

ENVIRONMENTAL ASSESSMENT

for

AMENDMENTS TO

21 CFR 589

**SUBSTANCES PROHIBITED FROM USE IN
ANIMAL FOOD OR FEED**

§ 589.2001 Cattle Materials Prohibited in Animal Food or Feed

PROPOSED RULE

FOOD AND DRUG ADMINISTRATION
September 22, 2005

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I. Description of the Action

The Food and Drug Administration (FDA) is proposing to amend its regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals. These materials include: 1) the brains and spinal cords from cattle 30 months of age and older; 2) the brains and spinal cords from all cattle not inspected and passed for human consumption; 3) the entire carcass of cattle not inspected and passed for human consumption if the brains and spinal cords have not been removed; 4) tallow that is derived from materials prohibited by the proposed rule unless such tallow contains no more than 0.15% insoluble impurities; and 5) mechanically separated beef that is derived from materials prohibited by the proposed rule.

II. Purpose and Need for Action

The purpose of the additional prohibitions and requirements is to strengthen existing safeguards designed to help prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle. The present regulation (21 CFR 589.2000) prohibits most protein derived from mammalian tissues in ruminant feed because of potential contamination of those tissues with the infectious agents that cause transmissible spongiform encephalopathies (TSEs). BSE (sometimes referred to as "mad cow disease") belongs to the unusual group of progressively degenerative neurological diseases known as transmissible spongiform encephalopathies (TSEs).

The existing regulation prohibits the use in ruminant feed of any protein-containing portion of mammalian animals with the exception of certain products believed to pose a minimal risk of TSE transmission. The exempted products include blood, blood products, gelatin, milk, milk products; protein derived solely from porcine and equine sources, and inspected meat products which have been offered for human food and further heat processed for feed. The existing regulation also permits the manufacture of animal feed containing processed animal protein for ruminant and non-ruminant species on the same premises, provided separate lines are used in the production of ruminant feed or adequate clean-out procedures or other means adequate to prevent carry-over of prohibited material in ruminant feeds are used.

The proposed rule would prohibit the use in animal feed, including in pet food, of 1) the brains and spinal cords from cattle 30 months of age and older; 2) the brains and spinal cords from all cattle not inspected and passed for human consumption; 3) the entire carcass of cattle not inspected and passed for human consumption if the brains and spinal cords have not been removed; 4) tallow that is derived from materials prohibited by the proposed rule unless such tallow contains no more than 0.15% insoluble impurities; and 5) mechanically separated beef that is derived from materials prohibited by the proposed rule.

FDA believes that the presence of high-risk cattle materials in the non-ruminant feed supply presents a risk of BSE to cattle in the United States. The agency believes that the only way to make certain that these tissues are not fed to ruminants is to eliminate them from the animal feed chain. By eliminating this high risk material at the top of the feed chain, the opportunity for intentional or accidental exposure of cattle to this material would be greatly reduced.

In reaching the decision to propose to exclude brain and spinal cord materials from cattle 30 months of age or older and carcasses from cattle not inspected and passed for human consumption from which brain and spinal cord material were not removed, FDA considered the magnitude of the BSE risk in the United States as well as economic and environmental factors. The agency believes that the risk of BSE to U.S. cattle is still very low despite the recent North American cases. As of July 2005, the United States Department of Agriculture (USDA) has tested over 418,000 high-risk cattle under its enhanced BSE surveillance program and has found one positive animal. FDA recognizes that this surveillance program is ongoing and could reveal new information on BSE risks in the future.

FDA also considered information regarding the tissue distribution of BSE infectivity. Since, according to pathogenesis studies, the brain and spinal cord contains about 90 percent of BSE infectivity, FDA believes that the most appropriate course of action is to concentrate efforts on excluding these highest risk tissues from animal feed.

FDA believes that excluding brain and spinal cord from all cattle 30 months of age and older from entering animal feed channels will provide substantial additional protection against BSE. FDA also believes that other feed controls such as those announced by the Department of Health and Human Services in January 2004 are not needed if these high risk tissues are excluded from animal feed channels.

The full rationale for these changes is discussed in the preamble to the proposed regulation.

III. Actions in the United States to Date

In the Federal Register of June 5, 1997 (62 FR 30936), FDA issued a final regulation which provided that animal protein derived from mammalian tissues for use in ruminant feed, with certain exemptions, is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act). The use or intended use in

ruminant feed of any material that contains protein derived from mammalian tissues causes the feed to be adulterated and in violation of the act, unless it is the subject of a food additive regulation or an effective notice of claimed investigational exemption for a food additive. The preamble to the 1997 final rule included a discussion of the basis of FDA's conclusion that protein derived from mammalian tissues (with certain exemptions) in ruminant feed is not generally recognized as safe (GRAS), but rather is a food additive under the Act. An Environmental Assessment (EA) was prepared and a Finding of No Significant Impact (FONSI) was made for the 1997 rule. The EA and FONSI may be found at http://www.fda.gov/cvm/Documents/Bse_all.pdf (FDA, 1996).

On October 30, 2001, FDA held a public hearing in Kansas City, MO to hear views from the public on the adequacy of the regulation. Many representing the animal feed industry, regulatory agencies, consumers and consumer organizations expressed their views on the adequacy of the current rule.

Shortly after the public hearing, USDA released a report prepared by the Harvard Center for Risk Analysis (Cohen et al., 2001) on the findings of a major 3-year initiative to develop a risk assessment model that allows evaluation of the impact of various risks and potential pathways for exposure of U.S. cattle and U.S. citizens to the BSE agent. The assessment of then present situation in the United States using this model concluded that, due to control measures already in place, the risk to U.S. cattle and to U.S. consumers from BSE is very low. The model also demonstrated that certain new control measures could reduce the small risk even further.

As a result of the Harvard Risk Analysis and information obtained from the public hearing, FDA once again asked for information from the affected industries and the public on several ways that the ruminant feed ban regulation could be strengthened (Advance Notice of Proposed Rulemaking (ANPRM); 67 FR 67572, November 6, 2002).

Following identification of a BSE-positive cow in the United States in December 2003, USDA published, on January 12, 2004 (69 FR 1862), an interim final rule banning the use of specified risk materials (SRMs) from USDA-regulated human food. SRMs are defined as brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle. The USDA rule also prohibits in human food any materials from non-ambulatory disabled cattle, and mechanically separated (MS) (beef).

On July 14, 2004, FDA and USDA published (69 FR 42288) a joint Advance Notice of Proposed Rulemaking (ANPRM) that requested comments and scientific information on several additional measures related to animal feed under consideration to help prevent the spread of BSE in the United States. Some of these measures included in the ANPRM were:

- removing specified risk materials (SRMs) from all animal feed, including pet food, in order to control the risks of cross contamination throughout feed manufacture and distribution and on the farm due to misfeeding;
- requiring dedicated equipment or facilities for handling and storing feed and ingredients during manufacturing and transportation, to prevent cross contamination;
- prohibiting the use of all mammalian and poultry protein in ruminant feed, to prevent cross contamination; and
- prohibiting materials from non-ambulatory disabled cattle and dead stock from use in all animal feed.

Comments submitted in response to the 2004 ANPRM that relate to SRMs are summarized in the preamble to the proposed regulation.

On July 14, 2004, FDA also issued an interim final rule prohibiting the use of certain cattle material in FDA-regulated human food and cosmetics. The prohibited cattle materials included SRMs, small intestine of all cattle, material from non-ambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated beef. The rule was amended on September 7, 2005, to allow for the use of the small intestine in human food and cosmetics provided that the distal ileum has been removed (70 FR 53063). The USDA published a similar amendment to the interim final rule (70 FR 53043).

IV. Alternatives

This document evaluates the environmental impacts from the proposed action, an SRM prohibition alternative and ‘no action’. The areas that this EA examines are the proposed prohibition on the use of the described materials. An evaluation of the environmental impacts associated with the existing ruminant feed ban and other regulatory alternatives considered regarding ruminant feed were described in the Environmental Assessment for 21 CFR 589.2000: Prohibition of Protein Derived from Ruminant and Mink Tissues in Ruminant Feeds (FDA, 1996).

