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 to Prevent the Transmission of Bovine Spongiform Encephalopathy

FINAL RULE

FOOD AND DRUG ADMINISTRATION
April 2008

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I. Description of the Action

The Food and Drug Administration (FDA) is amending its regulations by adding 21 CFR 589.2001 to prohibit the use of certain cattle origin materials in the food or feed of all animals. Cattle materials prohibited in animal feed (CMPAF) under 589.2001 include: (1) the entire carcass of bovine spongiform encephalopathy (BSE)-positive cattle; (2) the brains and spinal cords from cattle 30 months of age and older; (3) the entire carcass of cattle not inspected and passed for human consumption unless these cattle are shown to be less than 30 months of age or the brains and spinal cords were effectively removed or effectively excluded from animal feed; (4) tallow that is derived from BSE-positive cattle; (5) tallow that is derived from the other materials prohibited by this rule that contains more than 0.15 percent insoluble impurities; and (6) mechanically separated beef that is derived from the materials prohibited by this rule.

II. Purpose and Need for Action

The purpose of these new prohibitions and requirements is to strengthen existing safeguards designed to help prevent the spread of BSE in U.S. cattle. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). In addition to BSE, TSEs also include scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and variant Creutzfeldt-Jakob disease (vCJD) in humans. Though extremely rare, the cases of vCJD in the United Kingdom and Saudi Arabia have been scientifically linked to exposure to the BSE agent, most likely through human consumption of beef products contaminated with the BSE agent. The present regulation (21 CFR 589.2000), which became effective in August 1997, prohibits most protein derived from mammalian tissues in ruminant feed because these tissues could potentially contain infectious agents that cause TSEs. As explained more fully in the preamble to the final rule, FDA now believes that the presence in animal feed of certain central nervous system (CNS) tissues, namely brains and spinal cords from older cattle, poses a potential BSE risk to cattle in the United States. The Agency believes that the most effective way to be certain that these tissues are not fed to ruminants is to eliminate them from the animal feed chain. Eliminating this material at the top of the feed chain greatly reduces the opportunity for intentional or accidental exposure of cattle to this material. This final regulation (21 CFR 589.2001) provides the measures industry must take to ensure these tissues do not enter the feed chain.

The definition of CMPAF used in the proposed rule, which was published in the Federal Register on October 6, 2005, has been revised in this final rule. The proposed rule would have required that the brain and spinal cord from all cattle not inspected and passed for human consumption be defined as CMPAF. If the brain and spinal cord were not removed, the entire carcass would have been prohibited in animal feed to prevent BSE. However, in response to the October 2005 proposed rule, FDA received comments on the relatively low risk reduction achieved by excluding such cattle if they were less than 30 months of age and on the feasibility of aging such cattle. FDA considered these comments, the low risk of BSE to U.S. cattle, the strong feed protection provided by the existing ruminant feed rule, and the added secondary level of protection provided by the other provisions of this final rule. Based on these factors, FDA concluded that it was not necessary to include in the definition of CMPAF cattle not inspected and passed for human consumption that are under 30 months of age.

In reaching the decision on which materials should be defined as CMPAF, FDA considered the magnitude of the BSE risk in the United States. The Agency believes that the risk of BSE to U.S. cattle is still very low, despite the recent North American cases. As of September 20, 2006, the United States Department of Agriculture (USDA) has tested 787,711 high-risk cattle under its enhanced BSE surveillance program and has found two positive animals. In September 2006, USDA transitioned to an ongoing surveillance plan under which approximately 40,000 cattle are tested per year.

