribution of the economic impacts of the regulatory alternatives. A number noted that FDA summed the revenue impacts across sectors and asserted that FDA was concerned only with the aggregate size of the combined cost impacts and not with the separate impacts on each agricultural sector. Actually, FDA aggregated the cost impacts for the purpose of providing a concise and comprehensive accounting of the societal impacts, as is normally performed for regulatory analysis.

FDA estimates that the final rule will impose total annualized direct compliance costs of $6.3 m on rendering facilities, $30.0 m on feedmills, and $8.0 m on ruminant producers. Renderers will also incur an initial revenue decline of $171.0 m per year which will be largely passed on to other agricultural sectors. As noted, producers of nonruminant animals and other purchasers of meat and bone meal containing mammalian protein will benefit from a decline in feed prices of $162.5 m per year.

(Comment 127). Many comments expressed concern that FDA had not adequately considered the economic impact on their particular industry.

FDA notes that the preamble to the proposed rule included only a summary of the ERG final report. That ERG report, as well as the more recent addendum, addresses the economic impacts on all of the affected sectors.

(2) *Market adjustments.*

(Comment 128). Several comments noted that renderers will endeavor to pass the majority of the revenue losses to others in the agricultural market.

FDA finds that the affected markets will adjust to this rule in numerous ways. The primary adjustments are: (1) Renderer payments for raw materials will decrease, and charges for rendering services, such as dead stock pickup, will increase; (2) meat packing plants will reduce prices paid for cattle, and small meat packing plants, often referred to as locker plants, will increase charges for custom slaughtering services; (3) ruminant animal producers will pay increased feed prices as they substitute other protein sources for meat and bone meal; and (4) ruminant and other affected livestock producers will decrease their demand for grazing lands in the long run, in response to the decline in the value of cattle and other affected livestock.

Renderers will experience the greatest initial lost revenues, but these losses will largely be passed on back to the meat packers and animal producers that supply the raw materials. SCI explained that most renderers have contracts with raw material suppliers that link prices paid for animal tissue to publicly available information on the price of meat and bone meal. Its analysis reported that:

> Although the rendering industry will be on the front lines of any cost shock emanating from the FDA regulation, the economic impact eventually would be distributed among the individuals and companies that form the marketing chain for cattle (ruminants) and derived products—affecting cattle producers, beef packers, meat fabricator/processors, and renderers unevenly. The costs will not disappear as they make their way down the marketing chain; rather, they will be shared.

FDA agrees with this assessment, but finds that the rendering industry will continue to incur negative impacts due to the gradual decline in raw material throughput and the other costs and incremental marketing expenses associated with the rule.

(Comment 129). Some comments claimed that renderer pickups of animal offal would cease, arguing that the regulatory impacts would make meat and bone meal unmarketable. Others predicted that the regulatory impacts would create substantial disposal costs. A number of comments noted that local landfills will not accept animal offal or dead stock.

As noted above, both ERG and the industry-sponsored study by SCI predicted that ruminant-derived meat and bone meal will most likely continue to be marketed, albeit at lower prices. Thus, FDA expects that renderers will continue to pick up animal offal from nearly all of their raw material suppliers, negating the need for substantial new disposal costs for animal offal.

Nevertheless, as discussed in the previous section on environmental impacts, a move by renderers to raise pickup fees may reduce the number of dead animals supplied to renderers. ERG found that this effect is likely to be strongest among those small-scale animal producers that could respond to increased renderer charges by simply dragging animals off to remote areas and leaving them. In comparison, the larger operations were thought less likely to change management practices in response to a decline in renderer payments (or an increase in pickup charges) for dead animals, because of limitations on available land or other complications involved with changing methods for managing dead stock disposal.

ERG found that the costs reflected in Table 1 of this section imply a drop in

the market value of protein in animal carcasses of about $2 per calf or pig, and up to $7 per head for a 900-lb cow. Thus, although some renderers may raise their pickup fees by amounts that cause the loss of some dead stock, such fee hikes would be unprofitable, and therefore unlikely, if the resulting loss to the renderer exceeded $2 per calf or pig, or $7 per cow. As a result, the costs included in Table 1 reflect an upper bound estimate of the regulatory costs and any subsequent market adjustments will serve only to redistribute or potentially reduce these costs.

