FINDING OF NO SIGNIFICANT IMPACT

AND

ENVIRONMENTAL ASSESSMENT

FOR

21 CFR 589.2000
PROHIBITION OF PROTEIN DERIVED
FROM RUMINANT AND MINK TISSUES IN RUMINANT FEEDS

CENTER FOR VETERINARY MEDICINE

FOOD AND DRUG ADMINISTRATION

NOVEMBER 1996

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PROPOSED RULE

The Center for Veterinary Medicine (CVM) of the Food and Drug Administration (FDA) has carefully considered the environmental impact of prohibiting the use of protein derived from bovine (cattle family), ovine (sheep family), caprine (goat family), cervine (deer family) and mink in the feed of ruminants. The proposed action is being taken under 21 CFR 589.2000 to avoid the introduction and spread of transmissible spongiform encephalopathies (TSE's) among ruminants in the United States. The effect of the action is that the products made with proteins derived from ruminants and mink will, instead of being processed for use in ruminant feed, be used for other purposes or be disposed.

All potential sources of protein derived from ruminants and mink are included in the prohibition except blood from bovines, milk and gelatin. Such proteins would, under the proposed rule, not generally be recognized as safe for use as a ruminant feed because they may contain TSE infective material and would be an unapproved food additive prohibited from use in ruminant feed. Fats derived from ruminants and mink are not included in the prohibition, as they are not considered to contain protein.

Processed ruminant and mink proteins prohibited in ruminant feeds and the feeds containing them are required to be labeled. Recordkeeping, identification of prohibited proteins, and/or procedures to prevent commingling or cross-contamination of finished products are also required of renderers, blenders, feed manufacturers and distributors, and ruminant producers as the means to enforce the new restrictions.

These procedures are intended to prevent the introduction and spread of TSE's among ruminants. Scrapie in sheep and goats, chronic wasting disease (CWD) in the deer family, bovine spongiform encephalopathy (BSE) and transmissible mink encephalopathy (TME) are all types of TSE's. Scrapie, TME and CWD occur, although infrequently, in the

United States (US). BSE has not been found in the US. In the United Kingdom (UK), however, BSE has become a serious disease of cattle. It is sometimes referred to there as "mad cow disease." The source of BSE in the UK may have been originally scrapie from sheep-derived proteins used in cattle feed. After it was introduced into cattle, BSE likely spread by the practice of feeding proteins derived from portions of cattle containing the BSE agent to cattle.

The proposed action, therefore would minimize the chances of scrapie, TME or CWD agents crossing over to cattle and would also prevent the spread of BSE among cattle, should it be accidentally imported or occur spontaneously. The action would also inhibit the spread of TSE's among sheep, goats, and deer to the extent that ingestion of the prohibited proteins are a route for the spread of these agents in those species.

It is possible that the proposed rule would indirectly cause a decline in the proportion of dead, dying, disabled or diseased (4-D) animals and inedible (to humans) slaughter products that are utilized by renderers. There could be a concomitant increase in the proportion of these materials that are buried on farms, buried in local landfills, and/or incinerated. In analyzing the possible environmental consequences of such a shift, we assume that disposal in landfills and incineration would be subject to environmental laws that would provide adequate protection with regard to potential environmental contamination by TSE's and any other potentially deleterious substance. Any decline in rendering of 4-D animals and inedible slaughter products would likely be short-lived, as new procedures were put into place to efficiently utilize these protein sources. Therefore, any increases in on-farm disposal that might be a consequence of the proposed action also would likely be short-lived.

We believe the potential incremental increase in on-farm burial of cattle, sheep, goats and mink and any possible consequential harm to the environment as a result of the proposed action would likely be minimal. We assume that on-farm burial might, in some cases, be subject to the same environmental laws as landfills and incinerators. Further, precedent for the practice of on-farm burial of infected or high risk sheep was already established as a recommended means of disposal by the Animal and Plant Health Inspection Service (APHIS) in the indemnity portion of its voluntary scrapie certification program.

Adoption of the proposed rule should decrease the prospects of BSE occurring in the US; this would have a positive environmental consequence. If FDA adopts the proposed rule

and BSE nonetheless occurs undiagnosed in the US, there is a possible increased exposure to wildlife (predators/scavengers), the consequence of which is not known. If BSE occurs and is subsequently diagnosed, there is likely to be a marked increase in on-farm disposal of animals with some potential increased exposure to wildlife, as producers make efforts to eradicate BSE. These environmental effects are likely to be less pronounced, however, than if the agency did not adopt the proposed rule.

The Center for Veterinary Medicine has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment. Therefore, an environmental impact statement is not required. The evidence supporting this finding is contained in the attached environmental assessment, which was prepared under 21 CFR 25.31b of FDA's environmental regulations (21 CFR 25) and the Council on Environmental Quality's regulations (40 CFR 1500-1508) implementing the National Environmental Policy Act.

11-1-96 /s/
Date John C. Matheson III, MSPH
Preparer, Senior Environmental Scientist,
Division of Toxicology & Environmental Sciences

11-1-96 /s/
Date Randall A. Lovell, DVM, Ph.D.
Preparer,
Division of Animal Feeds

11/1/96 /s/

Date John P. Honstead, DVM, MS
Preparer,
Division of Animal Feeds

12/16/96 /s/

Date Stephen F. Sundlof, DVM, Ph.D.
Director,
Center for Veterinary Medicine

Attachment: Environmental Assessment, dated November 1996

ENVIRONMENTAL ASSESSMENT
TABLE OF CONTENTS

FIGURES.

TABLE.

Environmental Assessment

Prohibition of Protein Derived from Ruminant and Mink Tissues in Ruminant Feeds October 1996

I. DESCRIPTION OF THE NEED FOR ACTION AND THE PROPOSED ACTION

A. Need for Action

The Food and Drug Administration (FDA) and the US Department of Agriculture (USDA) have been monitoring the development and spread of a serious disease of cattle in the United Kingdom (UK). The disease, bovine spongiform encephalopathy (BSE), also known as "mad cow disease," belongs to a family of transmissible spongiform encephalopathies (TSE's) including scrapie in sheep and goats, chronic wasting disease (CWD) of deer and elk, and transmissible mink encephalopathy (TME) in mink. TSE's are also known to occur in humans, including Creutzfeldt-Jakob disease (CJD), Gerstmann-Straussler-Scheinker syndrome (GSS), fatal familial insomnia (FFI), and kuru. TSE's are thought to be caused by prions, which appear to be post-translationally modified isoforms of a host-encoded protein (native proteins that have been re-folded into a different configuration) that are resistant to many of the typical measures used to inactivate viruses and bacteria.

Because the agents that appear to cause TSE's are proteins, they are not easily detected. The principle means of diagnosing BSE in cattle is through clinical signs (odd behaviors) and through histopathological examinations of sections from brains of suspected animals that have been killed. Clinical signs of TSE's occur after a prolonged incubation period (2-8 years in cattle). The agent is presumably present in the brains of the animal for some time before enough damage is done to result in clinical signs. A bioassay using rodents is sometimes used, but is very time consuming and expensive. None of these approaches is satisfactory for the widespread screening of apparently healthy cattle populations or feed ingredients. This inability to easily screen for TSE's in living animal populations or in feed ingredients is a major factor in the formulating of approaches to controlling or preventing the spread of TSE's.

BSE was first diagnosed in the UK in 1986. One way BSE is thought to have been introduced into cattle in the UK is through the processing of sheep infected with scrapie into cattle feed ingredients. Efforts to control BSE in the UK went into effect in 1988. In spite of these efforts, over 155,600 cattle in 33,000 herds have been affected with BSE.

The export of cattle and, possibly, ruminant-derived protein feed ingredients from the UK have resulted in BSE being found in several other countries. As a consequence, many countries, including those in Europe and the US have placed into effect measures to restrict the import of cattle, of food for humans derived from cattle, and of rendered feed ingredients that may contain proteins derived from cattle. Much effort has been required in the US and Canada to track down and monitor cattle that were imported from the UK before the import restrictions went into effect.

BSE has not been diagnosed in the US. However, scrapie has been present in the sheep and goat populations since the 1940's. CWD has also been found in mule deer and elk in 4 contiguous counties in Colorado and Wyoming. Five TME outbreaks, involving 11 mink farms, have been reported in the US in the last 50 years. It is possible that, like familial CJD in humans, BSE could occur spontaneously in healthy cattle at some low rate. It is also possible that BSE could be imported from the UK or from some other country where BSE has occurred but remains undiagnosed. In other words, at least some of the factors are present that could result in the introduction of BSE into the US cattle population.

The introduction and spread of BSE in the US cattle population would have major adverse consequences for that industry. In addition to the loss of cattle to the disease and the expense of controlling it, major overseas markets for US cattle products might be closed.

An additional concern is that BSE might cross over from infected cows to man, just as it may have reached cattle from sheep. In the UK, 10 cases of a variant form of CJD (v-CJD) have been identified with a new neuropathological profile. Other consistent features among the new cases are the young age at onset of clinical signs, and the absence of electroencephalogram features typical of CJD. The v-CJD may be causally related to BSE, however, a direct link to BSE cannot be confirmed on the basis of these ten cases alone. (See 61 FR 24253ff and the *Federal Register* notice and proposed rule that this EA accompanies for details and additional references.) The possibility of BSE crossing

over to humans adds much urgency to the need to take measures to prevent the spread of BSE among world-wide cattle populations.

B. Actions in the US to Date

The TSE situation in animals has been monitored through the USDA, Animal and Plant Health Inspection Service (APHIS), which monitors animal diseases, and the Food Safety Inspection Service (FSIS), which inspects slaughter of animals. The FDA CVM is responsible for feed ingredients of animals.

Since 1952, APHIS has had a scrapie control program which is responsible for the relatively low incidence of scrapie in US sheep. In 1993, there were 108 scrapie infected flocks containing a total of 7,430 sheep out of 112,000 US flocks containing 11 million sheep. (Usually, only a few sheep in each scrapie-infected flock show signs of the disease.) In 1992, APHIS instituted a voluntary certification program for sheep flocks free of scrapie for at least 5 years in order to further decrease the incidence of scrapie.

In 1989, APHIS prohibited the importation of cattle from BSE infected countries and began tracing the movement and health status of 459 cattle imported from the UK between 1981 and 1989. In 1991, APHIS placed a ban on importation of certain products of ruminant origin from countries known to have BSE.

In 1989, the US rendering industry instituted a voluntary ban on the rendering of adult sheep offal into ruminant feed ingredients. The aim of the ban was to reduce the chance of protein products from scrapie-infected sheep entering the diet of ruminants. In 1992, the FDA surveyed major sheep rendering plants to determine whether the voluntary ban was being followed. FDA found that the voluntary ban was not fully implemented at the time of the survey. (See 59 FR 44583ff for details.)

In August 1994, FDA sent letters to manufacturers of all FDA-regulated animal products and requested that they not use bovine-origin materials from countries with BSE. On August 29, 1994, FDA proposed a rule that would have banned the use of certain protein products derived from adult sheep and goats as feed ingredients for ruminants. (59 FR 44583ff)

Shortly following the March 1996 announcements about the 10 cases of v-CJD in the UK, the National Cattlemen's Beef Association announced, in conjunction with several other groups, that they were developing a voluntary program that would prevent ruminant-derived proteins from being used as feed ingredients for other ruminants. FDA/CVM and APHIS co-hosted a symposium on May 13-14, 1996, to gather additional scientific information on TSE's and to discuss approaches to controlling animal products and feed in order to manage any risk of TSE to animal health. After evaluating comments received on the proposed adult sheep and goat rule and considering new developments in our understanding of the etiology and spread of TSE's, FDA published an advanced notice of proposed rulemaking stating that it was considering a broader action that would ban all ruminant-derived proteins from being used in the feed of ruminants. (61 FR 24253ff)

C. Approach to Selecting a Proposed Rule

How should the FDA participate in managing the potential risks posed by TSE's to the US animal and human populations?

The perception of risk to both animals and man is different among the many interested parties that include the general public, cattlemen, renderers, feed manufacturers, public health professionals, veterinarians, physicians, and the many industries that manufacture food, biologicals, and other products derived from ruminants. Many approaches are possible, with a wide range of coverage and costs, and with differing perceptions of effectiveness in addressing the risks. There are arguments that sound reasonable to support the entire spectrum of possibilities, from watchful waiting all the way to a ban on all mammalian-derived proteins from being fed to ruminants. The interplay of new information about TSE's, the BSE control measures being undertaken in the UK, and the diversity of the various interested parties all make the formulation of a proposed rule that is supported by a consensus especially difficult. These forces have resulted in a wide array of opinions on how best to proceed and a consensus is not likely to be reached until better knowledge of TSE's and their control is available. This environmental assessment will briefly survey the spectrum of options and then attempt to assess the impact potential of each relative to the others. The types of uncertainties will be identified to the extent possible, as they preclude quantitative predictions of impacts.

Option 1. Watchful Waiting.

The point of view here is that the actions being taken now are all that are justified until such time as BSE is diagnosed in the US. Watchful waiting, i.e., continued monitoring of cattle by animal health professionals at slaughterhouses and in diagnostic labs, the import restrictions and the current scrapie program of APHIS, and the voluntary efforts of the renderers and cattlemen, is enough to deter the introduction of BSE and to detect it at a reasonably early date when remedies necessary to eradicate it would be low in costs.

Option 2. Prohibit Specified Offal from Adult Sheep and Goats in Ruminant Feeds.

This approach was described in the FDA proposed rule of August 29, 1994 (59 FR 44583ff). The point of view here is that the voluntary efforts of renderers to prevent the processing of potentially scrapie-infected adult sheep and goats need to be supported by an enforceable rulemaking. Scrapie is present in the US and, if scrapie is the source of BSE in cattle, this measure will prevent proteins from the potentially most highly infected sheep and goats, i.e., adults, from entering the ruminant food supply. Non-proteinaceous materials, like tallow and fat, are unaffected by this alternative and would be allowed in ruminant feeds. This action in addition to the *watchful waiting* measures described above in Option 1 would be all that is justified prior to the diagnosis of BSE in the US. This approach attempts to reduce the level of scrapie prions present in feeds for ruminants, with the assumption that the spread of scrapie from sheep and goats across to cattle is in some manner dose-related.

Option 3. Prohibit Proteins Derived from Sheep, Goats, Deer, Elk and Mink from Ruminant Feeds.

This approach could be regarded as a more inclusive version of Option 2. All proteins derived from an animal species where a TSE has been diagnosed in the US would be prohibited from ruminant feeds. There would not be the age limitations or the specified offal provisions found in Option 2. With the exception of milk and gelatin, protein products derived from offal from slaughter, grocery returns and all 4-D carcasses of the identified species could not enter the food supply of ruminants. Fats, as non-

proteinaceous materials, would be permitted. Since BSE has not been identified in cattle in the US, rendered feed ingredients from cattle could be fed without restriction to any species, including cattle and other ruminants. The watchful waiting measures in Option 1 would also be implemented under Option 3.

Option 4. Prohibit Proteins Derived from Ruminants and Mink in Ruminant Feeds.

This approach was briefly described in the advance notice of proposed rulemaking (61 FR 24253ff). It is broader than the above actions, in that it affects the management of many more materials passing through the slaughterers/renderers/processors/feed manufacturers food chain, as it would include all sheep, goats, cattle, and wild ruminants, such as deer, elk and bison. Mink, as a known US host of a TSE, would also be prohibited as a source of protein for ruminant feeds. The goal of this option is to prevent the use of feed ingredients that may contain ruminant and mink-derived protein in ruminant feeds. The potential for introductions of BSE into the US cattle population through imported BSE infected feed ingredients and for scrapie- or TME- or CWD-to-BSE crossovers are addressed by this option. The amplification of spontaneous BSE or any other introduced TSE source would also be addressed by preventing the materials from infected ruminants from being recycled as feed ingredients for ruminants. Blood from bovines, gelatin and milk, three protein sources where there is reasonable agreement that they are not potentially TSE infective, would be permitted in ruminant feeds. Non-proteinaceous materials from ruminants and mink, like tallow and fat, would be unaffected by this alternative and would be allowed in ruminant feeds. Option 4 is similar to the recommendation of an expert panel convened by the World Health Organization (WHO) in April 1996.

Labeling and identification of proteins and feed ingredients derived from ruminants and mink would be required. Additional recordkeeping, operating procedures and controls on the handling of these materials to prevent their inadvertent incorporation in ruminant feeds would also be required.

Option 4 is the FDA proposed action and is described in more detail in the Federal Register preamble and proposed rule that this Environmental Assessment accompanies.

Option 5. Prohibit Proteins from Designated Tissues in Ruminant Feeds.

This approach is similar to the ruminant-to-ruminant protein ban in Option 4 above, but is modified to exclude from the ban certain tissues of cattle which have not transmitted BSE to lab animals following intracerebral injection. These tissues are therefore regarded as being less infective than can be determined by the only available bioassay. This action would declare that protein derived from designated tissues would, under the proposed rule, not be generally recognized as safe for use in ruminant feed and would be an unapproved food additive under Section 409 of the Federal Food, Drug and Cosmetic Act (the act) when added to ruminant feed. Protein derived from the designated tissues is defined as: any and all protein that is derived from 1) any portions of ovine, caprine, cervine, and mink; 2) all dead, dying, disabled, or diseased (4-D) bovine; and 3) the brain, spinal cord, eyes and distal ileum of bovine slaughtered for human consumption.

Processed proteins derived from designated tissues would be prohibited in ruminant feeds and the feeds containing them and would be required to be labeled as not to be fed to ruminants. Recordkeeping, identification of prohibited proteins, and procedures to prevent cross-contamination of finished products could be required of slaughterhouses, renderer/processors, feed manufacturers and producers as the means to enforce the new restrictions.

Gelatin and milk proteins derived from ovine, caprine and cervine would not be defined as derived from designated tissues. Nor would blood products from bovines. All proteins derived from non 4-D bovine that are not from the tissues identified in 3) above are excluded from the prohibition, i.e., these are allowed to be used in ruminant feeds. Non-proteinaceous materials, like tallow and fat, are also unaffected by Option 5 and would be allowed in ruminant feeds. Thus, this approach seeks to have about the same effectiveness of a ruminant-to-ruminant ban in preventing the crossover and spread of TSE's in the ruminant population while attempting to minimize the volume of materials affected.

Option 6. Prohibit All Mammalian-Derived Proteins In Ruminant Feeds.

The point of view in this approach is that TSE's may be present in a variety of mammalian-derived proteins, that mammalian-derived proteins are not required in the diets of ruminants, and that a simple ban of all mammalian proteins in ruminant feeds would be

the easiest to comply with and to enforce, as there would be minimum chances of cross-contamination at the rendering and feed production facilities and because screening methods for mammalian proteins are available. This approach assumes that the factors causing TSE's to occur spontaneously will always be present and that the public health implications and economic seriousness of widespread TSE's occurring in ruminant populations require measures that will effectively prevent the spread of TSE's indefinitely.