III. Actions in the United States to Date

In the Federal Register of June 5, 1997 (62 FR 30936), FDA issued a final regulation, with certain exemptions, which provided that animal protein derived from mammalian tissues for use in ruminant feed is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act). The use or intended use in ruminant feed of any material that contains protein derived from mammalian tissues causes the feed to be adulterated and in violation of the act, unless it is the subject of 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 persons representing the animal feed industry, regulatory agencies, consumers, and consumer organizations expressed 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 potential pathways for animal and human exposure to the BSE agent, and the impact of various risk mitigation measures on reducing human and animal exposure. The 2001 assessment 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

was 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 options for strengthening the ruminant feed ban regulation (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 were defined in the rule 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 prohibited 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 ANPRM pertaining to federal measures to mitigate BSE risks and requested comments and scientific information about several options being considered for strengthening feed controls to help prevent the spread of BSE in the United States. Some of the options FDA asked for comment on were removing SRMs from all animal feed, including pet food; requiring dedicated equipment or facilities for manufacturing, transporting, and storing animal feed and feed ingredients; prohibiting the use of all mammalian and poultry protein in ruminant feed; and prohibiting materials from non-ambulatory disabled cattle and dead stock from use in all animal feed.

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 MS 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). USDA published a similar amendment to its interim final rule (70 FR 53043).

On October 6, 2005, FDA proposed to amend its regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals. As proposed, these materials included the following: (1) the brains and spinal cords from cattle 30 months of age and older; (2) the brains and spinal cords from cattle of any age 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 the materials prohibited by this proposed rule that contains more than 0.15 percent insoluble impurities; (5) and MS beef that is derived from the materials prohibited by the proposed rule. These measures were designed to further strengthen existing safeguards designed to help prevent the spread of BSE in U.S. cattle.

On July 25, 2006, USDA's Food Safety and Inspection Service (FSIS) released a new report by the Harvard Center for Risk Analysis. This latest study confirmed the 2001 findings that, with the protective measures that were in place in the United States in 2003, the introduction of BSE would result in limited spread, and the disease would be eliminated over time. Of the

feed-related mitigation measures evaluated, the model predicted that removal of SRMs from animal feed would result in a substantial reduction in the spread of BSE among cattle, and that banning the use of blood products in ruminant feed would have very little impact. Requiring dedicated equipment or facilities, or prohibiting the use of all meat and bone meal (MBM) in ruminant feed, would have only a slight impact because neither measure would eliminate transmissions resulting from on-farm misfeeding.

IV. Current Disposal Methods

In this section, we describe the methods currently available for disposing of cattle mortalities and cattle by-products, provide an estimate of the volume of this material generated in the United States, and an estimate of the percentage of material currently being disposed of by each method. In section V, we discuss how the Agency believes the disposal patterns will change as a result of this final rule and two alternative actions.

- Rendering for animal feed use – By far the most commonly used method for disposing of cattle mortalities and slaughter by-products is to render this material for use in non-ruminant animal feeds. 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, water is evaporated and fats are separated from the protein and bone fractions.

- Landfill – Modern landfills are highly regulated operations constructed with containment systems to protect the environment. While some states prohibit disposal of unprocessed dead animal parts or carcasses in landfills, in most states animal carcasses and slaughter by-products can be sent directly to disposal with no processing. Actual disposal costs could vary substantially, based on local conditions and the landfill's willingness to accept materials.

- Burial – Because it is not as well regulated as landfill, the major concern associated with burial is avoiding groundwater and surface water contamination. Cattle carcasses should be buried away from any surface watercourses, sinkholes, springs, or wells, and buried at appropriate depths. Many states have guidelines and regulations pertaining to the burial of carcasses.

- Rendering for disposal – In this scenario, materials are first rendered into meat and bone meal and tallow to provide volume reduction and stabilization. Instead of using the meat and bone meal in feed, however, it is disposed of by incineration, landfill, burial, used for industrial purposes, or burned for its fuel value. These alternative disposal methods would need to be conducted in accordance with all local, state, and federal requirements.

- Composting – Composting of carcasses is accomplished by adding carbon sources, such as sawdust or straw to create a composting pile that enhances biological decomposition. 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 of spreading 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 can generate considerable community opposition. High temperature incineration can result in complete combustion of solid wastes, resulting in the reduction of air pollutants, odor, and smoke.

