



NATIONAL MEAT ASSOCIATION

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August 13, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket Number 2004N-0264; Federal Measures to Mitigate BSE Risks:
Considerations for Further Action

The National Meat Association (NMA) appreciates the opportunity to comment on the Advance Notice of Proposed Rulemaking (ANPR) regarding federal measures to mitigate BSE risks published in the July 14, 2004 *Federal Register*. NMA is a national trade association that has been advocating the interests of the meat industry since 1946. NMA members include packers, processors, and distributors of meat and meat products, including beef and beef products. NMA has also joined in a separate letter of comment with a group which includes associations representing packers, processors, producers and renderers.

The ANPR solicits comments on an international panel of experts' recommendations for the U.S. response to the detection of BSE in an imported dairy cow in Washington State in December, 2003, and on additional measures for meaningful additional public and animal health benefit.

BSE was first identified in the United Kingdom and made a "reportable" disease in the U.S. in 1986. From that date on, USDA has had to be notified of suspect cases. In 1989, the Animal and Plant Health Inspection Service (APHIS) banned the importation of all ruminants and restricted the importation of certain cattle products from the United Kingdom and other countries where BSE was diagnosed. In 1997, the U.S. government prohibited the import of live ruminants and most ruminant products from all of Europe; that same year, FDA prohibited the use of most mammalian protein in the manufacture of animal feeds fed to ruminants.¹

¹ Harvard/Tuskegee Study, Section 2.4.4, pages 41-42.

After the discovery in December 2003 of a cow imported from Canada which tested positive for BSE, USDA's Foreign Animal and Poultry Disease Advisory Committee (hereinafter "Foreign Animal Disease Advisory Committee") requested that an international team review the U.S. response, and designated that international team to act as a Subcommittee of the Foreign Animal Disease Advisory Committee. The international team recommended that Specified Risk Materials (SRMs) be excluded from all animal feed, including pet food, because in its judgment:

"It is probable that other infected animals have been imported from Canada and also possibly from Europe [into the United States]. These animals have not been detected and therefore infective material has likely been rendered, fed to cattle, amplified within the cattle population so that cattle in the U.S.A. have also been indigenously infected."²

The international team's assumption that BSE is circulating in the U.S. cattle herd is contradicted by the failure thus far in government surveillance testing focused on high risk livestock to find a single native case, or to find a North American case in an animal born after the implementation of the feed ban in late 1997.

When the report of the international team was brought back to the Advisory Committee on Foreign Animal Diseases, the Committee found that it could not "adequately resolve the differing BSE risk assessment presented by the subcommittee as compared to the assessment by Harvard University." The Committee noted that, "a major discrepancy exists with the Subcommittee's conclusions that BSE continues to circulate or even amplify in the U.S. and North America, when compared with the Harvard Risk Assessment. The Committee must have this issue of risk resolved prior to completing its recommendations to the Secretary. **"It is imperative that the Secretary has the best available science and more precise risk assessments in order to make appropriate regulatory decisions"** (emphasis in original).³

A principal question asked by FDA in connection with the ANPR is what support exists for the recommendation of the Subcommittee that SRMs should be excluded from all animal feed, including pet food. As explained above, this recommendation is based on the review team's opinion that "infective material has likely been rendered, fed to cattle, and amplified within the cattle population, so that cattle in the U.S.A. have also been indigenously infected."⁴ This premise is contradicted by the risk assessment study conducted for USDA by the Harvard Center for Risk Analysis and the Tuskegee Center

² Subcommittee Report, page 3.

³ Report of the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases; Measures Relating to Bovine Spongiform Encephalopathy in the United States, February 13, 2004, page 2.

⁴ Subcommittee Report, *supra* note 2, at page 3.

for Computational Epidemiology. In the Harvard/Tuskegee Evaluation of the Potential for BSE in the U.S., completed in November, 2001, the authors review the restrictions which have been in place in the U.S. since 1989 on the importation of animals and animal products from the United Kingdom and the restrictions in place since 1991 on importations from Europe, together with U.S. restrictions on the feeding of mammalian protein to ruminants, which have been in place since 1997, and conclude on the basis of a highly sophisticated, probabilistic simulation model that “the U.S. is highly resistant to any introduction of BSE or a similar disease. BSE is extremely unlikely to become established in the U.S.”⁵ The Harvard/Tuskegee work has recently been updated with newly available compliance data, and the new update reaches similar conclusions and results.