V. Environmental Consequences of the Potential Actions

This section discusses the likely environmental impacts of ‘no action’, an SRM prohibition alternative, and of the actions set out in the proposed rule. This assessment is based on information available at the time of the proposed rule's publication.

A. No Action (present situation)

Introduction

In this section, the major routes of cattle and cattle offal, including SRM, disposition will be described. Then basic information on the processes used in the rendering and processing industries will be provided. An estimate of the total amount of inedible slaughter products and SRM produced from cattle in the U.S. will also be provided.

Major Routes of Disposition of Animals and Animal Offal

Animals are presented to processing and rendering industries by two primary routes. First, apparently healthy animals are sent to slaughter establishments, if not condemned on ante-mortem or post-mortem inspection, and processed into edible products for human consumption (meat, etc.) and into inedible products (often called offal). The vast majority of cattle inedible products from slaughter establishments are rendered or processed for potential use in non-ruminant animal feed or for industrial purposes. Many of the larger animal slaughtering operations in the U.S. are integrated with rendering operations.

Second, dead and downer cattle and non-ambulatory disabled cattle (defined as cattle that are unable to rise from a recumbent position) are processed by the rendering and pet food industries after the animals have died, been killed by the owner, or condemned at slaughter establishments. Animals condemned at slaughter establishments may also be sent to a landfill if no renderer is available. The recently instituted USDA rule (69 FR 1862) provides that non-ambulatory disabled cattle are ineligible to be slaughtered for human consumption. FDA has also prohibited these cattle in FDA-regulated human food and cosmetics. Many cattle mortalities 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, placement in landfills, composting or incineration. Very few dead and downer cattle and non-ambulatory disabled cattle, with the possible exception of those delivered to diagnostic laboratories, are believed to be disposed of by incineration.

Some portions of the United States are not served by independent renderers. Therefore, disposal of dead animals must be handled on farm or ranch in these parts of the country. Also, most independent renderers now charge a pick-up fee. Fees vary widely, and are dependent on a variety of factors, but generally producers located close to the rendering plant and those which can supply a steady stream of animals will likely pay a smaller fee than producers located farther away and who may only have an occasional carcass to dispose. The renderer may choose not to pick up the occasional carcass from a distant producer, or the producer may not be willing to pay the fee if they believe it is too high. In either case if local environmental regulations allow, these animals will need to be disposed of on farm. In addition, renderers prefer to utilize carcasses prior to carcass autolysis.

As discussed above, there are various alternatives for disposing of cattle offal and carcasses. A brief description of different methods is provided below. It is also likely that the industry will develop additional approaches that are more cost-effective

- Landfilling – In this option, materials are separated at slaughter and sent directly to disposal with no processing. Actual disposal costs could vary substantially with local conditions and county or state willingness to accept materials. Some states prohibit disposal of unprocessed dead animal parts or carcasses in landfills. Landfilling raw cattle materials increases the potential for leachate and odor development and can shorten the usable life of a landfill site.
- Burial – Many states have guidelines and regulations pertaining to the burial of carcasses. Selected locations for cattle carcasses must be placed away from any surface watercourses, sinkholes, springs or wells, and buried at appropriate depths. Groundwater and surface water contamination must be avoided.
- Rendering for disposal or industrial uses – In this scenario, materials are rendered and tallow is recovered. The rendered material (now MBM) is then disposed of by incineration, landfill, or local burial, used for industrial purposes, or burned for their fuel value. If no industrial uses are found for all of the protein products from designated tissues or downer animals, then the renderer/processor would probably dispose of the products. This disposal would need to be conducted in accordance with all local, State, and Federal requirements.

Under a new USDA program, a \$50 million loan guarantee program is being set up to help small businesses in rural areas develop ways to turn cattle SRM into biofuels (<http://www.usda.gov/Newsroom/0195.04.html>).

- Composting –Composting of dead livestock can be accomplished in compliance with environmental regulations in most states. The temperatures achieved during composting will kill or greatly reduce most pathogens, reducing the chance to spread disease.
- Disposal through alkaline hydrolysis digesters – Alkaline hydrolysis involves the use of a concentrated alkaline solution along with high temperatures and pressures to hydrolyze or digest tissues.
- Incineration –Incineration might be accomplished in centralized facilities or in small on-farm incinerators. Permitting and siting for incineration units might generate considerable political opposition. High temperature incineration can result in complete combustion of solid wastes resulting in the reduction of criteria air pollutants as well as odor and smoke.

Basic Processes Used in the Rendering and Processing Industries

Presently, carcasses of non-ambulatory disabled cattle and the inedible slaughter products from animals can be rendered for non-ruminant animal feeds. The rendering

process generally involves grinding the raw material and then heating 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, fats and oils are separated from the protein and bone fractions.

The inedible slaughter products from animals can also be processed by other means instead of the general rendering process. This includes, but is not limited to: heating, drying, grinding, extracting, defatting, neutralizing, straining, hydrolyzing, burning, charring, cooking, dehydrating, evaporating, freezing, mechanically separating, and treating with steam, pressure, an acid, and/or a base. During processing, the fats and oils may be extracted or separated from the protein and bone fraction. These types of operations are limited in number and tend to produce a product for a specific use, and probably do not process a significant volume of material.

Estimated Quantities of Cattle Offal

According to National Agricultural Statistics Service reports (USDA, 2003), 98.7 percent of cattle in 2003 were slaughtered and processed at federally inspected establishments. Commercial cattle slaughter during 2002 totaled 35.7 million head, with federal inspection comprising 98.3 percent of the total. Steers comprised 49.9 percent of the total federally inspected slaughter, heifers 32.3 percent, dairy cows 7.4 percent, other cows 8.7 percent, and bulls 1.7 percent.

Using various assumptions (cattle average weight 1,200 lbs; 30% offal), we estimated that 6,458,688 tons of inedible offal were produced at federally inspected slaughter plants in FY 2002.

Estimated Quantities of Cattle Mortalities and Material Rendered

Renderers obtain non-ambulatory disabled cattle and dead stock from large and small farmers and ranchers, dairy farms, and feedlots. Detailed estimates of farm mortalities and materials rendered is provided by ERG (2005a) and Informa (2004) (see Appendix). Informa estimates that approximately 35.1 percent of cattle mortalities and downers are rendered (41.9 percent rendered by volume). ERG (see table, below) estimates that approximately 17 percent of dead downer and ante-mortem cattle are rendered.

ERG, (2005a) (data generated from Table 2-2):

**Prohibited Materials Quantities from Dead, Downer and Ante-mortem
Condemed Cattle**

	Number of Head (000)	Percent Rendered	Head Rendered (000)
All deads under 500 lbs	2,365	5	118
Feedlot deads	300	90	270
Beef cow deads & downers	1,400	10	140
Dairy cow deads & downers	400	60	240
Deads and downer totals	4,465	17	768

Environmental Consequences of “No Action”

If the FDA decides to take the “no action” alternative, FDA would not issue this proposed rule with additional requirements related to the use of cattle material in animal feed. Accordingly, there would likely be no change in environmental impacts from the current situation. Dispositions of dead and downer stock and offal from ruminants will continue unaffected, divided among on-farm disposal, landfill, incineration, and rendering/processing. An estimate of mortality disposal methods is provided by Informa (2004) (see Appendix).

B. SRM Prohibition Alternative

An alternative considered by the FDA is the prohibition from use in animal feeds of specified risk materials, material from non-ambulatory disabled cattle and cattle not inspected and passed for human consumption, and mechanically separated beef. This is referred to in this discussion as the “SRM prohibition” alternative.

Feed Ingredients Affected

Specified risk materials (SRMs) include the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle.

Non-ambulatory disabled cattle are cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

Cattle not inspected and passed for human consumption means cattle of any age that were not inspected and passed for human consumption by the appropriate regulatory

authority. This term includes dead and downer stock and non-ambulatory disabled cattle. Collectively these cattle are often referred to as “dead and downers”.