Other sectors will also adjust to these impacts by raising fees or reducing payments. ERG calculated that a $68 decline in the price per ton of meat and bone meal implies a 3.4 cents per lb decline in the value of protein from current values of around 15 cents per pound. Most meat packing plants are likely to pass this loss on to customers through an increase in the charge for slaughtering, although some small locker plants may have difficulty. Manufacturers of ruminant feeds will shift increased costs to ruminant producers, who could face feed price increases of 1.6 cents per pound of meat and bone meal replaced. Other sectors, however, will gain by these market adjustments. For example, nonruminant producers will experience lower feed prices and hog producers are likely to see a small increase in slaughter values as increases in porcine meat and bone meal prices increase the value of hog offal.

In the long run, each adversely affected sector will experience some cost impacts that cannot be passed on. Renderers will experience lower raw material throughput to the extent that fewer animals are slaughtered and more dead stock remain unrendered. Meat packers will see a reduced supply of slaughter animals due to the lower prices paid for cattle and the increased charges for custom slaughtering services. Livestock producers will make modest reductions in the size of their herds because of the reduced animal prices. If the predominant part of the decline in the value of meat and bone meal is passed back to cattle producers, the value of cattle would fall by roughly $3 per head (about one-half of one percent). One official of a major cattleman's association acknowledged that the high range cost estimate could result in a cost to cattle producers of $6 a head, but recognized the need for regulation and explained that, ''[w]e made a commitment to incur this cost.''

v. *Additional small business impacts.*

(1) *Statement of purpose and objectives of the final rule.*

The Regulatory Flexibility Act requires that agencies present a succinct statement of the purpose and objectives of any rule that will have a significant effect on a substantial number of small entities. As explained earlier in this document, FDA is instituting this rule to reduce the risk of BSE becoming established and amplified in the United States through feed. Existing epidemiological evidence suggests a link between the incidence and proliferation of BSE in the United Kingdom and the practice of feeding mammalian proteins to cattle. This rule prohibits that practice. Thus, the need for regulatory action is based on the need to prevent the spread of BSE among the nation's livestock.

(2) *Description of the affected small entities.*

Most businesses in the affected agricultural industries are small, as defined by the standards used by the Small Business Administration (SBA). SBA provided information to FDA on the employment size of businesses in several of the affected sectors. SBA noted that 86.9 percent of the businesses in the Animal and Marine Fats and Oils Industry (which encompasses animal rendering) employ fewer than 500 employees. In the meat packing industry and sausage and other prepared meats industries, 96.1 percent and 93.3 percent of businesses, respectively, employ fewer than 500 workers. Similarly, the great majority of cattle producers are also small, family-owned businesses. According to statistics collected by the National Beef Cattlemen's Association, 98 percent of cattle producers are small- to mid-sized family businesses with less than 500 head. In 1993, the average size of beef cow herds was 38.3 head (NCA, 1996). Among the feedmills classified in Standard Industrial Classification (SIC) 2048 (Prepared Feeds and Feed Ingredients for Animals and Fowls, Except Dogs and Cats) and SIC 5191 (Farm Supplies), the large majority employ fewer than 500 employees, and thus are small businesses. SBA data show that 95 percent of feedmill firms in SIC 2048 and 99 percent of firms in SIC 5191 employ fewer than 500 employees. The small businesses in SIC 2048 operate 70 percent of all feedmill establishments. A total of 61 large companies operate the remaining 30 percent of feedmills classified in SIC 2048 (Bureau of the Census, 1996). The ERG final report projects the number of establishments in all of these sectors with less than or greater than 500 employees.

c. *Description of economic impacts.*

i. *Small renderers.*

The ERG final report provided detailed information on the expected economic impacts of the proposed rule on small renderers. The addendum presents ERG's revised estimates of the impacts of the final rule on small independent renderers. On average, each of these establishments is estimated to incur initial revenue declines of approximately $371,000 per year. (Meat-and-bone-meal price reductions greater or smaller than the estimated $68 per ton would yield proportional changes in these estimates.)

