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FIGURES.

TABLE.

Environmental Assessment

Prohibition of Specified Offal from Adult Sheep and Goats in Ruminant Feed

I. Description of the Proposed Action

Proposed Action.

The Food and Drug Administration (FDA) proposes to declare that specified offal from adult (more than 12 months of age) sheep and goats is not generally recognized as safe for use in ruminant feed and is an unapproved food additive when added to ruminant feed. Specified offal is defined as any tissue from the brain, spinal cord, spleen, thymus, tonsil, lymph nodes, or intestines (duodenum to anus, inclusive) of sheep or goats, or any processed product that is reasonably expected to contain specified offal. Accordingly, use in ruminant feed of ingredients containing specified offal from adult sheep or goat will cause the feeds to be considered adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act (the act), in absence of an approved food additive regulation or investigational exemption. Such specified offal, when added to ruminant animal feed, is a food additive under the act because it is not generally recognized as safe (GRAS).

The FDA is proposing this action because the specified offal may contain the agent that causes scrapie, a transmissible spongiform encephalopathy (TSE) (Appendix A) of sheep and goats. In the United Kingdom, scrapie (Appendix B) has been epidemiologically associated with the occurrence of bovine spongiform encephalopathy (BSE) (Appendix C), another TSE. Since we cannot positively determine that there is no direct association between scrapie or BSE and human TSE (Appendix A), the FDA is proposing this action to protect the health of animals and man. TSEs of animals other than sheep, goats, and cattle are known (Appendix D), but their relationship to BSE is unclear.

Regulatory Authority.

"Food" as defined in the act includes animal feed. Section 201(f) of the act (21 U.S.C. 321 (f)) defines food as "articles used in food or drink for man or other animals" and "articles used for components of any such article." Furthermore, any substance whose intended use results or may reasonably be expected to result in its becoming a component of food is a "food additive", unless among other things it is generally recognized by experts as safe (GRAS) or is subject of a prior sanction. Section 402(a)(2)(C) deems food adulterated if it contains a food additive that is unsafe within the meaning of section 409. Under section 409(a)(2), a food additive is unsafe unless a food additive regulation is in effect with respect to its use or its intended use.

A food additive regulation is established by the submission and approval of a food additive petition, as provided in 21 CFR 571.1, or on FDA's initiative as provided in 21 CFR 570.38. The Commissioner, on his own initiative, or at the request of an interested party, may propose to determine that a substance intended for use in animal feed is not GRAS and is a food additive subject to section 409 of the act and 21 CFR 570.38. Subsequent to the publication of such a proposal, and after consideration of public comments, the Commissioner may issue a final rule declaring the substance to be a food additive and require discontinuation of its use except when used in compliance with a food additive regulation.

GRAS Determination.

A determination that a substance added directly or indirectly to a food is generally recognized as safe (GRAS) is generally based on specific information regarding the composition of the substance, its use, method of preparation, methods for detecting its presence in food, and information about its functionality in food (21 CFR 570.35) as determined by experts qualified by scientific training and experience to evaluate the safety of such a substance. A substance added to food becomes GRAS as the result of a common understanding about the substance throughout the scientific community familiar with safety of such substances. The basis of expert views may be either (1) scientific procedures or

(2) in the case of a substance used in food prior to January 1, 1958, experience based on common use in food (21 CFR 570.30(a)).

General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific studies required for the approval of a food additive regulation. However, substances that are GRAS based on such use must be currently recognized as safe based on their pre-1958 use. United States v. Naremco, 553 F.2d 1138 (8th Cir. 1977); compare United States v, Western Serum, 666 F.2d 335 (9th Cir. 1982). A recognition of safety through common use is ordinarily to be based on generally available data and information (21 CFR 570.30(c)). An ingredient that was not in common use in food prior to January 1, 1958, may achieve general recognition of safety only through scientific procedures.

General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient [21 CFR 570.30(a)]; United States v. Naremco, supra, 553 F. 2d at 1143. A substance is not generally recognized as safe if there is a genuine dispute among experts as to its recognition. An Article of Drug*** Furestrol Vaginal Suppositories, 251 F. Supp. 1307 (N.D. Ga. 1968) aff'd 415 F.2d 390 (5th Cir. 1969). Further, general recognition of safety through scientific procedures must be based upon published studies. United states v. Articles of Food and Drug Colitrol 80 Medicated, 372 F. Supp. 915 (N.D. GA. 1974), aff'd, 518 F.2d 743, 747 (5th Cir. 1975), so that the results are generally available to experts. It is not enough, in attempting to establish that a substance is generally recognized as safe, to establish that there is an absence of scientific studies that demonstrate the substance to be unsafe; there must be studies that show the substance to be safe. United States v. An Article of Food, 752 F.2d 11, 15 (1st Cir. 1985).

Conversely, a substance may be ineligible for GRAS status if studies show that the substance is, or may be, unsafe. This is true whether the studies are published or unpublished (50 FR 27294). If there are studies that tend to support a finding that a particular substance is GRAS, but also studies that tend to support a contrary position, the conflict in the studies, just as a conflict in expert opinion, may prevent the general recognition of the safe use of the substance.

Food Additive Status of Specified Offal from Adult Sheep and Goats.

The agency recognizes that the processed slaughter by-products and 4-D adult sheep and goats have a long history of use in animal feeds without known adverse effects. However, the evidence for the development of a new pattern of disease transmission now indicates that these ingredients can no longer be categorically regarded as safe. The agency believes that the epidemiological evidence linking the occurrence of BSE in ruminants with the feed ingredients containing specified offal from adult sheep and goats precludes any claim of reliance upon a general recognition of safety as a sufficient basis for the continued use of the specified offal in food.

The agency reached this conclusion in light of the findings regarding a possible mechanism for the transmission of BSE to ruminants as a result of feed ingredients containing specified offal from scrapie-infected adult sheep and goats (USDA/APHIS, 1991) (USDA/APHIS, 1991a) (Appendices B and C). FDA cannot determine what level of feed ingredients from processed adult sheep and goat products, if any, is safe in ruminant feed.