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

Disposition of SRM and Prohibited Materials from Dead and Downer Cattle

There are basically three major sources of SRMs and dead and downer cattle that must be processed or disposed of and that will be discussed in this EA. SRMs will be generated primarily at cattle slaughter operations; dead and downer cattle are sourced at animal production sites including farms, feedlots and dairies; and animals condemned at ante-mortem inspections are generated primarily from slaughtering facilities. There are various alternatives for disposing of SRM including landfilling, burial, composting, alkaline hydrolysis digestion, incineration, rendering to produce meat and bone meal and tallow, and rendering for disposal.

Estimated Amounts of SRM and Dead and Downer Cattle Materials

The FDA economic analysis for this alternative as prepared by the Eastern Research Group, Inc (ERG, 2005) has provided estimates of the amount of SRM materials that may be generated under the SRM prohibition alternative (Table 1: Appendix). Cattle 30 months of age and older generate considerably more SRM. To quantify the SRM generation, slaughterers are forecast to extract on average 28.3 lbs of SRM from cattle less than 30 months of age and 88.5 lbs from cattle over 30 months of age. The average total cattle weight at slaughter was calculated in 2003 at approximately 1,250 lbs, of which hides and skin represent approximately 5 percent and for which cattle offal represents 34.1 percent. This translates to approximately 425 lbs of offal per animal before SRM are removed. Based on these calculations, SRM will represent 6.7 to 20.8 percent of offal of the animal.

Data in Table 2 (Appendix) allows for an estimate of yearly SRM quantities available for rendering from slaughterhouses and materials from dead and downer cattle. SRMs from healthy slaughtered cattle constitute approximately 1,423,044,000 lbs with 624,508,000 lbs from cattle over 30 months of age and 798,535,000 lbs from cattle less than 30 months of age. There are approximately 4,465,000 dead and downer cattle in the United States per year. At present, ERG estimates that 17 percent of these animals are rendered (approximately 692,100,000 lbs). Informa (2004) estimates that 35.1 percent of dead and downers are rendered. According to the Informa report this translates to approximately 1,133,020,000 lbs of material. Since all materials from these cattle would be prohibited in animal feeds under the SRM prohibition alternative, the amount of material that would continue to be rendered is difficult to predict.

Effect on the Rendering and Processing Industries

It is anticipated that the SRM prohibition alternative would cause the rendering and processing industries to consider alternative processes to economically separate the prohibited bovine materials and render or otherwise process the material for disposal or for non-feed use.

ERG (2005a) discussed the impact of an SRM prohibition alternative with selected rendering industry executives and requested forecasts on the potential capital investment plans for the industry in view of a possible ban. The executives noted that if, under the alternative, a substantial flow of materials is generated that are prohibited from animal feed, renderers might dedicate some facilities to rendering for disposal. The executives forecast, however, that industry will not necessarily build new rendering plants for the purpose of disposal. This forecast doesn't consider the potential for geographical imbalances between existing and SRM rendering capabilities throughout agricultural areas. Such imbalances as occur might encourage construction of new rendering facilities.

Effect on Large Slaughterhouse/Packaging Operations

The SRM prohibition alternative would likely result in slaughterers separating SRM from other ruminant offal and disposing of the material. Slaughterers will modify their animal killing operations to arrange for the separation of SRM and delivery of the materials to a disposal or disposal/rendering operation. The processing and disposal of SRM might occur in several different ways. The rendered MBM from the SRM will then be able to be landfilled or used for industrial purposes.

Slaughterers will also pay for SRM removal, rendering, and disposal. Slaughterers will have considerable potential for passing costs backward to animal producers and forward to consumers.

Many of the largest animal slaughtering operations are integrated with rendering operations. Thus, the same entity captures the meat value and the value of animal by-products. At these operations, the slaughtering operation removes meat and other valuable animal parts from the carcass and then transfers the animal offal to the rendering operation. The integrated facilities are usually specialized in slaughtering and rendering of a single animal species. The on-site slaughtering operations provide a consistent, single-species source of raw materials to the renderer. The rendering operation incurs essentially no transportation costs to acquire raw materials. Also, the larger volume of these operations sometimes allows more cost-effective capture of animal by-product materials for relatively specialized operations. For example, cattle by-products used for specialized pharmaceutical uses are more likely to be harvested at integrated operations than at independent renderers.

Under the total SRM prohibition alternative, some renderers might convert facilities to handling of only SRM. However, they would presumably have to be paid for this service by slaughterers in order to make this economically feasible. Because

landfilling of raw cattle parts is prohibited in many states, much SRM material would need to be rendered to facilitate disposal. Some renderers may switch facilities to dedicated SRM rendering to replace a portion of their normal rendering revenues with revenues for dedicated SRM rendering charges. However, it is unclear to what extent such changes would occur.

An analysis by Sparks (2001) indicates that given the choice between rendering for disposal and disposal in a landfill, livestock packers would save considerable expense by using rendering for disposal even if rendering fees were charged. The report estimates that processing and disposing of materials in landfills would average \$105 per ton whereas “disposal rendering” fees would average \$60 per ton.

Effect on Small Slaughterhouse/Packaging Operations

Medium and small slaughterhouses (packers) typically rely on independent rendering operations for the processing of waste materials. Under the SRM prohibition alternative, the disposal of SRM material from these facilities would be dependent on the emergence of disposal rendering and the existence of incentives for continued pick-up by independent renderers.

Independent renderers collect and process multi-species raw materials from a variety of sources including medium and small slaughterhouses, deadstock from animal producers, including medium and small farms, meat processing plants, grocery store butcher shops and large restaurants, pet food manufacturers, and other sources that provide protein-rich raw materials. The independent renderer generally operates a fleet of collection trucks and provides an essential animal or waste product disposal service for its customers. Many independent renderers sell a mixed-species MBM product or a partially processed protein mix, which usually includes or is presumed to include ruminant protein, to feed mills or to protein blenders. The latter might mix protein sources from several sources and perform further processing. Independent renderers might also produce blood meal, but do so only where they have a relatively large and stable source of animals where blood can be extracted.

As producers of ruminant-containing MBM, the independent renderers operate at an economic disadvantage to the much larger scale of the integrated packer/renderers. They must support the costs of a collection truck fleet (often operating over a service radius of several hundred miles), they have less consistent raw material inputs to their processes, and the numbers of small and medium packers have been declining.

Prior to the development of concerns over BSE in the 1990s, it had been common for renderers to pay many of their suppliers for their raw materials, with the size of the payment varying with market conditions. Competition among renderers and the value of the raw material as a processing input generated positive values for raw material suppliers. ERG presumes that with reduced ruminant protein values, however, renderers are generally charging suppliers for raw material pickups. Some suppliers of raw material, however, might be paid for supplying large quantities of raw material to renderers.

As renderer pick-up charges for dead animals have increased over time, and some small independent renderers have closed operations, renderers now pick up a smaller share of fallen animals than they did in the early 1990s. While exact statistics do not exist, various renderers estimated for ERG that renderers pick up only 30 to 60 percent of dairy cow deadstock and a much smaller percentage of beef cattle deadstock. The Informa (2004) report estimates that 35.1 percent of mortalities and downers are rendered. Rendering plants are not uniformly distributed in the U.S and there are many locations where transportation costs make the use of a render prohibitive. Pick up charges for an individual mortality in a remote area not serviced by a local rendering facility could be in excess of \$100.00 (Sparks 2002)

Over the last decade, there has been considerable consolidation in the industry. The number of independent rendering facilities has declined over the last decade. More significantly, there has been considerable consolidation in the industry. The FDA database indicates that there are 238 rendering facilities, including all packer renderers and independent renderers. In the mid 1990s, this figure was approximately 280.