As noted in the SCI report, most of the revenue impacts will quickly be passed on to material suppliers. The smallest independent renderers, however, are likely to experience the most severe impacts. According to ERG, the number of rendering establishments has been decreasing for a number of years, and many small operations have already closed. Moreover, since the smallest renderers tend to be those most dependent on the availability of dead stock supplies for raw materials, these operations will be least able to shift losses to raw material suppliers. (Larger renderers obtain raw material supplies predominantly from medium to large meat packing plants and are less dependent on dead stock supplies, which could fall in response to increased pick up fees.)

ERG estimated in its final report that 20 to 25 rendering establishments are in this vulnerable group of small businesses. While many renderers submitted comments on the proposed regulation, no rendering companies submitted comments predicting plant closures. The SCI study did not address plant closures other than in the case, which it described as unlikely, that all meat and bone meal is unmarketable. No other comments provided additional information on the number of possible plant closures. Nevertheless, as suggested in the ERG report, FDA agrees that some business closures are possible among these companies, but the data are not sufficient to determine how many closures may occur.

ii. *Small meat packing operations.*

Many small meat packing facilities will be required by their renderers, generally through contractual arrangements, to pay higher prices for renderer pickups of animal offal. Large and medium meat packing operations (many of which are small businesses according to the SBA definitions) will continue to receive payments from renderers for raw materials, although the size of the payments will decline with the fall in restricted meat and bone meal prices. These plants will endeavor

to pass through costs by paying less for slaughter cattle. To the extent that competitive market conditions exist, all meat packers will experience similar declines in renderer payments, and new equilibrium prices will reflect a pass-through of these charges to producers of cattle and other affected livestock.

The smallest plants in the industry, often referred to as locker plants, provide custom slaughtering services, thereby differentiating themselves from the large packer/renderers. Small meat packing or locker plants have been in decline for a number of years for several reasons, including the decline in small farm operations and in the consumption of red meat and custom meat products. ERG reported that the smallest meat packing plants, i.e., those with 2 to 5 employees, are at a cost disadvantage relative to even slightly larger plants, such as those with 12 or more employees.

To assess whether impacts on these small plants are significant, ERG developed revenue estimates for locker plants with slaughtering rates representative of the smallest plants in the industry. The smallest locker plants have substantially less raw material for rendering, and the renderers' charges (which are heavily influenced by the fixed costs of operating the collection truck) currently represent a relatively large share of plant operating costs. Also, because animal offal cannot be stored for long periods, small operations require nearly as many renderer pickups as much larger facilities. ERG determined that the increase in renderer charges will represent approximately one percent of revenues for these plants and that these increased charges might be sufficient to depress profits by significant amounts.

According to ERG, some industry representatives predicted that increased renderer pickup charges would precipitate failures among the smallest meat packers. Other small meat packers anticipated that they would be able to pass on some charges to customers and expected to remain in business. ERG concluded that some of the smallest meat packers, particularly those with five or fewer employees, are vulnerable to increased renderer charges and, in the context of a poor economic environment, some might cease operations. No reliable quantitative estimate could be made, however, of the number or percentage of facilities likely to close.

iii. *Small cattle producers.*

The reduction in slaughter prices and the increase in cattle feed prices are not expected to differentially impact small ruminant producers, as the impact of this decline on cattle producers will be directly proportional to the size of the producer's herd. Nevertheless, all cattle producers will experience lost revenues of roughly $3 per head, or about one-half of one percent of the animal's market value.

iv. *Small feedmills.*

Feedmills will incur costs to document their handling of mammalian protein and to perform clean out procedures to ensure separation of mammalian and pure porcine or pure equine meat and bone meal. Also, feedmills that currently serve both ruminant and nonruminant producers, but lack the capacity to handle two types of feeds, will be encouraged to add storage capacity if the price of the two types of meat and bone meal diverge significantly. The ERG study indicates that these capital and operating costs may be substantial, but finds that the larger feedmills would be much more likely to make this investment.

