

Consultation concluded that digestive contents and fecal material from livestock or poultry being fed meat and bone meal (MBM) potentially contaminated with BSE should not be used as an ingredient in animal feed.

(Response) In the preamble to the October 2005 proposed rule, FDA provided calculations submitted in comments to the advance notice of proposed rulemaking (ANPRM) that published in the *Federal Register* on July 14, 2004 (69 FR 42288), showing that a cow would need to consume a very large volume of poultry litter to ingest an infectious dose of BSE, assuming that the poultry feed spilled into the litter was formulated with MBM derived from a BSE-infected cow. Based on this analysis, FDA believes that the risk of cattle exposure to an infectious dose of BSE through poultry litter is low. The measures contained in this final regulation should reduce that risk even further because removing CMPAF from all animal feed prevents BSE infectivity from reaching poultry in the first place.

(Comment 15) Several comments disagreed with the need for prohibiting poultry litter in cattle feed if FDA finalizes the proposed measures. Two comments said that there is no scientific basis for prohibiting poultry material in ruminant rations. Another comment pointed out that banning poultry litter would create significant disposal issues.

(Response) As discussed in the response to the previous comment, because the rule prohibits the use of the highest risk cattle-derived materials in all animal feed, FDA agrees that it is not necessary to prohibit poultry litter from being fed to cattle.

(Comment 16) Several comments recommended that dedicated facilities and equipment be required in order to prevent cross-contamination. One comment disagreed, stating that requiring dedicated facilities would force some renderers to discontinue operations.

(Response) As explained in the preamble to the October 2005 proposed rule (70 FR 58570 at 58584), FDA fully expects this final rule to reduce substantially the remaining risk associated with cross-contamination, and therefore does not believe that the rule needs to also require dedicated facilities and equipment.

(Comment 17) One comment suggested a "systems approach" as a substitute for the measures presented in the proposed rule. This approach, according to the comment, would prohibit the entire carcass (except skeletal muscle) of mature dead cattle and the brain and spinal cord of mature

slaughter cattle from all animal feed. It would also prohibit the use of hypobaric (vacuum) rendering for processing inedible ruminant material. The commenter submitted modeling data obtained using the Harvard Risk Assessment model, which showed that this approach is as protective of animal and public health as a complete SRMs ban, while creating a much smaller disposal challenge. According to the modeling results, the "systems approach" and the full SRMs approach would reduce cases of BSE by 97 percent and 99 percent, respectively. FDA's proposed measures would reduce new cases by 40 percent to 63 percent, depending on the effectiveness of brain and spinal cord removal. The comment acknowledged that the "systems approach" would initially create disposal challenges, especially in the dairy sector, but that cost-effective carcass disposal methods could be implemented.

(Response) The difference between the comment's "systems approach" and the approach in this final rule is that the "systems approach" would exclude the entire carcass of dead cattle 30 months of age or older rather than only the brain and spinal cord. As the comment acknowledges, eliminating the rendering option (other than disposal rendering) for disposal of all dead cattle 30 months of age or older may create major disposal challenges in some regions of the country (see "Environmental Assessment" for this final rule, Docket No. 2002N-0273). Modeling results submitted by the same commenter in response to the ANPRM showed that eliminating vacuum rendering contributed very little to the effectiveness of the "systems approach." The agency believes that excluding brain and spinal cord from all cattle 30 months of age or older, and not the complete list of SRMs, is the most appropriate course of action for the United States where the BSE prevalence is low and strong feed controls are already in place.

(Comment 18) Citing the link of BSE cases in Alberta to hypobaric (or vacuum) rendering, one comment recommended that the use of hypobaric rendering be prohibited because it provides no TSE inactivation.

(Response) FDA agrees that the cluster of BSE cases associated with a vacuum renderer in Alberta underscores the concern about the ability of this process to inactivate BSE infectivity. A major advantage of the measures in this final rule over other options considered is that they prevent the highest risk cattle-derived materials from all animal feed,

thereby reducing concerns about vacuum rendering.

(Comment 19) One comment said that FDA should prohibit the use of mammalian protein in feed for food producing animals, and cited the following recent research to support this position:

- Infectious dose may be smaller than previously thought: Attack rate studies in the United Kingdom have demonstrated transmission at a 0.001 gram (g) dose (no reference), 10 times lower than the 0.01 g dose described by FDA in the proposal.

- Repeated low dose exposure: A study in which scrapie was injected into mice (Jacquemot 2005) showed that repeated low doses caused scrapie when a single dose of the same size did not. A second study in which scrapie was administered orally to hamsters (Diringer 1998) showed a higher incidence of scrapie in hamsters receiving repeated doses than in hamsters receiving a single dose.

- Additional organs may be infectious: Disease-specific prion protein (PrP<sup>sc</sup>) was found in the kidney, pancreas, and liver of scrapie infected mice when inflammation was induced in these organs (Heikenwalder 2005). Another study showed PrP<sup>sc</sup> in the urine of scrapie infected mice with kidney inflammation. A third study found PrP<sup>sc</sup> present in mammary glands of sheep with mastitis (Ligios 2005).

- Interspecies barrier may be smaller than previously thought: Some studies have shown interspecies inoculation produced subclinical disease but not clinical disease, suggesting that previously assumed species barriers were not complete (Hill 2000).

(Response) FDA is aware that BSE transmission has been demonstrated at a 0.001 g dose. FDA is also aware of the other recent scientific findings and considered this information as we were developing the final rule. The agency believes that the risks associated with repeated low dose exposure, infectivity in inflamed organs, and unapparent carriers of BSE infectivity are very low. The agency believes the risks of BSE infection are adequately addressed by the 1997 ruminant feed rule and this final rule, and that it is not necessary to prohibit all mammalian protein in feed for food-producing animals.

(Comment 20) One comment noted that species which appear to be resistant may in fact be unapparent carriers and over time could become sources of the BSE agent. Another comment added that failure to detect infectivity in tissues of experimentally infected pigs and chickens might be due to insufficiently sensitive bioassay techniques. Another