Effects of Rule on the Disposition of Slaughter House Generated SRM Materials

It is expected that packing plants with their own rendering facilities will separate the waste streams, and will find a disposal route for the SRM waste stream. The economic analysis indicates that disposal rendering may be the least costly disposal option, especially when land filling costs and limitations are considered. If packing plants without their own rendering facilities have sufficient volume, it is expected that they will separate their materials and have the allowable material go to feed rendering and SRM to disposal rendering. Small operations that slaughter a few head/week (small locker plant, for example) may not have sufficient volume to justify the work, change in procedure, to make it worthwhile to be picked up by a renderer.

For those packing plants (of all sizes) without on-site rendering, it is anticipated that independent renderers will pick up the material. It is further assumed that these will dedicate certain of their rendering plants to be used to render feed ingredients and other facilities for disposal rendering.

As discussed above, it is expected that rendering/processing will continue to be a competitive disposal option usually favored over landfilling and incineration. Material that is not rendered will be disposed of primarily in landfills.

Effects of the Rule on the Disposition of Dead, Downer and Non-Ambulatory Disabled Cattle

At present, we assume that between 17 and 35.1 percent (42 percent by volume) of dead and downer cattle are collected by renderers and utilized for the production of animal feed and animal by-products such as tallow and hide (ERG, 2005a,b; Informa, 2004).

With the implementation of the USDA rule, additional non-ambulatory cattle have become available for rendering. As indicated, at present these materials are rendered primarily for animal feeds and the ability of renderers to market products such as animal feeds from these mortalities has helped keep the fees charged for carcass collection in check.

With the implementation of the SRM prohibition alternative, the amounts and costs of disposition of dead, downer, and non-ambulatory cattle would be affected by the ability of the rendering industry to develop alternative uses for the finished product and the recovery of marketable animal by-products such as tallow. If these products could no longer be marketed, renderers may need to charge higher fees to cover collection and disposal costs. At present, renderers sometimes pay large suppliers of dead or downer cows to acquire raw materials, but will generally charge small suppliers to pick up such animals. Thus renderers might pay feedlots and dairy farms that generate substantial numbers of animal carcasses, but will charge small ranchers located in remote areas to pick up a single dead animal. Small ranchers with only one or two dead animals at a time generally are now paying for rendering pickups.

To avoid these charges some ranchers and farmers will dispose of more dead animals on their own land, thereby reducing the amount of dead stock going to rendering. On-farm disposal would be expected to increase especially for small producers that generate limited amounts of dead stock. Feedlots, dairy farms, and other land-constrained operations (or operations subject to effective state enforcement for animal carcass disposal) appear to have fewer options for on-site disposal (unless they are willing to pay for incinerators or other technologies) and appear likely to pay increased renderer charges. The costs of dead and downer SRM rendering and disposal will be borne directly or indirectly by various entities including beef cattle producers, feed lot operators, and dairy farmers through service charges paid to renderers.

Environmental Consequences of the “SRM Prohibition” Alternative

The environmental consequences of the SRM prohibition alternative, if implemented, are difficult to predict. Given the large volume of SRM material that would require alternative disposal, the extent of the potential environmental impacts are greatly dependent upon the emergence of a disposal rendering industry. Although our discussion of potential impacts assumes that some rendering of material would occur, it is unclear whether the economic incentives would be sufficient to stimulate the establishment of a viable industry with equipment dedicated to rendering the SRM material for disposal or non-feed use. In the absence of adequate disposal rendering capacity, the agency is concerned that the environmental consequences associated with this alternative could be quite significant.

It is anticipated that the implementation of this alternative would result in a decrease in the proportion of materials rendered with a corresponding increase in the number of cattle buried on-farm, abandoned, landfilled, composted, or incinerated. Based on

the above analysis, it would appear that on-farm burial and abandonment of dead and downer animals would be the most likely area of increased disposition. The magnitude of this increase would be determined by the availability of disposal renderers and the fees charged by the disposal rendering industry. It is estimated that presently most on-farm mortalities are either buried or abandoned with approximately 17 percent to 35.1 percent of such animals collected by renderers. In addition, rendering plants are not uniformly distributed in the U.S and there are many locations where transportation costs make the use of a render prohibitive. In the absence of a viable disposal rendering industry, the decrease in the number of dead and downer cattle rendered is expected to be significantly greater.

The environmental consequences of a substantial increase in the number of animals now buried on farm or abandoned include increased potential for environmental contamination, surface and ground water contamination, odor production and the spread of disease or other pathogens due to interaction with wild animals or predators. Landfilling raw cattle materials increases the potential for leachate development and can shorten the usable life of a landfill site. A discussion of alternative methods for carcass disposal and potential consequences is provided in the USDA ANPRM for risk reduction strategies involving downer and dead stock (68 FR 2703).

Slaughter facilities will also face challenges in the disposal of now prohibited materials. According to the USDA rule (69 FR 1862), ante-mortem condemned cattle and SRM materials must be disposed of properly. Whether disposal occurs by landfill, incineration or rendering, slaughter facilities must develop SOPs that details how these materials will be disposed. It is anticipated that due to the high volume of SRM material generated by the SRM prohibition alternative, these materials will need to be processed by renderers and used for industrial purposes or disposal.

It is also anticipated that dead and downer cattle from feedlots and dairy operations will be rendered. These operations produce a high volume of mortalities and often have limited land available for burial or composting. In addition, on-farm burial may require considerable management oversight. Confined animal feeding operations (CAFO) regulations also require that animal mortalities be handled properly (68 FR 7175).

In addition, if industrial uses are not developed for the rendered materials, disposal of rendered materials would occur primarily through landfilling. Rendered material is a stabilized product and would not be expected to generate odors or effluents. Disposal of this previously utilizable material in landfills may however have an impact on the longevity of a specific landfill and may in the long run require the development of additional landfill sites.

It is unlikely that significant amounts of raw slaughter byproducts could be sent directly to landfills. In fact, landfilling raw animal material is prohibited or restricted in many locales. It may be more economical for packers to pay renderers to process and dispose of the material. Furthermore, other products such as tallow and grease might still be produced and sold by renderers to recover their costs.

Wildlife may be exposed to the BSE agent via the carcasses of dead cattle that have been disposed of on-farm. The consequences of these exposures are not known and have not been studied, to the agency's knowledge. Only a single case of BSE has been detected in the U.S. and exposure by this route remains a hypothetical situation.

C. Agency Proposed Rule

The Food and Drug Administration (FDA) is issuing a proposed rule published in the *Federal Register* accompanying this environmental assessment to prohibit the use of certain cattle origin materials in the food or feed of all animals.

Feed Ingredients Affected

Under the proposed rule, the following cattle origin materials would be prohibited (cattle materials prohibited in animal feed or CMPAF) in the food or feed of all animals:

- (1) the brains and spinal cords from cattle 30 months of age and older;
- (2) the brains and spinal cords from all cattle not inspected and passed for human consumption;
- (3) the entire carcass of cattle not inspected and passed for human consumption if the brains and spinal cords have not been removed.

In addition the following cattle byproducts would be prohibited:

- (1) tallow that is derived from materials prohibited by this proposed rule unless such tallow contains no more than 0.15 percent insoluble impurities; and
- (2) mechanically separated beef that is derived from materials prohibited by this proposed rule.

Additional provisions of the proposed rule would require that renderers that handle cattle material prohibited in animal feed use separate equipment or containers to handle this prohibited cattle material once such material has been separated from other cattle materials, label and mark prohibited materials, keep records, and provide FDA access to such records.

Proposed Definitions

Proposed § 589.2001(a) defines the following terms for the purposes of the proposed rule:

- (1) *Cattle materials prohibited in animal feed* means the brains and spinal cords of cattle 30 months of age and older; the brains and spinal cords of cattle of any age not inspected and passed for human consumption; the entire carcass of cattle not inspected and passed for human consumption from which brains and spinal cords

were not removed; mechanically separated beef that is derived from materials prohibited by this proposed rule; and tallow that is derived from materials prohibited by this proposed rule unless the tallow contains no more than 0.15 percent insoluble impurities. Tallow derivatives are not considered cattle material prohibited in animal feed.