Whereas the previous approaches attempt to manage the problem by applying controls to the slaughterers, renderers, processors, feed manufacturers and the producers to follow additional safeguards, in the face of a continuing economic conflict of interest, this approach seeks to apply controls primarily at the feed ingredients level. In comparison to Options 4 and 5, this option does not appear to require much change in the current slaughtering and rendering/processing practices, as these industries are already roughly segregated into poultry, mammal/mixed species, and fish. Instead, Option 6 largely requires that the current products be marketed differently, with the protein products derived from mammal/mixed species excluded from the ruminant feeds market. As with Options 4 and 5 above, some labeling and recordkeeping measures would be required, however the need for changes in other manufacturing practices would be much reduced.

As part of a much larger program to eradicate BSE, the UK is implementing a similar action to Option 6. Option 6 may be re-examined in light of whether the UK effort has proven effective.

D. Proposed Action

The Food and Drug Administration (FDA) proposes (in a proposed rule published in the *Federal Register* accompanying this environmental assessment) to declare that protein derived from ruminant and mink tissues would not be generally recognized as safe for use in ruminant feed and would be an unapproved food additive under Section 409 of the Federal Food, Drug and Cosmetic Act (the act) when added to ruminant feed. In the absence of an effective notice of claimed investigational exemption for a food additive under 21 CFR 570.17 or an approved food additive petition, the use or intended use in a ruminant feed of any material that contains protein derived from ruminant or mink tissues causes the feed to be adulterated and in violation of the act. FDA has also determined that ruminant and mink derived proteins are not prior sanctioned for use in ruminant feeds.

All potential sources of ruminant and mink protein are included, except blood from bovines, milk proteins and gelatin.

Recordkeeping, identification of prohibited proteins, and written procedures to prevent commingling or cross-contamination of finished products are also required of renderers, blenders, feed manufacturers and distributors, and ruminant producers as the means to enforce the new restrictions. These requirements are detailed in the preamble to the proposed rule in the *Federal Register*.

Use **in ruminant feed** of proteinaceous material derived from ruminant or mink tissues will cause the feeds to be considered adulterated and subject to seizure and the persons responsible for the adulteration would be subject to court orders and/or civil or criminal penalties under the act.

The same proteinaceous material derived from ruminant and mink tissues, however, may be used **in feed for non-ruminant animals**. Processed products containing proteinaceous material derived from ruminant or mink tissues must identify on the label that such proteins are present.

E. Regulatory Authority

Please see the preamble to the *Federal Register* notice containing the proposed rule for a detailed discussion of the authority being used under the Federal Food, Drug and Cosmetic Act. Briefly, the new information available with respect to TSE's led the FDA to conclude that proteins derived from ruminant and mink tissues are not generally recognized as safe when present in the feeds of ruminants. Since information showing the safety of these proteins has not been provided in an approved food additive petition, ruminant feeds containing them are adulterated and subject to agency enforcement. Several procedures and controls, including labeling, are required to prevent the prohibited feed ingredients from being included in the diets of ruminants.

F. How the Proposed Action Addresses the Need for Action

1. *BSE Risk Factors.*

Investigators have identified major risk factors that apparently contributed to the emergence of the BSE epidemic in the United Kingdom (USDA/APHIS, 1991) (USDA/APHIS, 1991a) (Walker et al., 1991) (USDA, 1993). These include:

(1) a large sheep population, relative to cattle population,

(2) a high scrapie incidence rate,

(3) the practice of feeding rendered products from BSE-infected cattle to young cattle at high amounts (up to four percent of the diet),

(4) the feeding of "greaves," and

(5) changes in the rendering process.

With the exception of the rendering processes, which are currently similar in the US and the UK (both use heat extraction methods), the other major risk factors are markedly lower in the US in comparison to the UK. The US has approximately 11 million sheep, and a sheep to cattle ratio of approximately 0.11 to 1 (USDA/APHIS, 1991) (USDA/APHIS, 1991a). There are approximately 108 scrapie-infected or source flocks in the US with about 7,430 animals. APHIS also has implemented a voluntary scrapie certification program and has sponsored several scrapie indemnification projects, the last of which ended in June, 1993 (57 FR 58132). This compares to the United Kingdom which has approximately 42.9 million sheep (1989 estimate), a sheep to cattle ratio of approximately 3.6 to 1, and has had no national movement to control or report scrapie.

The US feed manufacturers typically use all vegetable proteins in their beef and dairy calf rations and if animal proteins are incorporated, they are generally used in minimal amounts. The feeding of "greaves" is not followed in the US and has stopped in the UK. In the UK, whole dead animals were processed in two steps as a source of tallow. The bone and protein solids remaining after the first heating step, termed "greaves", were used as dairy calf feed and may have contained the BSE agent.

In 1981-82 the rendering industry in the UK reduced the use of hydrocarbon solvent extraction in the rendering process (Wilesmith, 1991). The appearance of BSE in the UK approximately 5 years after the change in the rendering process is consistent with the 2 to 8 year incubation period of BSE. It was theorized that the additional heating step with

steam in the hydrocarbon extraction method of rendering was more likely than the heat extraction method of rendering to inactivate any scrapie-like agents present in rendered animal by-products (Kimberlin, 1992) (USDA/APHIS, 1991a). The heat extraction method is the most common rendering process currently in use world wide.

2. *Minimizes the Potential for Spread of TSE's to Ruminants via the Feed.*

Because of the prolonged application of heat and the associated transformation of the tissues, rendering is generally regarded by FDA as a process that ensures that the ingredients pose no threat of disease to animals when included in their feed or to the health of humans who consume animal-derived products such as meat, milk and eggs. In its role as regulator of rendering practices, FDA has focused on the efficacy of a facility's rendering process in the prevention of disease transmission and the prevention of contamination of the finished products (FDA, 1980). Prior to the BSE epidemic, FDA had no previous evidence of an animal or human health TSE hazard associated with the feeding of rendered ingredients to animals. Rendered animal products also have a long history of safe use in the US as a source of nutrients for animals.

As explained more fully in the accompanying *Federal Register* notice, epidemiological evidence from the UK suggests that scrapie, a TSE of sheep, may have survived the rendering process to cause BSE in cattle. This is the first reported instance in which it is suspected that a disease agent survived rendering. The agent responsible for the transmission of BSE and related TSE diseases is not fully characterized, but is believed to be a cattle variant of the sheep scrapie agent (Hope et al., 1988) (Kimberlin, 1990). The TSE agents have been termed *prions*, and are believed to be abnormal forms of neuronal membrane proteins that are already present in all animals (Prusiner et al., 1993) (Stahl and Prusiner, 1991). Prions are resistant to most methods of sterilization and survive severe environmental conditions such as 360° C dry heat (Brown et al., 1989) and burial for 3 years (Brown and Gadjusek, 1991).

Epidemiological studies of the outbreak of BSE in the UK, including a computer simulation of the BSE epidemic, have characterized it as an extended common-source epidemic. Each case has been considered a primary case resulting from exposure to a single common source of infection. It is believed that rendered feed ingredients contaminated with sheep scrapie and BSE agents served as the common source of infection (USDA/APHIS, 1991) (USDA/APHIS, 1991a). One study demonstrated that

meat and bone meal could be incorporated into the cattle feed in sufficient quantity to initiate clinical BSE in some of the animals that consumed the feed (Collee, 1990). Thus far, other research has not confirmed that the feeding of scrapie-infected feed ingredients to cattle produces BSE. Therefore, the theory that BSE evolved naturally in cattle has not been ruled out (Fraser, 1992).

The UK studies suggest that the spread of BSE appeared to have been exacerbated by the practice of feeding ingredients from rendered BSE-infected cattle to cattle, a practice that was subsequently banned in the UK in 1989. Incomplete immediate compliance with the feeding ban may account for the fact that some calves born after the ban continue to be infected with BSE and has complicated any theory of vertical transmission of the disease. Maternal transmission may be occurring; however, its role in maintaining the epidemic in the UK is being debated (Robinson, 1992; Hoinville, 1995; MAFF, 1996).

Once TSE's are present, a closed loop food chain is likely the fastest way to spread them. The current rendering and offal processing practices in the US likely contribute to a partially closed loop food chain. The proposed action addresses potentially infective tissues by trying to keep them out of the loop in the ruminant food chain.

Finally, the potential for TME, a rare TSE in the US, to be transmitted from mink to ruminants was also considered in this proposed rule. The proposed rule prohibits the use of all proteinaceous material derived from mink for use in ruminant feeds.

II. ENVIRONMENTAL CONSEQUENCES OF THE PROPOSED ACTION AND ALTERNATIVES

Our goal in this section is to discuss the likely environmental consequences of no additional action, the proposed action, and the other action options. The environmental consequences of each of the six options seriously considered will be discussed in two scenarios--Immediate Impacts (assumes BSE is not present) and Long Term Impacts (assumes BSE is present or will occur)--and will be summarized at the end of this section.

A. Option 1. Watchful Waiting - No Additional Action

1. *Introduction.*

In this section, a flow chart will be provided for the major routes of disposition of ruminants and mink. Then we will provide basic information on the processes used in the rendering and processing industries. An estimate of the total amount of inedible slaughter products produced from cattle, calves, lambs, mature sheep, mature goats, kids and mink in the US in 1992 will also be provided. Finally, the results from the FDA survey of sheep renderers will be reviewed.

a. *Major Routes of Disposition of Animals.*

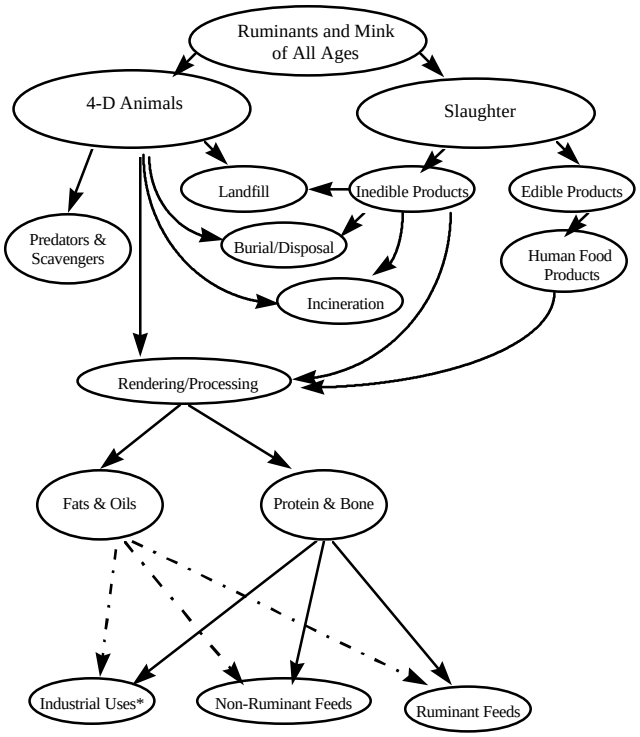
Animals are presented to the rendering and processing industries by two routes (Figure 1). First, apparently healthy animals are sent to slaughter plants where, if they are not condemned on antemortem or postmortem inspection, they are processed into edible products for human consumption (meat, etc.) and into inedible products (often called offal). It is believed that the vast majority of the inedible products from all slaughter plants are sold to renderers/processors for potential use in animal feed and for industrial purposes.

Second, the carcasses of dead, dying, disabled, or diseased (4-D) animals are picked up by the rendering/processing industry after the animals have died, been killed by the owner, or been condemned at a slaughter facility. In comparison to 4-D sheep and goats, 4-D cattle are more likely to be picked up because of their larger size, greater numbers, and less scattered distribution. Many 4-D animals are not available to the rendering/ processing industry as they may be eaten by scavengers or predators or disposed of by the owner via on-farm burial or placement in a local landfill. Very few 4-D animals, with the possible exception of those delivered to diagnostic laboratories, are believed to be disposed of by incineration.

b. *Basic Processes Used in the Rendering and Processing Industries.*

The 4-D carcasses and the inedible slaughter products from animals can be rendered. The rendering process generally involves grinding the raw material and then heating it to temperatures of 230 ° F to 290° F for at least 20 minutes. Generally, raw materials

Figure 1. Disposition Patterns for Ruminants and Mink in the US - Option 1.



*includes, but is not limited to, fertilizers and lubricants.

contain approximately 50 percent moisture, 25 percent fat and 25 percent protein and bone (John, 1990). During the rendering process, the fats and oils are separated from the protein and bone fraction.

The inedible slaughter products from animals can also be processed by other means instead of the general rendering process. This includes, but is not limited to: heating, drying, grinding, extracting, defatting, neutralizing, straining, hydrolyzing, burning, charring, cooking, dehydrating, evaporating, freezing, mechanically separating, and treating with steam, pressure, an acid, and/or a base. During the processing, the fats and oils may be extracted or separated from the protein and bone fraction.

c. *Estimated Amounts of Ruminant and Mink Offal.*

In FY 1992 the Animal Disease Reporting Service (ADRS) of the USDA's Food Safety and Inspection Service (FSIS) indicated that there were 30,759,499 cattle, 1,352,864 calves, 5,129,339 sheep/lambs, and 224,704 goats slaughtered at federally inspected slaughter plants in the US and its territories. Using various assumptions, we estimated that the following amounts of inedible offal were produced at federally inspected slaughter plants in FY 1992 (Appendix G and H). Mink slaughter and offal tonnage were estimated from separate USDA data.

cattle	5,536,710 tons
lambs	79,176 tons
calves	50,732 tons
mature sheep	7,443 tons
mature goats	1,838 tons
kids	1,502 tons
mink	3365 tons*

* 2,692,000 mink slaughtered in 1994 and assuming 2.5 pounds of offal per carcass (USDA, 1996).

d. *Estimated Amount of 4-D Animals Used by the Rendering Industry.*

The FDA could not locate any estimates on the number of 4-D carcasses that are rendered or otherwise processed each year; however, one can obtain an estimate of the total amount of 4-D animals that were processed by the industry using various assumptions. First, we

estimated from slaughter data the amount of offal from swine, equine, and other species (Appendix I) and added it to the amount from ruminants (Appendix G and H). We divided the totals in Appendix G, H, and I by 2, since they contain approximately 50% water (John, 1990), to arrive at an estimate for the total amount of finished products (fats and oils, and proteins and bones) derived from rendering the offal of all livestock, except poultry.

We then located data on the amount of finished products derived from the rendering/processing of poultry (Eastern Research Group, Inc., 1993) and estimated the amount of fats and oils that likely came from sources other than 4-D animals (fat trimmings and fats and oils from restaurants and fast food chains). We then subtracted all these amounts from the total amount of finished products produced by the rendering industry in 1992 (7,647,500 tons) (Eastern Research Group, Inc., 1993) to arrive at an estimate that renderers picked up approximately 1,950,770 tons of 4-D animals of all species. This amount of 4-D animals represents approximately 975,385 tons of finished product or approximately 13% of the total amount of finished products produced by the rendering industry in 1992 (Appendix J).

e. *FDA Survey of Sheep Renderers.*

In 1989, the National Renderers Association (NRA) and the Animal Protein Producers Industry (APPI) recommended to its members that they stop rendering adult sheep or sheep offal for sale as meat and bone meal for inclusion in cattle feed (Bisplinghoff, 1989). Following adoption of the voluntary ban, the FDA carried out a survey of current practices in the United States for rendering or otherwise disposing of adult sheep carcasses and parts, specifically head, brain and spinal cord. Limited inspections of rendering plants were conducted to: (1) assess compliance by United States renderers with the industry imposed voluntary ban on rendering adult sheep for cattle feed, (2) identify rendering plant practices concerning adult sheep, and (3) determine if rendered adult sheep protein by-products were being sold or labeled for use as feed or feed components for cattle.

Of the 19 plants surveyed, 15 rendered carcasses or offal of adult sheep. These 15 plants processed more than 85 percent of the adult sheep rendered in the United States. Eleven of the 15 rendered carcasses of adult sheep with heads, 7 of the 15 rendered sheep carcasses separately from other species, 6 of the 15 maintained meat and bone meal from

adult sheep separate from meat and bone meal from other species, and 4 of the 15 rendered sheep that had died of causes other than slaughter. Six of the 11 renderers processing adult sheep with heads had sold meat and bone meal to manufacturers of cattle feed thus, the rendering industry's voluntary ban was not fully implemented at the time of the survey (FDA, 1993).

The 1989 voluntary ban recommended by the NRA and APPI appears to be partially effective as survey results show that the percentage of renderers processing dead sheep has declined from 39% in 1985 to 7% in 1990 (USDA/APHIS, 1993b). Results from the same surveys show that the percentage of renderers processing inedible sheep offal has also declined from 44% in 1985 to 13% in 1990 (USDA/APHIS, 1993b). These results suggest that the percentage of adult 4-D sheep picked up by renderers and the percentage of inedible sheep offal utilized by renderers has likely declined as a result of this voluntary ban. The FDA believes that compliance by the rendering industry with the voluntary ban will continue at approximately the same level under the Option 1 Watchful Waiting scenario.

2. Environmental Consequences--Immediate Impacts.

If the FDA decides to take Option 1 and BSE does not occur in the US, then there will likely be no change in environmental effects from the current situation. Dispositions of 4-D carcasses and offal from ruminants will continue unaffected, divided among on-farm disposal, placement in a landfill, incineration, and rendering/processing. Wildlife have been exposed to the scrapie agent in the US, via the carcasses of dead sheep that have been disposed of on-farm, since at least 1947, when scrapie was first diagnosed (Appendix B). The consequences of these exposures are not known and have not been studied, to the agency's knowledge.

3. Environmental Consequences--Long Term Impacts.

Although BSE was recently confirmed in Canada in a cow that was imported from the United Kingdom (Grow, 1993), BSE has not been diagnosed in the US. Most of the major risk factors identified for the BSE epidemic in the UK are markedly lower in the US and the qualitative analysis of these risk factors suggests little evidence for a broad risk for BSE within the US (USDA/APHIS, 1991) (USDA/APHIS, 1991a). The USDA/APHIS

has also taken several regulatory actions to try and prevent the occurrence of BSE in the US (See above, Actions to Date).

If Option 1 is taken and BSE nonetheless occurs in the US, then there could be adverse environmental effects. In comparison to the other alternatives considered, the BSE outbreak would be expected to be the most severe with Option 1 as there would be no prevention of the potential spread of the scrapie/BSE agent(s) to and among cattle during the several year period that BSE is undiagnosed. Increasing numbers of 4-D ruminants could contain the scrapie/BSE agent(s), thereby also increasing the exposure to wildlife that may prey on or scavenge these animals. Since it would likely take more time to control the BSE outbreak, the number of affected and potentially affected cattle that need to be buried, landfilled, or incinerated, and the potential wildlife and human exposure to a TSE agent would be greatest under this scenario. It is anticipated that the long term environmental costs in terms of resources and labor required by the cattle, slaughter, rendering, processing, feed manufacturing, and regulatory industries would be highest under Option 1.

