

**FINDING OF NO SIGNIFICANT IMPACT
AND
ENVIRONMENTAL ASSESSMENT
FOR
SPECIFIED OFFAL FROM ADULT SHEEP AND GOATS**

**CENTER FOR VETERINARY MEDICINE
FOOD AND DRUG ADMINISTRATION
DECEMBER 1993**

FINDING OF NO SIGNIFICANT IMPACT

for

SPECIFIED OFFAL FROM ADULT SHEEP AND GOATS

PROPOSED RULE

The Center for Veterinary Medicine (Center) of the Food and Drug Administration (FDA) has carefully considered the environmental impact of prohibiting the use of specified offal from adult sheep and goats in the feed of ruminants. The proposed action is being taken under 21 CFR 570.38. The effect of the action is that the specified offal will, instead of being processed for use in ruminant feed, be used for other purposes.

Scrapie is a slowly progressive, fatal, neurologic disease affecting a small number of mature sheep and goats in the U.S. The scrapie agent is not fully characterized, but it is believed to be a protein. Studies have shown that the largest amounts of the scrapie agent are present in specified offal (brain, spinal cord, spleen, thymus, tonsils, lymph nodes, or intestines [duodenum to anus, inclusive]) of affected sheep and that the feeding of rendered products from scrapie-infected sheep may have initiated the bovine spongiform encephalopathy (BSE) epidemic in the United Kingdom. The proposed rule will ban the use in ruminant feed of products that are reasonably expected to contain a specified offal from adult sheep and goats (see Figure 2 in the Environmental Assessment). The major purpose of this proposed rule is to prevent the potential spread of scrapie or scrapie-like diseases (such as BSE) to other ruminants.

An estimated 39,682 tons of carcasses from 4-D (dead, dying, diseased and disabled) adult sheep and goats were available for disposal in 1992. Historically, the vast majority of these animals have either been picked up by renderers or disposed of via local burial or placement in a landfill. Survey results show that the percentage of renderers processing dead sheep has declined from 39% in 1985 to 7% in 1990. These results suggest that the percentage of adult 4-D sheep picked up by renderers likely declined after the Animal Protein Producers Industry and the National Renderers Association recommended to their members, in 1989, that they stop rendering adult sheep or sheep offal for sale as meat and bone meal for inclusion in cattle feed.

An estimated 9,281 tons of inedible slaughter products from adult sheep and goats were available for disposal in 1992. Historically, it is believed that the vast majority of all inedible slaughter products have been rendered or otherwise processed for feed or industrial uses. Survey results show that the percentage of renderers processing inedible slaughter products (offal) of sheep has declined from 44% in 1985 to 13% in 1990. These results suggest that the percentage of the inedible slaughter products from adult sheep utilized by renderers has likely declined since the 1989 voluntary ban was implemented by the rendering industry.

It is possible that the proposed rule would cause a further decline in the proportion of 4-D animals and inedible slaughter products that are utilized by renderers/processors. There could be a concomitant increase in the proportion of these materials that are buried on farms, buried in local landfills, and/or incinerated. In analyzing the possible environmental consequences of such a shift, we assume that disposal in landfills and incineration would be subject to environmental laws that would provide adequate protection with regard to environmental contamination by the scrapie agent and any other potentially deleterious substance.

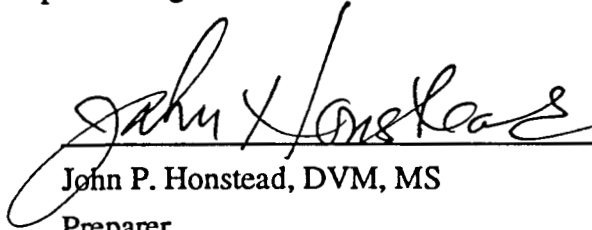
We believe the potential incremental increase in on-farm burial of sheep and goats and any possible concomitant harm to the environment as a result of the regulation would likely be minimal. We assume that on-farm burial might, in some cases, be subject to the same environmental laws as landfills and incineration. Further, on-farm burial of infected or high risk sheep was a recommended means of disposal by APHIS in the indemnity portion of its voluntary scrapie certification program. Finally, the proposed regulation would tend to encourage sheep and goat producers to become certified as scrapie free.

Adoption of the proposed rule should decrease the prospects of BSE occurring in the U.S.; this would have a positive environmental consequence. If FDA adopts the proposed rule and BSE nonetheless occurs undiagnosed in the U.S., there is a possible increased exposure to wildlife (predators/scavengers), the consequence of which is not known. If BSE is diagnosed, there is likely to be a marked increase in on-farm disposal of animals with a concomitant increased exposure to wildlife. These environmental effects are likely to be less pronounced, however, than if the agency did not adopt the proposed rule.

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

Dec 22, 1993

Date




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Dec. 17, 1993

Date



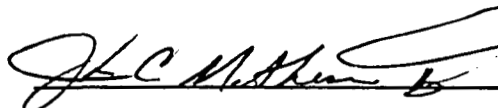
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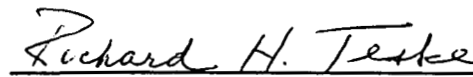
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Attachment: Environmental Assessment, dated December 1993