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

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

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

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

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

Sourcing of Cattle Materials Prohibited in Animal Feed

There are basically three major sources of brain and spinal cord materials and cattle carcasses that must be processed or disposed. Brain and spinal cord materials will be generated primarily at cattle slaughter establishments. Cattle carcass processing at rendering and pet food facilities will also generate brain and spinal cord materials. These facilities usually source non-ambulatory disabled cattle and dead animals from animal production sites including farms, feedlots, and dairies, and cattle condemned at ante-mortem inspections from slaughtering establishments. After removal of brain and spinal cord materials at rendering and pet food facilities, the remainder of the carcass will be rendered for use in non-ruminant feed and other products. Carcasses from which brain and spinal cord material is not removed cannot be processed into feed.

These materials will not be permitted to enter food or feed supplies and will be disposed. There are various permitted options for the disposal of brain and spinal cord materials including landfilling, burial, composting, alkaline hydrolysis digestion, incineration, and rendering for disposal. Carcasses from which brain and spinal cord material could not be removed are usually deemed unusable on the farm by the farmer and are often abandoned or buried.

**Estimated Amounts of Cattle Materials Prohibited in Animal Feed
(Brain and Spinal Cord Materials and Carcasses from which
Brain and Spinal Cord Materials cannot be Removed) Under the
Proposed Rule**

The study of the impacts on industry of the proposed rule prepared by the Eastern Research Group, Inc (ERG, 2005b) for FDA in connection with this proposed rule provides estimates of the amount of brain and spinal cord materials and non-ambulatory cattle material that may be generated under the proposed rule.

The estimates presented in Table 3 (Appendix), show the quantity of materials slaughterers or renderers would remove prior to acquiring information about the animals' age. Under those terms, slaughterers would extract 1.3 pounds of CMPAF from an animal that is, or is assumed to be, 30 months of age or older, and up to 53 pounds of CMPAF from an animal where efficient removal of CMPAF is not possible. Thus, the weight removed will vary with the age or condition of the animal and the capability of the facility processing the animal. The average total cattle weight at slaughter was calculated in 2003 at approximately 1,250 lbs, of which hides and skin represent approximately 5 percent and cattle offal represents 34.1 percent. This translates to approximately 425 lbs of offal per animal before CMPAF are removed. Based on these calculations, CMPAF will represent 0.3 percent to 12.5 percent of offal from each animal.

Under the definition of CMPAF, ambulatory cattle under 30 months of age do not generate any CMPAF and their slaughter and disposition would not be affected under the proposed rule. Most large slaughter establishments handle cattle below 30 months of age. Small slaughterers would generally handle a larger percentage of older animals. All so-called deads and downers (cattle not inspected and passed for human consumption), regardless of age, will also generate materials prohibited by the proposed rule. Since some slaughterers may not have a practical means for determining age at slaughter, this analysis assumes, as a worst case assumption, that all cattle will have brain and spinal cord removed prior to processing.

Table 4 (Appendix), presents the estimated quantities of CMPAF produced per year. The total includes the quantities of CMPAF from cattle not inspected and passed for human consumption and from slaughtered animals. The CMPAF calculations were based on the 2003 annual cattle slaughter of approximately 35.3 million animals. The table includes several estimates concerning the current share of cattle not inspected and passed for human consumption that are now rendered. The table also includes ERG's forecasted share of cattle not inspected and passed for human consumption

that will be rendered under the provisions of the proposed CMPAF rule. ERG projects only modest declines for the rendering of cattle not inspected and passed for human consumption. Most of the animal offal can still be rendered for animal feed purposes. As indicated above, this analysis assumes as a worst case scenario that all cattle, including cattle below 30 months, will have brain and spinal cord removed prior to processing.

Effects of the Proposed Rule on the Rendering and Processing Industries

It is anticipated that the requirements of the proposed rule would result in the rendering and processing industries determining if they can economically separate and render, and properly dispose of the cattle materials prohibited in animal feed. Since the majority of the carcass can be recovered for processing, little impact on the industry as a whole is expected. Several options are available for disposal of the prohibited brain and spinal cord materials including landfilling, burial, composting, alkaline hydrolysis digestion, incineration, and rendering for disposal.

Using the assumptions and estimates of the CMPAF quantities withdrawn from animal feed use, the overall impact of the regulatory option in the proposed rule on the rendering industry is expected to be modest. The amount of material removed from the rendering stream amounts to 0.1 percent of meat and bone meal (MBM) production and less than 0.1 percent of tallow production (ERG, 2005b).

Effects of the Proposed Rule on Large Slaughter/Packaging Establishments

The proposed regulation would likely result in slaughterers separating brain and spinal cord materials from other ruminant offal and disposing of the material by means other than to renderers for animal feed use. It is expected that slaughterers will modify their animal killing operations to arrange for the separation of brain and spinal cord materials and delivery of the materials prohibited by the proposed rule to a disposal or disposal/rendering operation. Under the proposed rule, the remaining offal would remain available for rendering into non-ruminant animal feed.

Slaughterers will also pay for brain and spinal cord materials removal, and disposal. Slaughterers will have considerable potential for passing costs backward to animal producers and forward to consumers.

Many of the largest animal slaughtering operations are integrated with rendering operations. Thus, the same entity captures the meat value and the value of animal by-products. At these operations, the slaughtering operation removes meat and other valuable animal parts from the carcass and then transfers the animal offal to the rendering operation. The integrated facilities are usually specialized in slaughtering and rendering of a single animal species. The on-site slaughtering operations provide a consistent, single-species source of raw materials to the renderer. The rendering operation incurs essentially no transportation costs to acquire raw materials. Also, the

larger volume of these operations sometimes allows more cost-effective capture of animal by-product materials for relatively specialized operations. For example, cattle by-products used for specialized pharmaceutical uses are more likely to be harvested at integrated operations than at independent renderers.

Under the proposed rule, slaughterers might modify their animal killing operations to separate brain and spinal cord and deliver these materials to a disposal or disposal rendering facility. Federally inspected slaughterers have been routinely removing the spinal cord, and brain in order to comply with USDA requirements regarding cattle processing for human food use. These parts are now mixed with general offal, and the plants may change their practices to remove CMPAF for separate handling and disposal. This change might require investments in modifications to the kill floor, additional labor during slaughtering, changes in the transport of animal byproducts through the slaughtering facility, and payments for disposal or processing and disposal of the materials. Due to the small volumes of CMPAF involved, however, major process changes are not expected. Most slaughterers can collect CMPAF in bins and manually transport them to a disposal area in the plant. Space constraints or other issues may result in some additional changes besides purchases of dedicated disposal bins for CMPAF (ERG 2005b).

Effects of the Proposed Rule on Small Slaughter/Packaging Establishments

Medium and small slaughter establishments (packers) typically rely on independent rendering operations for the processing of waste materials. These renderers collect and process multi-species raw materials from a variety of sources including medium and small slaughter establishments, deadstock from animal producers, including medium and small farms, meat processing plants, grocery store butcher shops and large restaurants, pet food manufacturers, and other sources that provide protein-rich raw materials. The independent renderer generally operates a fleet of collection trucks and provides an essential animal or waste product disposal service for its customers. Many independent renderers sell a mixed-species MBM product or a partially processed protein mix, which usually includes or is presumed to include ruminant protein, to feed mills or to protein blenders. The latter might mix protein sources from several sources and perform further processing. Independent renderers might also produce blood meal, but do so only where they have a relatively large and stable source of animals where blood can be extracted.

As producers of ruminant-containing MBM, the independent renderers operate at an economic disadvantage to the much larger scale of the integrated packer/renderers. They must support the costs of a collection truck fleet (often operating over a service radius of several hundred miles), they have less consistent raw material inputs to their processes, and the numbers of small and medium packers have been declining.

Prior to the development of concerns over BSE in the 1990s, it had been common for renderers to pay many of their suppliers for their raw materials, with the size of the payment varying with market conditions. Competition among renderers and the value

of the raw material as a processing input generated positive values for raw material suppliers. ERG presumes that with reduced ruminant protein values, however, renderers are generally charging suppliers for raw material pickups. Some suppliers of raw material, however, might be paid for supplying large quantities of raw material to renderers.

