

October 12, 2004

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Docket No. 2004N-0081; Use of Materials Derived From Cattle in Human  
Food and Cosmetics; 69 Fed. Reg. 134 (July 14, 2004)**

On behalf of the Center for Science in the Public Interest (CSPI), we appreciate the opportunity to comment on the Interim Final Rule prohibiting the use of specified risk materials (SRMs) for human food and cosmetics. 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 890,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants.

Although beef is regulated by the United States Department of Agriculture (USDA), the issue of SRMs in cattle is an important issue for the Food and Drug Administration (FDA) to address given the multitude of FDA-regulated products containing beef or cattle by-products. Many processed foods, including canned soups, stews, dried sauce mixes, beef bullion and frozen pizzas, contain beef broth or meat. Additionally, some glandular supplements, gelatin-coated capsules, vaccines, and cosmetics, such as lipstick and mascara, are derived from cattle by-products.

Based on the USDA's previous regulation, the FDA has concluded that: 1) the brain,

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skull, eyes, trigeminal ganglia, spinal cord, vertebral column, and dorsal root ganglia (DRG) of cattle 30 months of age and older, as well as the tonsils and distal ileum of the small intestine of cattle of all ages, are unfit for human food and is designating them as specified risk materials (SRMs); 2) mechanically separated beef is unfit for human food; and 3) carcasses of non-ambulatory disabled cattle are unfit for human food and should be condemned at slaughter.<sup>1</sup> The agency has requested comment on whether these measures are the most appropriate for preventing human exposure to the agent causing bovine spongiform encephalopathy (BSE) in the United States now that a BSE-positive cow has been discovered in this country.

While the SRM ban on high-risk organs from cattle 30 months and older would help keep some potentially infective tissues out of FDA-regulated foods and cosmetics, FDA needs to take additional measures to fully protect consumers from the risk of exposure to BSE-causing agents. Given the wide array of products FDA regulates together with the fact that scientists still do not fully understand all of the avenues in which the BSE agent could infect humans, the FDA should provide greater protection in this regulation than is provided by USDA's definition of SRM. Specifically, FDA should expand its definition of SRM to include materials from all cattle older than 12 months and meat obtained from vertebral columns processed with Advanced Meat Recovery (AMR) systems.

#### **1. The List Of SRMs Should Be Extended To Cattle 12 Months and Older**

FDA has designated certain parts, including the vertebral column, spinal cord, and brain from cattle 30 months and older as specified risk material. While this action helps to ensure that high risk materials from older cattle do not enter FDA-regulated products, the interim final rule

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<sup>1</sup> 69 Fed. Reg. 1862-1863 (Jan. 12, 2004); 69 Fed. Reg. 42259 (July 14, 2004).

still allows potentially risky material, including brain, spinal cord, and DRG, from cattle under 30 months to enter these products. The only way FDA can ensure that no bovine materials that can transmit BSE are consumed by people is to designate high-risk materials - including the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column and DRG - as SRMs in all bovines 12 months and older. This action is warranted for several reasons:

- *There is continued scientific uncertainty over the pathogenesis of the disease in cattle*

The typical incubation period for BSE is believed to be from two to eight years.<sup>2</sup> 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 concerning when during the incubation period infectivity appears. In both Japan and the United Kingdom, cattle as young as 21 months have tested positive for BSE.<sup>3</sup>

In addition, 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 Food Safety and Inspection Service (FSIS) has acknowledged these uncertainties, noting that the agent that causes BSE and other TSEs “has yet to be fully characterized,” and that the “distribution and amount of the BSE agent in cattle infected with BSE is not known with certainty.”<sup>4</sup> FSIS also has recognized that the implications of the recent detection of BSE in two

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<sup>2</sup> 69 Fed. Reg. 1861, 1863 (Jan. 12, 2004).

<sup>3</sup> 69 Fed. Reg. at 42259.

<sup>4</sup> 69 Fed. Reg. at 1863.

animals younger than 24 months of age in Japan, “are not readily apparent at this time.”<sup>5</sup>

The lack of scientific certainty was heightened recently when a team of Italian scientists announced the discovery of the existence of another form of mad cow disease, known as bovine amyloidotic spongiform encephalopathy (BASE). According to one expert, this discovery ““opens the possibility of a second strain of the agent in circulation – and that’s probably not good news.””<sup>6</sup>

Given the lack of scientific understanding concerning the pathogenesis of this disease and the possibility of a new strain, FDA’s goal should be to minimize human exposure to all animal materials that could potentially harbor the BSE agent. As long as there is uncertainty, SRMs from cattle over 12 months of age should not be used in FDA-regulated products.