Disposal of Cattle Mortalities and Cattle By-Products

Cattle and cattle by-products that are currently being rendered arrive at rendering plants by one of two routes. Apparently healthy animals are sent to slaughter establishments where they are processed into edible products for human consumption. Carcasses condemned on antemortem or postmortem inspection, as well as the inedible by-products of the slaughtering operation, are sent to rendering to be processed for use in non-ruminant animal feed or for industrial purposes. Many of the larger animal slaughtering operations in the United States are integrated with rendering operations. Medium and small slaughter establishments typically rely on independent rendering operations for the processing of waste materials. Carcasses of animals condemned at slaughter establishments may, in some cases, be sent to a landfill if no renderer is available.

Dead and non-ambulatory disabled cattle (defined as cattle that are unable to rise from a recumbent position) are ineligible for slaughter, but may be processed by the rendering or pet food industries after the animals have died, been killed by the owner, or condemned at slaughter establishments. Most deads that are rendered are rendered by an independent renderer, that is, a rendering plant that is not associated with a large slaughter establishment. Independent renderers typically collect and process multi-species raw materials from a variety of sources, including medium and small slaughter establishments, dead stock 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 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 from slaughter establishments where blood is collected.

Many cattle mortalities are not available to the rendering industry. Some portions of the United States are not served by a rendering facility. In these areas, dead animals are commonly disposed of on farms or ranches. Most independent renderers now charge pick-up fees, with amounts varying widely, depending on a variety of factors. Generally, producers located close to rendering plants and those producers who can supply a steady stream of animals pay a smaller fee than producers who have only an occasional carcass to dispose of, or who are located farther away from a rendering plant. Renderers may choose not to pick up the occasional carcass from a distant producer or choose not to pick up decomposed carcasses. Producers may not be willing to pay the collection fee if they believe the fee is too high. Cattle mortalities not collected by the rendering industry are typically disposed of by

the owner via abandonment in the field, on-farm burial (where local environmental regulations allow), placement in landfills, burning/incineration, or composting.

In summary, nearly all slaughter by-products are currently disposed of by rendering the material for use in animal feed. Disposal of carcasses of cattle mortalities, however, is accomplished by a variety of methods. The table below from the 2004 Informa Report provides an estimate of the percentage of dairy and beef cattle mortalities disposed of by each method:

Table 1. 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	0	34.6
Rendered	43.8	62.4	94.1	20.0
Composted	10.1	6.9	0	0
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 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

Estimated Volume of Cattle Slaughter By-Products

In 2005, approximately 6.9 million tons of inedible cattle offal were produced at commercial slaughter plants in 2005. This estimate is based on data showing that 32.4 million head of cattle, with an average live weight of 1,256 pounds per head, were slaughtered in 2005 (NASS 2006), and that offal comprises 34.1 percent of the live weight (Sparks 2001). These slaughter by-products are generally rendered for animal feed use at packer-associated rendering plants, or at independent rendering plants that collect the offal from packing plants.

Share of Cattle Mortalities Currently Rendered

Renderers obtain non-ambulatory disabled cattle and dead stock from large and small farmers and ranchers, dairy farms, and feedlots. Beef and dairy cattle losses are estimated to be 4.2 million head per year (Informa 2005, Eastern Research Group (ERG) 2007). Based on a weighted average of 650 pounds per head (ERG 2007), the weight of cattle mortalities is estimated at 2.7 billion pounds annually. Of this quantity, 1.9 million head (1.2 billion pounds) of cattle mortalities are currently being rendered. The remaining 1.5 billion pounds are being disposed of by non-feed disposal, primarily by on-farm burial, as shown in Table 1.

V. Environmental Consequences

This EA, in addition to presenting the evaluation of the environmental impacts from the final action, also includes an environmental evaluation for two alternative actions. The

alternatives are 1) no action (i.e., no amendment of the FDA regulations) and 2) a total SRM prohibition. Expected environmental impacts resulting from changes in the disposal of material prohibited for use in feed by this final rule or by the alternative action that would prohibit the full list of SRMs from use in animal feed are examined.

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 EA for 21 CFR 589.2000: Prohibition of Protein Derived from Ruminant and Mink Tissues in Ruminant Feeds (FDA, 1996).