As renderer pick-up charges for dead animals have increased over time, and some small independent renderers have closed operations, renderers now pick up a smaller share of fallen animals than they did in the early 1990s. In addition, rendering plants are not uniformly distributed in the United States and there are many locations where transportation costs make the use of a renderer prohibitive. Pick-up charges for an individual mortality in a remote area not serviced by a local rendering facility could be in excess of \$100.00 (Sparks 2002).

Over the last decade, there has been considerable consolidation in the industry and the number of independent rendering facilities has declined. The FDA database indicates that there are 238 rendering facilities, including all packer renderers and independent renderers. In the mid 1990s, this figure was approximately 280.

Effects of Proposed Rule on the Disposition of Slaughter, Renderer and Pet Food Establishment-Generated Cattle Materials Prohibited in Animal Feed (brain and spinal cord materials)

The effect of this proposed rule will be to directly prohibit a small share of animal offal from production of MBM and tallow. The brain and spinal cord of an average slaughter cow weighs only 1.3 lbs. Slaughterers and renderers both have or can acquire the capability to remove such materials from the animals they process. It is expected that slaughter/packing establishments with their own rendering facilities will separate the waste streams and find a disposal route for the CMPAF. If packing plants without their own rendering facilities have sufficient volume, it is expected that they will separate their materials and have the allowable material go to feed rendering and the CMPAF routed to disposal. Small operations that slaughter a few head/week (small locker plant, for example) may not have sufficient volume to justify the work, change in procedure, or make it worthwhile to be picked up by a feed renderer.

Under the present proposal, some renderers might convert facilities to handling of brain and spinal cord materials from slaughter and pet food establishments for disposal purposes. Alkaline hydrolysis tissue digestion or incineration processes may be instituted. They will presumably be paid for this service by slaughterers. This may be more common in states or locations where landfilling of raw cattle parts is prohibited.

Renderer operations that remove brain and spinal cord materials will separate these materials from the remaining permitted materials and dispose according to existing State and local regulations. Facilities with large volumes of material may convert facilities to handling of brain and spinal cord materials for disposal purposes. An analysis by Sparks (2002) indicates that given the choice between rendering for

disposal and disposal in a landfill, livestock packers would save considerable expense by using rendering even if rendering fees were charges. The report estimates that processing and disposing of materials in landfills would average \$105 per ton whereas “disposal rendering” fees would average \$60 per ton.

Effects of the Proposed Rule on the Disposition of Cattle Carcasses from which Brain and Spinal Cord were not Removed

At present, approximately 17 to 35 percent (42 percent by volume) of cattle including non-ambulatory cattle, 4-D cattle, and cattle condemned at the time of slaughter are collected by renderers and utilized for the production of animal feed and animal by-products such as tallow and hide (ERG, 2005b, Informa, 2004).

With the implementation of the USDA rule, additional non-ambulatory cattle have become available for rendering. As indicated, at present these materials are rendered primarily for animal feeds and the ability of renderers to market products such as animal feeds from these mortalities has helped keep the fees charged for carcass collection in check.

The economic analysis set out in the FDA proposed rule predicts a slight decrease in the number of animals processed by renderers. In addition, animals that renderers determine cannot be salvaged for MBM will be left on the farm for disposal. These are cattle that have decayed to the point that the brain and spinal cord cannot be removed or that are not processed for economic considerations. Although difficult to estimate, the number of such animals is not expected to be significant. It is predicted (see *Federal Register* proposed rule accompanying this environmental assessment) that about 26,000 more cattle (0.6 percent of all dead and non-ambulatory disabled cattle; or about 3.5 percent of all cattle not inspected and passed for human consumption that are rendered) would not be rendered, comprised primarily of beef cows (no additional feedlot cattle included) and cattle under 500 lbs. Using the Informa 42 percent estimate of cattle rendered and the same 3.5 percent relative change in reduction we estimate that at the high end of the range about 64,000 additional cattle would no longer be rendered

Regulations on Disposal of Animal Raw Materials and Carcasses

State and local regulations on the disposal of farm animal carcasses have been promulgated throughout the United States. Guidance on burial, composting and incineration is available through government agencies or agriculture extension services. Burial as a means of on-farm disposal of ruminants was recommended by APHIS as means of disposal of infected or high risk sheep (57 FR 58132, December 9, 1992). The Environmental Protection Agency (EPA) has provided recommended practices for the large-scale disposal in landfills of potentially contaminated chronic wasting disease (CWD) carcasses and wastes (<http://www.epa.gov/epaoswer/non-hw/muncpl/disposal.htm>).

In the USDA interim final rule prohibiting the use of SRM for human food (69 FR 1862) FSIS is requiring that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. Establishments are responsible for ensuring that SRMs are completely removed from the carcass, segregated from edible products, and disposed in an appropriate manner. Establishments must address their control procedures in their HACCP plans, Sanitation SOPs, or other prerequisite programs. FSIS will ensure the adequacy and effectiveness of the establishment's procedures. The USDA interim final rule also requires that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle maintain daily records that document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs, and that the establishments make these records available to FSIS personnel on request. (69 FR 1862, 1869).

FSIS will also develop compliance guidelines for use by very small and small establishments to assist them in the development of validated methods for meeting the requirements of its interim final rule. (69 FR 1862, 1869).

The EPA Concentrated Animal Feed Operations (CAFO) rule (68 FR 7175; February 12, 2003) provides requirements for the handling of animal wastes including animal mortalities. The rule states that mortalities must not be disposed of in any liquid manure or process wastewater system and must be handled in such a way as to prevent the discharge of pollutants to surface water.

The Animal and Plant Health Inspection Service published an advance notice of proposed rulemaking on January 21, 2003 (68 FR 2703). The FR notice, titled "Risk Reduction Strategies for Potential BSE Pathways Involving Downer Cattle and Dead Stock of Cattle and Other Species", solicited comments from the public and regulated industries to help APHIS develop an approach to control risks associated with disposal of nonambulatory and dead livestock.

The USDA recently established a pilot project to fund small businesses that generate energy production from cattle products. The new loan guarantee pilot project is aimed at developing renewable energy systems from the use of livestock as a raw material (69 FR 28111, May 18, 2004).

Many locales prohibit the landfilling of raw cattle materials. In such locales, raw cattle materials will need to be processed prior to disposal in landfills.

Environmental Consequences of the Proposed Rule

Under the proposed rule, a new waste stream of material would be created that would need to be disposed. According to the proposed rule, this material will be sourced at slaughter establishments from cattle 30 months of age and older and from cattle not inspected and passed for human consumption at rendering plants and pet food facilities. The new waste stream will consist of a relatively small volume of material.

Most (80 percent) of the slaughtered cattle in the U.S. are under 30 months of age and all materials from these animals can be legally rendered for non-ruminant animal feed. Offal from slaughter facilities and inedible cattle carcasses will be processed as they are at present by rendering facilities into non-ruminant animal feeds and other byproducts.

Limiting the list of SRMs as proposed by this rule as compared to a full SRM ban reduces the volume of slaughter byproducts that would require alternative disposal from 1.4 billion pounds to less than 52 million pounds. Two differences account for this reduction in volume. First, this proposal does not divert from animal feed use the small intestine and tonsils (weighing 28 pounds per animal) from the 28 million head of cattle under 30 months of age that are slaughtered annually. Second, only the brain and spinal cord (weighing 1.3 pounds per animal) rather than the head, spinal column, and small intestine, (weighing 88.5 pounds per animal) are diverted. This value could decrease to as little as 10 million pounds once procedures are in place to determine the age of the animal. In this case, material may be removed only from the estimated 7 million head of cattle over 30 months of age that are slaughtered annually in the U.S. FDA believes that this material from slaughter operations can be disposed of through landfill, incineration, alkaline digestion and composting.