B. Option 2. Prohibit Specified Offal from Adult Sheep and Goats in Ruminant Feeds

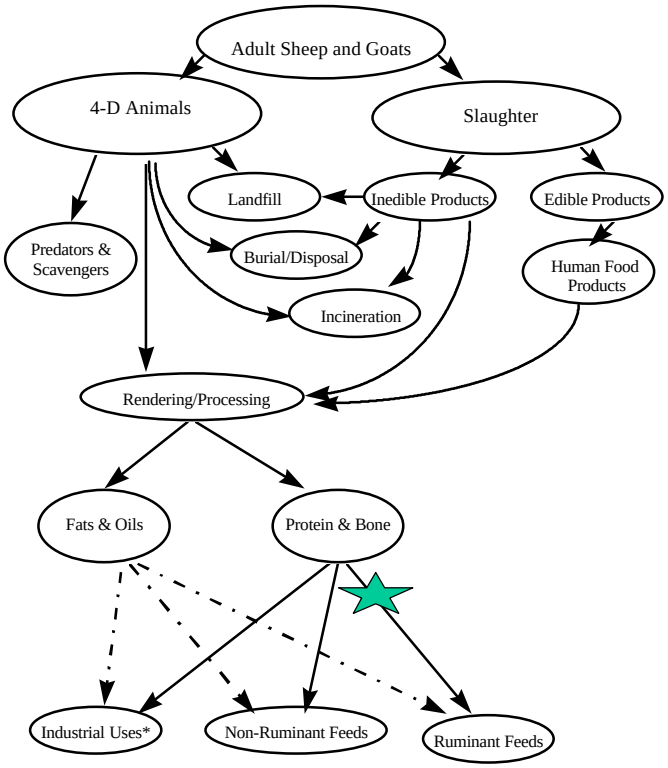
This approach was described in the FDA proposed rule of August 29, 1994 (59 FR 44583ff) (Figure 2).

1. *Feed Ingredients Affected.*

The only tissues of adult sheep and goats directly affected by Option 2 would be the specified offal [brain, spinal cord, lymph nodes, spleen, tonsils, thymus, and intestines (duodenum to anus inclusive)]. Option 2 would only affect the ingredients produced by the rendering/processing industry reasonably expected to contain, in whole or in part, specified offal from adult sheep and goats (Figure 2) and intended for use in feed of ruminants (cattle, goat, sheep, deer, elk, llama, antelope, etc.). The FDA would not object to the use of these in feed of non-ruminants (pig, chicken, horse, fish, dog, cat, etc.) or for industrial purposes.

The feed ingredients, as defined in the Official Publication 1996 of the Association of the American Feed Control Officials, Inc. (AAFCO, 1996), affected by the proposed action include, but are not limited to, the following: meat by-products, dried meat solubles,

Figure 2. Disposition Patterns for Adult Sheep and Goats in the US - Option 2.



*includes, but is not limited to, fertilizers and lubricants.

☆ pathway partially blocked, some proteins from adult sheep & goats permitted in ruminant feeds.

glandular meal and extracted glandular meal, animal digest, meat meal, meat and bone meal, animal by-product meal, meat meal tankage, meat and bone meal tankage, bone ash, bone charcoal, spent bone charcoal, cooked bone meal, steamed bone meal, and bone phosphate.

Since the proposed TSE agent is a protein and has not been detected in fat (MAFF, 1993), the FDA would not object to the use in ruminant feeds of fats and oils derived from adult sheep and goats.

2. *Estimated Amounts of 4-D Carcasses from Adult Sheep and Goats.*

The USDA estimated that, in 1990, there were 439,000 deaths from all causes (excluding slaughter) in mature sheep. They also estimated in 1990 that 14,700 adult sheep were lost to predators. After subtracting the estimated losses caused by predators from the total number of deaths and using various assumptions, we estimated that the following amounts of 4-D carcasses were available for rendering or disposal (Appendix H).

mature sheep	31,823 tons
mature goats	7,859 tons

The agency has no data on the percentage of all mature 4-D sheep and goats that were picked up by renderers or disposed of by local burial, in landfills, or by incineration. It is believed that, historically, on-farm burial and pick up by renderers have accounted for the overwhelming majority of 4-D sheep and goats.

3. *Costs Associated with the Various Disposition Options for the 4-D Carcasses and Offal of Adult Sheep and Goats.*

Rendering, in comparison to on-farm burial, placement in landfills and incineration, is the most economically feasible route of disposition for the inedible products and 4-D carcasses of adult sheep and goats (Appendix K). The finished products of rendering are useful for animal feed and industrial purposes, whereas neither burial, landfill or incineration produce a useable product. The FDA recognizes the valuable job the rendering industry performs in recycling offal and dead stock into useful products.

It appears that on-farm disposal is a much more economically feasible route of disposition for carcasses of adult sheep and goats than placement in landfills or incineration. Based on a 100 pound carcass and a 1990 review of tipping costs for municipal solid wastes ($11 to $65 per ton; Osborne, 1993), it would cost producers approximately $1.90 (range of $0.55 to $3.25) per animal in tipping fees alone to place the animal in a landfill. Based on a 100 pound carcass and estimates for incinerating municipal solid wastes ($50 to $75 per ton; Osborne, 1993), it would likely cost producers approximately $3.13 (range of $2.50 to $3.75) in incineration costs alone to have an animal incinerated. If the carcasses are classified as medical hazardous waste, the incineration costs alone may be as high as $10.00 per animal ($200 per ton) (Osborne, 1993). The labor and equipment costs per animal to place them in a landfill or have them incinerated would likely be higher than for on-farm burial and would often be much more time consuming.

4. *Effect on the Rendering and Processing Industries.*

a. *Rendering Industry*

The FDA believes that Option 2 would make the rendering industry determine if it can economically 1) separate the specified offal from other inedible slaughter products and the 4-D carcasses of adult sheep and goats from those of other animals; and, 2) sell the rendered products derived from the specified offal for use in non-ruminant feed or for industrial purposes. The rendered products affected by Option 2 would include, but are not limited to, the following feed ingredients, as defined in the Official Publication 1996 of AAFCO: meat meal, meat and bone meal, animal by-product meal, meat meal tankage, meat and bone meal tankage. The raw materials for these rendered products would need to be sorted to remove the specified offal from adult sheep and goats, if the finished products would be intended to be used in ruminant feed. The raw materials would not need to be sorted if the finished products were intended for use in non-ruminant feed. Raw materials from adult sheep and goats containing the specified offal could still be processed for use in non-ruminant feeds.

The finished products identified above currently are mostly used in the feeds of non-ruminants. The breakdown of the end use products of meat and bone meal, showed that 34% went to pet food, 34% went to poultry, 17% went to swine, 13% went to cattle, and 2% miscellaneous (USDA, APHIS, 1991). Assuming that the 2% miscellaneous all went to feed of ruminants other than cattle, we have estimated that 15% (13% cattle + 2%

miscellaneous) of the meat and bone meal goes into the feed of ruminants and 85% goes into the feed of non-ruminants. Option 2 would not prohibit the sale of any rendered products from adult sheep and goats to non-ruminant feeds (approximately 85% of the market), but will prohibit specific products (some but not all) from adult sheep and goats from use in ruminant feeds (approximately 15% of the market).

Option 2 would not have a drastic effect on the rendering industry as a whole as renderers pick up approximately 91,000,000 pounds of material per day (16,607,500 tons per year) (Franco, 1993). Assuming a worst case scenario where all inedible slaughter products (7,443 tons + 1,838 tons) and all 4-D carcasses (31,823 tons + 7,859 tons) from adult sheep and goats that died (except those lost to predators and scavengers; see Appendix G and H) were utilized by the rendering industry, the proposed action could affect only 0.295% (48,963 tons/16,607,500 tons) of their business. If one considers that fats and oils comprise approximately 50% of the finished products and are not affected by the proposed action, then one would estimate that this proposed action could affect only 0.1475% of their business. If one also considers that meat and bone meal is by far the greatest protein and bone derived product produced by the rendering industry and only 15% of it has been estimated to go into ruminant feeds, then one would estimate that this proposed action could affect only 0.022% of the rendering industry as a whole.

At rendering facilities that sell their products to ruminant feed manufacturers, Option 2 would require segregation of the inedible slaughter products and carcasses of adult sheep and goats, and rendering this material separately. Rendering plants processing large amounts of adult sheep and goats may find segregation and rendering separately to be feasible. However, plants processing small amounts of adult sheep and goats are unlikely to find segregation and separation economically feasible, and may refuse to process adult sheep and goats. Collection points for adult sheep and goat offal may be needed to facilitate disposal at rendering facilities that process few of these animals.

If the rendered protein and bone products of adult sheep and goats that would normally go into ruminant feed cannot be used in non-ruminant feed, then the renderer can sell it for industrial uses, such as fertilizers, provided it is in accord with any applicable local, state, and federal requirements. If no feed or industrial uses are found, then the renderer would be required to dispose of the rendered protein/bone products. This disposal would likely be by landfill, incineration, or local burying and would need to be conducted in accordance with all local, state, and federal requirements. The FDA, however, believes that very little

rendered products will have to be disposed. If renderers cannot recoup their expenses, there will be a strong economic incentive to not collect and process the inedible slaughter products and the carcasses of adult sheep and goats.

b. *Processing Industry.*

The FDA believes that Option 2 would make the processing industry (other than rendering) determine if it can economically 1) separate the specified inedible slaughter products from adult sheep and goats; and, 2) sell the products that are reasonably expected to contain at least one of the specified offal from adult sheep and goats for use in non-ruminant feed or for industrial purposes. The FDA's objections to the use of these products in ruminant feed would include, but not be limited to, the following feed ingredients, as defined in the Official Publication 1996 of the Association of American Feed Control Officials, Inc. (AAFCO, 1996): meat by-products, dried meat solubles, glandular meal and extracted glandular meal, animal digest, feed grade fat product, bone ash, bone charcoal, spent bone charcoal, cooked bone meal, steamed bone meal, and bone phosphate.

The FDA believes that Option 2 would not have a drastic effect on the processing industry as a whole. Four of the above mentioned AAFCO feed ingredients (meat by-products, dried meat solubles, glandular meal and extracted glandular meal, and animal digest) are rarely, if ever, incorporated into ruminant rations. The other six AAFCO feed ingredients [bone ash, bone charcoal, spent bone charcoal, cooked bone meal, steamed bone meal, and bone phosphate] are only occasionally incorporated into ruminant rations and then at levels below 5% of the total ration. Non-rendered products are included in Option 2 because: 1) the scrapie/BSE agent(s) is likely to survive the processing described in many feed ingredient definitions, and 2) the concern that if only rendered products were included in the proposed action, then the use of non-rendered products containing specified offal from adult sheep and goats would increase in ruminant feed.

If the above mentioned products from adult sheep and goats cannot be used in non-ruminant feed, then the processor can sell them for industrial uses, such as fertilizers and lubricants, provided it is in accord with any applicable local, state, and federal requirements. If no feed or industrial uses are found, then the processor would be required to dispose of the non-rendered protein and bone products. This disposal would likely be by incineration, landfill, or local burying and would need to be conducted in

accordance with all local, state, and federal requirements. The FDA, however, believes that very little non-rendered processed products would have to be disposed. If processors could not recoup their expenses, there would be a strong economic incentive to not collect and utilize the inedible slaughter products of adult sheep and goats.

5. *Effect on the Slaughter Industry.*

The FDA believes that Option 2 would make the slaughter industry determine if it could economically 1) separate the inedible slaughter products and condemned carcasses from adult sheep and goats; and, 2) sell them to the rendering/processing industry or for industrial purposes.

The FDA believes that there would be only a minimal effect on the number of sheep and goats slaughtered as a result of Option 2 as it does not prohibit the slaughter of adult sheep and goats, does not affect the use of edible products from sheep and goats for human consumption, and does not affect lambs and kids. Even if the slaughter of adult sheep and goats were greatly reduced by the proposed action, it is unlikely to have a major effect on the slaughter industry as a whole. In 1992, adult sheep and all goats comprised only 0.4% of all livestock processed at federally inspected slaughter plants (Appendix G, J and I) (Bauer, 1993).

The FDA realizes that slaughter plants that process only a few sheep and goats on an irregular basis might have to increase their rates to cover the increased costs related to processing and disposing; however, most sheep and goats are currently slaughtered in large groups at a few plants. In these plants, it is believed that separation of the offal should not cause marked effects.

6. *Effect on the Feed Manufacturing Industry.*

The FDA believes that the only portion of the feed manufacturing industry affected by Option 2 would be those producing ruminant feeds. Ruminant feed manufacturers might require certification from the renderer/processor that affected feed ingredients do not contain any specified offal from adult sheep or goats. Animal products normally comprise less than 5% of the total diet of ruminants and there are several substitutes for the essential nutrients (mostly protein, calcium and phosphorus) provided by these products. Substitutes for rendered/processed products derived from adult sheep and goats in animal

feeds include, but are not limited to, 1) rendered/processed products from other animals, 2) vegetable proteins from soybeans, cottonseed, canola, and peanuts, and 3) mineral products such as calcium carbonate, calcium chloride, calcium sulfate, clam shells, magnesium phosphate, and di- and mono calcium phosphate.

7. *Effect on the Sheep and Goat Producers.*

The brunt of the environmental effects from Option 2 would be borne by the adult sheep and goat producers. Decreased short term demand for meat and other products derived from adult sheep and goats plus the increased cost of disposal of 4-D animals are possible consequences of the Option 2. Although it does adversely affect the adult sheep and goat producer, Option 2 does not affect sheep and goats under 1 year of age and does not prohibit the use of any rendered/processed products derived from adult sheep and goats in non-ruminant feeds. Lambs comprised approximately 93% of the sheep that were slaughtered at federally-inspected slaughter plants in 1992 (USDA/APHIS, 1993a) (Bauer, 1993).

8. *Environmental Consequences--Immediate Impacts.*

Adoption of Option 2 should decrease the prospects of BSE occurring in the US; this would have a positive environmental consequence. It is possible that the Option 2 would cause a further decline in the proportion of inedible slaughter products and 4-D carcasses from adult sheep and goats that are utilized by renderers/processors. There could be a concomitant increase in the proportion of these materials that are buried on-farm, buried in local landfills, and/or incinerated. Based on our estimated costs for disposition, it would appear that the greatest increase would occur in on-farm burial.

In analyzing the possible environmental consequences of such a shift, we assume that disposal in landfills and incineration would be subject to environmental laws that would provide adequate protection with regard to environmental contamination by the scrapie agent and any other potentially deleterious substance. We believe the potential incremental increase in on-farm burial of adult sheep and goats and any possible harm to the environment as a result of the regulation would likely be minimal. On-farm burial might, in some cases, be subject to the same environmental laws as landfills and incineration. Further, on-farm burial of infected or high risk sheep was a recommended means of disposal by APHIS in the indemnity portion of its scrapie certification program.

Finally, Option 2 would tend to encourage sheep and goat producers to maintain a certified flock in the USDA/APHIS voluntary scrapie flock certification program (57 FR 58132). If the US became a scrapie free country, then Option 2 might no longer be required and could be appropriately modified.

9. *Environmental Consequences--Long Term Impacts.*

If FDA adopts Option 2 and BSE occurs undiagnosed in the US anyway, Option 2 would reduce the spread of the scrapie agent from sheep and goats to cattle, but would not prevent the recycling and amplification of the BSE agent from cattle to cattle. Exposure to wildlife of the scrapie agent during the time BSE is undiagnosed, but present, would be expected to be reduced in comparison to Option 1. Wildlife exposure to the BSE agent before it is diagnosed might be reduced in comparison to Option 1, provided that the scrapie agent is the source of BSE in the US. Otherwise, exposures would be similar.

During subsequent control efforts after BSE is diagnosed, the number of cattle that would need to be buried, landfilled, or incinerated and the potential wildlife and human exposure to the BSE agent would likely be similar to Option 1, since BSE amplification from cattle to cattle would occur for years before detection.

C. Option 3. Prohibit Proteins Derived from Sheep, Goats, Deer, Elk and Mink from Ruminant Feeds.

TSE's have been identified in the US in sheep and goats (scrapie), deer and elk (chronic wasting disease, CWD), and mink (transmissible mink encephalopathy). In the United Kingdom, one theory for the origin of BSE in cattle was that it crossed over through feed ingredients derived from scrapie positive sheep. Broader than Option 2, above, Option 3 would attempt to prevent the crossover to cattle of any TSE from a species where TSE's have been shown to occur in the US. It would also prevent the amplification of TSE's among ruminant species other than cattle via the feed route, to the extent that this occurs. For example, scrapie and CWD could not be spread among ruminants through the feed route if this option were implemented.

No proteinaceous feed ingredient, with the exception of milk and gelatin, derived from the identified species could enter the food supply of ruminants. Fats, as nonproteinaceous materials, would be permitted. Since BSE has not been identified in cattle in the US, rendered feed ingredients derived from cattle could be fed without restriction to any species, including cattle and other ruminants. The watchful waiting measures in Option 1 would also be implemented under Option 3.

Option 3 addresses several risk factors not well addressed by Option 2. It includes all species where TSE's have been found in the US, not just sheep and goats. It includes all ages of animal, not just the older animals addressed by Option 2. While clinical signs of TSE's occur in older animals, it is likely that many of them are affected subclinically at much younger ages, including the possibility of maternal transfer prior to birth.

Option 3 does not initially affect cattle slaughter, rendering or feeding practices. While this may be attractive economically in the short term, it leaves open the possibility that BSE, the TSE best adapted to cattle, will eventually enter and spread throughout the US cattle population.

For Option 3 to be effective, several conditions must hold. BSE must not be currently present undiagnosed in the US. Second, BSE must not occur spontaneously in cattle. Lastly, import controls in place in the US must completely prevent both cattle or feed ingredients containing BSE from entering the US. If BSE occurs in the US, either now or at some future date, this option does not prevent amplification and spread of the original case to many other cattle through bovine-derived, BSE-contaminated feed ingredients.

All three of the conditions listed above are subject to much uncertainty and disagreement among experts. Because of the long incubation period, BSE may already be present undiagnosed in the US. Some researchers believe that BSE-affected cows are "downers" at the farm level and not being evaluated for possible BSE. "Downer" cattle do not enter the USDA inspection process, being sent instead directly to rendering facilities. Some

researchers consider that BSE, like CJD in humans, may occur spontaneously in a low percentage of the cattle population in the US. Lastly, import controls against feed ingredients and cattle that might be the source of BSE are applied to other countries *where BSE has been reported to occur*. In countries where BSE may be present undiagnosed, cattle and feed ingredients may be exported to the US.