The Agency prepared an EA for the October 2005 proposed rule. In the EA, the Agency forecasted that the proposed rule would not significantly reduce the number of on-farm mortalities that are processed by renderers for animal feed use. Since disposal of cattle mortalities by means other than rendering for feed use was thought to be the major source of impact on the environment, FDA also concluded that the effect on the quality of the human environment would not be that great. However, based on comments received, and based on new information gathered by ERG, the Agency now believes that it underestimated how much the proposed rule would reduce the number of cattle mortalities collected for rendering. Had the agency finalized the proposed rule, a revised EA would have reflected a greater environmental impact due to the increase in number of dead stock carcasses that would be disposed of by means other than rendering for feed use.

A. Final Action

This EA focuses on the impacts to the environment of the change in method of disposal of the brains and spinal cords from cattle over 30 months of age, and the change in disposal of carcasses of those cattle mortalities that are not verified to be less than 30 months of age, or from which the brains and spinal cords are not effectively removed or effectively excluded from animal feed. The other requirements of the rule are expected to have very little impact. Specifically, the entire carcass of BSE-positive cattle will not be permitted in animal feed, but based on USDA's prevalence estimate of 4 to 7 BSE-positive cattle in the adult cattle population in the United States (USDA 2006), this source will generate very little volume of material requiring non-feed disposal. Further, new restrictions on use of tallow and MS beef derived from CMPAF are not expected to significantly alter current disposal patterns. With the exception of all tallow derived from BSE-positive cattle that is prohibited from use in animal feed, tallow that might be derived from other CMPAF would be expected to meet the impurity standard, allowing it be used in animal feed. Similarly, pet food manufacturers are expected to meet the requirement in the final rule to first remove CMPAF before subjecting material to the mechanical separation process.

Effect on Disposal of Slaughter By-Products

Slaughter establishments have been routinely removing the brain and spinal cord from cattle over 30 months of age to comply with USDA and FDA regulations that prohibit the use of SRMs for human food. These parts are now commingled with other offal. As explained in more detail later in this document, it is expected that to meet the requirements of this final rule, federal and state inspected slaughter establishments that kill older cattle will modify their animal killing operations to arrange for the separation of brain and spinal cord from other offal and the delivery of the materials prohibited by the final rule to a non-feed disposal

operation. Under the final rule, the remaining offal would continue to be available for rendering into non-ruminant animal feed.

According to the 2007 ERG report, the estimated CMPAF that will be generated by slaughter establishments is a little over 28 million pounds. This quantity is based on ERG's calculations that approximately 18 percent of slaughtered cattle are over 30 months of age, and therefore require that CMPAF be removed. ERG also judged that CMPAF will be removed from a small percentage (estimated at 1 to 5 percent for federally and state-inspected slaughterers) of additional cattle where the slaughterer prefers not to determine (to save on examination costs) or cannot determine an animal's age. The ERG calculations further assume that 1 percent of federally-inspected plants and 5 percent of state-inspected plants lack the capability to remove the CMPAF efficiently, and therefore will remove the skull and spinal column, weighing 53 pounds rather than the brain and spinal cord, which weigh 1.3 pounds. Under the definition of CMPAF, cattle inspected and passed for human consumption under 30 months of age do not generate any CMPAF and their slaughter and disposition would not be affected under this final rule.

Effect on Disposal of Cattle Mortalities

Sources of carcasses that will require non-feed disposal as a result of this final rule will be all types of cattle producers except those whose cattle mortalities are picked up by or delivered to rendering or pet food facilities where either the brains and spinal cords are removed or the animals are verified to be less than 30 months of age. Those rendering and pet food operations that remove the brain and spinal cord so that the remainder of the carcasses of cattle mortalities can be used in animal feed without violating this final rule will have small volumes of material requiring non-feed disposal.