A search of the scientific literature did not reveal information that would provide a basis for the GRAS status of feed ingredients derived from processed adult sheep or goat slaughter by-products. Nor is the agency aware of a prior sanction for any feed products that contain these products.

FDA has preliminarily concluded that the addition of specified offal to ruminant feed constitutes, in light of the epidemiological evidence about BSE, the use of an unapproved food additive. A regulation for the use of processed adult sheep and goat specified offal in ruminant feed is not in effect. Therefore, it is FDA's preliminary conclusion that any ruminant feed that contains such an ingredient is adulterated. Accordingly, FDA is proposing to list specified offal from sheep or goat over 12 months of age in 21 CFR part 589, Substances Prohibited From Use in Animal Food or Feed.

Purpose and Need for the Proposed Action.

The rendering process generally involves grinding the animal tissues and then heating them to temperatures of 230 ° F to 290° F for at least 20 minutes (John, 1990). 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 or to the health of humans who consume animal 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). FDA has no previous evidence of a human or animal health TSE hazard or any other health hazard associated with the feeding of rendering process ingredients to animals. Processed animal products have a long history of safe use in the United States as a source of nutrients for animals.

As explained more fully below, epidemiological evidence from the United Kingdom suggests that a disease agent contained in 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 proposed 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 United Kingdom, 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 United Kingdom studies suggest that the spread of BSE appeared to have been exacerbated by the practice of feeding ingredients from rendered BSE-infected cattle to calves, a practice that was subsequently banned (Appendix E). 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 has complicated any theory of vertical transmission of the disease. If maternal transmission occurs, it occurs at a rate insufficient to maintain the epidemic (Robinson, 1992).

Investigators have identified major risk factors that apparently contributed to the emergence of 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." In the United Kingdom, whole dead animals were processed as a source of tallow. The remaining unextracted bone and protein solids, termed "greaves", were used as dairy calf feed and may have contained the BSE agent.

(5) changes in the rendering process. In 1981-82 the rendering industry in the United Kingdom reduced the use of hydrocarbon solvent extraction in the rendering process (Wilesmith, 1991). The appearance of BSE in the United Kingdom approximately 5 years after the change in the rendering process is consistent with the 2 to 8 year incubation period of BSE. Laboratory tests based on intracerebral injection studies in rodents indicated that the hydrocarbon extraction method inactivated the scrapie-like agent present in rendered animal by-products, while the heat extraction method did not (Kimberlin, 1992) (USDA/APHIS, 1991a). The heat extraction method is the most common rendering process currently in use world wide.

With the exception of the rendering processes, which are similar in the U.S. and the United Kingdom (both use heat extraction methods), the other major risk factors are markedly lower in the U.S. in comparison to the United Kingdom. The U.S. 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 86 scrapie-infected or source flocks in the U.S. with about 4,300 animals (58 FR 59955). The Animal and Plant Health Inspection Service (APHIS) of the USDA 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 U.S. 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 United States and has stopped in the United Kingdom. The regulatory actions taken by the United Kingdom and the U.S. concerning BSE and related TSEs are provided in Appendix E and F, respectively.

The major purpose of this action is to prevent the occurrence and spread of scrapie or scrapie-like diseases (such as BSE) from sheep and goats to other ruminants in the U.S. Although the risk of transmitting scrapie or a scrapie-like agent via the feed is low in the U.S., the U.S. does have scrapie-infected sheep and goat flocks and the rendering processes used here will not inactivate the agent. This proposed action is needed to provide further protection of animal and human health.

The occurrence of BSE in cattle has not been shown to cause a TSE disease in humans (Taylor, 1990). On the other hand, the possibility of a causal relationship has not been disproved. BSE has not been diagnosed in cattle in the United States (USDA, 1993); however, sheep scrapie is present in the U.S. Accordingly, the agency believes that the potential implications for human as well as animal

health require regulatory action to minimize the possibility for the introduction of the disease into cattle in the U.S.

How the Proposed Action Addresses the Need for Action.

The proposed action addresses the need for action by banning the use of specified offal derived from mature sheep and goats in ruminant feed. In the U.S., mature sheep and goats are the only domesticated food producing animals with a diagnosed TSE. The proposed action also addresses the need for action by excluding from ruminant feed those tissues (the specified offal) with the largest amounts of the scrapie agent (Hadlow et al., 1982).

Although the transmission of BSE to cattle from sheep or goats products is not known to have occurred in the U.S., the agency believes that the potential implications for animal health require regulatory action to minimize the possibility for the introduction of the disease in U.S. cattle. Considering the absence of BSE in the U.S. (Appendix F), as well as the differences indicated above in risk factors between the U.S. and the United Kingdom, the agency is not proposing, at this time, to impose a ban on the feeding of ingredients derived from ruminants back to ruminants. The agency does not believe that a ruminant protein to ruminant ban, at this time, would markedly increase protection of animal and human health over that from the specified offal ban in adult sheep and goats.

The exclusion of animal tissues from young animals is based on the observation that sheep less than 12 months old rarely exhibit clinical symptoms of scrapie, although a few cases have been reported in sheep as young as seven months (Lamming, 1992). Historically, APHIS scrapie regulations and indemnity programs have used a 12 month cutoff for eligible adult sheep. The NRA and APPI voluntary ban on rendering sheep for cattle feed also used a 12 month cutoff for high-risk sheep. The median age of onset of clinical scrapie is 3 1/2 years, and 82% of sheep died of scrapie between the ages of two and five (Detwiler, 1992). Based on all of the available data, the agency has tentatively concluded that any ruminant feed ingredients derived from sheep and goats under 12 months of age represent a minimal risk of exposure to the scrapie agent.

II. Environmental Consequences of the Proposed Action

Our goal in this section is to discuss the likely environmental consequences of no action, the proposed action, and a ruminant protein to ruminant ban. The environmental consequences of each of these three options 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.