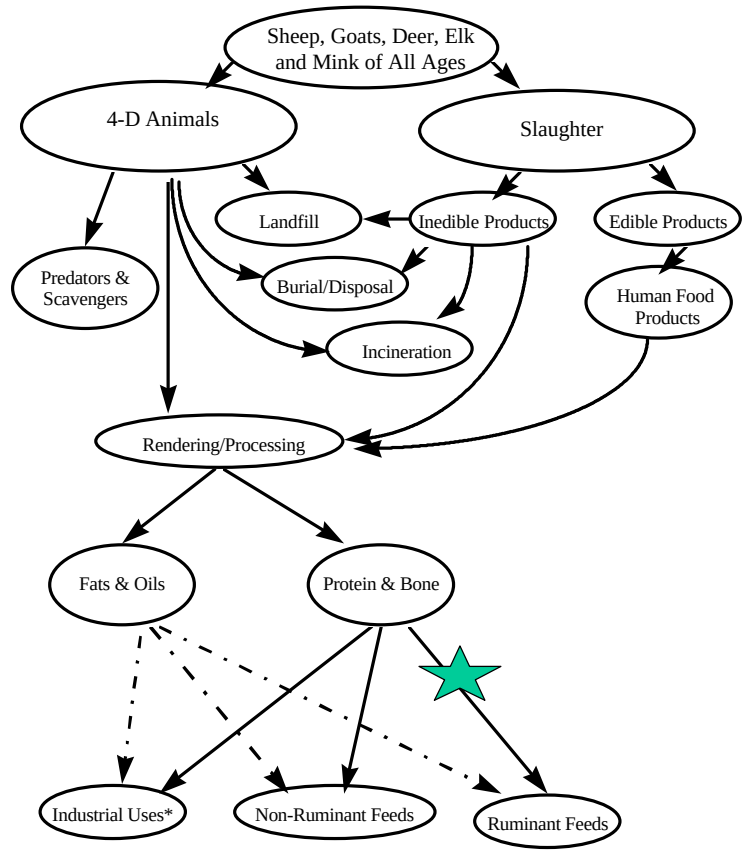
Thus, while Option 3 could be expected to be more effective than Option 2 in preventing crossover events from other species with a TSE in the US, it would not prevent the spread of BSE to cattle via the feed should BSE occur undiagnosed in the US. Implementation of Option 3 would not be very reassuring if one believes that the occurrence of BSE in native US cattle is inevitable. Improved knowledge about the etiology and spread of BSE and methods to quickly screen live animals and feed ingredients for the BSE prion would make Option 3 more effective.

1. Feed Ingredients Affected.

If Option 3 were implemented (Figure 3), feed ingredients containing or potentially containing protein derived from sheep, goats, deer, elk or mink could not be used in ruminant feeds. The FDA would not object to the use of any feed ingredients derived from the identified species if they were used in the feed of non-ruminants or for industrial purposes. Fats, gelatin and milk products derived from the identified species would not be restricted, as these products are not regarded to transmit TSE's.

The feed ingredients, as defined by the Official Publication 1996 of the Association of the American Feed control officials (AAFCO, 1996), affected by Option 3 would include, but are not limited to, the following: meat by-products, dried meat solubles, glandular meal and extracted glandular meal, animal digest, meat meal, meat and bone meal, animal by-product meal, meat meal tankage, meat and bone meal tankage, bone ash bone charcoal, spent bone charcoal, cooked bone meal steamed bone meal, and bone phosphate. The

Figure 3. Prohibit Proteins from Sheep, Goats, Deer, Elk and Mink in Ruminant Feeds in the US - Option 3.



* includes but is not limited to fertilizers and lubricants.

pathway partially blocked, milk products and gelatin from identified species are permitted in ruminant feeds.

presence or absence of the listed species in these feed ingredients would affect whether they could be fed to ruminants.

2. Estimated Amount ofOffal and 4-D Carcasses Affected by Option 3.

Option 3 would affect offal from the slaughter of sheep, lambs, goats, kids, deer, elk and mink:

Species/Grouping	Number Slaughtered/Year	Tons Offal
Adult Sheep	330,800	7,443
Lambs	4,798,539	79,176
Adult Goats	81,667	1,838
Kids	143,037	1,502
Deer and Elk*	Unknown	Unknown
Mink	2,692,000	3,365
Totals	8,046,043	93,324

See Appendices G and H for additional information.

*Deer and elk derived feed ingredients are largely the by-products of hunting. Since most are field-dressed, the parts offered to renderers are usually bone and heads remaining after butchering or taxidermy. No numbers of deer or elk taken by hunting or other means and offered to renderers were found.

In Appendix H, worst case estimations were made for the total number of mature sheep and goat deaths (other than slaughter or predation) each year. Some fraction, potentially all, of these animals could be picked up by renderers as 4-D animals.

Species/Grouping	Number per Year	Tons
Mature Sheep	424,300	31,823
Mature Goats	104,785	7,859
Totals	529,085	39,682

Option 3 may affect the value of these carcasses to renderers, making it less likely that animals dying at producer sites will be picked up. Consequently, more animals might be disposed of at the farm by burial, disposition at the local landfill, or by incineration. This amount would be comparable to Option 2, however.

Deer and elk are raised domestically; however, the numbers available as 4-D animals to renderers are not known. Road kill may be an additional source of deer and elk materials offered to renderers, but again the numbers are not known. 4-D mink, lambs and kids are believed to be largely disposed of on site because of their small size.

3. Costs of Disposition Alternatives.

Rendering should be the most economically feasible and environmentally benign means for disposal of offal and 4-D carcasses of all species. Rendering produces valuable feed ingredients that offset the costs of animal disposal.

If rendering became economically unfeasible for mink, sheep, goats, deer and elk, disposal alternatives would most likely be on-farm burial for 4-D animals and landfilling or incineration for slaughterhouse offal. Some state laws may consider dead animals or offal

to be potentially infectious medical waste and require disposal in that manner, so estimates for this method are included.

The cost comparisons below are based on a 1990 review (Osborne, 1993), however, the relationships of disposal costs probably have not changed significantly.

Disposal Method*	Cost per 100 pounds-		Cost per Ton
	Average	Range	Range
Burial	$1.50		$30
Landfilling	$1.90	$0.55 - $3.25	$11 - $65
Incineration	$3.13	$2.50 - $3.75	$50 - $75
Medical Waste	$10	-	$200

*Does not include transportation costs. See Appendix K for additional details.

4. Effect on Rendering and Processing Industries.

Option 3 is larger than Option 2 in terms of the tonnage of materials affected, as lamb and kids are included, as well as deer, elk and mink. As discussed under Option 2 (Section 4), over 85% of rendered and processed proteins are currently being directed to non-ruminants. One would expect that no more than 15% of the amount affected by Option 3 would need to be redirected. A total of 133,006 tons (39,682 + 93,324) of offal and 4-D animals per year could be potentially affected by Option 3. The redirected amount would be 0.15 X 133,006 = 19,951 tons per year. The redirected amount represents approximately 0.1% (19,951/16,607,500) of the rendering business.

At rendering and processing facilities that sell their products to ruminant feed manufacturers, Option 3 would require the segregation of offal and 4-D animals from the identified species and the rendering or processing of this material separately. Fats and gelatin produced from the identified species could be marketed without restriction.

Protein products from a segregated process could be marketed to specialty uses, such as pet food. Alternatively, the segregated protein products could be marketed along with mixed species protein products for non-ruminant feed uses, currently already the vast majority of the market. While some market disruption is possible, it is expected to be small and short lived, given the relatively small quantities of products that would be involved and the large non-ruminant feed market for these products. Little, if any, protein products derived from the identified species is expected to be disposed of as waste and none of the fat or gelatin products.

5. Effect on the Slaughter Industry.

Option 3 affects lambs and kids in addition to the adult sheep and goats described for Option 2, and thus must be regarded as potentially affecting more slaughter facilities. The option does not affect the marketability or suitability of sheep or goat of any age for use as human food. Because it could require some recordkeeping and alternative marketing for offal from the slaughter of these species, it may increase the costs of some facilities, particularly those that slaughter these species irregularly. Offal should still have enough value to a renderer for it to be picked up. After all, fats and gelatin derived from these raw materials are still marketable without restriction. Protein derived from these species will still be in demand for non-ruminant use. For this reason, if there is an increase in disposal of slaughterhouse offal containing these species, it should be short-lived.

6. Effect on the Feed Manufacturing Industry.

As in Option 2, the FDA believes that the only portion of the feed industry affected by Option 3 would that part producing feeds for ruminants. Ruminant feed manufacturers might require certification from renderers/processors that affected feed ingredients do not contain any protein derived from the identified species. This would be important in the absence of a fast method to distinguish goat, sheep, elk and deer proteins from cattle and non-ruminants. The problem with confirming the contents of feed ingredients might lead to ingredient switching to products: 1) derived from integrated poultry or swine operations where source material could be better controlled, 2) vegetable proteins from soybeans, cottonseed, canola, and peanuts, and 3) mineral product substitutes for bone such as calcium carbonate, calcium chloride, calcium sulfate clam shells, magnesium phosphate, and di- and mono calcium phosphate. The degree of switching presumably would be price driven: switches would be expected where the cost of the meat and bone meal product plus the cost of species content confirmation is greater than the cost of alternatives.

The switching behavior for ruminants might be mirrored by ingredient switches in non-ruminant species, based on the new prices for ingredients. Option 3 affects so little product in the rendering/processing industry there would be expected to be plenty of room for such switching to occur without waste increases. The products being switched do not seem to be scarce resources that intrinsically increase the environmental costs of the meat and poultry industries in the US.

7. Effect on the Sheep, Goat, Deer, Elk and Mink Producers.

US sheep and goat producers would appear to be most affected by Option 3. It is possible that they will bear increased costs of rearing animals through additional disposal costs for 4-D animals. They may get less for their animals at market. If there were an additional environmental cost to bear for the disposal of slaughterhouse offal, that would be reflected

in the live animal value. The magnitude of these costs will affect how well US producers compete with imported sheep and goat products and, ultimately, whether the US producers switch to other lines of business. Similar effects on deer, elk and mink producers would likely also occur. The uncertainties in this assessment preclude anything but qualitative speculation - the effects of Option 3 might be disruptive at first but should be minimized by producers, slaughterhouses, renderer processors and feed manufacturers with time.

8. Environmental Consequences - Immediate Impacts.

Option 3 would be expected to be more protective than Option 1 or 2 in preventing crossovers of TSE's from sheep, goats, elk, deer and mink to cattle. This option focuses nearly all environmental costs on this segment of the animal industry. While the number of 4-D animals to dispose of would be basically unchanged compared to Option 2, there would be the additional issue of the redirection of slaughterhouse offal from lambs and kids that is much greater in volume than in Option 2. This may require more time for adjustment and may result in some additional 4-D animals and offal from the identified species not being welcome at render/processors that produce feed ingredients for ruminants. In the context of the entire meat and poultry industry, the effects are small, however.

9. Environmental Consequences - Long Term.

Long term consequences of Option 3 are similar to Option 2. Neither option provides any additional protection from the uncontrolled amplification of BSE through feed ingredients in the US cattle population, once a BSE case occurs undiagnosed. Crossover of TSE's from the identified species is but one of the ways that BSE could enter the US cattle population. While the practices used by renderers in the US may be effective in inactivating BSE prions, this has not yet been shown convincingly. Other unknown factors in the US may prevent the spread of BSE. Until the risk profile for the US cattle

population is better known, however, it will be uncertain as to whether BSE will be introduced and spread. Whatever the probability, this is a risk that would probably be unacceptable to the US cattle industry and the public in general.

During subsequent control efforts after BSE is diagnosed, the number of cattle that would need to be buried, landfilled, or incinerated and the potential wildlife and human exposure would be similar to Option 2.

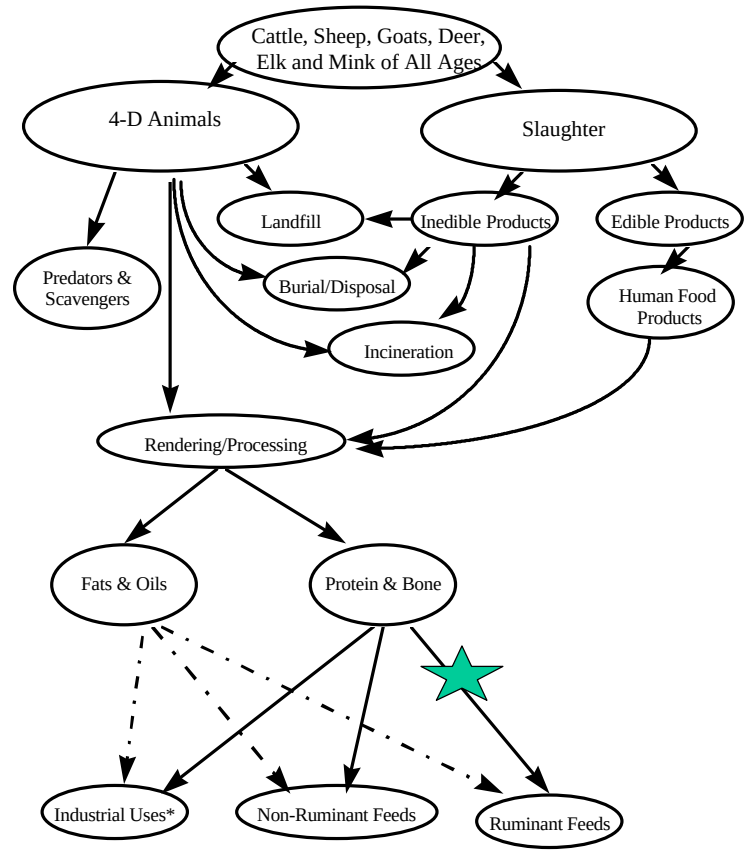
D. Option 4. Prohibit Ruminant-and Mink-Derived Protein in Ruminant Feeds - Proposed Action

Also known as the "ruminant to ruminant ban," this approach was briefly described in the advance notice of proposed rulemaking (61 FR 24253ff). It is discussed in detail in the *Federal Register* notice that this EA accompanies. It is broader than the above options, in that it affects the management of many more materials passing through the rendering/processing to feed ingredient route. It would include raw materials from all ages of sheep, goats, cattle, wild ruminants, such as deer, elk and bison, and all ages of mink. The approach attempts to prevent the use of feed ingredients that may contain ruminant or mink origin TSE's in ruminant feeds by simply banning all ruminant and mink proteins (except blood from bovines, gelatin and milk) in ruminant feeds. This approach assumes that spontaneous BSE and scrapie-to-BSE, TME-to-BSE, or CWD-to-BSE crossovers may occur in the US at some low level. It also addresses the need to break the closed loop food chain for ruminants in order to prevent the amplification and spread of TSE's and any other pathogens capable of surviving rendering/processing. Option 4 was included among other recommendations from an expert panel convened by the World Health Organization (WHO) in April 1996. See the discussion above for Proposed Action and the *Federal Register* notice that this EA accompanies for additional details.

1. *Feed Ingredients Affected.*

If the proposed action were implemented (Figure 4), then most protein feed ingredients that were derived in whole or in part from the inedible slaughter products or carcasses of

Figure 4. Prohibit Proteins Derived from Ruminants and Mink in Ruminant Feeds in the US - Option 4.



* includes but is not limited to fertilizers and lubricants.

pathway partially blocked, milk products and gelatin from ruminants and bovine blood products permitted in ruminant feeds.

ruminants and mink could not be used in the feed of ruminants. The FDA would not object to the use of any feed ingredients derived from ruminants if they were intended for use in feed of non-ruminants or for industrial purposes. Non-proteinaceous materials from ruminants, like tallow and fat, are unaffected by this option and would be allowed in ruminant feeds. Blood from bovines, gelatin and milk proteins are also excluded from controls by this option, as they are not regarded to transmit TSE's.

The feed ingredients that would be affected are numerous. The definitions for these feed ingredients are located in the Official Publication 1996 of AAFCO in Section 9 on Animal Products and in Section 57 on Mineral Products (AAFCO, 1996). These include, but are not limited to, the following:

Animal Products: meat, meat by-products, animal liver, dried meat solubles, fleshings hydrolysate, hydrolyzed hair, hydrolyzed leather meal, glandular meal and extracted glandular meal, unborn calf carcasses, animal digest, cooked bone marrow, mechanically separated bone marrow, meat meal, meat and bone meal, animal by-product meal, meat meal tankage, meat and bone meal tankage, stock, meat protein isolate, and leather hydrolysate.

Mineral Products: bone ash, bone charcoal, spent bone charcoal, cooked bone meal, steamed bone meal, and bone phosphate.

2. *Estimated Amount of 4-D Carcasses from Ruminants.*

The agency has no data on the percentage of all ruminants that were picked up by renderers or disposed of by on-farm burial, placement in a landfill, or by incineration. Historically, it is believed that on-farm disposal and pick up by renderers accounted for the overwhelming majority. In Appendix J, we estimated that approximately 1,950,770 tons of carcasses from 4-D animals were rendered in 1992. Although the agency could not locate data on the number of 4-D animals rendered by species, we believe that cattle, because of their size and numbers, contributed more than any other species.

3. *Costs Associated with the Various Disposition Options for the 4-D Carcasses and Offal of Ruminants.*

Rendering-processing, in comparison to on-farm disposal, placement in landfills and incineration, is the most economically feasible route of disposition for the inedible products and 4-D carcasses of ruminants (Appendix L). The finished products of rendering are useful for animal feed and industrial purposes, whereas neither local burial, landfill or incineration produce a useable product.

It appears that on-farm disposal is a more economically feasible route of disposition for offal and carcasses of ruminants than placement in landfills or incineration. Based on a 1000 pound carcass and a 1990 review of tipping costs for municipal solid wastes ($11 to $65 per ton; Osborne, 1993), it would cost producers approximately $19.00 (range of $5.50 to $32.50) per animal in tipping fees alone to place the animal in a landfill. Based on a 1000 pound carcass and the estimated costs for incinerating municipal solid wastes ($50 to $75 per ton; Osborne, 1993), it would cost producers approximately $31.30 (range of $25.00 to $37.50) in incineration costs alone to have an animal incinerated. If they are classified as medical hazardous waste, the incineration costs alone may be as high as $100.00 per animal ($200 per ton; Osborne, 1993). The labor and equipment costs per animal to place them in a landfill or have them incinerated would likely be higher than for on-farm burial and would often be much more time consuming.

4. *Effect on the Rendering and Processing Industries.*

a. *Rendering Industry.*

The FDA believes that Option 4 would make the rendering industry determine if it can economically 1) separate the ruminant and mink inedible slaughter products and the ruminant and mink 4-D carcasses from those of non-ruminants; and, 2) sell the rendered products for use in non-ruminant feed or for industrial purposes. Option 4 would prevent any rendered protein product that is reasonably expected to contain offal or carcasses from ruminants or mink from being used in ruminant feed.

Option 4 affects much more of the rendering industry than Option 1 or 2, as it was estimated in 1989 that ruminants were responsible for approximately 59.6% (59% cattle

and 0.6% sheep) of the rendered animal protein produced (USDA, APHIS, 1991). Option 4 would prohibit the use of any ruminant derived protein product produced by rendering from use in ruminant feed. If one assumes that only 15% of all rendered protein products are utilized in ruminant feed (as was the estimate for meat and bone meal; USDA, APHIS, 1991), then Option 4 would affect 8.9% (0.596 X 0.15) of the business of the rendering industry as a whole.

At rendering facilities that sell their products to ruminant feed manufacturers, Option 4 would require segregation of the inedible slaughter products and carcasses of 4-D ruminants and mink and rendering this material separately. Rendering plants processing large amounts of ruminants or mink may find segregation and rendering separately to be feasible. However, plants rendering small amounts of ruminants or mink may not find segregation/isolation and rendering separately economically feasible, and may refuse to process ruminants or mink. Alternatively, these facilities could continue as before with no changes in their procedures but market their products only to non-ruminant feed manufacturers. Separation and isolation of ruminant and mink raw materials under this option is probably more straightforward and easily accomplished than the procedures that would be needed under Option 2 above and Option 5, below. Collection points for offal and carcasses from ruminants may be needed to facilitate disposal at rendering facilities that process few of these animals.