d. *Description of the recordkeeping burden of the rule.*

The Regulatory Flexibility Act directs agencies to describe the recordkeeping requirements of its rules. This regulation will require certain feed manufacturers to develop new written operating procedures. No unusual skills or expertise will be required to establish such systems. In addition, many firms will have to retain invoices or other materials sufficient to track the materials, but FDA believes that the retention of such records is already a widely accepted business practice. The addendum to the ERG report summarizes the paperwork and the other documentation costs for the final regulation and for each alternative considered.

e. *Analysis of regulatory alternatives.*

The Regulatory Flexibility Act requires an evaluation of any regulatory overlaps and regulatory alternatives that would minimize the costs to small entities. FDA is unaware of any significant regulatory conflicts with other Federal rules. FDA examined six regulatory alternatives in addition to the no action alternative: (1) The mammalian-to-ruminant prohibition; (2) the mammalian (with exceptions)-to-ruminant prohibition; (3) the ruminant-to-ruminant prohibition; (4) the partial ruminant-to-ruminant prohibition; (5) the prohibition of all sheep, goat, mink, deer, and elk proteins in ruminant feed; and (6) the prohibition of sheep and goat proteins in ruminant feed. As described above, FDA and its contractor, ERG, have prepared a detailed comparison of the respective impacts of these alternatives and have found that the estimated net costs of the final regulation are lower under the mammalian-to-ruminant prohibition, with exceptions, than it would have been under the full mammalian-to-ruminant prohibition (no exceptions), and are comparable to the costs of the proposed ruminant-to-ruminant prohibition. Although the partial ruminant-to-ruminant prohibition is probably less costly, and the other two alternatives would be considerably less costly, these alternatives would not be as effective in reducing the risk of an outbreak and spread of BSE. Thus, FDA believes that the rule selected is the most cost-effective regulatory alternative that meets the objective of the agency.

In response to the many comments from small businesses requesting agency consideration of their views, FDA has revised the rule in several ways to decrease the burden on small entities. For example, FDA has exempted all pet food at the retail level from the requirement to display the cautionary statement on labeling. This exemption will substantially mitigate the lost value of mammalian meat and bone meal, lessening the market adjustments for all entities. Also, the agency has exempted plate wastes and used cellulosic food casings from coverage of the rule. Moreover, the scope of the recordkeeping burden has decreased, so that those producers using only nonmammalian protein products will be exempt from recordkeeping requirements for these products. Finally, FDA has accepted industry comments urging the acceptance of GMP definitions of acceptable clean out procedures for feedmills. This interpretation will reduce the need for any additional training of medicated feedmill employees. Most feedmills manufacture medicated feeds and the employees in those mills are already familiar with good manufacturing practices.

f. *Miscellaneous comments on the analysis of impacts discussion in the proposed rule.*

(Comment 130). Several comments, including several oral comments at the public meetings, claimed that FDA erred in not declaring the proposed rule to be a ''major rule.''

The comments appear to have misinterpreted the proposed rule and the terminology used in the proposed rule. The preamble to the proposed rule clearly stated that the rule ''constitutes an economically significant rule as described in (Executive Order 12866)'' (62 FR 552 at 573). The Executive Order 12866 process uses the term ''economically significant'' to denote those rules which may have an annual

effect on the economy of $100 m or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (see Executive Order 12866, Section 3(f)(1)). This definition is similar to the definition of ''major rule'' in Executive Order 12291 (which declared a rule to be a major rule if it was likely to have an annual effect on the economy of $100 m or more, a major increase in costs or prices for consumers, industries, governments, or geographic regions, or significant adverse effects on competition, jobs, investment, productivity, innovation, or competition with foreign-based enterprises). However, Executive Order 12866 revoked Executive Order 12291. Thus, when FDA said that the rule was an economically significant rule within Executive Order 12866, it was using current terminology.