The ERG Report forecasts that the final rule will cause a 26.2 to 41.6 percent decrease in the number of calves and cattle sent to rendering. Based on this assumption, between 369 million and 577 million pounds of material from cattle mortalities previously rendered for animal feed use will be disposed of by some other means when this final rule becomes effective. This estimation is based on assumptions that there will be a significant decrease in collection of cattle mortalities due to higher collection fees, and that about one-half of all mortalities of cattle greater than 30 months of age are too decomposed to allow brain and spinal cord removal. Cattle producers will need to arrange for disposal of these carcasses.

Environmental Consequences of this Final Rule

The Agency believes that an estimated 28 million pounds of slaughter by-products that are currently being rendered for animal feed use will, as a result of this rule, be disposed of by some other means. The rule will also add an estimated 582 - 705 million pounds of cattle mortalities to the 1.5 billion pounds currently being disposed of by means other than rendering for animal feed use. The impact on the environment of diverting 610-732 million pounds of CMPAF from rendering will depend to a large extent on the availability of alternative disposal methods in locations where this material is being generated.

The slaughter by-products portion of the CMPAF will be generated at slaughter establishments that slaughter older cattle. These plants are widely distributed across the United States. It is expected that the disposal of brain and spinal cord materials from slaughter establishments will at least initially occur primarily through landfill. If sufficient material is available or if land filling of unprocessed cattle materials is prohibited or

restricted by regulations, other technologies may be utilized, such as incineration, alkaline hydrolysis tissue digestion, or 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.

The cattle mortality portion of the CMPAF will be generated primarily at beef cow-calf ranches and at dairy farms. These ranches and farms are located throughout the United States. Because beef cow-calf operations tend to be located in sparsely populated areas of the country, the Agency anticipates that the primary means of disposing of mortalities will continue to be burial or burning/incineration, and in the most remote areas, abandonment.

Dairy farms are more likely than beef operations to be located in the vicinity of densely populated areas. Therefore, dairy farms are less likely to have enough land available for on-farm burial. The Agency expects that where space limitations do not permit on-farm burial, disposal of dairy cow mortalities will be by landfill or composting. For both beef and dairy farms, where the volume of available material is high, or where restrictive disposal regulations limit other options, it may be economically feasible for a rendering firm to dedicate a plant to disposal rendering in order to meet new disposal demand.

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 the Animal and Plant Health Inspection Service (APHIS) as a means of disposal of infected or high-risk sheep (57 FR 58130, 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). Many locales prohibit the land filling of raw cattle materials. In such locales, raw cattle materials could be rendered prior to disposal in landfills.

In the USDA interim final rule prohibiting the use of SRM for human food (69 FR 1862), the Food Safety and Inspection Service (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 of in an appropriate manner. Establishments must address their control procedures in their Hazard Analysis Critical Control Points 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.

Environmental Hazards

Land filling of slaughter by-products and cattle carcasses would not be expected to present significant environmental hazards because modern landfills are well-engineered facilities that are located, designed, operated, monitored, closed, cared for after closure, cleaned up when necessary, and financed to ensure 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. 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.

The environmental hazards that could result from the disposal of CMPAF are mainly hazards associated with abandonment, on-farm burial, or improper composting of cattle carcasses. These hazards include environmental contamination and pollution of ground or surface waters, odor production, release of pathogenic microorganisms into environments where susceptible animals or humans could be exposed, or the attraction of mammals, birds, or insects to unprocessed animal tissues. Wildlife may be exposed to the BSE agent via the carcasses of dead cattle that have been disposed of on-farm. The consequences of wildlife exposure are not known and have not been studied, to the Agency's knowledge.