If the rendered ruminant products cannot all be used in non-ruminant feed, then the renderer can sell it for industrial uses, such as fertilizers, provided it is in accord with any applicable local, state, and federal requirements. If no non-ruminant feed or industrial uses are found, then the renderer would be required to dispose of the rendered products. This disposal would likely be by landfill, incineration, or local burial and would need to be conducted in accordance with all local, state, and federal requirements. The FDA, however, believes that very little rendered product would have to be disposed. If renderers cannot recoup their expenses, there will be a strong economic incentive to not collect and process the inedible slaughter products and the carcasses of ruminants and/or mink.

b. *Processing Industry.*

The FDA believes that Option 4 would make the processing (non-rendering) industry determine if it can economically 1) separate the inedible slaughter products of ruminants

and mink from non-ruminants; and, 2) sell the products derived from ruminants and mink for use in non-ruminant feed or for industrial purposes.

The FDA believes that Option 4 has about the same potential for requiring changes in the processing industry as Option 3. Most of the above mentioned AAFCO feed ingredients under Animal Products are rarely, if ever, incorporated into ruminant rations. Blood meal, spray dried blood meal, and flash dried blood meal are processed products that are sometimes placed in ruminant rations because they are high in proteins that are not degraded in the rumen (bypass proteins). These products when derived from bovine or non-ruminants would be unaffected by Option 4. However, blood products derived from ovine, caprine or cervine ruminants would be prohibited in ruminant feed under Option 4, as in Option 3. The AAFCO feed ingredients under Mineral Products are occasionally incorporated into ruminant rations at levels less than 5% of the ration. The AAFCO feed ingredients under Miscellaneous Products and Recycled Animal Waste Products, although not commonly used, have been incorporated into the rations of ruminants at levels of more than 10%. The status of these products under Option 4 has not been determined.

If the above mentioned products derived from ruminants or mink cannot be used in non-ruminant feed, then the processor can sell them for industrial uses, such as fertilizers, provided it is in accord with any applicable local, state, and federal requirements. If no non-ruminant feed or industrial uses are found, then the processor would be required to dispose of the products. This disposal would likely be by landfill, incineration, or local burying and would need to be conducted in accordance with all local, state, and federal requirements. The FDA, however, believes that very little non-rendered processed products would have to be disposed. If processors cannot recoup their expenses, there will be a strong economic incentive to not collect and utilize the inedible slaughter products of ruminants or mink.

Farm-raised mink are a specialty market in a few northern US locations. There is probably little processing value in the carcasses after the pelts have been removed, other than to serve as a feed ingredient. It is likely that few mink carcasses are currently making their way into ruminant feed products as many may be fed to other mink. Option 4 would probably have little effect on current practices. Option 4, the proposed action, does not restrict the recycling of mink proteins to mink or other non-ruminants via either processing or rendering.

5. *Effect on the Slaughter Industry.*

The FDA believes that adoption of Option 4 would make the slaughter industry determine if it can economically 1) separate the inedible slaughter products and condemned carcasses from ruminants from non-ruminants; and, 2) sell them to the rendering/processing industry or for industrial purposes.

It is possible that slaughter plants that process ruminants on an irregular basis may increase their rates to cover the increased costs related to processing and disposing; however, most ruminants are currently slaughtered in large groups at many plants. In plants that slaughter large numbers of ruminants on a regular basis or are dedicated facilities that slaughter only ruminants, the agency believes that separation of the offal should not cause any change in current practices.

The FDA believes that there would be only a minimal long term effect on the number of ruminants slaughtered as a result of Option 4 as it does not prohibit the slaughter of ruminants, does not affect the use of edible products from ruminants for human consumption, does not prohibit the use of any rendered/processed products derived from ruminants in non-ruminant feed, and does not limit in any manner the use of fats and oils derived from ruminants. The slaughter industry is probably also becoming prepared for Option 4, as it was called for by the National Cattlemen's Beef Association and other animal associations, by the World Health Organization expert panel and was discussed in the FDA advance notice of proposed rulemaking.

6. *Effect on the Feed Manufacturing Industry.*

The only portion of the feed manufacturing industry affected by Option 4 would be those producing ruminant feeds. Ruminant feed manufacturers might require certification that affected feed ingredients do not contain any ruminant or mink derived protein. Animal products normally comprise less than 5% of the total diet of ruminants and there are several substitutes for the essential nutrients (mostly protein, calcium and phosphorus) provided by these products. Substitutes for rendered/processed ruminant products in animal feeds include, but are not limited to, 1) rendered/processed products from non-ruminants other than mink, 2) vegetable proteins from soybeans, cottonseed, canola, and peanuts, and 3) mineral products such as calcium carbonate, calcium chloride, calcium sulfate, clam shells, magnesium phosphate, di- and mono calcium phosphate, di- and mono sodium phosphate, and di- and mono ammonium phosphate.

7. *Effect on the Ruminant and Mink Producers.*

Option 4 might affect the ability of some ruminant and mink producers to have 4-D animals collected at the production site. Decreased short term demand from renderers and processors for 4-D ruminants and mink may result in a short-term increase in alternate disposal methods, especially on-farm burial.

However, Option 4 would not prohibit the use of rendered/processed products derived from ruminants and mink in non-ruminant feeds or for industrial purposes. The volume of raw materials and their value in non-ruminant feeds suggests that either current renderers and processors would make adjustments in their operating procedures or new players in this industry would develop to utilize these materials. Since proteins derived from ruminants and mink are mostly used for non-ruminant feeds currently, it is likely that renderer/processors that specialize in finished feed ingredients derived primarily from ruminant raw materials will choose to leave the ruminant feed market, if separation/isolation procedures prove too difficult or expensive for the individual situations. After adjustments in procedures in the rendering and processing industries are completed, there would not be any expected changes from the current situation for the availability of rendering and processing for ruminant and mink offal and 4-D animals.

It should be noted that beef and sheep industry representatives have indicated that their associations are supporting a voluntary ruminant protein to ruminant ban. Disposal of dead animals and slaughterhouse offal under a voluntary ban does not seem to be perceived as being an insurmountable problem by many ruminant producers.

8. *Environmental Consequences--Immediate Impacts.*

In comparison to Options 1, 2 and 3, Option 4 would cause greater changes in procedures for the isolation and separate processing of inedible slaughter products and 4-D carcasses from ruminants and mink that are utilized by renderers/processors (because of the greater volume involved). The possible disruption caused by these process changes could result in a short term increase in the proportion of these materials that are buried on-farm, placed in local landfills, and/or incinerated. Based on our costs for disposition, it would appear that on-farm burial for 4-D animals would be the most likely area of increased disposition (Appendix L).

In analyzing the possible environmental consequences of such a shift, we assumed that disposal in landfills and incineration would be subject to environmental laws that would provide adequate protection with regard to environmental contamination by the TSE agents and any other potentially deleterious substance.

On-farm disposal might, in some cases, be subject to the same environmental laws as landfills and incineration. Further, on-farm disposal of infected or high risk sheep was a recommended means of disposal by APHIS in the indemnity portion of its scrapie certification program (57 FR 58132). Finally, Option 4 is probably slightly less effective than Option 2 in providing incentive for sheep and goat producers to become certified as scrapie free. Option 4 is not focused on sheep and goats, but includes other classes of ruminants, some of which are not thought to be currently infected with TSE's in the US.

9. *Environmental Consequences--Long Term Impacts.*

If FDA implemented Option 4 and BSE occurred undiagnosed in the US anyway, this action would reduce the number of potential incidents of crossover of the scrapie and CWD agents from sheep, goats and deer to cattle, would reduce the number of ruminants affected in locations where BSE could have been imported or occurred spontaneously, and would greatly reduce the potential recycling and amplification of the BSE agent from cattle to ruminants. Dietary exposure of wildlife (predators, scavengers) to the scrapie/BSE agent(s) during the time BSE is undiagnosed but present would be expected to be greatly reduced in comparison to Options 1, 2 and 3. This is because the number of cattle exposed prior to a time when BSE is diagnosed is expected to be reduced. The number of cattle that subsequently would need to be buried, landfilled, or incinerated and the potential human exposure to the scrapie/BSE agent(s) would also be greatly reduced. Because Option 4 is more easily enforced than Option 5, it would be expected to be more effective in preventing the spread of BSE. Option 4 is probably less easily implemented by industry than Option 6, and so may be slightly less effective than that option in preventing the spread of an introduced or spontaneous case of BSE.

E. Option 5. Prohibit Proteins Derived from Designated Tissues in Ruminant Feeds.

This approach is similar to the ruminant-to-ruminant protein ban in Option 4 above, but is different in that protein derived from certain tissues from cattle would be banned in ruminant feed and other protein products derived from cattle would be permitted . (Figure 5). This action declares that protein derived from *designated tissues* would not be generally recognized as safe for use in ruminant feed and would be an unapproved food additive under Section 409 of the Federal Food, Drug and Cosmetic Act when added to ruminant feed. Protein derived from the designated tissues is defined as: any and all protein that is derived from 1) any portions of ovine, caprine, cervine, and mink; 2) all dead, dying, disabled, or diseased (4-D) bovine; and 3) the brain, spinal cord, eyes and distal ileum of bovine slaughtered for human consumption.

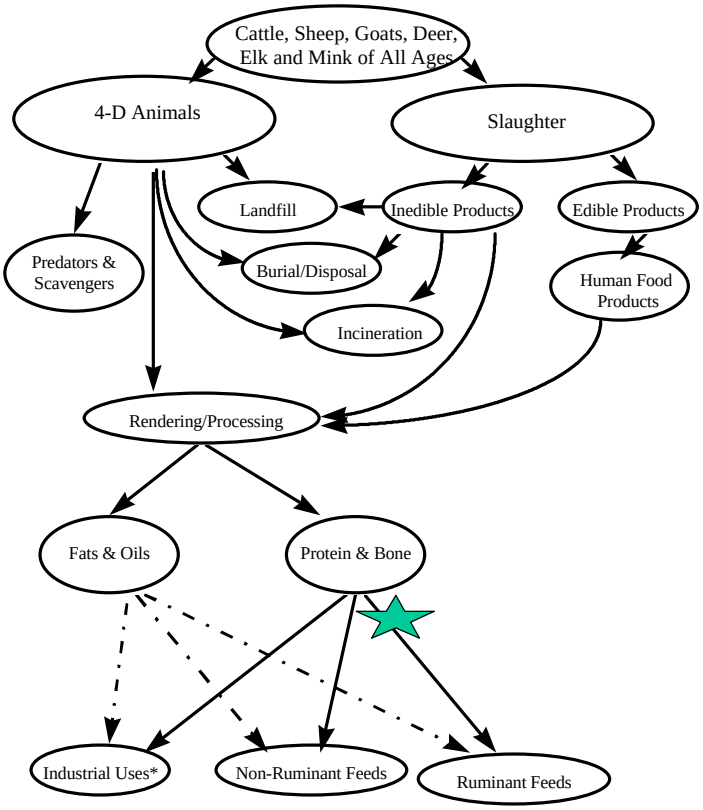
Protein derived from designated tissues and feed (intended for farm animals) containing protein derived from designated tissues would be labeled as not to be fed to ruminants. Recordkeeping, identification of prohibited proteins, and procedures to prevent cross-contamination of finished products are also required of slaughterhouses, renderer/processors, feed manufacturers and producers as the means to enforce the new restrictions.

Proteins derived from designated tissues would not include blood from bovines, and milk proteins and gelatin derived from bovine, ovine, caprine and cervine. All proteins derived from non 4-D bovine that are not from the portions identified in 3) above are also excluded from the prohibition, i.e., these are allowed to be used in ruminant feeds. Non-proteinaceous materials, like tallow and fat, are also unaffected by Option 5 and would be allowed in ruminant feeds. Thus, this approach seeks to have the same effectiveness of Option 4 in preventing the crossover and spread of TSE's in the ruminant population while attempting to minimize the volume of materials affected.

1. *Feed Ingredients Affected.*

If Option 5 were implemented (Figure 5), the feed ingredients that would be affected are numerous and the same as those in Option 4. (See AAFCO, 1996 for definitions.) These include, but are not limited to, the following:

Figure 5. Disposition Patterns for Proteins Derived from Designated Tissues - Option 5



* includes but is not limited to, fertilizers and lubricants.

☆ pathway partially blocked, some protein products from non-4-D bovine, bovine blood products and milk products and gelatin from bovine, ovine, caprine and cervine are permitted in ruminant feeds.

Animal Products: meat, meat by-products, animal liver, dried meat solubles, fleshings hydrolysate, hydrolyzed hair, hydrolyzed leather meal, glandular meal and extracted glandular meal, unborn calf carcasses, animal digest, cooked bone marrow, mechanically separated bone marrow, meat meal, meat and bone meal, animal by-product meal, meat meal tankage, meat and bone meal tankage, stock, meat protein isolate, and leather hydrolysate.

Mineral Products: bone ash, bone charcoal, spent bone charcoal, cooked bone meal, steamed bone meal, and bone phosphate.

Many of the above products could be made from bovine offal in a manner that would be suitable for use in ruminant feed, i.e., if they were derived solely from offal from non 4-D cattle that was subject to the separation and other controls on processing and handling that would assure that the designated bovine tissues (brain, spinal cord, distal ileum and eyes) were not included. If the controls were not in place to be so assured, the product would be labeled to not be used in ruminant feeds.

Because there is no laboratory technique to determine the designated tissues or their origin (e.g., slaughter or 4-D) when they have been processed into protein feed ingredients, Option 5 relies primarily on recordkeeping and written procedures for enforcement. Materials of concern may be processed into a wide variety of feed ingredients and subsequently, into a wide variety of feeds. Whether such feeds and feed ingredients contain protein products derived from designated tissues cannot be readily determined by the recipients. It would therefore be necessary that all persons involved in the chain of manufacture, distribution, and use of such products assume responsibility for determining, ensuring, and appropriately maintaining the identity of the specific nature of the components of animal protein products. Otherwise, the public and animal health objectives of Option 5 could not be assured. The absence of laboratory screening methods, that would identify the designated tissues and the products made from them, introduces a significant voluntary compliance aspect to the implementation of this option. Poor compliance and any resulting cross-contamination of ruminant feeds with protein from designated tissues would be difficult to detect.

2. *4-D Carcasses - Amounts and Costs of Disposition.*

The amounts and costs of disposition of 4-D carcasses affected by Option 5 would probably be similar to the estimations in Option 4 above. However, one line of thought would suggest that the time for adjustment to Option 5 would be longer than Option 4. Since Option 5 creates two classes of ruminant derived protein products, buyers must ask if the protein product being presented is derived from the whole ruminant including the designated tissues or the bovine offal minus the designated tissues. They might also ask if the product is derived from 4-D bovine or slaughtered bovine or both. Such products would not be distinguishable from each other except by a label and a manufacturer certification. The confusion over the new product category, the need for extensive process and operation changes to separate and isolate designated tissues and to find markets for the different products might result in a longer disruption of the market than Option 4. This could translate into more 4-D animals not being picked up by renderers.

FDA has no information indicating that mink protein is currently being used as a feed ingredient for ruminants, although it may be admixed with other mixed source rendered proteins and offered in this manner as a feed ingredient for ruminant feeds. The quantity of mink entering rendering are likely to be small, localized to mink farming regions of the northern US, and dwarfed by the ruminant category.

3. *Effect on the Rendering and Processing Industries.*

The FDA believes that Option 5 would make the rendering/processing industries determine if each can economically: 1) separate and render/process the designated tissues from ruminants and mink and, 2) sell the separated finished products for use in non-ruminant feed or for industrial purposes. Option 5 differs from Option 4 in that it provides a means for renderer/processors to utilize much of the offal from non 4-D cattle in the manufacture of protein ingredients for ruminants. It is not different from Option 4 with respect to sheep, goats, deer, other ruminants and mink, or 4-D bovines, all of which would be banned from ruminant feeds. If the renderer/processor finds that the separate

processing of the specified tissues is uneconomic in his/her situation, then the resulting products can still be sold to the majority of the feed market, labeled as not for use in ruminant feeds.

The segregation and separate rendering and processing of the designated tissues from the rest of the offal from non 4-D cattle would be more complicated than Option 4, probably requiring new written procedures at both the renderer/processor and the slaughterhouses supplying the raw materials. Procedures and equipment changes would be most complicated for renderer/processors obtaining raw materials from a variety of sources, so-called "mixed renderers." The labeling and recordkeeping in Option 5 would likely be more complicated than in Option 4 as persons purchasing protein feed ingredients derived from non 4-D bovine may require extensive documentation before using them in ruminant feeds.

Facilities processing large amounts of offal from slaughtered cattle may find segregation and separate processing to be feasible. If not, the protein products may still be sold for non-ruminant feeds and industrial uses. These non-ruminant feed uses are the majority of the animal-derived protein market. The fats and oils from a renderer not separating designated tissues would be available for ruminant feeds and all other uses without restriction.

If no non-ruminant feed or industrial uses are found for all of the protein products from designated tissues, then the renderer/processor would probably dispose of the products. This disposal would likely be by incineration, landfill, or local burial and would need to be conducted in accordance with all local, state, and federal requirements. The FDA, however, believes that very little product would have to be disposed. If renderer/processors cannot recoup their expenses, there will be a strong economic incentive to not collect and process the inedible slaughter products and/or the carcasses of ruminants and mink.

4. *Effect on the Slaughter Industry.*

Adoption of Option 5 would make the slaughter industry determine if it can economically 1) separate the inedible slaughter products and condemned carcasses from ruminants and mink; and, 2) sell them to the rendering/processing industry or for industrial purposes.

There would be only a minimal, short-term effect on the number of ruminants and mink slaughtered as a result of Option 5. Option 5 does not prohibit the slaughter of ruminants or mink, does not affect the use of edible products from ruminants for human consumption, does not prohibit the use of any rendered/processed products derived from ruminants or mink in non-ruminant feed, and does not limit in any manner the use of fats and oils derived from ruminants or mink.

It is possible that slaughter plants that process ruminants or mink on an irregular basis may increase their rates to cover the increased costs related to processing and disposing; however, most ruminants are currently slaughtered in large groups at many plants. Option 5 may involve the slaughter plants in the chain of recordkeeping and in the separation of offal from non 4-D bovine in a manner different from the more sweeping, simplistic Option 4. There is a heavier reliance on recordkeeping in Option 5 as a means of enforcement. It appears that Option 4 might be supported by laboratory tests for ruminant proteins in finished products; however, these same tests would probably not be useful under Option 5, as it is acceptable for some bovine proteins to be present in ruminant feeds. If in general, renderer/processors cannot reach agreements with cattle slaughterhouses on the separate handling of designated bovine tissues (brain, spinal cord, distal ileum and eyes) under Option 5, the end result would be for Option 5 to have the same effect as Option 4, a ruminant protein to ruminant ban.