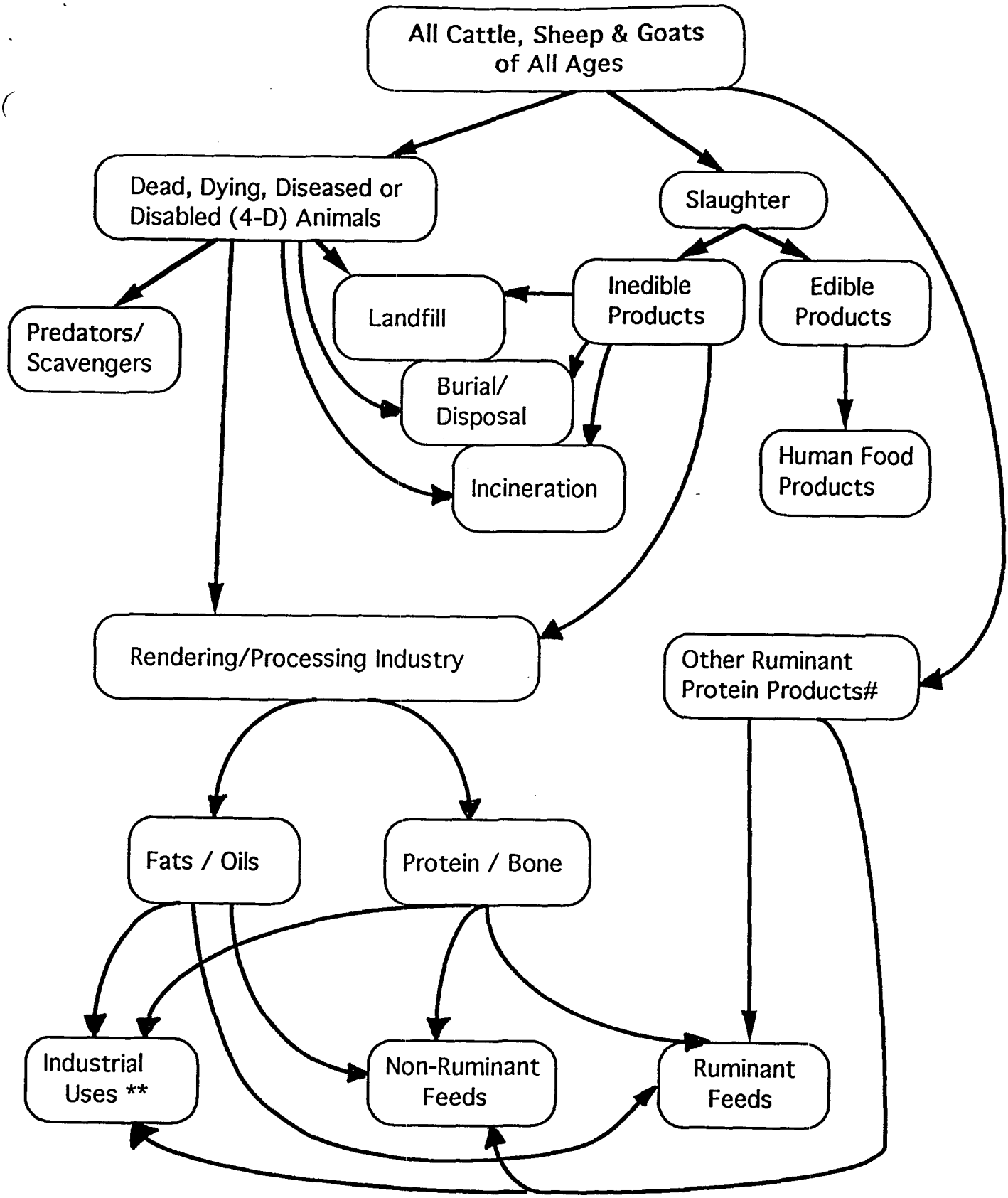
NO ACTION

Introduction.

In this section we will provide information on the rendering/ processing industry. First a flow chart will be provided for the major routes of disposition of ruminants. Then an estimate of the total annual amount of inedible slaughter products produced from cattle, calves, lambs, mature sheep, mature goats, and kids in the U.S. will be provided. Finally, the results from surveys of sheep renderers will be reviewed.

Ruminants are presented to the rendering/processing industry 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, diseased, or disabled (4-D) ruminants are picked up by the rendering/processing industry after the animals have died or been killed by the owner. 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



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

#. Includes milk products, recycled ruminant waste, dehydrated food waste, dehydrated paunch product, dehydrated garbage. See AAFCO for definitions.

Figure 1. Disposition patterns for ruminants in the U.S. - No Action Alternative

few 4-D animals, with the possible exception of those delivered to diagnostic laboratories, are believed to be disposed of by incineration.

The 4-D carcasses and the inedible slaughter products from ruminants 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 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 ruminants can also be processed by means other than rendering. This includes, but is not limited to, the following: 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.

Estimates of Ruminant 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 (data not available for kids vs. mature goats) slaughtered at federally inspected slaughter plants in the U.S. 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).

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

Estimate of the Amount of 4-D Animals Used by the Rendering/Processing 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).

Surveys 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

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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 to the agency 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 No Action-No BSE scenario.

Environmental Consequences--Immediate Impacts.

If the FDA decides to take no regulatory action and BSE does not occur in the U.S., then there will 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 U.S., 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 exposure are not known and have not been studied, to the agency's knowledge.

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 U.S. Most of the major risk factors identified for the BSE epidemic in the United Kingdom are markedly lower in the U.S. and the qualitative analysis of these risk factors suggests little evidence for a broad risk for BSE within the U.S. as a nation (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 U.S. (Appendix F).