It is expected that environmentally sound disposal of CMPAF may be difficult in localized areas of the country if a combination of conditions existed. As previously mentioned, only 1.9 million of the estimated 4.2 million calf and cattle mortalities are currently being rendered, meaning that 2.3 million head are being disposed of primarily by abandonment in the field, on-farm burial, and composting. FDA is not aware that current levels of non-feed disposal of dead stock cattle are causing serious environmental concerns. The addition of 500,000-800,000 head (26.2-41.6% reduction in the number rendered) to the number not rendered, as a result of this final rule, could be expected to pose environmental concerns under certain circumstances. Scenarios in which the environment could be adversely affected are more likely in areas of the country where 1) older cattle are concentrated, 2) rendering is currently being used extensively for disposal of cattle mortalities, and 3) rendering of mortalities is discontinued, either on the part of the renderer or because of unwillingness of producers to pay higher collection fees. This scenario would also require that other disposal options be unavailable. This could be the situation where local landfills do not have the capacity to handle the additional burden, or where the landfill operators or state or local regulations do not permit landfill of unprocessed animal products. Alternative means of disposal could also be limited in areas of the country where the soil is not suitable for carcass burial.

The Agency believes that sufficient time will be allowed before implementation of the rule to allow mitigation measures, described in the mitigation section, to be put in place that could alleviate much of the adverse environmental impacts.

B. No Action Alternative

Had FDA decided to take no action to amend the current rule at 21 CFR 589.2000, there would likely be little change in environmental impacts from the current situation. Disposal of slaughter by-products and cattle mortalities would likely continue unaffected. Almost all slaughter by-products would be disposed of by rendering for animal feed use. Approximately 45 percent of cattle and calf mortalities would be disposed of by rendering for animal feed use, while the remainder would be divided between on-farm burial, landfill, burning/incineration, composting, or abandonment in the field. The Agency is aware of claims by the cattle industry that there has been a gradual decline in pick up of livestock mortalities because of declining profitability to independent renderers for operating collection routes. FDA has no data to support this assertion, but if it is correct, then it would mean that non-feed disposal of cattle mortalities could be expected to increase somewhat, even if FDA takes no action. Further, it is reasonable to expect that fuel costs could influence collection fees, so that collection of cattle mortalities could be expected to decline when fuel prices increase.

C. Full SRM Ban Alternative

In both the July 2004 ANPRM and the October 2005 Proposed Rule, FDA requested comment on the option to prohibit a larger list of cattle tissues (the full SRM list) from use in all animal feeds. Under this option, SRMs would be defined as the skull, brain, eyes; spinal cord, trigeminal ganglia, 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 all cattle over 30 months of age, and the tonsils and distal ileum of all cattle regardless of age. Additionally, this option would prohibit the small intestine of all cattle, all material from nonambulatory disabled cattle, all material from cattle that are not inspected and passed for human consumption, and MS beef. Lastly, tallow derived from other prohibited materials and containing more than 0.15 percent insoluble impurities would also be prohibited from use in all animal feeds under the full SRM ban option.

Estimated SRM volume

A full SRM ban would require that slaughter establishments separate from other offal approximately 28 pounds of material from each animal less than 30 months of age, and 88 pounds from animals over 30 months of age. According to the 2007 ERG Report, roughly 35.7 million cattle were slaughtered in the United States in 2005, of which 16.6 percent (5.9 million) were cattle over 30 months of age. Based on these figures, a full SRM ban would change disposal patterns of the slaughter industry by removing 1.35 billion pounds (29.8 million head times 28 lbs. per head, plus 5.9 million head times 88 lbs. per head) of SRMs from the stream of inedible material that is currently sent to be rendered for animal feed use.

As mentioned in Section IV of this document, of the 4.2 million head of cattle and calves that die each year in the United States, an estimated 1.9 million are being rendered for use in animal feed. Under a full SRM ban, these cattle mortalities, estimated to weigh 1.2 billion pounds, would have to be diverted from the normal rendering stream and disposed of by some other means.

Impact on Disposal

The Agency anticipates that, under a full SRM ban, a new disposal infrastructure would be developed to handle the large volume of material that could no longer be rendered for animal feed use. ERG (2005a,b) discussed the impact of a full SRM ban with selected rendering industry executives and asked that they forecast the capital investments that would be needed in the event such a ban were promulgated. The executives said that prohibiting a substantial flow of materials from animal feed to prevent BSE might prompt renderers to dedicate some facilities to disposal rendering. However, this would not necessarily mean that the rendering industry would build new rendering plants for the purpose of disposal. Theoretically, since a full SRM ban would not increase the total amount of raw material for disposal, industry capacity would already be adequate to handle both material flows. This forecast did not consider the potential for geographical imbalances between where traditional and disposal rendering plants would be located, and where each type would be needed. Such imbalances could encourage construction of new rendering facilities.

