

04-047-1  
p9



August 5, 2004

0302 10:06:11 2004

Docket No. 04-047-1  
Regulatory Analysis and Development  
PPD, APHIS, Station 3C71  
4700 River Road Unit 118  
Riverdale MD 20737-1238

RE: Docket N. 2004N-0264, Federal Measures to Mitigate  
BSE Risks: Considerations for Further Action

To Whom It May Concern:

The following comments on the **STRENGTHENED SAFEGUARDS AGAINST BSE ANNOUNCED BY USDA AND HHS ON JULY 9, 2004**, are being submitted by Washington Beef LLC located in Toppenish WA. Washington Beef LLC (WB) is a fed-cattle processor and renderer. WB renders by-products from the slaughter and fabrication processes at its Toppenish plant.

At WB, we appreciate and understand the need for both the FDA and USDA to take steps to help prevent BSE in the United States given the discovery of a single case in a cow in Washington State. We feel that up to this point, both agencies have taken a scientific systems based approach to adopting safeguards. Having said this, we are somewhat taken back by the FDA's advanced notice of proposed rulemaking (ANPRM) regarding the ban of all SRM from animal foods. The current proposed rule, seems to ignore much of the scientific research that has been undertaken up to this point and deemphasizes the current safeguards that are currently in place, primarily the FDA Feed Ban and the increased surveillance plan that has only been in operation for 60-days.

The current proposed rule will have a significant impact upon our operation as well as other processors and renderers. The simple fact of the matter is that most, if not nearly all of the meat and bone meal generated by our rendering facility and others, is ultimately used for feed for other species such as poultry and fish. The subject rules now prohibit the use of certain cattle-derived materials in human food which means that the traditional rendering process will no longer be appropriate for the disposition of Specified Risk Materials (SRMs).

We question the reasoning behind taking such drastic steps without further research given the following facts:

WASHINGTON BEEF LLC  
201 ELMWOOD ROAD  
P O BOX 832  
TOPPENISH WA 97948  
PHONE 509.865.2121 FAX 509.865.2827

RECEIVED  
AUG 10 2004

2004N-0264

C 32

**Lack of Supporting Scientific Information:**

- Inspections and audits conducted by the USDA and others have indicated a 99% compliance rate with the MBM ban for ruminant animals.
- There has been no scientific research conducted to our knowledge that indicates there is an increased risk of BSE incidence by including the distal ileum in animal feeds.
- There is no scientific evidence available indicating that bovine blood or blood products in feed poses a risk of BSE transmission in cattle and other ruminants.
- There is no scientific evidence available that shows tallow derived from the rendering of SRM's, dead stock and non-ambulatory cattle poses significant risk of BSE transmission if the insoluble impurities in the tallow are less than .15%

**Harvard Risk Assessment:**

- A review of the Harvard Risk Assessment report issued in 2001 indicated that the disease rate of BSE had peaked and would eventually be self-extinguishing.
- The assessment also indicated that the US mandatory Feed Ban of 1997 significantly reduced the chances of a significant BSE incidence in the US. A fact that has been reaffirmed by both the USDA and the FDA on numerous occasions.
- The ANPRM cites the Harvard Tuskegee Study of 2003 in stating that the removal of SRM's may result in an 88% reduction in potential exposure of cattle to BSE. However, the ANPRM fails to mention that recent audits by the USDA and others, indicate a 99% compliance rate with the current FDA feed ban, with 1% noncompliance associated with recordkeeping and not cross-contamination. As such, compliance with the feed ban is obviously sufficient to eliminate the chance of BSE transmission. Further removal of SRM's is not required.

**Environmental Consequences:**

- USDA and FDA have failed to consider the impacts on the rendering industry of existing alternative options for the disposition of SRMs. The fact is that at present, aside from rendering SRMs in dedicated facilities and disposing the meat and bone meal generated by SRMs at landfills, there are no other practical options.

- Neither USDA nor FDA has requested comments from the public regarding the disposition of SRM's in landfills. If FDA and USDA have serious concerns about the potential for transmission of BSE through these materials, then it seems logical that they also examine the potential environmental contamination arising from potential BSE contaminated tissues. The volume of materials that would have to be disposed at landfills is overwhelming. Over the last four years, federally inspected slaughter has exceeded 35 million beef animals annually. Assuming that 100 pounds of SRMs is generated with the slaughter of each animal, the beef processing industry will generate close to 1.8 million tons of unprocessed SRMs.
- Prior to implementing this rule, a serious environmental impact study should be done. Included in this study should be alternative means for disposal of SRM's as well as government incentive programs to help pay for them.

#### Financial Consequences:

- We take issue with FDA's position that they need not address the economic consequences of this proposal. FDA is basing this assumption on Executive Order 12866, specifically that the effects of this proposal will not have an economic impact to the economy of over \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition or adversely jobs.
  - As stated above, based solely upon the number of live cattle slaughtered in the US per year, approximately 1.8 million tons of unprocessed SRM's are produced annually. A 25% yield based upon current market values equates to a value of \$230 per ton or \$103 million dollars. This does not include additional losses associated with the transportation and disposal of the product.
  - In addition, it is obvious from these proposed rules that dedicated facilities and transportation equipment will be required to meet the proposed regulations. This added cost should also be evaluated and considered by the FDA as part of their process.
  - It is our understanding that SRM's cannot be effectively removed from dead animals. As such, it is feasible that the entire value of dead stock animals may be lost as a result of this proposed rule. This will have an obvious impact upon the rendering industry. That impact will trickle down until it ultimately reaches farmers and ranchers who rely upon the rendering industry to provide a cost effective means of disposing of cattle that die on the farm. We fear that this proposed rule will remove the economic incentive for rendering companies to provide this service in a cost-effective manner and will ultimately lead to farmers searching for a more economical means of disposing their dead cattle i.e., burying. Aside

from obvious issues with this practice, we fear that the unintended consequence may also be to reduce the population of animals that USDA has targeted for testing. FDA should include this potential added cost when evaluating this proposed rule.

- When considering the cumulative financial effects of these actions, it is inconceivable to conclude that a sector of the economy will not be severely impacted by this rule. In addition, it is obvious that jobs will be lost. As such, we feel that the FDA has erred in their conclusion that the economic impacts of this proposal are insignificant.

Conclusion:

With the help and guidance of the USDA and FDA, our industry has been a leader in establishing preventative practices against the spread of BSE in the United States. Up to this point, these practices have been based upon sound science and have been validated by independent studies such as the Harvard Risk Assessment. Up to this point, we have achieved these successes through cooperative efforts between the governmental regulatory agencies and all segments of the beef industry. Our beef supply has remained safe and the US consumer has shown their confidence in our product through record beef demand. Despite these successes, the USDA and FDA seem now willing to abandon these science-based approaches and appear headed down a path of mandated regulation through hysteria.

We are strongly opposed to this type of regulation and urge that rather than moving forward with implementation of rules that have unintended consequences, and simply do not work, USDA and HHS work with industry to find solutions to these problems prior to implementation of the rules.

We appreciate the opportunity to comment.

Sincerely,

WASHINGTON BEEF LLC



GAYLAND G. PEDHIRNEY  
President

GGP/indb