

## **Is More BSE Regulatory Action Contemplated? Yes!**

With the finding of a BSE case in the U.S. in 2003, speculation has been rampant about what FDA will do with its BSE feed rule (21 CFR § 589.2000). At press time, FDA is reviewing options and reports that no rule has left the agency for outside review. One of the issues delaying matters is USDA's ongoing BSE surveillance initiative. This program is nearing 200,000 tested samples since June 2004 with no further cases uncovered.

On the other hand, Canada has discovered a BSE case in a native cow born after Canadian feed controls were put in place in 1997, the same time U.S. controls were finalized. Canadian officials have correctly noted that the cow was born during a ramping up and education phase of the BSE feed rule. Since Canada exports the majority of its beef, it has lost many markets and led the government to propose fairly draconian BSE rule changes. This is being done in an attempt to recapture those markets and prompt FDA action in the U.S.

The Canadian feed rule proposal would ban all specified risk materials (SRMs) in any feed, and require ingredients statements on feed labels (now an option). This latter proposal without the U.S. concept of "collective terms" would prove very costly to the feed industry by requiring label changes for each and every ingredient change. Canada is also considering further changes, including a requirement for dyeing each feed containing prohibited mammalian protein. Such a stigmatized action would likely "demonize" the proteins and cause a major usage shift without scientific justification.

SRMs are skull, brain, spinal cord, vertebral column, two specific ganglia, and eyes in cattle over 30 months of age and distal ileum (or small intestines) and tonsils from all cattle.

Although FDA is considering an SRM ban similar to that proposed by Canada, several issues seem to be hindering the proposal. One, mentioned previously, is the impressive results from USDA's BSE surveillance as well as the lack of finding other BSE cases. A second hindrance stems from the legal issue of banning an ingredient in species (e.g. swine and poultry) that have not contracted this disease. Thirdly, there is legitimate concern that banning SRMs in all feed will stop on-farm deadstock pickup, thereby losing a large potentially high-risk sampling group. Finally, the potential environmental issues posed by disposing of a large amount of SRM material looms as a major problem.

Public comments by FDA are limited (during rulemaking the agency is prohibited from discussing what it is doing). AFIA knows that several options are being considered and weighed from every vantage point, including environmental, economic and practicality.

When a rule is published, AFIA will prepare well-reasoned comments after collecting information and holding discussions with a wide range of member input groups. However, the rule is likely to have a very short comment period. In the meantime, AFIA advises its members not to make purchasing changes until a final rule is published. Any proposed rule could change, die or be re-proposed before the final rule is published.