It is expected that for SRMs removed at slaughter, disposal rendering would be used where it is available, and where it is not available SRMs would be disposed of primarily by landfill. An analysis by Sparks (2001) found that the cost to slaughter establishments for disposal rendering would be less than the cost for landfill. The report estimated that processing and disposing of materials in landfills would average $105 per ton, whereas fees for disposal rendering would average $60 per ton. Disposal of cattle mortalities under a full SRM ban would also be determined by the availability and cost of disposal rendering. An increase in the number of cattle buried on-farm, abandoned, land filled, composted, or incinerated would be expected in areas where disposal rendering is unavailable.

Environmental Consequences

As with the final action, the environmental hazards associated with the full SRM ban are related to diverting slaughter by-products and carcasses of cattle mortalities from the existing disposal channels. For cattle mortalities, these hazards could be environmental contamination and pollution of ground or surface waters, odor production, release of pathogenic microorganisms into environments where susceptible animals or humans could be exposed, or the attraction of mammals, birds, or insects to unprocessed animal tissues. For slaughter by-products, the hazards would primarily be related to land fill of unprocessed cattle materials.

The volume of material diverted from existing disposal channels would be four times greater for the full SRM ban option than for the actions being taken in this final rule. The full SRM ban would generate 2.6 billion pounds, compared to 670 million pounds for the final action. In areas of the country where the SRMs supply is concentrated and disposal fees are sufficient to offset costs, disposal rendering or biofuel production might be developed such that the adverse impact on the environment may not be that great. However, even after equilibrium, it is unlikely that environmentally sound disposal methods will exactly match the supply of cattle materials that will have to be disposed of by non-feed disposal. Therefore, it is reasonable to expect that the environmental impact of a full SRM ban could be high in some areas of the country.

D. Comparison of Regulatory Options

The volume of cattle by-products that would no longer be recycled in animal feed under various regulatory options is summarized in Table 2. Because the volumes were underestimated in the proposed rule, revised figures from the latest economic analysis are provided in the "revised estimates" column of the table. In the revised estimates, the volume of slaughter by-products expected to be diverted from animal feed is less than the estimated volume in the 2005 analysis. This is because of an assumption in the 2005 analysis that brain and spinal cord would be removed from all cattle slaughtered for human consumption, not just cattle over 30 months of age. The revised analysis assumes that brain and spinal cord will be removed only from the 18% of cattle slaughtered for human consumption that are over 30 months of age. Overall, however, the revised estimates show a substantial increase in the estimated volume of cattle mortalities diverted from animal feed. Under the final rule, the estimated volume of cattle mortalities diverted from animal feed is lower than the revised estimate because the final rule does not require brain and spinal cord removal from cattle mortalities less 30 months of age. Had the Agency decided a full SRM ban was needed to prevent BSE, the volume of material diverted from animal feed use would be approximately four times greater than the estimate for the final rule. Finally, the "no action" column indicates that current levels of slaughter by-products and cattle mortalities will continue to be rendered for animal feed use.

Table 2. Volume of cattle material diverted from animal feed use (million pounds)

	Proposed Rule Oct. 6, 2005	Revised Estimates	Final Rule	Full SRM Ban	No Action
Slaughter by-products	51.6	28.0	28.0	1,355	0.0
Cattle mortalities	12.7	696-947	582-704	1,200	0.0
Total	64.3	724-975	610-732	2,555	0.0

