CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
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Division of Dockets Management
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RE: Substances Prohibited from Use in Animal Food or Feed
Docket No. 2002N-0273
70 Fed. Reg. 58569 (October 6, 2005)

The Center for the Science in the Public Interest (CSPI) appreciates this opportunity to comment on the Food and Drug Administration's (FDA) proposal to amend the agency's animal feed regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals. CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by the 900,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants.

Under the proposed rule, renderers must keep records demonstrating the absence of prohibited cattle materials in their products as a way to assure compliance with the ban on prohibited cattle materials. We have a number of comments on the proposed rule.

I. A Ban on All SRMs Would Provide Greater Public Health Protection Than The Proposed Partial Ban

The proposed rule bans certain cattle materials, including the brains and spinal cords from cattle 30 months and older, brains and spinal cords from cattle of any age not inspected and passed for human consumption, certain tallow, and mechanically separated beef from cattle, from all animal feed.[1] FDA is failing to ban many high risk cattle parts that are defined as specified risk materials (SRM), or bovine materials that are known to contain prions if an animal is infected with BSE.

[1] 70 Fed. Reg. 58570 (October 6, 2005).

This rule is a far cry from what Secretary Tommy Thompson announced would be done to increase protections against cattle being inadvertently fed prohibited protein. Specifically, Thompson promised to ban the use of mammalian blood and blood products, "poultry litter," and "plate waste" as components of cattle feed. In addition, Thompson said that FDA would "further minimize the possibility of cross-contamination of ruminant and non-ruminant animal feed by requiring equipment, facilities and production lines to be dedicated to non-ruminant animal feed if they use protein that is prohibited in ruminant feed."[2] While the proposed rule takes some important steps to bar the most infectious cattle parts from all animal feed, it hasn't delivered the additional protections promised by Secretary Thompson and the Bush Administration in 2003.

USDA and FDA define SRMs as:

> "brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebra if the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of cattle."[3]

The Scientific Steering Committee of the European Union estimated that the brain accounts for 64.1% of the total infective load per bovine, followed by spinal cord (25.6%), trigeminal ganglia (2.6%), dorsal root ganglia (3.8%), ileum (3.3%), spleen (0.3%), and eyes (0.04%). By excluding only brain and spinal cord from animal feed, only 90% of the total infective load is eliminated. Under the proposed rule, tissues potentially containing 10% of the infective load would remain in animal feed.[4]

While all ruminant material is still barred from cattle feed under the original ruminant feed regulation, the risk of cross-contamination in a feed mill has not been

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[2] Food and Drug Administration, News Release: Expanded "Mad Cow Safeguards Announced to Strengthen Existing Firewalls against BSE Transmission." (January 26, 2004) found at: www.hhs.gov/news/press/2004pres/20040126.html. FDA also recognizes the issue of cross-contamination in the feed mill in its preamble to the proposed rule: "…without fully dedicated equipment, it may not be possible to verify that there is zero carryover of feed or feed ingredients in equipment, even where a firm's clean out procedures have been judged to be adequate." 70 Fed. Reg. 58576

[3] 69 Fed. Reg. 42274 (July 14, 2004)

[4] Office International des Epizooties (OIE), *Joint WHO/FAO/OIE Technical Consultation on BSE: public health, animal health and trade* (Paris, June 11-14, 2001) found at: www.oie.int/esp/publicat/rapports/en_bse%20who-fao-oie.htm (hereinafter OIE Report)

adequately addressed in the proposed rule, nor has the risk that animal feed intended for another species may be fed to cattle.

Cattle of all ages are at risk of BSE infection, which can be transmitted through animal feed containing the remains of infected animals. In addition, animal feed intended for another species can also be easily feed to cattle on a farm or ranch. The typical incubation period for BSE is believed to be from two to eight years.[5] Consequently, sub-clinical infection is possible in cattle under 30 months of age. While it is generally believed that the total infective load of the BSE agent in cattle changes over time and is lower in cattle in the early stages of incubation than in those approaching the end of the incubation period, the pathogenesis of this disease in cattle is not clearly understood. There is still scientific uncertainty about when during the incubation period infectivity appears.

In both Japan and the United Kingdom (U.K.), cattle as young as 21 months have tested positive for BSE.[6] The post-mortem tests currently in use only identify the presence of the BSE agent near the end of the incubation period and do not identify pre-clinical cases at earlier stages of incubation. Thus, even animals that test negative could be harboring infectious prions.

The Harvard Risk Assessment said that "implementation of a U.K.-style ban on specified risk materials . . . from both human food and animal feed reduces the predicted number of BSE cases in cattle by 80% and the potential human exposure by 97%."[7] FDA's proposal clearly does not follow the Harvard Risk Assessment as the U.K. bans SRMs from cattle 12 months old and older. Banning only brains and spinal cord from cattle over 30 months, as FDA proposes, is therefore much less protective than the Harvard estimate of 80%.