(Comment 131). Some comments contended that prohibiting the use of protein derived from certain tissues in ruminant feed would impose an unfunded mandate on the States.

FDA disagrees with the comments. For purposes of determining whether an unfunded mandate will be imposed on the states, 2 U.S.C. 658 defines ''Federal intergovernmental mandate,'' in relevant part, as ''any provision in legislation, statute, or regulation that * * * would impose an enforceable duty upon State, local, or tribal governments.'' Therefore, the statute applies to regulations which impose a nondiscretionary function on a State, local, or tribal government and compliance with the regulation could be enforced against the State, local, or tribal government. Neither the proposed rule nor the final rule imposes any nondiscretionary functions on any State. Furthermore, no provisions of the proposed or final rule are enforceable against any State. As such, neither the proposed nor the final rule imposes any unfunded mandate on the States.

The agency noted in response to an earlier comment that states with employees commissioned by FDA under section 702(a) of the act could be used for enforcement of the final rule. The costs of these commissioned employees, however, are borne by FDA, not the states. In addition, states have worked with FDA for many years under voluntary cooperative agreements in regulating animal feeds. FDA expects that such voluntary cooperation from the states will continue.

VI. The 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 (44 U.S.C. 3501–3520) at the time the proposed rule was published (62 FR 552). The title, description, and the respondent description of the information collection provisions are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Animal Proteins Prohibited in Ruminant Feed—21 CFR 589.2000.

Description: This final rule (§ 589.2000) provides that protein derived from mammalian tissues (with some exceptions) for use in ruminant feed is a food additive subject to section 409 of the act (21 U.S.C. 348). Proteins derived from animal tissues contained in such feed ingredients in distribution cannot be readily identified (i.e., species) by recipients engaged in the manufacture, processing and distribution, and use of animal feeds and feed ingredients.

Thus, under the agency's authority in section 701(a) of the act (21 U.S.C. 371(a)) to issue regulations for the efficient enforcement of the act, this final rule places three general requirements on persons that manufacture, blend, process, distribute, or use products that contain or may contain protein derived from mammalian tissues, and feeds made from such products. The first requirement is for cautionary labeling of these products with direct language developed by FDA. This labeling requirement is exempt from the scope of the Paperwork Reduction Act because it is a ''public disclosure of information originally supplied by the Federal government for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

The second requirement is for these establishments to maintain and make available to FDA records that are sufficient to track any material that contains protein derived from mammalian tissues (as defined in § 589.2000(a)(1)) throughout the material's receipt, processing, and distribution. Based on available information, FDA believes that maintenance of such records is a usual and customary part of normal business activities for such firms. Therefore, this recordkeeping requirement creates no paperwork burden.

The third requirement is that individuals or firms that manufacture, blend, process, or distribute both mammalian and nonmammalian materials must maintain written procedures to prevent commingling and cross-contamination. An estimate of the burden resulting from this recordkeeping requirement is provided below. The estimate is based on the time required to develop the written procedures, which FDA anticipates will be a one-time effort.

In the preamble to the proposed rule, FDA included estimates for capital cost and operating cost in the recordkeeping burden chart. These estimates have been deleted from the chart below because the capital and operating costs, although properly included in the analysis of impacts discussion in this document, are not a result of the recordkeeping provisions of the rule and therefore are not part of the recordkeeping burden.

Description of respondents: Individuals or firms that manufacture, blend, process, distribute, or use feed or feed ingredients that contain or may contain protein derived from mammalian tissues.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	No. of record keepers/ firms	Frequency	Total annual records	Hours per record	Total hours
589.2000(e)(1)(iv)	2,000	1	2,000	14	28,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The January 1997 proposed rule provided a 45-day comment period and specifically requested comments regarding collection of information. OMB did not approve the package submitted with the proposed rule and filed the following comments as terms of clearance:

OMB is concerned that the reporting and recordkeeping requirements in the NPRM may be overly burdensome and not maximize utility, and wishes to allow the public the opportunity to consider the NPRM. When the paperwork package is resubmitted for OMB approval at the final rule stage, FDA will directly address OMB's concerns and all comments received on these issues in the preamble of the rule and in the paperwork submission package.