5. *Effect on the Feed Manufacturing Industry.*

The feed manufacturers, like the slaughterhouses, have a role in the separation, recordkeeping and labeling requirements of Option 5. They will need agreements with renderer/processors regarding the origin and raw material content of animal-derived protein feed ingredients that are intended for ruminants. If such agreements cannot be reached, Option 5 has the same effect as Option 4. If Option 5 is adopted, there might also be additional pressure for the use of non-animal derived proteins in ruminant feeds (i.e., plant and microbial origin proteins).

6. *Effect on the Ruminant and Mink Producers.*

Effects on ruminant producers should be similar to Option 4. Disruption in the availability of rendering as a disposal alternative for 4-D animals, if it occurs, should be temporary. 4-D ruminants would be useful for processing into proteins for non-ruminants and the potential uses of fats and tallow from 4-D animals would not be restricted in any way.

Similar effects on mink producers could also occur. Due to the small size of the mink carcass, the availability of rendering for mink may be much less than for ruminant producers.

7. *Environmental Consequences--Immediate Impacts.*

In comparison to Options 1, 2, 3 and 4, Option 5 would cause greater changes in procedures for the isolation and separate processing of inedible slaughter products and 4-D carcasses from ruminants that are utilized by renderers/processors. While adjustments are being made in the slaughterer-renderer/processor-feed manufacturer food chain, there could be a short term increase in the proportion of these materials that are buried on-farm, placed in local landfills, and/or incinerated. Based on our costs for disposition, it would appear that on-farm burial for 4-D animals would be the most likely area of increased disposition (Appendix L).

In analyzing the possible environmental consequences of such a shift, we assumed that disposal in landfills and incineration would be subject to environmental laws that would provide adequate protection with regard to environmental contamination by any TSE's or other potentially deleterious substance. On-farm disposal might, in some cases, be subject to the same environmental laws as landfills and incineration. Further, the precedent for environmentally acceptable on-farm disposal of ruminants was established when it was selected as a recommended means of disposal of infected or high risk sheep by APHIS in the indemnity portion of its scrapie certification program (57 FR 58132).

8. *Environmental Consequences--Long Term Impacts.*

If FDA implemented Option 5 and BSE occurred undiagnosed in the US anyway, this action would have benefits similar to or slightly less than Option 4 in reducing the scope and severity of the outbreak and the environmental impacts that might result. A fully implemented Option 5 would be expected to reduce the number of potential incidents of crossover of the scrapie and CWD agents from sheep, goats and deer to cattle, would reduce the number of animals affected in locations where BSE could have been imported or spontaneously occurred, and would greatly reduce the potential recycling and amplification of the BSE agent from cattle to ruminants. Dietary exposure of wildlife (predators, scavengers) to the TSE agent(s) during the time BSE is undiagnosed but present would be expected to be greatly reduced in comparison to Options 1 and 2 and be comparable to or slightly more than Option 4. This is because the number of cattle exposed prior to a time when BSE is diagnosed is expected to be reduced. The number of cattle that subsequently would need to be buried, landfilled, or incinerated and the potential human exposure to the BSE agent would also be greatly reduced compared to Options 1 and 2 and would be comparable to or slightly more than Option 4. The initial and continuing difficulty in implementing and enforcing Option 5 compared to Option 4, might result in Option 5 not being as effective as Option 4 in reducing the spread of a TSE through the ruminant population, and could result in slightly increased numbers of animals to dispose of when the outbreak was discovered and more wildlife (and human) exposure to the TSE agent.

F. Option 6 - Prohibit All Mammalian-Derived Protein in Ruminant Feeds

The point of view in this approach is that TSE's may be present in a variety of mammalian-derived proteins, that mammalian-derived proteins are not required in the diets of ruminants, and that a simple ban of all mammalian proteins in ruminant feeds would be the easiest to comply with and to enforce, as there would be minimum chances of cross-contamination at the rendering and feed production facilities and because screening methods for mammalian proteins are available. This approach assumes that the factors causing TSE's to occur spontaneously will always be present and that the public health implications and economic seriousness of widespread TSE's occurring in ruminant populations require measures that will effectively prevent the spread of TSE's indefinitely.

Whereas the previous approaches attempt to manage the problem by applying controls to the slaughterers, renderers, processors, feed manufacturers and the producers to follow additional safeguards, in the face of a continuing economic conflict of interest, this approach seeks to apply controls primarily at the feed ingredients level. In comparison to Options 4 and 5, this option does not appear to require much change in the current slaughtering and rendering/processing practices, as these industries are already roughly segregated into poultry, mammal/mixed species, and fish. Instead, Option 6 largely requires that the current products be marketed differently, with the protein products derived from mammal/mixed species excluded from the ruminant feeds market. As with Options 4 and 5 above, some labeling and recordkeeping measures would be required, however the need for changes in other manufacturing practices would be much reduced.

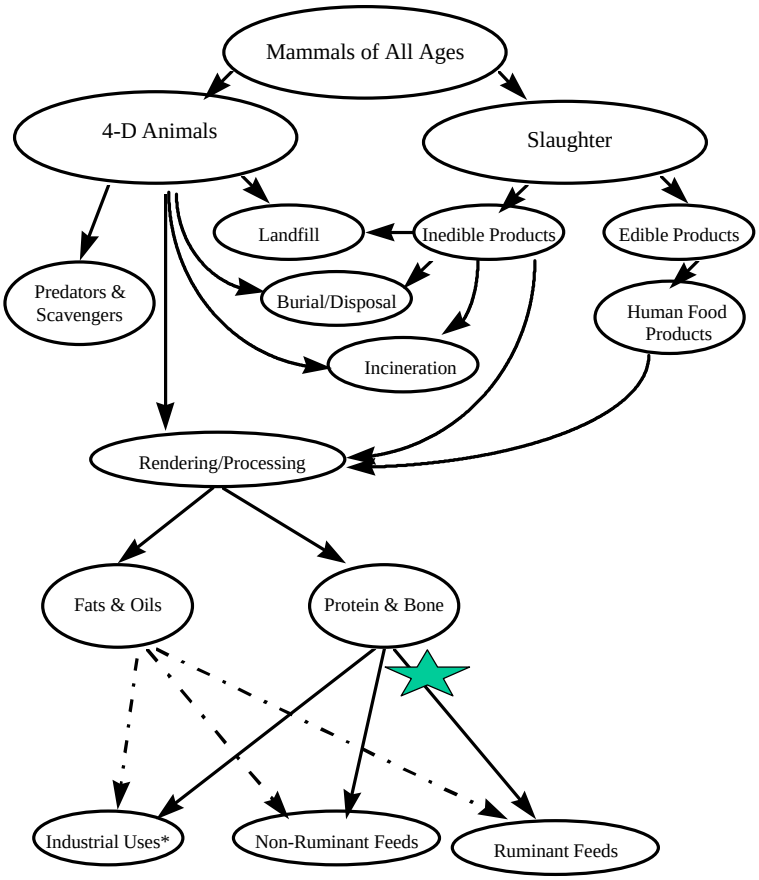
1. *Feed Ingredients Affected.*

If Option 6 were implemented (Figure 6), the feed ingredients that would be affected are numerous and the same as those in Option 4 and 5. (See AAFCO, 1996 for definitions.) These include, but are not limited to, the following:

Animal Products: meat, meat by-products, animal liver, dried meat solubles, fleshings hydrolysate, hydrolyzed hair, hydrolyzed leather meal, glandular meal and extracted glandular meal, unborn calf carcasses, animal digest, cooked bone marrow, mechanically separated bone marrow, meat meal, meat and bone meal, animal by-product meal, meat meal tankage, meat and bone meal tankage, stock, meat protein isolate, and leather hydrolysate.

Mineral Products: bone ash, bone charcoal, spent bone charcoal, cooked bone meal, steamed bone meal, and bone phosphate.

Figure 6. Disposition Patterns for Mammals in the US - Option 6 Mammalian Protein to Ruminant Feed Prohibition



* includes but is not limited to, fertilizers and lubricants.

☆ pathway partially blocked, milk products and gelatin are permitted in ruminant feeds.

The feed ingredient definitions affected by this option are much the same as in Options 4 and 5, however, a much broader range of input materials is affected and therefore, much larger quantities of ingredients. Protein products derived from all mammals would be subject to labeling and controls. For example, meat and bonemeal derived exclusively from hog offal would be subject to labeling and marketing restrictions. The same applies for mixed species products that did not include ruminant proteins.

2. *4-D Carcasses - Amounts and Costs of Disposition.*

The sweeping nature of this option makes any projection of whether there will be increased numbers of carcasses to be disposed of in a manner other than rendering subject to debate. As is stated below, this option has less effect on the operations of rendering and processing industries than Options 4 or 5, and consequently could be expected to have less effect on the willingness of renderers and processors to collect 4-D animals. On the other hand, more species are affected by this option, notably swine and equine, and the demand for 4-D animals of these species will certainly not be increased by this option, in contrast with Options 4 and 5 where demand for these species might be expected to increase at the expense of ruminants. See Appendices I and J for estimates of the quantities of offal and 4-D animals that are affected by this option.

3. *Effect on the Rendering and Processing Industries.*

The current practices of renderers and processors are not appreciably affected by this option and therefore, neither are the wastes produced and treated by these industries. The only segregation that might be considered by the rendering and processing industries is non-mammalian material (poultry and fish) from mammalian material (ruminants, swine and horses). Some labeling and recordkeeping might be expected, but otherwise the effects on these operations is similar to Option 1, *Watchful Waiting*. There would of course be a change in the marketing of mammalian derived feed ingredients to exclude them from use as feed for ruminants. However, as noted above, animal byproduct feeding to ruminants is not a major market for mammalian proteins, currently only 10-15%. At

least some components of the rendering industry appear to favor Option 6 over Options 4 and 5. See discussion in the preamble to the *Federal Register* notice that this EA accompanies.

4. *Effect on the Slaughter Industry.*

Option 6 would require no major changes in the manner in which ruminants and other mammals and their offal are handled at the slaughterhouse. This contrasts particularly with Option 2 and Option 5, both of which might require some separation of offal at the slaughterhouse (Option 2 - sheep and goats; Option 5 - cattle). Option 6 is similar in effect to Option 1 with regard to the environmental impacts of wastes generated by the slaughter industry. Both Options 1 and 6 should not appreciably affect the marketability of offal to renderers and processors, at least in the longer term.

5. *Effect on the Feed Manufacturing Industry.*

The focus of compliance efforts in Option 6 is on the feed manufacturing industry. Feed manufacturers should be able to test feeds and feed ingredients for presence of mammalian protein and they would be responsible for not including such ingredients in ruminant feeds. Product switching with poultry or fish would seem to be a possibility, to the extent that vegetable protein sources were more expensive than poultry and/or fish by-products. Labeling might be necessary to prevent cross-species feeding at the farm level. Feed facilities that produce feed for ruminants and other species would probably be most affected in the need for procedures to ensure thorough equipment cleanout when batches of ruminant feed follow non-ruminant feeds containing mammalian protein products. Cleanout materials are usually feed ingredients; they would be saved for the next batch of non-ruminant feed. Such facilities making a variety of feeds using the same equipment are expected to be a small minority of feed producers, as the feedlot, poultry and swine industries have become progressively vertically integrated, including the use of dedicated feed facilities. The American Feed Industry Association appears to support Option 6 over

Options 4 and 5, as indicated by their letter to the Center for Veterinary Medicine of August 2, 1996 (AFIA, 1996).

6. *Effect on the Producers of Mammals.*

Effects depend on whether uses can be found for all mammalian protein feed products. If not, there might be more 4-D ruminants, swine, mink, horses, etc. to dispose of in ways other than rendering. However, since ruminants and swine, particularly, are a bulk source of animal protein (currently about two-thirds of all material presented for rendering) and because ruminants and mink offal and carcasses would continue to be integrated with other mammalian sources, it is unlikely that there would be much effect on the ability of producers to have 4-D animals collected at the farm. Consequently, it is not expected that there would be any noticeable change in the use of renderers and processors as a means to dispose of 4-D mammals at the farm.

7. *Environmental Consequences--Immediate Impacts.*

Option 6 is not expected to cause any major changes in how 4-D animals are disposed or in the wastes generated by the slaughterer/renderers/processors/feed manufacturers food chain. Not enough information is available to accurately predict whether product switching and other marketing changes might cause temporary changes in the desirability of offal or 4-D animals from one or another species in various localities. These disruptions are expected to be local in nature, related to the distribution of animal rearing and slaughtering facilities, and temporary. It is expected that rendering/processing will continue to be a competitive disposal option usually favored over on-farm burial, landfilling and incineration. These temporary effects could be about comparable to those expected for Option 4, the Proposed Action.

8. *Environmental Consequences--Long Term Impacts.*

Option 6 would be expected to have the most efficacy of all the options considered in preventing the crossover of known or unknown TSE's from any mammal species to ruminants. Because it is reflective of current product divisions in the rendering industry, Option 6 is also probably the most easily implemented and enforced of the options and, for that reason could be expected to reduce the spread of a spontaneous or introduced TSE among ruminants, minimizing the number of animals that would be traced down and destroyed at the time a TSE outbreak is detected.

There are a number of unknowns in an option as extensive as this one that might result in enough market disruption to force alternate disposal methods for 4-D animals to be utilized. The experiences of the UK as they implement their mammalian protein to ruminant ban should be instructive in defining unknown or unanticipated long term environmental impacts of this option.

G. Summary and Comparison of the Proposed Action and Alternatives

The Proposed Action and the alternatives considered above, and summarized below in Table 1, represent a spectrum of possible actions that the agency might take to reduce the probability and severity of a high impact event - the introduction of BSE and its consequent spread in US cattle. Because diagnosis of TSE's in living ruminants is unreliable and because clinical signs usually develop in cows 2-8 years after exposure, BSE could occur and spread undetected for a time, in spite of intensive monitoring for the clinical cases. The potential extent of spread of a TSE before detection and the consequent effort necessary to eradicate a TSE from a ruminant population, is expected to differ among the possible actions - "Watchful Waiting," "Adult Sheep and Goat Controls," "Sheep, Goat, Deer, Elk and Mink Controls," the "Proposed Action," the "Designated Tissues Ban," and the "Mammalian Protein to Ruminants Ban."

Option 1, “Watchful Waiting” would rely on voluntary actions by the rendering and slaughtering industries to prevent the movement of the TSE agents from sheep to cattle and other ruminants. The potential for BSE to occur under this scenario is probably low, but is the highest probability of the five options. Option 1 is the least likely of the options considered to prevent BSE amplification via the feed in the US. The action is primarily reactive to BSE introduction or spontaneous occurrence, allowing amplification of the original case through feed for 2 to 8 years before detection. We do not know to what degree current rendering practices in the US may inactivate TSE’s. Spread of BSE among cattle, in the event BSE occurred, would be expected to be the most extensive under “Watchful Waiting.” Consequently, the long term environmental costs of “Watchful Waiting” are potentially the highest, if one expects BSE to eventually occur. On the other hand, the immediate environmental costs are limited to those already occurring, for example a low frequency of exposure of wildlife to scrapie and CWD agents in sheep, goat, mule deer and elk from carcasses disposed of on-farm or from animals dying in the wild.

Option 2, “Adult Sheep and Goat Controls” seeks to further reduce the probability of the transmission of the scrapie agent from sheep and goats to cattle. This option would remove from ruminant feeds the rendered/processed products derived from the specified offal of adult sheep and goats over 1 year of age. The potential for BSE to occur under this scenario is expected to be lower than “Watchful Waiting” but probably higher than Options 3, 4, 5 or 6. This is because this option only provides protection against the occurrence of BSE from crossover of the scrapie agent. It is possible that BSE could be imported in feed ingredients or cattle, occur spontaneously in cattle or occur from crossover of the CWD or TME agents. In the event that BSE subsequently occurs undiagnosed in cattle, Option 2 would not prevent the spread of the BSE agent from cattle to cattle through cattle-derived rendered/processed feed ingredients. Monitoring for BSE is the same as for Option 1. Consequently, the long term potential environmental costs are about the same as Option 1, if one expects BSE to eventually occur in the US and go for some period undiagnosed.

Option 2 only attempts to affect the probability of occurrence through a sheep or goat scrapie to cattle crossover. It does not remove risk factors that might spread BSE after introduction. On the other hand, the immediate environmental costs are small, limited to slight changes in on-farm dispositions, landfilling and incineration of adult sheep and goats and a possible slight increase in exposure of wildlife to scrapie infected carcasses. It also minimizes what some scientists believe is one of the greatest risks for initiating BSE in the US.

Option 3, "Sheep, Goat, Deer, Elk and Mink Controls," is an extended version of Option 2. It recognizes that sheep and goats younger than 1 year of age may have scrapie and also that there are other species in the US that could serve as a source of a TSE crossover to cattle. Option 3 could therefore be seen as a more thorough approach to prevention of TSE crossover events. Like Option 2, however, Option 3 does not directly address BSE in cattle. The implicit assumptions are that BSE is not currently in the US, BSE does not occur spontaneously in cattle, and that existing import controls will prevent indefinitely the accidental future introduction of BSE from abroad. If any of these assumptions prove incorrect, BSE could spread through feed ingredients throughout the US cattle population. Therefore, the long term consequences of Option 3 are probably the same as Options 1 and 2. If BSE is introduced into the US, it may spread freely through cattle feed for years before it is detected and eradication measures are initiated.

Immediate impacts of Option 3 are expected to be larger than Option 2, because the controls on the offal from slaughtered lambs and kids, in particular, will more than double the tonnage of materials affected. These amounts are still a small percentage of the entire rendering/processing industry, however, and adjustments to efficiently utilize these raw materials will likely be made quickly.

Option 4, "Proposed Action - Ruminant and Mink Protein to Ruminant Ban," would further reduce the probability of the transmission of the TSE agents from sheep and goats

to cattle and from cattle, wild ruminants and mink to cattle by removing from ruminant feeds all rendered/processed protein products derived from the offal or carcasses of ruminants and mink of any age or species (except blood from bovines, milk proteins and gelatin). This action is more easily enforceable than Option 2 or 5 due to its more all-inclusive nature. The potential for BSE to occur in the US under this scenario is probably far lower than Options 1, 2 or 3 and comparable or slightly lower than Option 5 and comparable or slightly higher than Option 6. In the event that BSE occurred undiagnosed in cattle anyway, the "Proposed Action" would be expected to be almost comparable to Option 6 in limiting the spread of BSE among ruminants prior to diagnosis, since both Options 4 and 6 prevent amplification of TSE's via the feed ingredient route. Consequently, the long term potential environmental costs of Options 4 and 6 are the lowest, if one expects BSE to eventually occur. The effectiveness of Option 5 in preventing the amplification of BSE in feeds is limited to our ability to correctly determine the potential infectivity of tissues throughout the bodies of cattle of all ages by mouse bioassay and to accurately exclude those tissues from other offal in order to prevent their use in the manufacture of ruminant feed products. Failures in both areas could be expected.