VI. Mitigation Measures

The rendering industry plays an important role in protecting the environment by recycling by-products of the livestock and meat industries. By-products subjected to the rendering process are recycled primarily as animal feed. After careful consideration of a number of options, FDA has concluded that it is necessary to restrict certain materials from being rendered for animal feed use in order to strengthen protections against the continued threat of BSE to U.S. cattle and the potential resulting risk of vCJD in the human population. As previously stated, FDA considered the environmental consequences when deciding which tissues should be diverted from animal feed channels. The Agency believes that, consistent with its responsibility to protect animal and human health, the actions in this final rule are appropriate, and minimize to the greatest extent possible the volume of CMPAF. Proposing to prohibit tissues containing approximately 90 percent of BSE infectivity, rather than the full list of SRMs, provides protection in proportion to the BSE risk in the United States. In

response to comments received that it is scientifically sound to allow cattle not inspected and passed for human consumption that are verified to be less than 30 months of age to be rendered, the Agency further reduced the volume of CMPAF that would be generated, by requiring brain and spinal cord removal only from such cattle over 30 months of age. Based on the average from the estimated ranges in Table 2, this revision is expected to reduce the volume of CMPAF by approximately 179 million pounds per year

Beyond minimizing the volume of CMPAF, the Agency intends to allow time to transition to new disposal methods so that environmental problems can be avoided in those areas of the country that, for example, have high densities of older cattle in combination with inadequate landfill capacity, or in combination with soil that is unsuitable for carcass burial. FDA believes that delaying implementation of the final regulation until 12 months after publication will allow sufficient time for market forces to work to provide new disposal capacity. Dedicated disposal rendering, incinerators, alkaline digesters, and biofuel production units could be put in place where new disposal capacity is needed. Delaying implementation will also allow time to modify state and local regulations to address new disposal requirements. In July 2006, FDA participated in a 2-day disposal roundtable meeting with representatives of other federal agencies, state agencies, and the feed, rendering, livestock, and meat industries, to begin discussions about addressing disposal issues related to this final rule. FDA intends to continue to assist with the transition to appropriate disposal of cattle by-products that can no longer be recycled in animal feed.

VII. Summary of Environmental Consequences

The EA has examined the environmental consequences of prohibiting the use in animal feed of brain and spinal cord from cattle 30 months of age and older, and the carcasses of cattle not inspected and passed for human consumption that were either not age verified or from which brain and spinal cord were not effectively removed. Our assessment indicates that, under this final rule, approximately 670 million pounds of cattle by-products that would normally be recycled in animal feed will be diverted to other forms of disposal. In most areas of the country, this change in disposal patterns is not expected to have a large impact on the environment. In some areas of the country, however, adverse environmental impacts could be expected unless new disposal capacity is developed. To allow time for development of new methods of disposal, the Agency is delaying implementation of this regulation for 12 months. We assume that disposal of the materials prohibited in animal feed by the final rule will be disposed of in accordance with local, State, and Federal laws and regulations.

VIII. List of Preparers

Burt Pritchett, a contributor to this document, is a veterinarian in the Division of Animal Feeds at FDA's Center for Veterinary Medicine. Since he joined the Center in February 2000, he has been responsible for providing scientific and technical support for the Center's activities related to animal feed controls for the prevention of TSE diseases. From 1991 until 2000, Dr. Pritchett served as a Veterinary Medical Officer in the Epidemiology and Emergency Programs Staff, and the Office of Public Health and Science, at USDA's Food Safety and Inspection Service, Washington, DC. Before coming to FSIS headquarters, he served for three years as a Supervisory Veterinary Medical Officer in Slaughter Operations in

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Walt Osborne joined FDA's Center for Veterinary Medicine in March 2006 as a Regulatory Policy Analyst. Prior to that, he spent 17 years in FDA's Office of the Commissioner, first as a Consumer Affairs Specialist and then as a Supervisory Policy Analyst. Before joining FDA, Mr. Osborne worked in the private sector for 15 years, serving as the Legal Ethics Advisor at the Los Angeles County Bar Association, and then as an Executive Legal Editor with Commerce Clearing House publishers, specializing in food, drug, and medical devices issues. He holds a Bachelor of Arts (*summa cum laude*) in foreign languages from UCLA, a Masters of Science in Human Resources Management from San Francisco's Golden Gate University, and a Juris Doctorate from Loyola Law School of Los Angeles.

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