The key element which FDA and USDA need to address in implementing regulations to control the introduction and spread of BSE is the basic reproduction rate (R_0), which is the basic analytical measure used by the Harvard/Tuskegee risk assessment study. “If R_0 exceeds unity, the disease will tend to spread. On the other hand, if R_0 is less than unity, the number of cases will tend to decline over time, and ultimately the disease will die out.”⁶ Unity is the situation in which for each animal infected, one additional animal will become infected. If this basic reproduction rate is less than a value of one ($R_0 < 1$), then BSE, if it exists in the United States will be self-extinguishing. Conversely, if R_0 is greater than 1 ($R_0 > 1$) then the disease will amplify and infect increasing numbers of cattle.

Although the review team stated that there may have been amplification of BSE in the U.S., the team cited no specific factual basis for this opinion and premise. On the other hand, the Harvard/Tuskegee team has on at least two occasions evaluated the controls which are already in place in the United States and concluded through statistical evaluation of the scope of these controls and the level of compliance and non-compliance measured by FDA, that any BSE existing in the U.S. should be self-extinguishing and should not amplify.

FDA’s goal should be to propose a set of regulations which will in combination, work to bring R_0 well below a value of 1, while minimizing the economic and environmental impacts of getting to that result. A total ban on the use of SRMs for animal feeding and pet food will have the most intrusive economic and environmental impact, because cattle producers will lose the value of properly regulated SRM utilization, and packers will have to dispose of SRMs by some method with adverse environmental implications, such as landfill or incineration.

⁵ Harvard/Tuskegee Study, *supra*, note 1 at Executive Summary, para. 3.

⁶ Harvard/Tuskegee Study, page 2 at para. 2.

As an alternative to a ban on the use of SRMs in animal feed, FDA should propose maintaining the present ban on the use of mammalian protein in ruminant feeds and add other elements, which will further moderate the coefficient of reproducibility ($R_0 < 1$). For example, FDA could tighten its compliance requirements so that SRMs could only be distributed and used by persons licensed by FDA, who agree to maintain detailed records of use and be subject to federal, state and third-party audits of their records. Other options which would tend to moderate the coefficient of reproducibility ($R_0 < 1$) include banning the feeding of plate waste from unknown species and poultry litter.

FDA can effectively comply with the requirements of the Federal, Food, Drug and Cosmetic Act by selecting a set of controls, which in the aggregate will comfortably achieve the progressive elimination of any BSE which may exist in the United States, while mitigating economic and environmental harm. FDA does not have authority to impose controls that exceed public health requirements, where those controls will cause economic and environmental harm that could be mitigated by a more sophisticated approach.

Any proposal to ban all SRM use in animal feed would require a Preliminary Regulatory Impact Analysis that assesses the costs and benefits of available regulatory alternatives.

Pursuant to Executive Order 12866, FDA is required to select a regulatory approach that maximizes net benefits, including economic and environmental benefits. In addition, the Regulatory Flexibility Act requires that FDA conduct an Initial Regulatory Flexibility Analysis, which must include "a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities." 5 U.S.C. § 603(c).

NMA is confident that FDA will not propose a rule which would ban all feed use of SRMs, without providing an analysis of other options which can provide an equivalent level of protection with significantly less economic and environmental harm.

Because any BSE rulemaking would have a significant economic impact on a substantial number of small entities, FDA is required to assure that small businesses have an opportunity to participate in the rulemaking. 5 U.S.C. § 609(a).⁷ While one option is to publish an ANPR that includes a statement alerting small entities to the potential impact of the rule on them, FDA's ANPR here did not include such notice. In this regard, it is also noteworthy that the ANPR offered only a 30 day comment period. It is not clear how FDA would assure that the many small businesses that would be affected

⁷ A rulemaking to ban all SRMs in all animal feed would undoubtedly have a significant impact on a substantial number of small entities.

Comments of the National Meat Association
FDA Docket # 2004N-0264
August 13, 2004
Page 5

by a ban on all SRMs in feed would receive notice of a proposed rulemaking in a manner which would allow their meaningful input.

In conclusion, NMA urges FDA to propose a strengthening of the existing feed regulation combined with additional measures to increase factors which cause BSE to be self-extinguishing.

Respectfully Submitted,
National Meat Association