If no regulatory action is taken and BSE nonetheless occurs in the U.S., 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 "No Action" as there would be no prevention of the potential spread of the scrapie/BSE agent(s) to and among cattle during the period that BSE is undiagnosed. Increasing numbers of 4-D ruminants could contain the scrapie/BSE agent(s), thereby 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 this scenario.

PROPOSED ACTION

Feed Ingredients Affected.

The only tissues of adult sheep and goats that are directly affected by the proposed action are the specified offal [brain, spinal cord, lymph nodes, spleen,

tonsils, thymus, and intestines (duodenum to anus inclusive)]. The proposed action only affects the ingredients produced by the rendering/processing industry that are reasonably expected to contain, in whole or in part, specified offal from adult sheep and goats (Figure 2) and are 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 ingredients if they are intended for use in feed of non-ruminants (pig, chicken, horse, dog, cat, etc.) or for industrial purposes.

The feed ingredients, as defined in the Official Publication 1993 of the Association of the American Feed Control Officials, Inc. (AAFCO, 1993), affected by the proposed action 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.

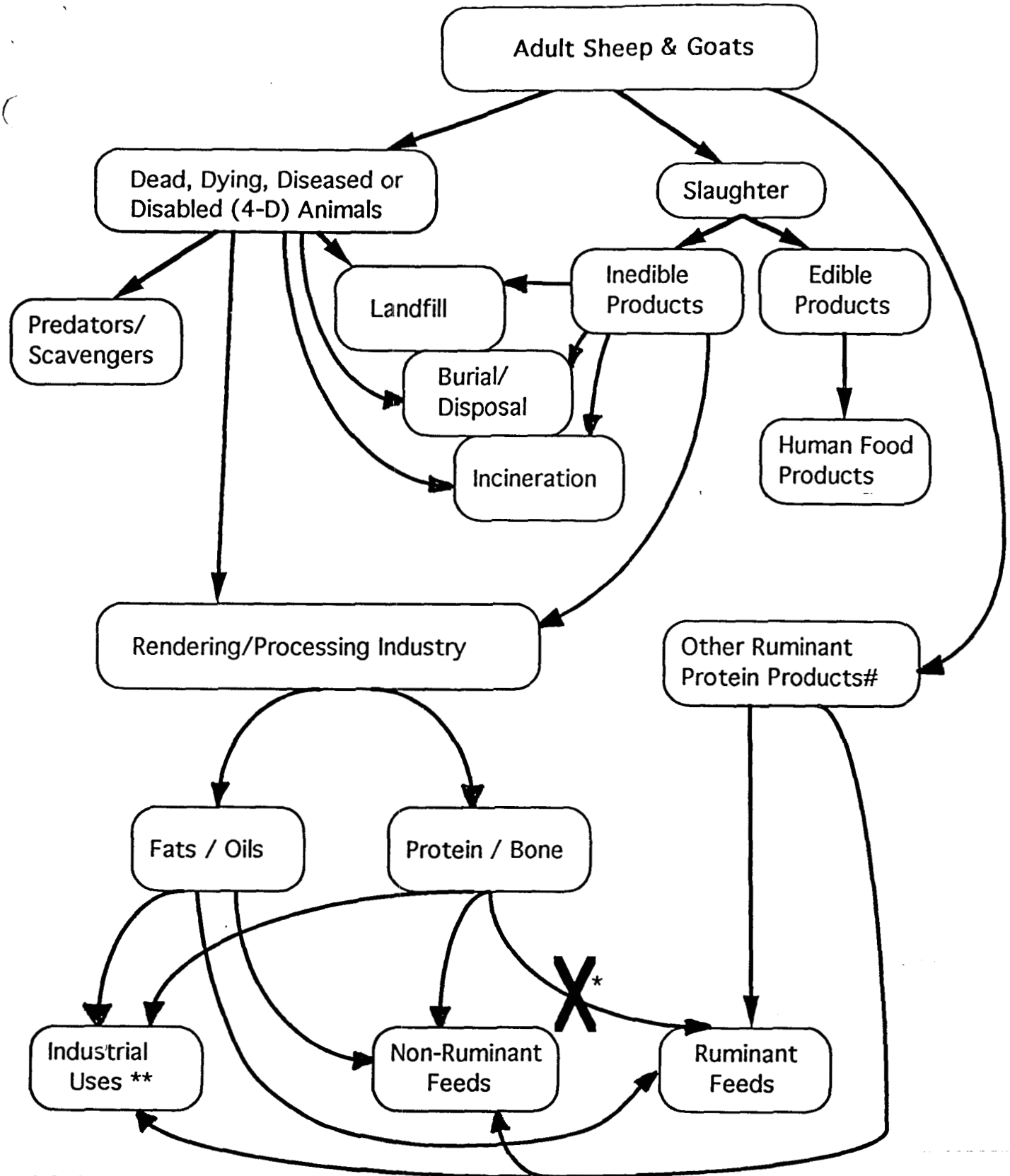
Since the proposed TSE agent is a protein and has not been detected in fat (MAFF, 1993), the FDA would not object, at this time, to the use in ruminant feeds of fats and oils derived from adult sheep and goats.

Estimates of the Amount of 4-D Carcasses from Adult Sheep and Goats.

The USDA estimated that 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. Historically, it is believed that on-farm burial and pick up by renderers have accounted for the overwhelming majority of 4-D sheep and goats.



* Pathways partially blocked by proposed action alternative. The ban involves specified, i.e., not all, protein products derived from adult sheep and goats.

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

\# Includes milk products, recycled ruminant waste, dehydrated food waste, dehydrated paunch product, dehydrated garbage. See AAFCO for definitions.

Figure 2. Disposition patterns for adult sheep and goats in the U.S. - Proposed Action

Costs Associated with 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 offal and 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 lb 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.

Effect on the Rendering Industry.

