

October 14, 2003

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

Re: Docket No. 2003N-0312; Discussion of Animal Feed Safety System;
68 Fed. Reg. 44,344 (July 28, 2003)

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to submit comments to the Food and Drug Administration (FDA) concerning whether current regulatory programs for feed safety should be strengthened. CSPI is a non-profit public health group that focuses primarily on nutrition and food-safety issues and is supported principally by approximately 800,000 subscribers to its *Nutrition Action Healthletter*.

In the *Federal Register* notice, FDA recognizes that the regulation of animal feed has important implications for human health.¹ To assess the need for and components of a comprehensive risk-based animal feed safety system (AFSS), FDA has raised a series of questions. CSPI submits its comments with respect to one aspect of the feed regulations – the ban on the feeding of protein derived from mammalian tissues to ruminant animals (ruminant feed ban) – which is intended to help prevent bovine spongiform encephalopathy (BSE) in the

¹ 68 Fed. Reg. 44,4344, 44,345 (July 28, 2003).

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United States cattle herd.

1. *Identify weakness in current Federal Regulatory programs for feed safety*

The ruminant feed ban, promulgated by FDA in 1997, is a vital component in the effort to prevent BSE from ever becoming established or spreading through the United States cattle herds and to minimize any public health risk posed if U.S. cattle were ever infected with BSE.² In October 2001, FDA asked whether amendments to the feed ban were needed to reduce the risk of BSE in this country.³ Subsequently, in November 2002, FDA published an Advanced Notice of Proposed Rulemaking discussing potential changes to the feed ban rule.⁴ Despite years of discussion, FDA has yet to take additional regulatory action that would help minimize the public health risk if BSE were to be discovered in the United States. Below, we identify some of the weaknesses in the current animal feed system.

- **The current regulations allow prohibited material, including meat-and-bone-meal (MBM), to be fed to non-ruminants such as pigs and poultry.**

While there is no evidence that pigs and poultry get BSE-like diseases from their food, the problem is that processing ruminants into animal feed opens the door for banned material to inadvertently be fed to cattle. This problem made headlines in January, 2001, when a Texas feedlot inadvertently fed meat-and-bone-meal (MBM) intended for pigs and poultry to more than 1,200 cattle.⁵ A clerk mistakenly mixed the pig-and poultry supplement into the company's cattle feed. Although the meal was produced in the United States from presumably BSE-free

² 21 C.F.R. § 589.2000.

³ 66 Fed. Reg. 50,929 (October 5, 2001).

⁴ 67 Fed. Reg. 67,572 (Nov. 6, 2002).

⁵ FDA News, *FDA Announces Test Results From Texas Feed Lot* (Jan. 30, 2001).

cattle, this demonstrates that the potential exists for inadvertent feeding of prohibited material to cattle as long as MBM can be fed to farmed animals.

- **FDA does not require dedicated facilities for production of feed containing prohibited material.**

In the absence of a complete ban on meat and bone meal in animal feed, the failure to require dedicated facilities to manufacture feed containing prohibited material creates a risk of accidental cross-contamination in those facilities that produce both feed with prohibited material and feed with non-prohibited material.

- **There is no mandatory notification requirement for renderers, protein blenders, and feed mills who inadvertently or otherwise sell feed containing prohibited materials without proper labeling.**

Under the ruminant feed ban, renderers and others who manufacture products that contain protein derived from mammalian tissue that are intended for use in animal feed must label that material with a specified warning.⁶ However, anyone who accidentally, or otherwise, sells feed material containing prohibited materials without the proper cautionary labeling is under no obligation to inform the FDA. This represents a significant flaw in the regulatory system, particularly since FDA's inspections of renderers, blenders, feed manufacturers and others are infrequent.

- **The rule does not define "routine" testing for purposes of exemptions**

When the FDA developed the ruminant feed rule, it provided an exemption from the labeling and recordkeeping requirements for renderers who "routinely" use a test method validated by the FDA to detect the presence of the agent that causes transmissible spongiform

⁶ 21 C.F.R. §§ 589.2000(c)(1), (e)(1).

encephalopathies (TSEs) in their products.⁷ The rule does not, however, identify what constitutes “routine” testing. As a result, feed could be contaminated by prohibited material but remain undetected for a significant period of time by a renderer who performs “routine” testing on an infrequent basis.

2. *Identify the components that should be included in a risk-based AFSS*

● **Implement mandatory HACCP systems for the production of animal feeds**

The feed industry should be required to develop hazard analysis and critical control points (HACCP) or best management practices that are put into regulatory form. Process controls are a necessary element for feed safety. Implementation of HACCP programs would help assure that systems and process controls -- such as clean-out and flushing procedures -- are really working to prevent cross-contamination and accidental mixing. HACCP records should be fully available to the government upon inspection. Firms should also be required to conduct ongoing verification demonstrating that their systems are working properly to prevent commingling and accidental contamination.