Under the proposed rule, carcasses that cannot be processed by a renderer in time to remove brain and spinal cord materials would not be permitted to enter the feed chain and would need to be disposed of in some alternative manner, as is presently the practice, usually by on-farm burial, abandonment, landfilling, composting or incineration. The most likely cattle population that would require this type of disposal is dead and non-ambulatory disabled beef cows and dead cattle under 500 lbs. A significant increase in the volume of such carcasses is not expected. However, the actual amount of farm deaths that are processed by renderers is more a function of the general availability of renderers and the fees charged for pick up. It is estimated that presently most on-farm mortalities are either buried or abandoned with only 17 percent to 35.1 percent of such animals collected by renderers. Presently, approximately 3 million dead stock are not rendered. We estimate that this rule could increase the number of animals disposed by means other than rendering by an additional 26,000 to 64,000 head. This increase would be widely distributed throughout the U.S. There would likely be no significant change in environmental impacts from the current situation.

It is expected that the disposal of brain and spinal cord materials from slaughter and rendering establishments would at least initially occur primarily through landfilling. If sufficient material is available or if the landfilling of raw cattle materials is prohibited or restricted, establishments may utilize other technologies such as incineration, alkaline hydrolysis tissue digestion, and composting to dispose of the material. Depending on the volume of available materials and economic considerations, dedicated disposal rendering facilities may also be developed in order to render the material for disposal or industrial uses. Rendered material is a stabilized product and would not be expected to generate odors or effluents.

The main environmental hazards identified from an increase in disposal of these materials would be the increase in hazards associated with landfilling. These include environmental contamination and pollution of ground or surface waters, odor production, and the interaction with wild animals or predators. A significant environmental impact from the increased disposition would not be expected for several reasons as described below.

According to the USDA rule (69 FR 1862), ante-mortem condemned cattle and SRM materials must be disposed of properly. Whether disposal occurs by landfill, incineration or rendering, slaughter facilities must develop SOPs that details how these materials will be disposed.

It is unlikely that significant amounts of raw slaughter byproducts would be sent directly to landfills. Some locales restrict or prohibit this practice but it may also be more economical to process the material prior to disposal. Furthermore, other products such as tallow and grease might still be produced and sold by renderers to recover their costs.

Modern landfills are well-engineered facilities that are located, designed, operated, monitored, closed, cared for after closure, cleaned up when necessary, and financed to insure compliance with federal regulations. Federal landfill regulations were established to protect human health and the environment (see 40 CFR 258). Such regulations establish strict criteria designed to minimize environmental impacts. Such criteria include location restrictions, design criteria including liner requirements, operating practices, groundwater monitoring, closure and post-closure care, corrective action controls and financial assurances. Many states have developed their own additional requirements and guidelines.

Additional Environmental Consequences of the Proposed Rule

The measures in the proposed rule are aimed at strengthening existing safeguards designed to help prevent the spread of BSE in U.S. cattle. Adoption of the proposed regulation should decrease the prospects of BSE spreading in the U.S. and this would be expected to have a positive environmental consequence. If BSE spreads in the U.S., there is likely to be a marked increase in on-farm disposal and non-edible rendering of animals with consequent environmental impacts. This is discussed in more detail in the EA and FONSI prepared for the 1997 ruminant feed rule (FDA, 1996).

Wildlife may be exposed to the BSE agent via the carcasses of dead cattle that have been disposed of on-farm. The consequences of these exposures are not known and have not been studied, to the agency's knowledge. Only two cases of BSE have been detected in the U.S. and exposure by this route remains a hypothetical situation.

VI. Mitigation Measures

The incremental increase in material that would need to be disposed of as a result of the proposed action would not be expected to significantly impact landfill or other disposal activities. We assume that disposal of the materials prohibited by the

proposed rule in landfills, on the farm, or by incineration, would be subject to local, State, and Federal laws and regulations. Therefore, the EA does not discuss mitigation measures because no significant environmental impact is expected.

VII. Summary of Environmental Consequences

The EA has examined the environmental consequences of prohibiting the use in animal feed of brain and spinal cord materials and cattle carcasses from which brain and spinal cord materials have not been removed. Our assessment indicates the proposed rule would not be expected to significantly increase the number of animals disposed by means other than rendering. This increase would be widely distributed throughout the U.S. There would likely be no significant change in environmental impacts from the current situation. In addition, the incremental increase in slaughterhouse and renderer material that will be disposed of as a result of this rule would not be expected to significantly impact landfill or other disposal activities. We assume that disposal of the materials prohibited by the proposed rule in landfills, incineration, and on-farm disposal would be subject to local, State, and Federal laws and regulations.

VIII. List of Preparers

Raanan A. Bloom, Ph.D., researched and prepared this Environmental Assessment. Dr. Bloom joined the Office of New Animal Drug Evaluation of the Center for Veterinary Medicine in 1990, serving in the Environmental Assessment and Residue Chemistry teams. He was employed at the EPA for 3 years where he prepared environmental risk assessments for pesticides and Toxics Release Inventory (TRI) candidate compounds. Dr. Bloom specializes in the environmental chemistry and fate of pharmaceuticals in both terrestrial and aquatic environments and the evaluation of potential environmental impact of products regulated by CVM. Additionally, he prepares environmental assessment documents as required for actions initiated by the Agency. He holds Bachelor of Science and Master of Science degrees from Drexel University, Philadelphia, PA, and a Ph.D. in Environmental Microbiology (1988) from Rutgers University, New Brunswick, NJ.

Shannon Jordre, a reviewer and contributor to this document, is a Consumer Safety Officer in the Division of Compliance at CVM, having served in that position since 2002, specializing in feed-related issues such as the inspection of feed mills for compliance with the medicated feed good manufacturing practice and BSE regulations, as well as other issues related to feed ingredients. Before coming to CVM, he spent 12 years as a state feed control official with the South Dakota Department of Agriculture. He has served on the Association of American Feed Control Officials (AAFCO) Board of Directors, as AAFCO President, and he continues to Chair the AAFCO Ingredient Definitions Committee. He has B.S. degrees in Microbiology and Biology from South Dakota State University.

IX. References

Cohen et al., 2001. Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States. Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University. November 26, 2001.

http://www.aphis.usda.gov/lpa/issues/bse/risk_assessment/mainreporttext.pdf

ERG, 2005a. Economic Impacts of Proposed FDA Regulatory Changes to Regulations of Animal Feeds Due to Risk of Bovine Spongiform Encephalopathy. Contract No. 223-03-8500, Task Order 3, Eastern Research Group, Inc., Lexington, MA, July 25, 2005.

ERG, 2005b. Economic Impacts of Alternative Changes to the FDA Regulation of Animal Feeds to Address the Risk of Bovine Spongiform Encephalopathy, Contract No. 223-98-8002, Task Order 2, Eastern Research Group, Lexington, MA, July 25, 2005.

EPA, 2002. Analyses of Final Revisions to the National Pollutant Discharge Elimination System Regulation and the Effluent Guidelines for Concentrated Animal Feeding Operations. U.S. Environmental Protection Agency, Washington, D.C. December 2002. http://www.epa.gov/npdes/pubs/cafo_benefit_p1.pdf

FDA, 1996. Finding of No Significant Impact and Environmental Assessment for 21 CFR 589.2000: Prohibition of Protein Derived from Ruminant and Mink Tissues in Ruminant Feeds. Center for Veterinary Medicine, FDA. November 1996.

http://www.fda.gov/cvm/Documents/Bse_all.pdf

Informa, 2004. An Economic and Environmental Assessment of Eliminating Specified Risk Materials and Cattle Mortalities from Existing Markets. Prepared for: The National Renderers Association. Informa Economics, Inc. Washington, D.C.

http://www.renderers.org/economic_impact/index.htm

John, R.E., 1990. "National Renderers Association Feed Safety Assurance Efforts", in a symposium on *Feed Quality Assurance, A System-Wide Approach*, 67-77, 1990.