In its review of the U.S. response to discovery the BSE-positive cow, the International Scientific Review Panel recommended that the U.S should give "strong

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[5] 69 Fed. Reg. 1861, 1863 (Jan. 12, 2004).
[6] Japanese Food Safety Commission, *Measures against Bovine Spongiform Encephalopathy (BSE) in Japan: Interim report* (September 2004)
[7] USDA, *Harvard Risk Assessment Study* (November 30, 2001), found at http://www.aphis.usda.gov/lpa/issues/bse/bse-riskassmt.html

consideration to excluding all SRM from both the human food and animal feed supplies," particularly since there is epidemiological evidence that the BSE agent was already circulating in ruminant feed prior to the 1997 feed ban.[8] This advice has also been ignored as FDA's proposal would allow all high risk materials from inspected cattle under 30 months to enter the food chain.

The Office International des Epizooties (OIE) reviewed data, including the tissue specific risk calculations from the EU's Scientific Steering Committee, and chose a more comprehensive definition of SRM than the bovine tissues that the FDA proposes to exclude from animal feed. The OIE also recommended that all SRM be "considered for removal and destruction," preventing their entry into the food cycle via animal feed.[9]

Since BSE was first discovered in North America, there has been an effort to create uniform standards between the United States and Canada. As the borders essentially allowed cattle to be traded freely across the border before BSE was discovered, the risk is essentially the same between the two countries. Yet, Canada has proposed barring all SRMs, under the Canadian definition, from animal feed.

In Canada, SRMs are defined as the skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord, and dorsal root ganglia of cattle aged 30 months or older, and the distal ileum of cattle of all ages. According to the CFIA, "these tissues are considered to contain the vast majority of infectivity in BSE-affected cattle (estimated at 99.8%), so removing them from use in animal food removes virtually all potential BSE infectivity. This would maximize the rate at which the incidence of BSE in Canada is reduced and is likely to be well received internationally."[10]

While the CFIA considered an alternative definition, including only the brain and spinal cord of animals over 30 months, they noted that this would result in only 90% of the BSE infectivity would be removed from the food chain, a difference in protection of nearly 10%.

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[8] USDA, Foreign Animal and Poultry Disease Advisory Committee, Subcommittee on the United States' Response to the Detection of a Case of Bovine Spongiform Envephalopathy, *Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States* (February 2, 2004), at p. 5

[9] OIE Report p. 11

[10] Canadian Food Inspection Agency (CFIA), *Information Paper: Development of Specific Regulatory Enhancements to Canada's BSE Feed Controls* (September 2004) p. 6

Since 2001, the European Union has had a total ban on animal protein in feed for animals. These measures resulted in a significant decrease in the number of cases of BSE in the EU since the implementation of these restrictions. [11, 12]

The U.S. is falling behind its global counterparts in BSE prevention. The U.S. allows the use of certain SRMs in cows over 30 month and all SRMs in cows younger than 30 months in animal fee, and a practice banned for the most part in other countries. Canada and EU countries have all opted for more comprehensive regulations to keep BSE prions out of animal feed. The scientific literature and the findings of several scientific steering committees support the need for more stringent prevention-oriented policies. The U.S. should also adopt commensurate standards to reduce the risk of BSE to humans.

To summarize, we oppose the lack of exclusion of all specified risk materials from cattle in animal feed. Including only brains and spinal cords of cattle over 30 months does not provide adequate protection. FDA should strengthen the proposal by banning all SRMs from all animal feed.

II. The Rule Will Be Difficult to Implement in the Absence of a Mandatory Animal Identification System in the United States

A. FDA Should Amend the Rule to Require that All Cattle Carry Specific Identification

FDA recognizes that once material is removed from cattle, it may be unable to determine the source of the material, whether it was from an animal over 30 months of age at slaughter, or whether the animal was inspected and passed.[13] As a result, renderers must rely on records from their suppliers of cattle materials to ensure that the source material does not contain prohibited cattle materials. However, these records are not reliable, due to the absence of a mandatory animal identification system in the United States.

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[11] European Union, *Questions and Answers on the TSE Roadmap (July 15, 2005)* Brussels
[12] European Union, *The TSE Roadmap (July15, 2005)* Brussels
[13] 70 Fed. Reg. 58583.

A mandatory identification system is essential in order to quickly and accurately identify cattle as they move from ranch to feed lot to slaughter facility to renderer. A system could be implemented requiring that no animal be sold or transported without information identifying its place of origin. This information could then be tracked at key points in the agricultural production chain, such as slaughter plants, rendering facilities and feedlots.

Such a system is vital to ensure that the records required by renderers adequately identify the history of the animals that arrive at the rendering facility. A tracking system capable of tracing the origins of an animal back to the farm or ranch is essential to protecting consumers from other threats as well.