● **Amend the feed ban rule to prohibit MBM in all animal feed**

The only way to ensure that mistakes will not happen in future, is to ban meat-and-bone meal to all farmed animals, not just feed for ruminants.⁸ A Working Group of the European Union’s Scientific Steering Committee has concluded that the evidence is “very strong” that the spread of BSE in Great Britain arose from the use of animal feed containing contaminated meat-

⁷ 21 C.F.R. § 589.2000(c)(2)(ii).

⁸ The Animal Feed Industry Association has advocated the voluntary withdrawal of ruminant-derived meat-and-bone meal from facilities that produce feed for ruminant animals. See *Renderers Assure Feed Ban Compliance With Audits*, *Render Magazine* (April 2000), at <<http://www.rendermagazine.com/April2001/Newsline.htm>>.

and-bone meal as a protein source.⁹ Since TSEs, including BSE, are spread through consumption of infected tissue, the feeding of all MBM to farmed animals grown for the production of food should be banned.

- **Amend the feed ban rule to require dedicated facilities for the production, storage and transportation of animal feed containing prohibited material**

If MBM is not prohibited in all animal feed, then the FDA should require dedicated manufacturing, storage, and transportation facilities for animal feed containing mammalian protein since this is the only way to guarantee there is no cross-contamination or commingling with feed for ruminants. Under the current FDA regulation, feed and feed ingredients for ruminant animals may be processed in a facility that also processes prohibited proteins, although the rule requires that those firms handling both prohibited and non-prohibited material must have a system and a written plan to prevent cross-contamination.

The ban on feeding mammalian meat and bone meal to ruminants has been characterized as the “most important measure to prevent the spread of BSE within the cattle population.”¹⁰ While progress has been made in enforcing the rule’s requirements, CVM’s most recent compliance data show that there still are firms whose compliance status is reported as “Official Action Indicated” (OAI).¹¹ In addition, the General Accounting Office has found serious deficiencies in the FDA’s enforcement strategy for feed ban compliance, including a lack of hierarchy of enforcement actions, criteria for actions to be taken, time frames for firms to correct violations and time frames for follow-up inspections to confirm that violations have been

⁹ European Union, Scientific Steering Committee, *Review of the Origin of BSE* (5 July 2001), at p. 5.

¹⁰ Center for Veterinary Medicine, Vol. XVII, FDA Veterinarian, *The Spread of BSE in Switzerland-Epidemiology and Ongoing Eradication of a Challenging Disease* (Sept./Oct. 2002), at p. 6.

¹¹ CVM, *CVM Update on Ruminant Feed (BSE) Enforcement Activities* (Sept. 30, 2003).

corrected.¹²

In the absence of a ban on MBM in all animal food, the feed industry should be required to test every batch of animal feed to confirm that it is free of protein derived from mammals, there has been no unintentional mixing or cross-contamination, and that the feed is, accordingly, properly labeled.

- **Subject renderers to mandatory separation and dedicated facility requirements**

Because renderers receive bovine heads and the heads of others slaughtered mammals, and brain tissue is the most infective part of an animal with clinical TSE, they should be subject to mandatory separation requirements.

Renderers are the first to handle rendered protein and send materials to feed mills and ruminant feeders. Making separation requirements mandatory is especially important since TSE's already exist in some animals in the United States, including deer, elk, and sheep, and renderers could receive such material for processing.¹³

- **Require dedicated transportation of animal feed containing prohibited mammalian protein to decrease the possibility of commingling of feed with non-prohibited material during transport.**

The director of Feed Control and Nutrition for the Association of American Feed Industry Association has indicated that one of the biggest concerns of feed mill operators is whether the hauler has complied with the clean-out and separation requirements of the rule.¹⁴ While a feed

¹² General Accounting Office, Report to Congressional Requesters, *Mad Cow Disease: Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts*, GAO-02-183 (Jan. 2002), at p. 24.

¹³ USDA, APHIS, Background: *Transmissible Spongiform Encephalopathies (TSE)* (July 2000).

¹⁴ FDA, Center for Veterinary Medicine, *A Report on the Questions Asked and Answered on the Air During the June 24 BSE Satellite Conference* (1998), at p. 9, Question 23. <http://www.fda.gov/cvm/index/bse/bsetrans.htm>.

manufacturer can inform the transporter of what is expected, FDA should not rely solely on the feed manufacturers to educate the haulers. The only way to assure that there is no commingling of feeds containing prohibited and non-prohibited material during transportation and that carriers have complied with the clean-out and separation requirements is to impose requirements directly on the hauler, whether truck or rail, to maintain separate facilities. If transportation providers have an obligation to be in compliance with the rule, then the rule requirements should be made directly applicable to them.

- **Implement a Certification Program for all Facilities Handling Prohibited Material**

The FDA should require every facility handling prohibited material to provide an independent audit to the FDA certifying annually that the facility is in compliance with the rule's requirements.¹⁵ Firms that fail to submit a certification would be subject to immediate inspection and possible suspension of registration.

- **Eliminate exemptions or, alternatively, define "routine" testing for the purpose of exempting firms from feed ban rule**

Under the existing rule, firms that conduct "routine testing" for the TSE agent are exempted from the rule's requirements.¹⁶ FDA should eliminate such an exemption since it opens the door for inadvertent contamination of feeds with prohibited materials. Previously, the USDA's Food Safety and Inspection Service exempted raw ground beef producers who conducted their own testing for *E. coli* O157:H7 from government testing requirements.