- *Brain and spinal cord, the most infective tissues for the BSE agent, may still enter the food supply through AMR and other mechanical systems*

Many FDA-regulated food products, such as canned soups, stews, and frozen pizzas, may contain small pieces of beef. To minimize the risk from these products, FDA needs to expand the definition of SRMs to include meat recovered from vertebral columns of cattle younger than 30 months processed with Advanced Meat Recovery (AMR) systems. While spinal cord must be removed before the vertebral column enters the AMR system, FSIS has acknowledged that removal of the spinal cord does not always ensure that spinal cord will not be incorporated in the final product, particularly when a carcass is mis-split.<sup>7</sup>

FSIS’s own testing data shows that spinal cord and DRG continue to be detected in beef

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<sup>5</sup> 69 Fed. Reg. at 1864.

<sup>6</sup> Donald G. McNeil, Jr., “Research in Italy Turns Up a New Form of Mad Cow Disease,” *The New York Times* (Feb. 17, 2004), at A7.

<sup>7</sup> 69 Fed. Reg. at 1866.

AMR products.<sup>8</sup> In its 2002 analysis of bovine AMR products, FSIS found that approximately 35% of finished AMR product samples had unacceptable nervous tissues detected, with 29% of the samples having spinal cord tissue.<sup>9</sup> Follow-up sampling between March and December 2003 found that approximately 33 percent of the samples were positive for CNS tissues, and that 35 percent of the establishments submitting follow-up samples tested positive for CNS tissues in their AMR product.<sup>10</sup> These results demonstrate that plants producing AMR products still are having difficulty keeping CNS tissues out of their AMR products. Potentially infective spinal cord and DRG are likely present in untested AMR product and can enter the food chain. The report by the Secretary's Foreign Animal and Poultry Disease Committee Subcommittee (hereafter the international scientific review panel) also noted that the vertebral column and skull are "not inherently infected, but cannot be separated from dorsal root/trigeminal ganglia or from residual contamination with CNS tissue."<sup>11</sup>

Potentially infective material from cattle under 30 months could also enter FDA-regulated products through edible rendering. In the preamble to the interim final rule, FSIS notes that cattle brains are permitted as human food, as a by-product ingredient in certain processed products, and as a source material in edible rendering, although the products must be properly

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<sup>8</sup> 69 Fed. Reg. at 1866.

<sup>9</sup> FSIS, *Analysis of 2002 FSIS Bovine AMR Products Survey Results* (Feb. 2003), at p. 2.

<sup>10</sup> FSIS, *The Follow-up to the Beef AMR Product Survey of 2002: Follow-up Results and Actions for the Elimination of CNS (Spinal Cord) Tissues from AMR Products Derived from Beef Vertebrae*, at p. 3.

<sup>11</sup> USDA, Foreign Animal and Poultry Disease Advisory Committee, Subcommittee on the United States' Response to the Detection of a Case of Bovine Spongiform Encephalopathy, *Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States* (Feb. 2, 2004), at p. 5 (hereafter International Scientific Review Panel Report, *Measures Relating to BSE in the United States*).

labeled.<sup>12</sup> Bones from the vertebral column of cattle, as well as spinal cord, also are permitted as raw materials in edible rendering where they are turned into products, such as beef broth.

According to USDA's Animal and Plant Health Inspection Service (APHIS), if a TSE agent is present in a rendered product, the continuous rendering process most used in the United States will only reduce infectivity by two logs or less, while batch rendering will reduce infectivity by three logs.<sup>13</sup> Because the BSE agent may survive the rendering process, potentially high risk material from cattle over 12 months should not be recycled to humans through the rendering process.

FDA should follow the lead of the European Union, which has designated the skull, including the brain and eyes, the tonsils, the vertebral column, including dorsal root ganglia and spinal cord, of bovine animals ages over 12 months as specified risk material.<sup>14</sup>

- *Expanding the list of SRMs to cattle 12 months and older is consistent with the recommendations of the International Scientific Review Panel*

In its review of the U.S. response to the finding of the BSE-positive cow, the International Scientific Review Panel recommended that, until aggressive surveillance proves the BSE risk in the United State is minimal, USDA should give "strong 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

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<sup>12</sup> 69 Fed. Reg. at 1865.

