TAB 37

AMERICAN FEED INDUSTRY ASSOCIATION

Comments to the Food & Drug Administration Public Hearing
Substances Prohibited From Use in Animal Food or Feed;
Animal Proteins Prohibited in Ruminant Feed
October 30, 2001
Kansas City, MO

My name is Richard Sellers, and I am vice president for feed control and nutrition of the American Feed Industry Association or AFIA. AFIA is the national feed trade association representing feed manufacturers, ingredient suppliers, equipment manufacturers, pet food manufacturers, animal health manufacturers and distributors and other service suppliers to the feed industry. AFIA members manufacture 75% of the primary commercial feed in the U.S. Therefore, AFIA members will be affected by the proposed regulations, and I present these comments on their behalf. More thorough comments will be provided the docket before November 21.

AFIA appreciates the agency offering this opportunity to review the rule and make comments on the current state of science of transmissible spongiform encephalopathies or TSEs. Only by collecting comments and information can the U.S. have the best prevention program. In fact, AFIA believes the risk of BSE in the U.S. is near zero, and that the vigilance and attention to detail by our government and industry have resulted in keeping the U.S. BSE-free for over 16 years.

The three firewalls mentioned by speakers today are very important, and AFIA pledges its continued commitment to 100% compliance with the second firewall which is the feed rule. We continue to support FDA's 100% inspections and believe our continued efforts to educate the industry about complying with this rule is the best risk reduction effort we can take. In fact, the Facility Certification Institute, which was created by AFIA as an independent, third party inspection system, is very much an educational organization designed to certify facilities' compliance with this rule.

AFIA believes the top enforcement priority of the agency should be education, followed by aggressive action against any firm or individual knowingly feeding prohibited protein to ruminants or distributing such material for that use.

The final rule is basically a labeling and recordkeeping rule, and compliance in the latter area of recordkeeping has been nearly perfect. We believe the labeling compliance is more complicated than the inspection numbers released by the agency. We have met with agency officials to express our concerns about the inspection form and inspection reporting. We fully support CVM's efforts to further clarify the compliance issues and its efforts to reduce subjectivity in the inspection form.

AFIA has taken an active role in promoting inspection and compliance with the states and seeking funding for them, where appropriate. We believe all the states should be

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and many are active partners in achieving full compliance with this rule. We urge FDA to fully fund these state inspections.

With respect to the adequacy of the current rule, AFIA believes the rule is adequate and further education and compliance efforts are the most effective way of reducing risk of BSE in the U.S. Such a continued, sustained effort would likely be far more effective in reducing risk than any changes to the current rule. We believe the exemptions in the rule are still scientifically justified. However, there needs to be a regular revisiting of the rule to strengthen it if new risks are identified or to remove restrictions if no longer justified by scientific assessment of risk.

AFIA believes that neither dedicated facilities nor vehicles will preclude all risk. We need full compliance with the current rule, which is dependent on continued extensive education and appropriate enforcement actions. AFIA acknowledges that commingling incidents have occurred. They have been small in number and many are of minor consequence. This low incidence is evidence of the industry's commitment to maintaining a BSE-free U.S.

Regarding licensing of firms to utilize prohibited protein, AFIA believes this would detract from the already limited funds to enforce the current rule. Licensing firms would rob the resources for the more important activities of education and compliance.

AFIA strongly supports the current cautionary labeling statement and does not believe that pet food products (except salvage pet food) should be labeled with this statement. This would confuse consumers, as FDA agreed in the 1997 rule's preamble. Again, FDA should place its efforts in educating the salvage dealers and gaining compliance using measured enforcement.

The recordkeeping provisions in the current rule are required to document compliance with the rule. The long latency period for this disease would require considerable record retention for investigatory purposes. The cost benefit of such a longer time is very high, as little is gained from maintaining records for 5-10 years. Again, education and compliance with rule should be the principal ways of decreasing risk. The agency's rationale for a one-year record retention is as valid now as it was in 1997.

Some may request the agency to change the ingredient listing to require species specific listings. This is a very costly undertaking and would be a reverse step to the 30 years of acceptance and use of collective terms. A much easier task is to look for the cautionary statement required for products containing restricted use protein products. The statement should be a clear and prominent one and one that assist the producer in assuring compliance.

As indicated earlier, the current cautionary statement is adequate. AFIA believes farmers have a clear understanding of the term "ruminants." AFIA is clearly in favor of a continued education campaign which will likely prove more effective in accomplishing the intended protection than expanding the cautionary statement.

AFIA believes the industry definitely needs test methodology that is both sensitive and specific in order to insure compliance and investigate illegal activities. Also, we believe false positive test results increase the perception of violations. AFIA supports the efforts for research in this area.

As mentioned earlier, AFIA created FCI to further educate the industry and certify compliance with this rule. AFIA and FCI believe the agency should demonstrate strong support this effort. FCI filed a draft partnership agreement with FDA yesterday to further enhance FCI's efforts and to recognize the unique nature of a potential formal relationship of the two organizations. This partnership would allow recognition of FCI's certifications and would encourage FDA to shift inspection resources from certified facilities to other compliance and educational activities designed to reduce risk of BSE in the U.S.

AFIA is concerned about the potential for the introduction of BSE into the U.S. via imports. The current inspection process for imports is not adequate and more funds should be directed to preclude the entry of restricted products. There is a real need for the agency to further strengthen this first, important firewall.

AFIA believes the agency has been most diligent in carrying out the responsibilities commensurate with reducing the risk of BSE being established and amplified in the U.S. However, Administration support lagged during the two-year 1999-2000 period as states were unable to secure complete funding for investigations and numbers of inspections were reduced from the first two years. Only after a series of negative media articles appeared earlier this year, did more funds and resources materialize with a new commitment to finish all of the inspections. This commitment was made in 1997 to finish the inspections within the first two years of the inspection program, but resources appeared to be moved to cover other "hot" agency issues.

This "see saw" commitment to the inspection program is unfortunate and unwarranted for an industry which has cooperated with the agency on an ongoing, constant basis for four years. We need these inspection resources; the American people deserve nothing less than the agency's full commitment to preventing this devastating disease from entering the U.S.

AFIA pledges its continuing commitment to a goal of 100% inspections, 100% compliance and assuring the federal/state agencies have the necessary resources to make that happen.

Thank you for the opportunity to submit these comments. I look forward to continuing our education and compliance efforts.

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