¹⁵ The Board of Directors of the Animal Protein Producers Industry and the American Feed Industry Association voted in February 2001 to create a self-certification program to ensure compliance with the FDA's mammalian protein feeding ban. See *Renderers Assure Feed Ban Compliance With Audits*, *Render Magazine* (April 200) <<http://www.rendermagazine.com/April2001/Newsline.htm>>. However, only a mandatory certification program will assure effective compliance.

¹⁶ 21 C.F.R. §589.2000(c)(2)(ii).

However, in December, 2002, FSIS eliminated this exemption, recognizing that even firms conducting their own testing were producing *E. coli* O157:H7-contaminated product.¹⁷

Alternatively, the rule should be amended to clarify and define what constitutes “routine” testing for the TSE agent for purpose of the exemption.. In particular, the agency must specify the frequency and appropriate intervals for testing if it is to allow an exemption from the rule’s requirements. At a minimum, such a test method should be conducted on every batch of ruminant feed produced.

- **Require Mandatory Testing or Use of Tracers For The Presence Of Mammalian Protein In Feed Intended For Ruminants**

The regulation should be amended to require all renderers and feed manufacturers who produce ruminant feed to test their material to assure it is free from prohibited substances. Such testing is critical to effective enforcement of the ruminant feed ban. The British government and European Union have adopted a test that differentiates mammalian from non-mammalian tissues to enforce their mammalian-to-ruminant feed ban,¹⁸ and a similar test should be used in the United States to enforce the feed ban.

In addition, FDA should impose testing requirements on transporters of feed. For instance, if MBM is transported in a truck before a load of soymeal is shipped in the same truck, then a sample of the soymeal from the bottom of the truck should be tested.

- **Implement Stricter Rules for Tracing Animal By-Products**

There must be stricter rules for tracing animal by-products used in feed, including the control of movements of specified risk material such as brain and spinal cord, through

¹⁷ 67 Fed. Reg. 62,333 (Oct. 7, 2002).

¹⁸ *The Inquiry Into BSE and variant CJD in the United Kingdom*, Vol. 2: Science, Chapter 5. Diagnosis and Therapy, Detection of Ruminant Protein in Animal Feed Stuff, 5.15 (2000), <<http://www.bseinquiry.gov.uk/report/volume2/chapter2/htm>>.

implementation of record-keeping systems and accompanying documents or health certifications, to assure that tissues likely to contain the BSE agent do not enter the human or animal food chain. The European Union has recognized that the requirement to remove specified high-risk materials, including brain, spinal cord, and retina from sheep, cattle and goats from the human and animal food chains is the single most important protective measure against BSE.¹⁹

- **Require compulsory notification if ruminant feed containing prohibited material has been distributed or sold without proper labeling**

The rule should be amended to provide that if a renderer, feed mill or protein blender learns that it has sold feed containing prohibited materials without proper labeling, it should be required to immediately notify the relevant FDA District Office. As a result, FDA would not have to wait until inspection to determine whether a firm is in compliance or not with the labeling requirement. In addition, FDA should consider new labeling regulations that would require feed manufacturers to specifically list what species are present in the feed.

- **Extend the time period for required recordkeeping**

Under the current rule, each firm subject to the rule and not otherwise exempt is required to maintain records for one year from the date of receipt or shipment of product.²⁰ The requirement to keep records should be extended for a minimum of five years because of the long incubation period associated with BSE (2-8 years). Without purchase invoices, copies of labels from each type of feed bought or sold, or other documents, government inspectors would be hampered in their ability to trace the source of contaminated feed through processing and distribution if it is inadvertently fed to ruminants, or if BSE is discovered in the United States.

¹⁹ European Commission, Press Release, *Commission Approves Further Protection Measures Against BSE*, (7 Feb. 2001).

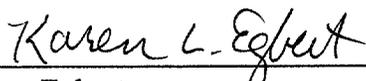
²⁰ 21 C.F.R. § 589.2000(h)(1).

The recent experience in Canada demonstrates that the United States must be prepared to trace the source of any potential infection back to the herd of origin. Indeed, if BSE ever were to be found in U.S. cattle, records concerning what feed was consumed by those cattle would provide a crucial link to finding the source for the contaminated feed and locating other potentially infected cattle. Therefore, recordkeeping requirements should be extended for at least five years or until a mandatory feed-testing regime is implemented. Such information would also be useful for a recall of any contaminated feed.

CONCLUSION

We appreciate the opportunity to comment on the need to strengthen current regulations regulating the animal feed industry. While BSE has never been found in U.S. cattle herds, it is clear that stronger precautionary measures are needed to prevent U.S. cattle from ever being infected and to prevent meat products potentially contaminated with infective tissue from ever posing a serious public health threat. CSPI endorses efforts by the FDA in its efforts to protect the American food supply from the threat BSE and urges adoption of the recommended measures.

Sincerely,



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