The FDA believes that the proposed action will make the rendering industry determine if it can economically 1) separate the inedible slaughter products and the 4-D carcasses of adult sheep and goats from those of other animals; and, 2) sell the rendered products for use in non-ruminant feed or for industrial purposes. The proposed action is to prevent any rendered product that is reasonably expected to contain specified offal from adult sheep and goats from being used in ruminant feed. The FDA's objections to the use of these rendered products in ruminant feed will include, but are not limited to, the following feed ingredients, as

defined in the Official Publication 1993 of AAFCO: meat meal, meat and bone meal, animal by-product meal, meat meal tankage, meat and bone meal tankage.

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. The proposed action would not prohibit the sale of rendered products from adult sheep and goats to non-ruminant feeds (approximately 85% of the market), but will prohibit their use in ruminant feeds (approximately 15% of the market).

The proposed action should not have a drastic effect on the rendering industry as a whole as renderers pick up approximately 91,000,000 lb 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 you consider 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, the proposed action will 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 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 renderer would be required to dispose of the rendered protein/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 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.

Effect on the Processing Industry.

The FDA believes that the proposed action will make the processing industry (other than rendering) determine if it can economically 1) separate the 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 will include, but are not limited to, the following feed ingredients, as defined in the Official Publication 1993 of the Association of American Feed Control Officials, Inc. (AAFCO, 1993): 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 this proposed action should 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 the proposed action, 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 will 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 adult sheep and goats.

Effect on the Slaughter Industry.

The FDA believes that the proposed action will make the slaughter industry determine if it can 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 will be only a minimal effect on the number of sheep and goats slaughtered as a result of this proposed action 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 may have to increase there 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.

Effect on the Feed Manufacturing Industry.

The FDA believes that the only portion of the feed manufacturing industry affected by the proposed action are those producing ruminant feeds. Ruminant feed manufacturers may 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, di- and mono calcium phosphate, di- and mono sodium phosphate, and di- and mono ammonium phosphate.

Effect on the Sheep and Goat Producers.

The brunt of the environmental effects from the proposed action will 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 anticipated consequences of the proposed action that will affect the producer's pocketbooks. Although it does adversely affect the adult sheep and goat producer, the proposed action does not affect sheep and goats under 1 year of age and does not prohibit the use of 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).

Environmental Consequences--Immediate Impacts.

Adoption of the proposed action should decrease the prospects of BSE occurring in the U.S.; this would have a positive environmental consequence. It is possible that the proposed action 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 costs for disposition, it would appear that the greatest concomitant increase would occur in on-farm burial.

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 scrapie agent and any other potentially deleterious substance. We believe the potential incremental increase in on-farm burial of sheep and goats and any possible concomitant 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, the proposed regulation 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 U.S. became a scrapie free country, then the proposed action would no longer be required.

Environmental Consequences--Long Term Impacts.

If FDA adopts the proposed action and BSE occurs undiagnosed in the U.S., the proposed action would reduce the spread of the scrapie agent from sheep and goats to cattle, but would not prevent the recycling 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 the

no action alternative. This is because the number of cattle exposed prior to a time when BSE is diagnosed is expected to be reduced.

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 also be reduced in comparison to the no action alternative. Finally, it would likely take much less time to control the BSE outbreak and the affected industries would be better prepared to deal with any further regulatory actions that might be needed to prevent the recycling of the BSE agent in cattle.

RUMINANT PROTEIN TO RUMINANT BAN

Feed Ingredients Affected.

If a ruminant protein to ruminant ban similar to the one in the United Kingdom were implemented (Figure 3), then protein feed ingredients that were derived in whole or in part from the inedible slaughter products or carcasses of a ruminant could not be used in the feed of other ruminants. At this time, 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.

The feed ingredients that would be affected by a ruminant protein to ruminant ban similar to the one in the United Kingdom are numerous. The definitions for these feed ingredients are located in the Official Publication 1993 of AAFCO in Section 9 on Animal Products, in Section 54 on Milk Products, in Section 57 on Mineral Products, in Section 60 on Miscellaneous Products, and in Section 74 on Recycled Animal Waste Products (AAFCO, 1993). 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, spray dried animal blood, flash dried blood meal, glandular meal and extracted glandular meal, unborn calf carcasses, blood protein, animal digest, cooked bone marrow, mechanically separated bone marrow, ensiled paunch product, meat meal, meat

and bone meal, animal by-product meal, meat meal tankage, meat and bone meal tankage, blood meal, animal plasma, and leather hydrolyzate.