On the other hand, the immediate, short term environmental costs of Options 4 and 5 appear to be higher than Options 1, 2 and 3. Option 5, with its extensive changes in operations and offal handling may be the highest of the options considered. The immediate, short term environmental costs of Option 6 are more unpredictable (as larger segments of the animal industry are potentially affected), but may be less than Option 4, as it requires marketing changes rather than operational and processing changes.

Option 6 is likely the most protective of all the alternatives considered in preventing known and unknown TSE's from crossing over to ruminants from other mammals. To the extent it is more easily and thoroughly implemented than the other options, it may also be the most effective in preventing the spread of any TSE's that occur among ruminants in spite of our efforts. As knowledge of TSE's increases, including the feasibility of methods

to inactivate TSE's, the presence of TSE's in other species, and even the true biological nature and interrelationship of the various diagnosed TSE's, Option 6 will merit re-examination.

In sum, the six alternative actions can be characterized as differing balances of impacts in the immediate term versus the long term. "Watchful Waiting" has the lowest immediate term impacts and the largest potential long term impacts. The "Ruminant and Mink Protein to Ruminant Ban," the "Designated Tissues Ban," and the "Mammalian Protein to Ruminant Ban" have higher immediate term impacts, but potentially the smallest long term impacts. Options 2 and 3 are intermediate, with smaller immediate term impacts and larger potential long term impacts when compared with the "Mammalian Protein to Ruminant Ban," the "Proposed Action" and the "Designated Tissues Ban."

To be factored in is the uncertainty of BSE occurrence in the US. There is a real possibility that the BSE risk factors, as they are understood today, are incomplete and that there are other factors in place such that BSE will never occur in the US. If that were so, our assessment of potential long term impacts, which is based on the US risk factors permitting the eventual occurrence of BSE, is irrelevant and only the immediate term impacts should be compared. There are also well considered arguments that BSE may already be present and incubating in the US. If that were the case, the long term impacts are the most relevant to be weighed and there would be no guessing about whether the low probability event would occur. Based on the available information, FDA does not believe that the public or animal health will be well served by taking the chance that BSE will not occur or will not be introduced into the US.

Table 1. Comparison of the Environmental Effects Associated with Potential Actions.

Environmental Effects	Potential Actions					
	Watchful Waiting	**Adult Sheep & Goat Controls**	**Sheep,Goat, Deer, Elk & Mink Controls**	**Ruminant Protein to Ruminant Ban**	**Designated Tissues Ban**	**Mammalian Protein to Ruminant Ban**
Immediate Impacts						
On-Farm Disposal	No Changes	Slight Increase	Slight Increase	Moderate Increase	Moderate Increase	Moderate Increase?
Landfill	No Changes	Slight Increase	Moderate Increase	Moderate Increase	Moderate Increase	Moderate Increase?
Incineration	No Changes	No Changes	Slight Increase	Slight Increase	Slight Increase	Slight Increase?
Industry Wastes Produced	No Changes	Slight Increase	Slight Increase	Slight Increase	Moderate Increase	Moderate Increase?
Probability of BSE Occurring in US	Minimum Effect	Some Reduction	Moderate Reduction	Near Maximum Reduction	Very High Reduction	Maximum Reduction

Table 1. Comparison of the Environmental Effects Associated with Potential Actions (continued).

Environmental Effects	Potential Actions (Continued)					
	Watchful Waiting	**Adult Sheep & Goat Controls**	**Sheep,Goat, Deer, Elk & Mink Controls**	**Ruminant Protein to Ruminant Ban**	**Designated Tissues Ban**	**Mammalian Protein to Ruminant Ban**
Consequences if BSE Occurs Long Term						
Production Losses & Impacts	Maximum Losses	Maximum Losses	Maximum Losses	Minimum Losses	Near Minimum Losses	Minimum Losses
Wildlife Exposure	Maximum Exposures	Maximum Exposures	Maximum Exposures	Minimum Exposures	Small Increase	Minimum Exposures
On-Farm Disposal	Largest Increase	Largest Increase	Largest Increase	Minimum Increase	Small Increase	Minimum Increase
Landfill	Largest Increase	Largest Increase	Largest Increase	Minimum Increase	Small Increase	Minimum Increase
Incineration	Largest Increase	Largest Increase	Largest Increase	Minimum Increase	Small Increase	Minimum Increase

III. MITIGATION MEASURES

A. Mitigation 1 -- Voluntary Programs.

In 1989, the National Renderers Association and the Animal Protein Producers Industry recommended to its members that they stop rendering adult sheep or sheep offal for sale as meat and bone meal for inclusion in cattle feed (Bisplinghoff, 1989). By comparing rendering surveys conducted in 1985 and 1990 (USDA/APHIS, 1993b), it would appear that these voluntary bans have had an effect as 1) there was a decrease in the percentage of renderers processing slaughtered mature (1 year or older) sheep from 44% in 1985 to 13% in 1990; 2) the percent of renderers using the heads from sheep decreased from 42% in 1985 to 8% in 1990; and, 3) the proportion of renderers processing dead sheep also decreased from 39% in 1985 to 7% in 1990. Voluntary compliance by the rendering industry has likely reduced the threat of transmitting the scrapie agent to other animals.

As a mitigation of Option 1, the FDA and renderer-processors could encourage expansion of this voluntary program to include more than just meat and bone meal and/or by expanding coverage to goats, deer, elk and mink.

Sheep producers and cattlemen have indicated their interest in undertaking a voluntary ruminant protein to ruminant feed ban. To the extent that these voluntary efforts go into effect before the FDA proposed action becomes final, the less the expected disruption of the rendering/processing industry from the FDA action.

B. Mitigation 2 -- Encouraging Research.

The rendering industry and the FDA have also encouraged research into new and alternative rendering methods that will inactivate the scrapie/BSE agent(s) and other TSE agents. The TSE's appear to be proteins resistant to many of the processes that would kill virtually all other known infectious agents. As a mitigation of any of the above Options,

the rendering/ processing industry and the FDA could encourage further research on more extensively characterizing the TSE agents and on developing and implementing methods that would inactivate all of the TSE agents in a cost effective manner.

The USDA, the FDA, and the sheep and goat industries have also encouraged research in ways of detecting scrapie positive animals prior to onset of clinical signs. If scrapie could be detected in clinically unaffected animals, then a producer could identify and separate these animals and reduce the potential spread of the agent to other animals. Since complete flock depopulation has been an established means of scrapie control, this would also prevent scrapie free animals in a scrapie positive flock from being destroyed . A similar test, if one were available, could be used to screen cattle in the US for BSE. As a mitigation of any of the Options, the FDA could support research aimed at developing an inexpensive test that will accurately distinguish TSE free from TSE positive animals that are not clinically affected.

C. Mitigation 3 -- Support the Voluntary Scrapie Flock Certification Program.

The Animal and Plant Health Inspection Service (APHIS) has implemented several programs aimed at controlling/limiting the spread of scrapie in the US, the most recent of which is called the voluntary scrapie flock certification (VSFC) program (57 FR 58132). The VSFC program is currently ongoing and attempts to reduce and ultimately eradicate scrapie. During the indemnity portion of this program, which ended in June, 1993, the USDA provided compensation to the owners of scrapie positive flocks that signed up. The FDA has assisted in the trace back aspects of this program by not objecting to the use of electronic implant devices in sheep.

As a mitigation to any of the above alternatives, the FDA could encourage the reinstatement of indemnity payments to owners of scrapie positive flocks that sign up for the VSFC program. If scrapie could be eliminated from the US sheep population, then a major risk factor in the introduction of BSE into the cattle population would be removed

and the need for the proposed action in its current form could be reconsidered in light of the decreased probability of BSE occurrence.

IV. LIST OF PREPARERS

John C. Matheson, III
Division of Toxicology and Environmental Sciences
Center for Veterinary Medicine

John Matheson evaluates the potential environmental impact of products regulated by the FDA Center for Veterinary Medicine. Additionally, he writes environmental assessments and environmental impact statements for actions initiated by CVM. He serves as the FDA focal point for technical and procedural matters dealing with compliance with the National Environmental Policy Act. He is the CVM Senior Environmental Scientist. He was Chief of the CVM Environmental Staff from 1980 to 1990. He has served as an environmental scientist with the FDA since 1975. He holds a Master of Science Degree in Public Health and a Bachelor of Science Degree in Biology, both obtained from the University of North Carolina, Chapel Hill, where he studied in the Department of Environmental Sciences and Engineering and the Department of Biology.

Randall A. Lovell
Division of Animal Feeds
Center for Veterinary Medicine

Randall Lovell is a veterinary toxicologist who assesses the safety of natural toxins, pesticides, heavy metals, and industrial chemicals in animal feed for the FDA Center for Veterinary Medicine. He serves as a scientific reviewer for many residue cases reported to FDA on the Contamination Response System. He has served as a veterinary medical officer with the FDA since 1991. He received a Bachelor of Science Degree in Animal Science and a Doctor of Veterinary Medicine from Oklahoma State University. At the University of Illinois, he completed a residency program in clinical veterinary toxicology

and obtained a Doctor of Philosophy in Veterinary Medical Sciences. He is also a diplomate of the American Board of Veterinary Toxicology.

John Honstead
Division of Animal Feeds
Center for Veterinary Medicine

John Honstead is a veterinary microbiologist that serves as a subject matter expert for bovine spongiform encephalopathy for the FDA, and provides epidemiology expertise for the Division of Animal Feeds. He has served as a veterinary medical officer in the FDA since 1991. From 1982 to 1991 he served in the Food Safety and Inspection Service and in the Animal and Plant Health Inspection Service of the USDA. He has a Bachelor of Science Degree in Biology and a Doctor of Veterinary Medicine from Kansas State University, and a Master of Science Degree in Medical Microbiology from the University of Georgia.

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VI. APPENDICES

Appendix A -- Transmissible Spongiform Encephalopathies

Transmissible spongiform encephalopathies (TSEs) are a group of diseases in animals and man that share many similar characteristics. This group of similar diseases includes scrapie in sheep and goats, bovine spongiform encephalopathy (BSE) in cattle, chronic wasting disease in mule deer, transmissible mink encephalopathy (TME) in mink, spongiform encephalopathies in zoo ruminants, feline spongiform encephalopathy in cats, and Creutzfeldt-Jakob disease (CJD), Gerstmann-Straussler Syndrome (GSS), and kuru in man. TSEs are characterized by a long incubation period, an absence of a host immune response, a progressive degeneration of the central nervous system, a relatively short clinical course of neurologic signs, and 100% mortality (McCaskey, 1991). In most cases the natural route of exposure to the TSE agent is suspected to be oral, although genetic disposition is known to play a role in some cases of sheep scrapie and in related human diseases (CJD, GSS, and kuru) (Hsiao, 1991).

The proposed TSE agents are not generally believed to be viruses, but rather a protein devoid of nucleic acid components. The proposed TSE agents have been termed prions, and are abnormal forms of neuronal membrane proteins that are already present in all animals (Stahl and Prusiner, 1991) (Prusiner et al., 1993). Prions are resistant to most methods of sterilization and survive severe environmental conditions such as 360° C dry heat (Brown et al., 1989) and burial for 3 years (Brown and Gajdusek, 1991). The proposed TSE agents do not provoke an antibody response in the host, removing the possibility of detecting their presence by serological techniques or of preparing protective vaccines (State Veterinary Service, 1988).

Since antemortem diagnostic tests for the detection of TSE do not exist, postmortem tests are required to confirm suspected TSE cases. The observation of histopathological changes in the brain, such as vacuolization of the brainstem, are positive indicators (Kimberlin, 1992). Other diagnostic tests available are immunohistochemical staining and immunoblotting the abnormal protein. (Detwiler, 1992). Detection of the TSE agent can also be accomplished by intracerebral inoculation in mice or hamsters with a brain homogenate from a suspected animal. After an appropriate incubation period, the brain of the laboratory animal is examined for histopathological changes characteristic of TSE (Hadlow et al., 1982).

Appendix B -- Scrapie

Introduction.

Scrapie is known to have existed in Britain, Ireland, France, and Germany for over 200 years. It has been observed in the US and Canada for about 50 years. The first case of scrapie in the US was diagnosed in sheep from Michigan in 1947. From 1947 through January, 1993, approximately 653 sheep flocks have been diagnosed with scrapie (USDA/APHIS, 1993). Sheep scrapie has been diagnosed in every state except Alaska, Arizona, Arkansas, Florida, Hawaii, Montana, North Dakota, and Rhode Island (Lang, 1993). In the US only four cases of scrapie have been diagnosed in goats (USDA/APHIS, 1993). All four goats were raised with sheep flocks in which sheep scrapie was present.

Scrapie occurs in both sexes and probably all breeds of sheep. The Suffolk breed was involved in approximately 74% of the scrapie infected flocks reported through June, 1989. The Hampshire and Cheviot are the other breeds most frequently reported as being affected with scrapie, and the Rambouillet and Targhee breeds have a low incidence of scrapie (Kimberling, 1988) (Gloyd, 1990). In the absence of an antemortem diagnostic test, it is not possible to establish with absolute certainty that a flock is free of scrapie infection. Moreover, lack of reporting, the long incubation period, and open range husbandry practices in the western United States make it difficult to detect classical clinical signs and accurately monitor scrapie in the United States.

Clinical Signs.

Scrapie is a slowly progressive, transmissible disease of the central nervous system in sheep and goats. Scrapie is characterized by a prolonged incubation period averaging 2 years, followed by a clinical course of 2 to 6 months when the animal exhibits sensory and motor malfunction, depression, and death. Early signs of scrapie include subtle changes in behavior or temperament which may be followed by scratching and rubbing against fixed objects. Other signs include loss of coordination, weight loss despite a good appetite, biting of feet and limbs, tremor around head and neck, and unusual walking habits (Kimberling, 1988).

Transmission.

The scrapie agent in sheep presumably moves from infected to susceptible animals by consumption of material that contains the scrapie agent; however, its spread has appeared to be both vertical (mother to offspring) (Foster et al., 1992) and horizontal (direct contact) between sheep (Hadlow et al., 1982). Further studies on the various modes of transmission of scrapie are needed.

Diagnosis.

Veterinarians diagnose scrapie on evidence of typical clinical signs and histopathological changes. Since there is no detectable immune response to scrapie, diagnosis of scrapie in live sheep is possible only when clinical signs are evident and must be confirmed by histopathology at postmortem (Detwiler, 1992). The most consistent histopathologic changes are neuronal shrinkage and vacuolization, astrocytic hypertrophy and proliferation, and spongiform degeneration. These changes occur in the spinal cord and brain stem, especially in the thalamus, medulla, and cerebellar peduncles. The diagnosis can be confirmed by inducing the characteristic disease in mice following intracerebral inoculation with suspect sheep brain (Kimberling, 1988).

Tissues of Greatest Risk.

The specified offal of adult sheep and goats [brain, spinal cord, spleen, thymus, tonsil, lymph nodes, and intestines (duodenum to anus inclusive)] pose the greatest risk of transmitting scrapie or a scrapie-like disease. The scrapie agent may be identified in lymphatic tissue (spleen, thymus, tonsil, and lymph nodes) in sheep with preclinical infections; however, in clinically affected adult sheep, the agent is identified in intestines, nervous tissues (brain and spinal cord), and lymphatic tissues (Hadlow et al., 1982). The brain and spinal cord have been shown to contain the highest scrapie infectivity of any body tissue.

Appendix C -- Bovine Spongiform Encephalopathy

Introduction.

BSE was first recognized as a new cattle disease by researchers at the Central Veterinary Laboratory of the British Ministry of Agriculture, Fisheries, and Foods at Weybridge, England in November, 1986. In retrospect, the literature indicates that the first clinical case of BSE may have been observed as early as April, 1985 (Wells et al., 1987). As of September, 1993, there have been more than 100,000 confirmed cases of BSE in England, Scotland and Wales. BSE has also been reported in Northern Ireland, Republic of Ireland, Switzerland, France, Oman, Falkland Islands, Denmark, and Portugal (Denny et al., 1993).

In the United Kingdom, 47.5% of the dairy herds and 10.9% of the beef suckler herds are infected (MAFF, 1993). The lower incidence of BSE in the beef herds vs. dairy herds in the United Kingdom is not attributable to any difference in breed predisposition, but to different feeding practices in dairy and beef herds. In dairy herds in the United Kingdom, the feeding of concentrate rations likely to contain meat and bone meal is common during the first six months of life (Wilesmith et al., 1992).

Clinical Signs.

BSE is a transmissible, slowly progressive, degenerative disease of the central nervous system (CNS) of adult cattle. This disease has a prolonged incubation period in cattle following oral exposure (2 to 8 years) and is always fatal. BSE is characterized by abnormalities of behavior, sensation, posture, and gait. The clinical signs usually begin with changes in animal behavior that are suggestive of apprehension, anxiety, and fear. There is increased reaction to sound and touch. A swaying gait is sometimes coupled with high stepping of the feet and is most evident in the hind limbs. Changes in the normal behavior of the individual cow may also include separation from the rest of the herd while at pasture, disorientation, or excessive licking of the nose or flanks (Hueston, 1991). The most common history given by the herdsman was "nervousness" or altered behavior or temperament, weakness associated with pelvic limb ataxia, paresis, and loss of body weight (Wilesmith et al, 1988). These signs are similar to those seen in sheep that are infected with scrapie.

Transmission.

Dietary exposure has been the most likely source of disease transmission in the United Kingdom. There is no evidence for the transmission of the BSE agent from cattle to cattle by direct contact or from scrapie-infected sheep to cattle by direct contact (Winter et al., 1989). If maternal transmission occurs, it occurs at a rate insufficient to maintain the epidemic (Robinson, 1992).

Pathology.

In most animals there are no gross pathologic changes associated with BSE, although some animals may exhibit contusions from falling. However, postmortem histopathology of BSE distinguish it from other neurological disorders (Wells et al., 1989) (Davis et al., 1991).

Vacuolar changes in the solitary tract nucleus and the spinal tract nucleus of the trigeminal nerve occurred with a high frequency in the brains of cattle with BSE (Bradley et al., 1990). Histopathological examination also demonstrated bilaterally symmetrical degenerative changes in certain brain stem gray matter locations (Wells et al., 1987). The histopathology of BSE closely resembles other TSEs. (Liberski et al., 1992) (Liberski et al., 1992a).

Scrapie-associated fibrils (SAF) are pathological aggregates of neuronal membrane proteins (Fancy et al., 1991) (Wilesmith et al., 1991) (Wilesmith et al., 1992) and they are often found in the brains of BSE infected cattle. The SAF provide an additional means of diagnosing BSE when postmortem autolysis renders CNS material unsuitable for histopathology (Scott et al., 1992).

Appendix D -- TSE's in Other Animals

Transmissible mink encephalopathy (TME) is a TSE of mink. TME produces clinical signs and brain lesions similar to those of sheep infected with scrapie. The development of TME on a mink farm that reportedly fed only cattle by-products has led some to believe that BSE exists at a low level in the United States (Marsh, 1993). TME is a rare disease in the United States with only five outbreaks (involving 11 mink farms) having been reported in the last 50 years. Based on available evidence, the United States Department of Agriculture (USDA) has concluded that the by-products from United States cattle are unlikely to have caused the TME outbreak on the mink farm (Bridges, 1991).