<sup>13</sup> 68 Fed. Reg. at 2703 (Jan. 21, 2003) (USDA, APHIS, Advanced Notice of Proposed Rulemaking: *Risk Reduction Strategies for Potential BSE Pathways Involving Downer Cattle and Dead Stock of Cattle and Other Species*). See also The BSE Inquiry: The Report, Volume 13: *Industry Processes and Controls*, 6. Rendering, 6.47. The solvent extraction process used by some renderers may also not inactive BSE and scrapie agents. See DM Taylor, *et al.*, Solvent extraction as an adjunct to rendering: the effect on BSE and scrapie agents of hot solvents followed by dry heat and steam. *Vet Rec.* 143(1): 6-9 (July 4, 1998).

<sup>14</sup> European Union, *Questions and Answers on BSE*, Memo/03/3 (Brussels, 8 Jan. 2002), Annex, Full SRM list. In addition, its has added the skull, brain and eyes, tonsils and spinal cord of sheep and goats as SRM.

1997 feed ban.<sup>15</sup> According to the panel, adoption of a 12-month age cut-off “represents a recognition of the fact that some cattle under 30 months of age may be slaughtered with infectivity present” in high risk tissues such as the brain and spinal cord.<sup>16</sup>

Current U.S. surveillance has not established the true prevalence of the disease in this country. The United States only tests a small portion of all cattle slaughtered in the United States annually and does not conduct random sampling of apparently healthy cattle. Second, current test methods only detect the presence of disease two to three months before onset of clinical disease.<sup>17</sup> In fact, this limitation in current testing methodologies is one reason why FSIS has designated materials from all 30-month-old animals as SRMs even if an individual animal tests negative for BSE.

Because USDA testing and surveillance at this point still cannot demonstrate that the BSE risk in this country is minimal, the FDA should adopt the Review Panel’s recommendation and designate a 12-month age cut-off for SRMs to assure that the highest risk materials do not enter FDA-regulated products.

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<sup>15</sup> International Scientific Review Panel Report, *Measures Relating to BSE in the United States*, at p. 5.

<sup>16</sup> International Scientific Review Panel Report, *Measures Relating to BSE in the United States*, at p. 5.

<sup>17</sup> 69 Fed. Reg. at 1871.

## **2. FDA Needs To Tighten Loopholes in the Interim Final Rules**

- *FDA should expand its SRM definition to include heads of cattle over 30 months and older, and cheek and head meat removed after the skull is fragmented in cattle 12 months and older*

Although skulls from cattle 30 months and older are now considered SRM, FSIS has concluded that head meat, cheek meat, and tongue are not part of the skull and therefore may still be used for human food provided they are not contaminated with SRM.<sup>18</sup>

This loophole opens the way for potentially high risk brain material to cross-contaminate other cattle tissues. In its 2002 Current Thinking Paper, FSIS noted that head or cheek meat may contain CNS materials if the meat is not removed before the skull is fragmented or split. Because of this, FSIS considered prohibiting the use of cheek meat from cattle aged 24 months and older for human food if the meat is not removed before the skull is fragmented or split.

Yet, in FSIS' interim final rule and the FDA's interim final rule, no such requirement is imposed. The only way FDA can ensure that there is no cross-contamination of cheek or head meat with high risk brain material is to designate as SRM the entire head of cattle 30 months and older and cheek and head meat of cattle 12 months and older that is removed after the skull is fragmented.

### ***Conclusion***

The USDA has been inconsistent in choosing an age for cattle at which time SRM restrictions should apply. In 2002, FSIS issued its "Current Thinking" in which it identified 24 months as the appropriate age limit to minimize human exposure to materials that could potentially contain the agent that causes BSE. Even though a BSE-positive cow has now been

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<sup>18</sup> 69 Fed. Reg. at 1868.

discovered in the United States and the scientific understanding of BSE has not significantly changed in the two years since the Current Thinking paper was issued, USDA's interim final rule only adopts a 30-month age cut-off for designating infectious parts as SRMs. Although FSIS previously considered a 24-month age cut-off necessary, it offered no justification of why a 30-month limit is now appropriate to protect public health. Considering USDA's inconsistencies regarding age-specific SRM restrictions, FDA needs to follow the more protective approach outlined in this comment. Specifically, FDA should ban SRMs from cattle 12 months or older from the products it regulates, and ban by-products derived from the heads of cattle over 30 months of age or cheek and head meat from younger cattle taken after the skull is fragmented. FDA's adoption of these additional measures will help prevent potential human exposure to the BSE-causing agent through FDA-regulated products.

Respectfully submitted,



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To Whom It May Concern:

Enclosed are comments on the Interim Final Rule prohibiting the use of specified risk materials for FDA-regulated products (Docket No. 2004N-0081). The Center for Science and the Public Interest appreciates the opportunity to submit these comments.

Sincerely,



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