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

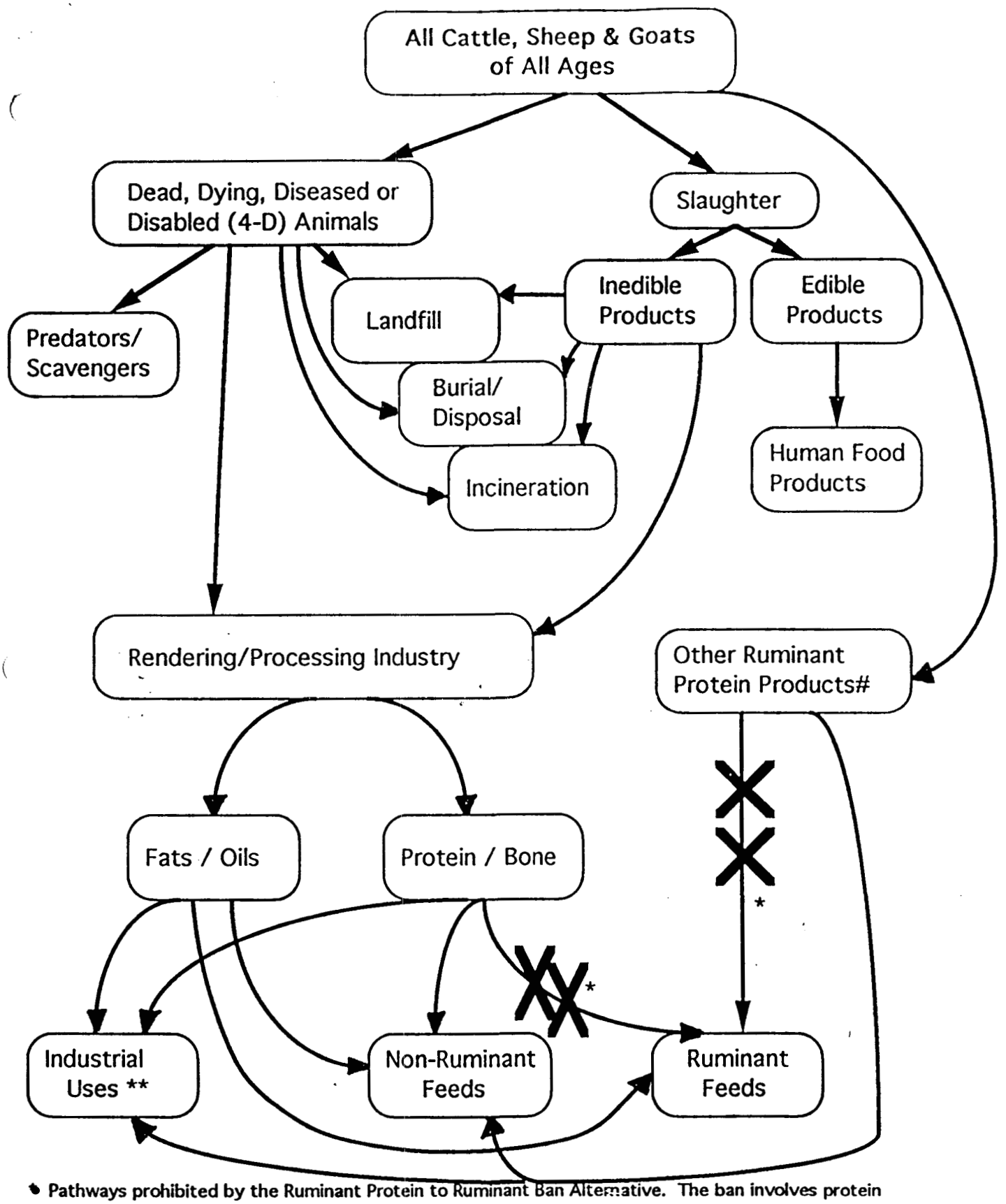
Milk Products: feed grade dried buttermilk, condensed buttermilk, feed grade dried skim milk, condensed skimmed milk, dried cultured skim milk, condensed cultured skim milk, dried (dry) whey, condensed whey, dried (dry) whey solubles, condensed whey solubles, dried hydrolyzed whey, condensed hydrolyzed whey, condensed whey product, dried (dry) whey product, condensed cultured whey, casein, cheese rind, dried lactalbumin, feed grade dried whole milk, dried milk protein, dried hydrolyzed casein, dairy food by-products, condensed modified whey solubles, whey, dried (dry) whey protein concentrate, dried cultured whey product, fermented ammoniated condensed whey, dried cultured whey, dried chocolate milk, feed grade dried milk, dried cheese, and dried cheese product.

Miscellaneous Products: dehydrated food waste, dehydrated garbage, and dehydrated paunch products.

Recycled Animal Waste Products: dried ruminant waste, undried processed animal waste products, and processed animal waste derivative.

Estimates of the 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 do believe that cattle, because of their size and numbers, likely contributed more than any other species.



• Pathways prohibited by the Ruminant Protein to Ruminant Ban Alternative. The ban involves protein products derived from ruminants of all ages, e.g., lambs, veal calves, feedlot cattle, etc.

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

Includes milk products, recycled ruminant waste, dehydrated food waste, dehydrated paunch product, dehydrated garbage. See AAFCO for definitions.

Figure 3. Disposition patterns for ruminants in the U.S. - Ruminant Protein to Ruminant Ban Alternative

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

Rendering, 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 much 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.

Effect on the Rendering Industry.

The FDA believes that a ruminant protein to ruminant ban will make the rendering industry determine if it can economically 1) separate the ruminant inedible slaughter products and the ruminant 4-D carcasses from those of non-ruminants; and, 2) sell the rendered products for use in non-ruminant feed or for industrial purposes. The ruminant protein to ruminant ban would prevent any rendered protein product that is reasonably expected to contain offal or carcasses from ruminants from being used in ruminant feed. The FDA's objections to the use of these rendered products in ruminant feed will include, but will not be limited to, the following feed ingredients, as defined in the Official Publication 1993 of AAFCO (AAFCO, 1993):

Animal Products: meat meal, meat and bone meal, animal by-product meal, meat meal tankage, and meat and bone meal tankage.

The ruminant protein to ruminant ban could have adverse effects on the rendering industry as a whole 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). A ruminant protein to ruminant ban 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 products are utilized in ruminant feed (as was the estimate for meat and bone meal; USDA, APHIS, 1991), then the ruminant protein to ruminant ban 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, the ruminant protein to ruminant ban will require segregation of the inedible slaughter products and carcasses of ruminants and rendering this material separately. Rendering plants processing large amounts of ruminants may find segregation and rendering separately to be feasible. However, plants rendering small amounts of ruminants are unlikely to find segregation/isolation and rendering separately economically feasible, and may refuse to process ruminants. 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 be used in non-ruminant feed, then the renderer can sell it for industrial uses, such as fertilizers and lubricants, 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 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 rendered products 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.

Effect on the Processing Industry.

The FDA believes that a ruminant protein to ruminant ban will make the processing (non-rendering) industry determine if it can economically 1) separate the inedible slaughter products of ruminants from non-ruminants; and, 2) sell the products derived from ruminants for use in non-ruminant feed or for industrial purposes. The FDA's objections to the use of these products in ruminant feed will include, but are not limited to, the following feed ingredients, as defined in the Official Publication 1993 of AAFCO (AAFCO, 1993).