Two biologically distinct strains of the TME agent have been identified by serial passage in outbred Syrian golden hamsters. The HYPER strain produces a clinical disease characterized by hyperexcitability, with an incubation period of 65 days. The DROWSEY strain exhibits only progressive lethargy with an incubation period of 168 days. These two strains have different biochemical and physical properties defined by sedimentation analysis, protease sensitivity and migration patterns on SDS-PAGE. These differences are most likely due to post-translational modification (Bessen and Marsh, 1992).

Other animals have TSE's with typical characteristics of long incubation, neurological degeneration and 100% death rate. These include elk and deer (Williams and Young, 1980) (Williams and Young, 1993), zoo ruminants (Jeffrey and Wells, 1988) (Fleetwood and Furley, 1990) (Kirkwood et al., 1990) and domestic cats (Leggett et al., 1990) (Wyatt et al., 1991).

Appendix E -- Regulatory Actions taken by the United Kingdom Concerning BSE

Regulatory controls taken to manage the BSE epidemic in the United Kingdom and to address public health concern include: (1) an action in June 1988 to make the disease reportable; (2) a ban in July 1988 on the feeding of ruminant-derived protein supplements to other ruminants; (3) an order in August 1988 for the compulsory slaughter and incineration of BSE suspect cattle; (4) a ban in November 1988 on the human consumption of specified offal (including brain, spinal cord, thymus, spleen, tonsils, and intestines) of ruminants (which was expanded to specified offals of calves in 1989); (5) a ban in September 1990 of feeding any ingredient containing specified offal to all pet and farm animals (Bradley, 1990) (Bradley, 1991) (Lamming, 1992); (6) a cattle slaughter program initiated in the Spring of 1996 intended to eradicate BSE; (7) the formulation of a ban on the feeding of mammalian meat and bone meal to any farmed animal; and (8) a ban on the use of cattle head meat for human consumption (JAVMA, 1996). See the *Federal Register* notice that this EA accompanies for additional details.

Appendix F -- Regulatory and Surveillance Activities Related to Scrapie and BSE in the US

In December, 1991 the USDA Animal and Plant Health Inspection Service (APHIS) placed a ban on importation of certain products of ruminant origin from countries known to have BSE (56 FR 63865). These products include meat-and-bone meal, bone meal, blood meal, offal, fat, and glands. In addition to prohibiting the materials listed above, the regulation requires that imported meat for human or animal consumption from the ruminants in the Bovidae family (e.g. cattle) be deboned, with visible lymphatic and nervous tissue removed; obtained from animals which have undergone a veterinary examination prior to slaughter; and obtained from ruminants which have not been in any country in which BSE has been reported during a period of time when that country permitted the use of ruminant protein in ruminant feed.

In addition to these import restrictions, APHIS has increased its surveillance efforts to verify that the United States is free of BSE, and to detect the disease should it be introduced into the US APHIS is tracing the movement and current health status of 459 cattle that were imported from United Kingdom between 1981 and 1989 (USDA/APHIS, 1992) (USDA, 1993).

Due to concerns about BSE in the US, USDA has implemented several programs to monitor US cattle (USDA/APHIS, 1992) (USDA, 1993). Pathologists at Iowa State University and the National Veterinary Service Laboratories (NVSL), of APHIS, USDA, are examining bovine brains submitted to NVSL from the following sources: (1) foreign animal disease investigations where suspected encephalitic conditions in cattle are reported, (2) Centers for Disease Control laboratories (specimens that were found negative for rabies), (3) the USDA Food Safety and Inspection Service (specimens from non-ambulatory, or "downer" cows), and (4) veterinary diagnostic laboratories in the United States. Between 1989 and October 1993, a total of 1,153 bovine brains were examined and none of these specimens contained lesions with the characteristics and distribution typical for BSE . This program is ongoing. Data on the incidence of cattle showing in the United States clinical symptoms of CNS disease that are similar to clinical symptoms of BSE have shown no increase during the past five years (Fancy et al., 1991).

To decrease the incidence of scrapie and the threat of BSE in the United States, APHIS in 1992 initiated a voluntary certification program for sheep (57 FR 58132). Flocks that

have not had a diagnosed case of scrapie within five years, or a case traced back to the flock in that period, may apply for APHIS certification and be officially identified as such.

The production of drugs and biologics (vaccines, etc.) may involve the use of tissues derived from ruminants. If this material were infected with the scrapie/BSE agent(s), then it would increase the risk of disease transmission to animals and man. The production of biologics for use in animals is regulated by the USDA. The production of drugs for use in man and animals and the production of biologics for man are regulated by the FDA. The FDA has sent a letter to manufacturers of drugs and biologics to not use bovine source material from BSE positive countries.

Appendix G -- Estimates of the Amounts of Inedible Slaughter Products from Cattle, Calves, Lambs and Kids

In FY 1992, the USDA/FSIS/Animal Disease Reporting System indicated that there were 30,759,499 cattle, 1,352,864 calves, 5,129,339 sheep/lambs, and 224,704 goats slaughtered at federally inspected slaughter plants in the US and its territories (Bauer, 1993). In Appendix H, we provided or estimated the numbers of adult sheep and goats slaughtered at federally inspected slaughter plants. After subtracting the numbers of adult sheep and goats from the total numbers of sheep and goats, we estimated that 4,798,539 lambs (5,129,339 sheep/lambs - 330,800 adult sheep) and 143,037 kids (224,704 total goats - 81,667 adult goats) were slaughtered at federally inspected slaughter plants.

The slaughter weights and % offal (inedible slaughter products) will vary, but for this document we estimated that 1) cattle averaged 1,200 lb. and were 30% offal; 2) calves averaged 250 lb. and were 30% offal; 3) lambs averaged 110 lb. and were 30% offal; and, 4) kids averaged 80 lb. and were 30% offal. We estimate that there were

5,536,710 tons of offal from cattle
[(30,759,499 animals X 1,200 lb./ animal X 30% (0.30)) / 2000 lb./ton],

50,732 tons of offal from calves
[(1,352,864 animals X 250 lb./animal X 0.30) / 2000 lb./ton],

79,176 tons of offal from lambs
[(4,798,539 animals X 110 lb./animal X 0.30) / 2000 lb./ton], and

1,502 tons of offal from kids
[(143,037 animals X 70 lb./animal X 0.30) / 2000 lb./ton].

Adding the inedible slaughter products from cattle, calves, lambs and kids gives a total of 5,668,120 tons (5,536,710 tons + 50,732 tons + 79,176 tons + 1502 tons).

Appendix H -- Estimates of the Amounts of Inedible Slaughter Products and 4-D Carcasses from Adult Sheep and Goats

In 1992, USDA/FSIS data indicated that there were 330,800 mature sheep slaughtered in the US in federally-inspected plants (USDA/APHIS, 1993a). We estimated 45 pounds of inedible slaughter products (offal) per adult sheep (150 lb. live weight X 30% offal). This amounts to 7,443 tons of inedible slaughter products from adult sheep available for disposal [(330,800 animals X 45 lb./animal) / 2000 lb./ton].

The USDA/National Agricultural Statistics Service (NASS) estimated that there were 439,000 deaths from all causes (excluding slaughter) in mature sheep. They also estimated in 1990 that 14,700 sheep and 27,600 lambs were lost to predators (USDA, NASS, 1991). Although many 4-D animals are not available to the renderer (on-farm disposal, etc.), we will make a worst case assumption that 424,300 mature sheep (439,000 total deaths in mature sheep - 14,700 sheep lost to predators) were available to the rendering/processing industry, but because of Option 2 being selected, they were not collected and had to be disposed. At an estimated 150 pounds per carcass, this amounts to 31,823 tons of 4-D carcasses from adult sheep [(424,300 animals X 150 lb./animal) / 2000 lb./ton]. Under this worst case scenario, the environmental consequences from Option 2 means that 39,266 tons (7,443 tons + 31,823 tons) of inedible slaughter products and 4-D carcasses from adult sheep would have to be disposed via landfill, incineration, or local burial.

The USDA/FSIS data on goat slaughter and inventories is, unfortunately, not as precise as for sheep. We do know that the total goat inventory in Texas for 1993 is estimated at 1,960,000 head (US Dept. of Commerce, 1989). Assuming that Texas still produces 78% of all goats, as it did in 1987 (US Dept. of Commerce, 1989), then we would estimate that the total goat inventory for the US in 1993 is 2,512,821 animals (1,960,000 / 0.78). This compares to the January 1, 1993, estimate of the total sheep inventory of 10,180,700 animals (USDA/APHIS, 1993a).

The USDA keeps records of total goat slaughter at federally inspected plants, but not on total adult goat slaughter. We will thus assume that the total adult goat slaughter at federally-inspected plants is the same percentage of total inventory as for adult sheep. Since the total adult sheep slaughter at federally inspected plants is 3.25% (330,800/10,180,700) (USDA/APHIS 1993a) of the total sheep inventory, then we will

assume that there were 81,667 mature goats (2,512,821 X 0.0325) slaughtered at federally-inspected plants in the US in 1992. Assuming 45 pounds of inedible slaughter products per animal (150 lb./animal X 30% offal), we estimate that 1,838 tons of inedible slaughter products from adult goats were available for disposal in 1992 [(81,667 animals X 45 lb./animal) / 2000 lb./ton].

We will assume that deaths from all causes (excluding slaughter and predators) in mature goats is the same percentage as in sheep. The total deaths in adult sheep from all causes (excluding slaughter and predators) was 4.17% of the total inventory (424,300/10,180,700) (USDA, NASS, 1991) (USDA/APHIS, 1993a). Although many 4-D animals are not available to the renderer (on-farm disposal, etc.), we will make the worst case assumption that 104,785 adult goats (2,512,821 X 0.0417) were available to the renderer, but because of the adoption of Option 2 they were not collected and had to be disposed. At an estimated 150 pounds per carcass, this amounts to 7,859 tons of 4-D carcasses from adult goats [(104,785 animals X 150 lb./animal) / 2000 lb./ton]. Under this estimated worst case scenario, the environmental consequences from Option 2 means that 9,697 tons (1,838 tons + 7,859 tons) of inedible slaughter products and 4-D carcasses from adult goats would have to be disposed via landfill, incineration, or local burial.

Under the estimated worst case scenarios described above, the environmental consequences from Option 2 means that 48,963 tons (39,266 tons + 9,697 tons) of adult sheep and goat offal and carcasses would have to be disposed via landfill, incineration, or local burial. The total amount of inedible slaughter products from adult sheep and goats is estimated to be 9,281 tons (1,838 tons + 7,443 tons).

Appendix I -- Estimates of the Amounts of Inedible Slaughter Products from Swine, Equine, and Other Species

In FY 1992 the USDA/FSIS/Animal Disease Reporting System also indicated that there were 89,210,132 swine, 243,585 equine, and 3,688 other species slaughtered at federally inspected slaughter plants in the US and its territories (Bauer, 1993). The slaughter weights and % offal (inedible slaughter products) will vary, but for this document we assumed that 1) the swine averaged 250 lb. and were 25% offal; 2) the equine averaged 1,200 lb. and were 30% offal; and, 3) the other species averaged 300 lb. and were 30% offal. We estimated that there were

2,787,817 tons of offal from swine
[(89,210,132 animals X 250 lb./ animal X 0.25) / 2000 lb./ton],

43,845 tons of offal from equine
[(243,585 animals X 1200 lb./animal X 0.30) / 2000 lb./ton], and

166 tons of offal from other species
[(3,688 animals X 300 lb./animal X 0.30) / 2000 lb./ton].

Adding the figures for inedible slaughter products from swine, equine, and other species (2,787,817 tons + 43,845 tons + 166 tons), gives a total of 2,831,828 tons.

Appendix J -- Estimate of the Amount of 4-D Animals Picked Up by the Rendering Industry in 1992

If one adds the amounts of inedible slaughter products from cattle, calves, lambs and kids (5,668,120 tons; Appendix G) and the amount from adult sheep and goats (9,281 tons; Appendix H) with the amount from swine, equine, and other species (2,831,828 tons; Appendix I), one would estimate that there are 8,509,229 tons of inedible slaughter products from all livestock (excludes poultry) that were available to the renderer. Assuming that this offal was 50% water (John, 1990), then there would be 4,254,615 tons of finished products (fats and oils, and protein and bone products) from this material.

There were 341,000 tons of feather meal and 545,500 tons of poultry by-product meal were produced by the rendering industry in 1992 (Eastern Research Group, Inc., 1993). Since approximately equal amounts of fats and oils, and protein and bone products are produced from most raw materials that are rendered (John, 1990), the agency also assumed that 545,500 tons of fats and oils (the same amount as the poultry by-product meal) were produced by rendering poultry offal. Thus, the agency believes that poultry produced approximately 1,432,000 tons of finished product (341,000 tons of feather meal, 545,000 tons of fats and oils, and 545,000 tons of poultry by-product meal) for the rendering industry in 1992.

The rendering industry produced approximately 7,647,500 tons of finished product in 1992 (Eastern Research Group, Inc., 1993). If you subtract the estimates for finished product from livestock (4,254,615 tons) and poultry (1,432,000 tons) from the above total, then you would estimate that 1,960,885 tons of finished product came from sources other than inedible slaughter offal.

The most likely sources for the remaining 1,960,885 tons of finished product are the carcasses of 4-D animals and other sources such as fat trimmings from edible cuts of meat, and fats and oils from restaurants and fast food chains. Assuming that 4-D animals produce equal amounts of fats and oils and protein and bone products, and that the other sources are solely from fats and oils, then one could estimate the contribution from 4-D animals. Since in 1992 there were 985,500 more tons of inedible fat and grease, edible tallow, and lard produced by the rendering industry than meat and bone meal and poultry by-product meal (Eastern Research Group, Inc., 1993), the agency will assume that this additional amount represented the contribution from sources other than 4-D animals.

Subtracting 985,500 tons from 1,960,885 tons gives 975,385 tons and provides us our best estimate for the amount of finished product that came from 4-D animals. This amount represents approximately 13% (0.975 million tons/ 7.65 million tons) of the entire finished products produced by the rendering industry. Since the most raw material that is rendered is 50% water (John, 1990),we will estimate for disposal purposes that it takes 1,950,770 tons of 4-D carcasses to produce 975,385 tons of finished product.

Appendix K -- Specified Offal Ban of Adult Sheep and Goats: Cost Estimates for Disposal by Local Burial, Landfill, Incineration, and Rendering

Local Burial.

No data were found on the cost for local burial, so we will assume that it takes 6 minutes per animal at $15 per hour for labor and equipment. Using these assumptions, we would estimate that it could cost $1.41 million (330,800 + 424,300 + 81,667 + 104,785 = 941,552 adult sheep and goats; Appendix H) (941,552 animals X 0.1 hr/animal X $15/hr) for local burial. This estimate of cost is a worst case scenario for adult sheep and goats since it includes all animals that were sent to slaughter and all the 4-D animals that were potentially available to the renderer. This cost will vary widely and may be affected by local, state, or federal ordinances.

Landfill.

We have estimated in Appendix G and H that 48,963 tons of offal and carcasses from adult sheep and goats are available for disposal in a worst case scenario. We would estimate, based on a 1990 review, that the tipping fees alone for placing this material in a landfill would cost between $0.54 million and $3.18 million ($11 to $65 per ton) (Osborne, 1993). Landfill space and availability will limit the use of this method.

Incineration.

We would estimate, under a worst case scenario, that incineration of the 48,963 tons of inedible slaughter products and carcasses of adult sheep and goats could cost between $2.45 million and $3.67 million ($50 to $75 per ton X 48,963 tons) provided it was classified as an industrial non-hazardous waste. If classified as a hazardous medical waste, then the cost for incineration could be as high as $200 per ton or $9.79 million (Osborne, 1993). Incinerator capacity and availability will limit the use of this method.

Rendering.

The cost for rendering inedible slaughter products and carcasses has been estimated at $60 to $80 per ton of finished product ($2,937,780 to $3,917,040 for the 48,963 tons from adult sheep and goats) and the finished products may sell for about $100 to $200 per ton

($4,896,300 to $9,792,600 for the 48,963 tons from adult sheep and goats) (Osborne, 1993). The finished products of rendering are useful for animal feed and industrial purposes, whereas neither burial, landfill or incineration produce a useable product.

Appendix L -- Ruminant Protein to Ruminant Ban: Cost Estimates for Disposal by Local Burial, Landfill, Incineration and Rendering

Local Burial.

No data were found on the cost for local burial, so we will assume that it takes 6 minutes per animal at $15 per hour for labor and equipment. Using these assumptions, we would estimate, in a worst case scenario, that it could cost $56.20 million (5,129,339 sheep/lambs + 224,704 goats + 30,759,499 cattle + 1,352,864 calves = 37,466,406 animals; Bauer, 1993) (37,466,406 animals X 0.1 hr/animal X $15/hr) for local burial of ruminants sent to slaughter only.

We will also assume a worst case situation where all 4-D animals utilized by the rendering/processing industry were ruminants and that they averaged 500 lb. Thus, one would estimate that an additional 7,803,080 4-D animals would have to be included in this calculations for the cost of local burial ([1,950,770 tons of 4-D carcasses (Appendix J) X 2000 lb./ton] / 500 lb. per animal). Assuming that it takes 6 minutes per animal at $15 per hour for labor and equipment, in a worst case scenario, it would cost $11.70 million ([7,803,080 animals X 0.1 hr/animal X $15/hr) for local burial of 4-D ruminants.

The total cost of local burial for both slaughtered and 4-D ruminants would total $67.90 million ([37,466,406 + 7,803,080 animals] X 0.1 hr/animal X $15/hr). This estimate of cost is a worst case scenario for ruminants since it includes all animals that were sent to slaughter and those picked up by renderers/ processors. This cost will vary widely and may be affected by local, state, or federal ordinances.

Landfill.

We have estimated in Appendix G, H and J that 7,628,171 tons of offal and 4-D carcasses from ruminants are available for disposal in a worst case scenario (5,677,401 tons of inedible slaughter products and 1,950,770 tons of 4-D animals). We would estimate, based on a 1990 review, that the tipping fees alone for placing this material in a landfill could cost between $83.91 million to $495.83 million ($11 to $65 per ton) (Osborne, 1993). Landfill space and availability will limit the use of this method.

Incineration.

We would estimate, under a worst case scenario, that incineration of the 7,628,171 tons of inedible slaughter products and carcasses of ruminants could cost between $381.41 million and $572.11 million ($50 to $75 per ton) provided it was classified as an industrial non-hazardous waste. If classified as a hazardous medical waste, then the cost for incineration could be as high as $200 per ton or $1,525.63 million (Osborne, 1993). Incinerator capacity and availability will limit the use of this method.

Rendering.

The cost for rendering inedible slaughter products and carcasses has been estimated at $60 to $80 per ton of finished product ($457,690,260 to 610,253,680 for the 7,628,171 tons from ruminants) and the finished products may sell for about $100 to $200 per ton ($762,817,100 to $1,525,634,200 for the 7,628,171 tons from ruminants) (Osborne, 1993). The finished products of rendering are useful for animal feed and industrial purposes, whereas neither burial, landfill or incineration produce a useable product.