During the 45-day comment period provided by the proposed rule, FDA received no comments regarding the requirement that individuals or firms that manufacture, blend, process, or distribute both mammalian and nonmammalian materials must maintain written procedures to prevent commingling and cross-contamination. Thus, FDA received no comments that suggested that the recordkeeping requirements were overly burdensome or did not maximize utility.

The agency also announced the availability of a draft rule in the **Federal Register** of April 17, 1997 (62 FR 18728). This document contained the codified section of the draft final rule and provided an additional comment period of 10 days. None of the comments received concerned collection of information.

FDA is announcing that the proposed collection of information has been submitted to OMB for review and clearance under the Paperwork Reduction Act of 1995. Section 589.2000(e)(1)(iv) will be effective upon approval by OMB. FDA now invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. FDA will announce the effective date in the **Federal Register**. Submit written comments on the collection of information by July 7, 1997.

Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. For further information contact: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1472. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VII. Federalism

FDA has analyzed the final rule in accordance with the principles set forth in Executive Order 12612 and has determined that this final rule does not warrant the preparation of a Federalism Assessment.

VIII. Congressional Review

This final rule has been determined to be a major rule for purposed of 5 U.S.C. 801 *et seq.*, Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121). FDA is submitting the information and reports as required by that statute.

IX. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Dawson, M., et. al., ''Parenteral Transmission of BSE to the Pig,'' *Veterinary Record*, 127: 338 (1990).
2. Ministry of Agriculture, Fisheries and Food, ''BSE in Great Britain a Progress Report,'' 24, November 1996.
3. Kimberlin, R. H., et. al., ''An Overview of Bovine Spongiform Encephalopathy,'' at the Symposium on Virological Aspects of the Safety of Biological Products, London, England, in *Developments in Biological Standardization*, 75: 75–82 (1990).
4. Collinge, J. et. al., ''Molecular Analysis of Prion Strain Variation and the Aetiology of 'New Variant' CJD,'' *Nature*, 383: 685–670 (1996).
5. Coucerne, S. N., ''Predicting the CJD Epidemic in Humans,'' *Nature*, 385: 197–198 (1997).
6. Davis, A., ''Bovine Spongiform Encephalopathy—United States Surveillance,'' *Dx Monitor*, Winter 1996—Spring 1997: 11 (1997).
7. Groschup, M. H., et. al., ''Detection of Scrapie Agent in Peripheral Nervous System of a Diseased Sheep,'' *Neurobiology of Diseases*, 3: 191–195 (1996).
8. Lasmezas, C. I., et. al., ''Transmission of the BSE Agent to Mice in the Absence of Detectable Abnormal Prion Protein,'' *Science*, 275: 402–405 (1997).
9. Moon, H., ''Bovine Spongiform Encephalopathy: Hypothetical Risk of Emergence as a Zoonotic Foodborne Epidemic,'' *Journal of Food Protection*, 59(10): 1106–1111 (1996).
10. Spraker, T. R., et. al., ''Spongiform Encephalopathy in Free-Ranging Mule Deer, White-Tailed Deer, and Rocky Mountain Elk in North Central Colorado,'' *Journal of Wildlife Diseases*, 33(1): 1–6 (1997).
11. European Commission, Decision, 27 June 1994, 94/381/EC, *Official Journal of the European Commission*, 172/23.
12. Davis, A., ''Bovine Spongiform Encephalopathy—United States Surveillance,'' *Dx Monitor*, Winter 1996—Spring 1997, 11 (1997).
13. Brown, P. and D. C. Gajdusek, ''Survival of Scrapie Virus After 3 Years'' Interment,'' *Lancet*, 337: 269–270 (1991).
14. Eastern Research Group, ''Cost Analysis of Regulatory Options to Reduce the Risk of an Outbreak of Transmissible Spongiform Encephalopathies (TSE's) in the United States,'' Addendum to the Final Report, April 29, 1997.