Animal Products: meat, meat by-products, animal liver, dried meat solubles, fleshings hydrolysate, hydrolyzed hair, hydrolyzed leather meal, spray dried animal blood, flash dried blood meal, glandular meal and extracted glandular meal, unborn calf carcasses, blood protein, animal digest, cooked bone marrow, mechanically separated bone marrow, blood meal, animal plasma, and leather hydrolyzate.

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

Milk Products: feed grade dried buttermilk, condensed buttermilk, feed grade dried skim milk, condensed skimmed milk, dried cultured skim milk, condensed cultured skim milk, dried (dry) whey, condensed whey, dried (dry) whey solubles, condensed whey solubles, dried hydrolyzed whey, condensed hydrolyzed whey, condensed whey product, dried (dry) whey product, condensed cultured whey, casein, cheese rind, dried lactalbumin, feed grade dried whole milk, dried milk protein, dried hydrolyzed casein, dairy food by-products, condensed modified whey solubles, whey, dried (dry) whey protein concentrate, dried cultured whey product, fermented ammoniated condensed whey, dried cultured whey, dried chocolate milk, feed grade dried milk, dried cheese, and dried cheese product.

Miscellaneous Products: dehydrated food waste, dehydrated garbage, and dehydrated paunch products.

Recycled Animal Waste Products: dried ruminant waste, undried processed animal waste products, and processed animal waste derivative.

The FDA believes that a ruminant protein to ruminant ban will have adverse effects on the processing industry. Most of the above mentioned AAFCO feed ingredients under Animal Products are rarely, if ever, incorporated into ruminant rations; however, blood meal, spray dried blood meal, and flash dried blood meal are commonly placed in ruminant rations because they are high in proteins that are not degraded in the rumen (bypass proteins). 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 Milk Products are usually only incorporated into the diets of young ruminants. 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%. Non-rendered products are included in the ruminant protein to ruminant ban, 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, then the use of non-rendered products derived from ruminants would increase in ruminant feed.

If the above mentioned products derived from ruminants 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 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 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 cannot recoup their expenses, there will be a strong economic incentive to not collect and utilize the inedible slaughter products of ruminants.

Effect on the Slaughter Industry.

The FDA believes that a ruminant protein to ruminant ban will make the slaughter industry determine if it can economically 1) separate the inedible slaughter products and condemned carcasses from ruminants; and, 2) sell them to the rendering/processing industry or for industrial purposes.

The FDA believes that there will be only a minimal long term effect on the number of ruminants slaughtered as a result of a ruminant protein to ruminant ban as it does not prohibit the slaughter of ruminants, does not affect the use of edible products from ruminants for human consumption, and does not prohibit the use of rendered/processed products derived from ruminants in non-ruminant feed.

The FDA realizes that slaughter plants that process ruminants on an irregular basis may have to 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, the agency believes that separation of the offal should not cause marked adverse affects.

Effect on the Feed Manufacturing Industry.

The FDA believes that the only portion of the feed manufacturing industry affected by the ruminant protein to ruminant ban are those producing ruminant feeds. Ruminant feed manufacturers will likely require certification that affected feed ingredients do not contain any ruminant derived tissue. 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, 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.

Effect on the Ruminant Producers.

The brunt of the economic effects from the ruminant protein to ruminant ban will be borne by the ruminant producers. Cattle producers would likely be the hardest hit as cattle are estimated from the inedible offal data (Appendix G and H) to be responsible for more than 98% of all ruminant-derived products produced by the rendering/processing industry . Decreased short term demand for meat and other products derived from ruminants plus the increased costs of disposal of 4-D animals are possible consequences of the ruminant protein to ruminant ban that would affect the producer; however, a ruminant protein to ruminant ban would not prohibit the use of rendered/ processed products derived from ruminants in non-ruminant feeds or for industrial purposes.

Environmental Consequences--Immediate Impacts.

Adoption of a ruminant protein to ruminant ban should decrease the prospects of BSE occurring in the U.S.; this would have a positive environmental consequence. In comparison to other alternatives, a ruminant protein to ruminant ban would cause the greatest decline in the proportion of inedible slaughter products and 4-D carcasses from ruminants 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 costs for disposition, it would appear that the greatest concomitant increase would occur in on-farm burial (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 scrapie agent and any other potentially deleterious substance. We believe the potential incremental increase in on-farm burial of ruminants and any possible concomitant harm to the environment as a result of the regulation would likely be the largest of the three alternatives.

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, a ruminant protein to ruminant ban would tend to encourage sheep and goat producers to become certified as scrapie free. If the U.S. became a scrapie free country and continued as a BSE free country, then a ruminant protein to ruminant ban would no longer be required.

Environmental Consequences--Long Term Impacts.

If FDA adopts a ruminant protein to ruminant ban and BSE occurs undiagnosed in the U.S., this action would reduce the spread of the scrapie agent from sheep and goats to cattle and would greatly reduce the potential recycling of the BSE agent from cattle to cattle. 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 reduced to the greatest extent in comparison to the other alternatives. 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 reduced to the greatest extent. Finally, fewer regulations and less time would be required to control a BSE outbreak if a ruminant protein to ruminant ban were implemented in comparison to the other alternatives.

SUMMARY OF 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 in response to a low probability but high impact event - the transmission of scrapie agent from sheep and goats to cattle and the consequent spread of BSE in U.S. cattle. Because there is no means other than the development of clinical signs to determine the presence of scrapie (the probable BSE agent) in ruminants and because clinical signs usually develop 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 BSE before detection and the consequent effort necessary to eradicate BSE from the cattle

herd, is expected to differ among the possible actions - "No Action," the "Proposed Action," and the "Ruminant Protein to Ruminant Ban."

"No Action" would rely on voluntary actions by the rendering and slaughtering industries to prevent the movement of the BSE agent 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 three alternatives. Spread of BSE among cattle, in the event BSE occurred, would be expected to be the most extensive under "No Action." Consequently, the long term environmental costs of "No Action" 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 agent in sheep and goat carcasses disposed of on-farm.