B. The Rule Should Impose Specific Record Keeping Requirements

Under the proposed rule, renderers must establish and maintain records "sufficient" to track cattle materials prohibited in animal feed to ensure such material is not introduced into animal feed. We agree with the requirement for renderers to maintain these records and to give FDA officials access to those records. However, the rule does not define what records are "sufficient" for this purpose.

Given FDA's recognition of the difficulty in tracking cattle parts once they are removed from the animal, we believe FDA should require every facility handling cattle materials to provide an independent audit to the FDA certifying annually that the facility is in compliance with the rule's requirements.[14] Imposing a certification requirement as an element of adequate recordkeeping would enhance FDA's ability to enforce compliance with the rule. In addition, we suggest that FDA specify the actual wording of the certification or affirmation in order to avoid ambiguity. This could be similar to the SRM statement that must be typed in the "Remarks" section of the export certificate required for ruminant meat and meat products exported to the E.U.[15]

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[14] We agree with FDA that a national animal identification system should making maintaining information about source animals less burdensome. For that reason, we encourage FDA to work with USDA to implement such a program as soon as possible.

[15] USDA, Food Safety and Inspection Service, Regulations & Policies: *Export Requirements for the European Union* (October 25, 2005), available at < *http://www.fsis.usda.gov/Regulations_ &_Policies/European_ Union_Requirements/index.asp#XI*>.

In addition, as part of their quality (and safety control), renderers should be required to keep records of any checks, tests, or other procedures performed to assure that prohibited cattle materials are kept separate from other cattle materials that can be used for animal food or feed to prevent commingling.[16] Such records should include procedures used to disinfect equipment and sites where prohibited materials are removed, where prohibited materials are kept, and how and when prohibited materials are used or disposed. In addition, renderers should be required to keep records that are sufficient to trace the movement of the prohibited cattle materials.

II. Recordkeeping Should Be Sufficient for Traceback and Recall

FDA recognizes that the records concerning the source of cattle parts used in animal food and feed are important for traceback and recall purposes. Yet, the proposed rule does not include any specific recordkeeping requirements that would assist the agency in conducting a traceback or recall.

For all products produced from cattle parts, renderers should be required to maintain records sufficient to identify the source of cattle parts that are used to make every lot of finished product, so that incoming ingredients can be linked to the outgoing finished products. FDA should require renderers to keep records not only relating to the source of their materials but to the distribution of any products containing cattle parts throughout the food supply chain. At a minimum, these records should include:

- sale and shipping records covering outgoing shipment of product to wholesalers, distributors, and customers, and sale/shipping invoices and records covering incoming shipments from suppliers for the shelf life of the product; and
- records indicating the receipt date of the shipment of source material and what and how much received; and lot number or lot codes received if available.

In addition, renderers should be required to have written plans for notifying FDA in the event of a recall of any animal food or feed that are discovered to contain prohibited cattle materials. Renderers should also have an affirmative duty to notify FDA

[16] According to the National Renderers Association, renderers typically incorporate Good Manufacturing Processes, hazard analysis and critical control point (HACCP), or ISO 9000 in their processes to assure that their products are made in a sanitary and wholesome fashion. National Renderers Association, *North American Rendering: A Source of Essential, High-Quality Products*. Accordingly, renderers could maintain the required records as part of their GMPs or HACCP systems.

where they have information that any animal food or feed may contain prohibited cattle materials.

III. Implement a Three Year Recordkeeping Requirement

FDA has proposed that required records be kept for only one year. We strongly support a longer record-retention requirement and believe that records showing the absence of prohibited materials should be kept for at least three years. Animal feed has a long shelf life, and it is important that records are kept for the natural shelf life of the product. These records would be critically important in the event that FDA needs to conduct a traceback or a recall. These justifications support a longer, three-year record keeping requirement.

CONCLUSION

FDA's proposal lacks several essential protections promised by the Bush Administration in 2003, including requiring equipment, facilities and production lines of feed mills to be dedicated to non-ruminant animal feed if they use protein that is prohibited in animal feed. In addition, FDA has not banned all SRMs from animal feed as recommend by the International Scientific Review Panel, but instead banned only brain and spinal cord in cattle over 30 months. Consequently, animal feed produced in the U.S. would have a greater chance of carrying the infectious agent for BSE than animal feed produced in other countries and regions. The proposed recordkeeping requirements are a necessary part of FDA's efforts to assure compliance with the ban on the use of prohibited cattle materials in all animal food and feed, and to conduct a traceback in the event that potentially contaminated products are distributed in the market place. However, FDA cannot assure compliance unless it considerably strengthens the proposed rule by imposing more specific recordkeeping requirements and a longer three year period for records retention.

Respectfully submitted,

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