List of Subjects in 21 CFR Part 589

Animal feeds, Animal foods, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Lead Deputy Commissioner, 21 CFR part 589 is amended as follows:

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

1. The authority citation in 21 CFR part 589 is revised to read as follows:

Authority: Secs. 201, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 343, 348, 371).

2. New § 589.2000 is added to subpart B to read as follows:

§ 589.2000 Animal proteins prohibited in ruminant feed.

(a) *Definitions.*—(1) *Protein derived from mammalian tissues* means any protein-containing portion of mammalian animals, excluding: Blood and blood products; gelatin; inspected meat products which have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings); milk products (milk and milk proteins); and any product whose only

mammalian protein consists entirely of porcine or equine protein.

(2) *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 here) whose intended use for the products may include animal feed. The term includes renderers that also blend animal protein products.

(3) *Blender* means any firm or individual which obtains processed animal protein from more than one source or from more than one species, and subsequently mixes (blends) or redistributes an animal protein product.

(4) *Feed manufacturer* includes manufacturers of complete and intermediate feeds intended for animals, and includes on-farm in addition to off-farm feed manufacturing and mixing operations.

(5) *Nonmammalian protein* includes proteins from nonmammalian animals.

(6) *Distributor* includes persons who distribute or transport feeds or feed ingredients intended for animals.

(7) *Ruminant* includes any member of the order of animals which has a stomach with four chambers (rumen, reticulum, omasum, and abomasum) through which feed passes in digestion. The order includes, but is not limited to, cattle, buffalo, sheep, goats, deer, elk, and antelopes.

(b) *Food additive status.* The Food and Drug Administration has determined that protein derived from mammalian tissues for use in ruminant feed is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act). The use or intended use in ruminant feed of any material that contains protein derived from mammalian tissues causes the feed to be adulterated and in violation of the act, unless it is the subject of an effective notice of claimed investigational exemption for a food additive under § 570.17 of this chapter.

(c) *Requirements for renderers that are not included in paragraph (e) of this section.* (1) Renderers that manufacture products that contain or may contain protein derived from mammalian tissues and that are intended for use in animal feed shall take the following measures to ensure that materials identified in paragraph (b) of this section are not used in the feed of ruminants:

(i) Label the materials as follows: ''Do not feed to cattle or other ruminants''; and

(ii) Maintain records sufficient to track the materials throughout their receipt, processing, and distribution, and make the copies available for inspection and copying by the Food and Drug Administration.

(2) Renderers described in paragraph (c)(1) of this section will be exempted from the requirements of paragraphs (c)(1)(i) and (c)(1)(ii) of this section if they:

(i) Use exclusively a manufacturing method that has been validated by the Food and Drug Administration to deactivate the agent that causes transmissible spongiform encephalopathy (TSE) and whose design has been made available to the public;

(ii) Use routinely a test method that has been validated by the Food and Drug Administration to detect the presence of the agent that causes TSE's and whose design has been made available to the public. Renderers whose products test positive for agents that cause TSE's must comply with paragraphs (c)(1)(i) and (c)(1)(ii) of this section. Records of the test results shall be made available for inspection by the Food and Drug Administration; or

(iii) Use exclusively a method for controlling the manufacturing process that minimizes the risk of the TSE agent entering the product and whose design has been made available to the public and validated by the Food and Drug Administration.

(3) Renderers described in paragraph (c)(1) of this section will be exempted from the requirements of paragraph (c)(1)(ii) of this section if they use a permanent method, approved by FDA, to make a mark indicating that the product contains or may contain protein derived from mammalian tissue. If the marking is by the use of an agent that cannot be detected on visual inspection, the renderer must use an agent whose presence can be detected by a method that has been validated by the Food and Drug Administration and whose design has been made available to the public.

(d) *Requirements for protein blenders, feed manufacturers, and distributors that are not included in paragraph (e) of this section.* (1) Protein blenders, feed manufacturers, and distributors that manufacture, blend, process, and distribute products that contain or may contain protein derived from mammalian tissues shall comply with paragraph (c)(1) of this section.