The "Proposed Action" seeks to further reduce the probability of the transmission of the scrapie/BSE agent from sheep and goats to cattle by removing from ruminant feeds the rendered/processed products derived from the specified offal of sheep and goats over 1 year of age. The potential for BSE to occur under this scenario is expected to be lower than "No Action" but probably higher than a "Ruminant Protein to Ruminant Ban." In the event that BSE subsequently occurs undiagnosed in cattle, the "Proposed Action" would not prevent the spread of the BSE agent from cattle to cattle through cattle-derived rendered/processed feed ingredients. Consequently, the long term potential environmental costs are intermediate among the three actions considered, if one expects BSE to eventually occur. 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.

A "Ruminant Protein to Ruminant Ban" would further reduce the probability of the transmission of the scrapie/BSE agent from sheep and goats to cattle and from cattle to cattle by removing from ruminant feeds all rendered/processed products derived from the offal or carcasses of ruminants of any age or species. This action is more enforceable than the Proposed Action due to its all-inclusive nature. The potential for BSE to occur under this scenario is probably the lowest of the three actions considered. In the event that BSE occurred undiagnosed in

cattle, the "Ruminant Protein to Ruminant Ban" would be expected to have the most effect on limiting the spread of BSE prior to diagnosis. Consequently, the long term potential environmental costs of this possible action are the lowest, if one expects BSE to eventually occur.

On the other hand, the immediate and continuing environmental costs of a ruminant protein to ruminant ban are the highest of the three alternative actions considered. Large quantities of rendered/processed products from cattle, sheep and goats would need to be re-routed to uses other than ruminant feeds. The oversupply of ruminant offal might affect the ability of animal producers to have 4-D ruminants picked up by renderer/processors, increasing the number of these animals disposed of on-farm and at local landfills.

In sum, the three alternative actions can be characterized as differing balances of impacts in the immediate term versus the long term. "No Action" has the lowest immediate term impacts and the largest potential long term impacts. The "Ruminant Protein to Ruminant Ban" has the highest immediate term impacts but potentially the smallest long term impacts. The "Proposed Action" is intermediate, with small immediate term impacts and larger potential long term impacts when compared with the "Ruminant Protein to Ruminant Ban." To be factored in is the real possibility that BSE will never occur in the U.S., so that our assessment of potential long term impacts, which is based on BSE occurring, is irrelevant and that only the immediate term impacts should be compared.

Mitigations, discussed in the next section, could have an effect on the need for or the nature of an action to control the spread of scrapie from sheep and goats to cattle. If scrapie were eradicated in the U.S., there would be no need for actions controlling the rendered/processed products derived from adult sheep and goat offal and 4-D animals. If a rendering process could be developed and validated that clearly inactivated the scrapie agent, alternative actions that would ensure the proper treatment of sheep and goat offal and carcasses could be pursued. If there were a means to determine the presence of scrapie agent in sheep, goats, or cattle prior to the development of clinical signs, effective disease control and certification measures different from those considered above could be devised. Clearly, from an environmental impact perspective, the preferred action would be to eliminate the scrapie agent from the ruminant population, in the U.S. This

would eliminate exposure of wildlife to the agent (with unknown effect) and permit the unrestricted rendering/ processing of animal offal and carcasses for useful products, instead of on-farm disposal, landfilling or incineration.

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

Environmental Effects	Potential Actions		
	No Action	Proposed Action	Ruminant Protein to Ruminant Ban
Immediate Impacts			
On-Farm Disposal	No Changes	Slight Increase	Largest Increase
Landfill	No Changes	Slight Increase	Largest Increase
Incineration	No Changes	No Changes	Slight Increase
Probability of BSE Occurring in U.S.	Low	Much Reduced	Maximum Reduction
Consequences if BSE Occurs Long Term			
Production Losses & Impacts	Maximum Losses	Much Reduced Losses	Minimum Losses
Wildlife Exposure	Maximum Exposures	Much Reduced Exposures	Minimum Exposures
On-Farm Disposal	Largest Increase	Moderate Increase	Minimum Increase
Landfill	Largest Increase	Moderate Increase	Minimum Increase
Incineration	Largest Increase	Moderate Increase	Minimum Increase

III. Mitigation Measures

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 any of the above alternatives, the FDA could encourage expansion of this voluntary program by expanding coverage to goats and/or by expanding coverage to more than just meat and bone meal.

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 scrapie agent appears to be a protein and it is resistant to many of the processes that would kill virtually all other known infectious agents. As a mitigation of any of the above alternatives, the rendering/ processing industry and the FDA could encourage further research on more extensively characterizing the TSE agents and on developing and implementing rendering 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 . As a mitigation of any of the above alternatives, the FDA could support research aimed at developing an inexpensive test that will accurately distinguish scrapie free from scrapie positive animals that are not clinically affected.

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

The Animal and Plant Health Inspection Service (APHIS) of USDA has implemented several programs aimed at controlling/limiting the spread of scrapie in the U.S., 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 provide support for further indemnity payments to owners of scrapie positive flocks that sign up for the VSFC program. If scrapie could be eliminated from the U.S. sheep population, then increased consumer confidence and demand for sheep and goat products as well as elimination of the need for this proposed action would likely follow.

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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 U.S. and Canada for about 50 years. The first case of scrapie in the U.S. 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 U.S. 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

TSEs 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 posttranslational modification (Bessen and Marsh, 1992).

Other animals have TSEs 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; and (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).

APPENDIX F

Regulatory and Surveillance Activities Related to Scrapie and BSE in the U.S.

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 U.S. 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 U.S., USDA has implemented several programs to monitor U.S. 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 is preparing a letter to manufacturers of drugs and biologics to not use bovine source material from BSE positive countries.

APPENDIX G

Estimates of 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 U.S. 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 this proposed action 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 the proposed action 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 U.S. 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 U.S. 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 this proposed action 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 the proposed action 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 the proposed action 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 U.S. 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

Proposed Action: 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.