Sparks, 2001. The Rendering Industry: Economic Impact of Future Feeding Regulations. Sparks Companies, Inc., McLean, VA, June 2001.

Sparks, 2002. Livestock Mortalities: Methods of Disposal and Their Potential Costs. Sparks Companies, Inc., McLean, VA, March 2002.

USDA, 2003. Livestock Slaughter, 2002 Summary. U.S. Department of Agriculture. 2003. Accessed online at <http://usda.mannlib.cornell.edu/reports/nassr/livestock/pls-bban/lsan0303.txt>

57 FR 58130: Scrapie Indemnification; Final Rule. December 9, 1992.

69 FR 1862: Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Interim Final Rules and Request for Comments. January 12, 2004.

69 FR 28111: Notice of Funds Availability (NOFA) Inviting Applications for the Specific Risk Materials and Certain Cattle Renewable Energy Guaranteed Loan Pilot Program. May 18, 2004.

68 FR 7175: National Pollutant Discharge Elimination System Permit Regulation and Effluent Limitation Guidelines and Standards for Concentrated Animal Feeding Operations (CAFOs); Final Rule. February 12, 2003.

68 FR 2703: Risk Reduction Strategies for Potential BSE Pathways Involving Downer Cattle and Dead Stock of Cattle and Other Species; ANPRM. January 21, 2003.

69 FR 42288: Federal Measures to Mitigate BSE Risks: Considerations for Further Action; ANPRM. July 14, 2004.

XI. Appendices

Table 1. Estimated Volumes of SRM, per Ambulatory Cow Slaughtered Over 30 Months, (ERG, 2005a)

Cattle part	Pounds	MBM Yield (%)	Tallow Yield (%)	MBM Yield (lbs)	Tallow Yield (lbs)
Brain	0.936	6%	5%	0.06	0.05
Spinal cord	0.374	7%	5%	0.03	0.02
Eyes	0.220	15%	10%	0.03	0.02
Dorsal root ganglia	NA	NA	NA	NA	NA
Tonsils	0.300	5%	15%	0.02	0.05
Skull (including trigeminal ganglia)	15.200	44%	11%	6.69	1.67
Vertebral column	36.500	48%	13%	17.52	4.75
Small intestine (incl. distal ileum) - < 30 months (a)	28.000	5%	16%	1.40	4.48
Small intestine (incl. distal ileum) - > 30 months (a)	35.000	5%	16%	1.75	5.60
Total - for cattle not over 30 months (Includes only tonsils and small intestine) (lbs)	28.3	NA	NA	1.42	4.53
Total - for cattle over 30 months old (lbs)	88.5	NA	NA	26.09	12.15

NA=Not applicable or not available

(a) The source estimates different values for cattle below or over 30 months of age

The SRM calculations were based on the 2003 annual cattle slaughter of approximately 35.3 million animals (USDA, 2004). Detailed information on the generation of these tables is provided in ERG, 2005a

Table 2: SRM Quantities from Dead, Downer and Slaughtered Cattle/Present Situation (from data in ERG, 2005a)

	Number of Head (000)	Percent Rendered	Number Rendered (000)	Avg. Wt. Per Head (lbs)	Total Wt. (000 lbs)
Cattle SRM					
For cattle over 30 months of age	7,054	100%	7,054	88.5	624,508
For cattle under 30 months of age	28,217	100%	28,217	28.3	798,535
SRM totals	35,271		35,271	116.8	1,423,044
Deads and Downers					
All deads under 500 lbs	2,365	5%	118	200.0	23,600
Feedlot deads	300	90%	270	750.0	202,500
Beef cow deads & downers	1,400	10%	140	1,100.0	154,000
Dairy cow deads & downers	400	60%	240	1,300.0	312,000
Deads and downer totals	4,465	17%	768		692,100
Total - All SRM and dead and downer animals					2,115,144

Table 3. Estimated Volumes of CMPAF per Ambulatory or Non-Ambulatory Cow Slaughtered (ERG, 2005b)

Cattle part	Pounds	MBM* Yield (%)	Tallow Yield (%)	MBM Yield (lbs)	Tallow Yield (lbs)
Brain	0.936	6%	5%	0.06	0.05
Spinal cord	0.374	7%	5%	0.03	0.02
Skull (including trigeminal ganglia, not incl. brain)	15.200	44%	11%	6.69	1.67
Vertebral column	36.500	48%	13%	17.52	4.75
Total – for slaughter cattle assumed or known 30 months old or older and other fresh dead cattle	1.31			0.08	0.07
Total – for slaughter cattle at small plants where brain is not extracted (skull becomes CMPAF)	16.51			6.77	1.74
Total—for dead cattle where skull and spinal cord removed	53.01			24.29	6.48

*Meat and bone meal (MBM)

Table 4. Prohibited Material Quantities from Slaughter Cattle and from Cattle Not Inspected and Passed for Human Consumption (Dead, Downer, and Ante-mortem Condemned Cattle) (ERG, 2005b)

	Number of Head (000)	Current Percent Rendered	Forecast Percent Rendered	Number Rendered (000)	Avg. Wt. Per Head (lbs)	Total Wt. (000lbs)
Slaughter CMPAF						
Federally inspected plants (99% of slaughter cattle)	34,918	100%	100%	34,918	1.3	45,743
State inspected plants (1% of slaughter cattle)	353	100%	100%	353	16.5	5,823
Prohibited materials totals	35,271			35,271		51,566
Deads and Downers Prohibited Materials						
All deads under 500 lbs	2,365	5%	4.5%	106	1.3-53.01	2,065
Feedlot deads	300	90%	90%	270	1.3-53.01	5,239
Beef cow deads	1,050	10%	9%	95	1.3-53.01	1,834
Beef cow downers	350	10%	9%	32	1.3	41
Dairy cow deads	300	60%	60%	180	1.3-53.01	3,493
Dairy cow downers	100	60%	60%	60	1.3	79
Deads and downer totals	4,465	17%	17%	742		12,751
Total - All CMPAF, slaughter and dead and downer animals						64,317

Table 3. Estimated Quantities of Dead and Downer Cattle Rendered, 2002

	Mortalities and Downers			Volume		
	Head	Rendered	Head Rendered	Produced ¹	Rendered	Percent Rendered
Cattle	<i>1,000</i>	<i>Percent</i>	<i>1,000</i>	<i>1,000 lbs</i>	<i>1,000 lbs</i>	
Dairy Cow/Bull	584.55	62.0	364.76	818,370	510,663	
Feedlot	300.00	94.4	283.20	270,000	254,880	
Beef Cow	1,025.75	20.0	205.15	1,025,750	205,150	
Total	1,910.30	44.7	853.11	2,114,120	970,693	45.9
Calves						
Dairy calves	740.43	43.8	324.31	185,107	81,077	
Beef calves	1,625.17	20.0	325.03	406,293	81,259	
Total	2,365.60	27.4	649.34	591,400	162,336	27.4
Total Cattle and Calves	4,275.90	35.1	1,502.45	2,705,520	1,133,028	41.9

1/. Assumes following weights per mortality: Dairy cow, 1400 lbs; Feedlot, 900 lbs; Beef cow, 1000 lbs; calves, 250 lbs

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Table 2. USDA Estimates of Mortality Disposal Methods

	Dairy ^{1,2}		Beef ³	
	Calves	Cows	Feedlots ⁴	Cow/Calf ⁵
Buried	35.3	22.7	5.3	33.5
Burned/incinerated	2.8	2.2	--	34.6
Rendered	43.8	62.4	94.1	20.0
Composted	10.1	6.9	--	--
Landfill	2.4	1.9	0.5	4.9
Other	5.6	3.9	0.1	7.0
Total	100	100	100	100

1/. Source: USDA/APHIS, National Animal Health Monitoring System, Dairy 2002

2/. Percent of operations using each disposal method (only data available)

3/. Percent of mortalities disposed on by each method

4/. Source: USDA/APHIS, National Animal Health Monitoring System, Feedlot 1999

5/. Source: USDA/APHIS, National Animal Health Monitoring System, Beef 1997

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