(2) Protein blenders, feed manufacturers, and distributors, shall be exempt from paragraphs (d)(1) of this section if they:

(i) Purchase animal products from renderers that certified compliance with paragraph (c)(2) of this section or purchase such materials from parties that certify that the materials were purchased from renderers that certified compliance with paragraph (c)(2) of this section; or

(ii) Comply with the requirements of paragraph (c)(2) of this section where appropriate.

(3) Protein blenders, feed manufacturers, and distributors, shall be exempt from paragraph (c)(1)(ii) of this section if they:

(i) Purchase animal protein products that are marked in accordance with paragraph (c)(3) of this section or purchase such materials from renderers that certified compliance with paragraph (c)(3) of this section, or purchase such materials from parties that certify that the materials were purchased from renderers that certified compliance with paragraph (c)(3) of this section; or

(ii) Comply with the requirements of paragraph (c)(3) of this section where appropriate.

(4) Pet food products that are sold or are intended for sale at retail and feeds for nonruminant laboratory animals are exempt from the labeling requirements in paragraphs (c) and (d) of this section. However, if the pet food products or feeds for nonruminant laboratory animals are sold or are intended for sale as distressed or salvage items, then such products shall be labeled in accordance with paragraph (c) or (d) of this section, as appropriate.

(5) Copies of certifications as described in paragraphs (d)(2) and (d)(3) of this section, shall be made available for inspection and copying by the Food and Drug Administration.

(e) *Requirements for persons that intend to separate mammalian and nonmammalian materials.* (1) Renderers, protein blenders, feed manufacturers, distributors, and others that manufacture, process, blend and distribute both products that contain or may contain protein derived from mammalian tissues or feeds containing such products, and protein products from other animal tissues or feeds containing such products, and that intend to keep those products separate shall:

(i) Comply with paragraphs (c)(1) or (d)(1) of this section as appropriate except that the labeling requirement shall apply only to products that contain or may contain protein derived from mammalian tissues or feeds containing such products;

(ii) In the case of a renderer, obtain nonmammalian or pure porcine or pure equine materials only from single-species slaughter facilities;

(iii) Provide for measures to avoid commingling or cross-contamination;

(A) Maintain separate equipment or facilities for the manufacture, processing, or blending of such materials; or

(B) Use clean-out procedures or other means adequate to prevent carry-over of products that contain or may contain protein derived from mammalian tissues into animal protein or feeds that may be used for ruminants; and

(iv) Maintain written procedures specifying the clean-out procedures or other means, and specifying the procedures for separating products that contain or may contain protein derived from mammalian tissue from all other protein products from the time of receipt until the time of shipment.

(2) Renderers, blenders, feed manufacturers, and distributors will be exempted from applicable requirements of paragraph (e)(1) of this section, if they meet the criteria for exemption under paragraphs (c)(2) or (c)(3) of this section, and (d)(2) or (d)(3) of this section.

(f) *Requirements for establishments and individuals that are responsible for feeding ruminant animals.* Establishments and individuals that are responsible for feeding ruminant animals shall maintain copies of purchase invoices and labeling for all feeds containing animal protein products received, and make the copies available for inspection and copying by the Food and Drug Administration.

(g) *Adulteration and misbranding.* (1) Animal protein products, and feeds containing such products, that are not in compliance with paragraphs (c) through (f) of this section, excluding labeling requirements, will be deemed adulterated under section 402(a)(2)(C) or 402(a)(4) of the act.

(2) Animal protein products, and feeds containing such products, that are not in compliance with the labeling requirements of paragraphs (c) through (f) of this section will be deemed misbranded under section 403(a)(1) or 403(f) of the act.

(h) *Inspection; records retention.* (1) Records that are to be made available for inspection and copying, as required by this section, shall be kept for a minimum of 1 year.

(2) Written procedures required by this section shall be made available for inspection and copying by the Food and Drug Administration.

Dated: May 9, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Dated: May 9, 1997.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 97–14682 Filed 6–3–97; 8:45 am]

BILLING CODE 4160–01–P