FINDING OF NO SIGNIFICANT IMPACT

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

§ 589.2000 Animal Proteins Prohibited in Ruminant Feed

FINAL RULE

FOOD AND DRUG ADMINISTRATION

CENTER FOR VETERINARY MEDICINE

April, 2008

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The Food and Drug Administration (FDA) is amending its regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals. Specifically, 21 CFR 589.2000 is amended and 21 CFR 589.2001 is added. Together, these changes identify cattle materials prohibited in animal feed (CMPAF) as follows: (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 that are 30 months of age or older from which brains and spinal cords were not effectively removed or otherwise 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.

The environmental assessment (EA, attached), prepared by the FDA Center for Veterinary Medicine (CVM) BSE Evaluation Team, for this final rule examines the potential environmental impacts from the final action and also includes an environmental evaluation for two alternative actions. The alternatives are 1) no action (i.e., no amendment or additions to Part 589 of the FDA regulations) and 2) banning the full list

of specified risk materials (SRMs) from use in all animal feed. The full list of SRMs as defined in U.S. Department of Agriculture and other FDA rulemaking includes 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. Also prohibited in animal feed under the full SRM ban alternative would be any materials from non-ambulatory disabled cattle and mechanically separated (MS) beef. Thus, the alternative actions bracket the final rule both in terms of number and quantity of materials prohibited and in terms of potential adverse environmental impacts. Both alternative actions have been requested by different stakeholders in this action.

The EA describes the major routes of disposition of CMPAF and the differences anticipated when compared to the alternative actions. The EA contains revised estimates of the quantity of CMPAF based on new studies conducted since the preparation of the EA for the proposed action in 2005 and discusses the possible effects of the rule on rendering and the alternative methods available for disposal of CMPAF.

The EA estimates 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. This is about one quarter of the quantity that would be diverted under a full SRM ban. For "no action," in the absence of a major outbreak of BSE in the United States, no CMPAF would be diverted from rendering for animal feed. It is not possible, however, to accurately estimate the various environmental impacts of "no action" should this alternative prove inadequate to prevent significant spread of BSE. The impact of new feed controls needed to regain control after a major increase in the prevalence of BSE could equal or exceed the impact of the full SRM ban.

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 potential BSE infectivity, rather than the full list of SRMs, provides protection in proportion to the BSE risk in the United States.

Beyond minimizing the volume of CMPAF, the Agency intends as a mitigation measure, 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 for 12 months 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. 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 because of the BSE risk.

FDA has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human

environment. Therefore, an environmental impact statement is not required. The evidence supporting this finding is contained in the attached EA, which was prepared under 21 CFR § 25.40 of FDA's environmental regulations and the Council on Environmental Quality's regulations, 40 CFR §§ 1500-1508, implementing the National Environmental Policy Act.

4/23/2008 Bernadette Dunham DVM, PhD.

Date Director, Center for Veterinary Medicine

Attachment: Environmental Assessment, dated April 2008