CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
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U.S. Department of Agriculture
Room 102, Cotton Annex Building
300 12th Street, S.W.
Washington, D.C. 20250-3700

03-038IF
03-038IF-25
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Re: Docket No. 03-038IF; Interim Final Rule on Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems; 69 Fed. Reg. 1874 (Jan. 12, 2004)

On behalf of the Center for Science in the Public Interest (CSPI), we appreciate the opportunity to comment on the Interim Final Rule on meat produced by advanced meat recovery (AMR) systems. CSPI is a non-profit consumer-advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by 800,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants.

CSPI supports FSIS's conclusion that its 1994 rule allowing AMR product to be defined as "meat" and various agency directives will not keep spinal cord and other central nervous system (CNS)-type tissue out of beef and pork product labeled as "meat." We agree that restrictions for CNS-type tissues need to be explicitly stated in the regulations.[1] In the interim final rule, FSIS has therefore modified the definition of meat to provide that it may not include "significant" portions of bone or "any amount of brain, trigeminal ganglia, spinal cord, or dorsal

[1] 69 Fed. Reg. 1874, 1878 (Jan. 12, 2004).

root ganglia (DRG)."[2]

Under the interim final rule, meat may be derived by mechanically separating muscle tissue from the bones of livestock, a process known as advanced meat recovery (AMR). However, the rule specifically bans the use of skulls and vertebral columns of cattle 30 months of age and older in such systems.[3] In the companion Specified Risk Material (SRM) rulemaking, FSIS has designated the skulls and vertebral columns of cattle 30 months and older as SRMs, which means that these parts are considered inedible and cannot be used in AMR systems.[4] If they are used, any product exiting the AMR system is considered adulterated.[5]

Under the interim final rule, the skulls and vertebral columns of cattle under 30 months are still allowed to be used in AMR systems.[6] For AMR product derived from the bones of these cattle, the "presence of CNS-type tissues will render the product misbranded."[7] Thus, for AMR product derived from the bones of these cattle, FSIS still considers the presence of spinal cord and other CNS tissue in AMR product as a mislabeling and not food safety issue. Given that BSE has now been discovered in this country, the rule does not go far enough because it still could allow potentially infected tissues from cattle 12 months and older to become part of AMR product.

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[2] 7 C.F.R. § 301.2(1)(ii).

[3] 7 C.F.R. § 318.24(a).

[4] 69 Fed. Reg. 1861 (Jan. 12, 2004).

[5] 69 Fed. Reg. at 1881.

[6] According to FSIS, it does not believe that AMR systems in this country use skulls.

[7] 69 Fed. Reg. at 1881.

1. *Skulls, Vertebral Columns and Neck Bones From Cattle 12 Months and Older Should Be Banned As Source Material in AMR Systems*

FSIS has justified the 30-month cutoff for designating skulls and vertebral columns as SRMs and banning their use in AMR systems based on age distribution data showing the onset of clinical BSE in cattle in the United Kingdom between 1988 and August 2003. According to this date, 0.01 percent of cattle were less than 30-months of age when testing positive for BSE.[8] Therefore, FSIS has determined that cattle under 30 months of age are less likely to contain high levels of BSE infectivity.

While cattle younger than 30 months may be less likely to contain high levels of BSE infectivity, it does not mean that they may not contain some BSE infectivity. In CSPI's comments on FSIS's Specified Risk Material rulemaking, we identified several reasons why FSIS should extend the list of SRMs to cattle 12 months and older.[9] These include the fact that:

- there is continued scientific uncertainty over the pathogenesis of the disease in cattle;
- cattle as young as 20 months have tested positive for BSE;
- the U.S. testing program has not yet established the true prevalence of the disease in this country;
- post-mortem tests only identify the presence of the disease at the end of the incubation period;
- the most infectious parts of a cow with BSE are the brain and spinal cord, estimated to contain nearly 90% of the total infectivity of the animal, and the dorsal root ganglia (DRG), estimated to contain approximately 3.8% of total infectivity;[10]

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[8] 69 Fed. Reg. at 1875.

[9] The European Union has designated the skull, tonsils, vertebral column, DRG and spinal cord of bovine animals over 12 months as SRM and requires their removal from AMR systems. *See* European Commission, *Questions and Answers on BSE*, Memo/03/3 (Brussels, 8 Jan. 2002), Annex, found at <*http://europa.eu.int/comm/food/fs/bse/bse36en.pdf*>.

[10] 69 Fed. Reg. at 1875.

- lowering the age for designating SRMs would be consistent with the recommendation of the Secretary's Foreign Animal and Poultry Disease Committee Subcommittee (hereafter the international scientific review panel);[11]

- FSIS previously recognized that prohibiting the use of vertebral column from cattle 24 months and older as source material in meat recovery systems would provide a better level of protection against potential human exposure to the BSE agent;[12] and

- FSIS verification testing demonstrates that AMR systems still allow spinal cord into AMR product.

As long as it cannot be demonstrated that an animal is not incubating BSE, SRMs from cattle over 12 months of age should not become part of the human food chain through the AMR process.

2. AMR Systems Still Allow CNS-Type Tissue in Recovered Product

A. Spinal Cord and DRG in AMR-Beef Products

In the interim final rule, FSIS recognizes that "[r]emoval of the spinal cord before the vertebral columns enter the AMR system does not always ensure that spinal cord or dorsal root ganglia (DRG) will not be incorporated in to the final product."[13] For instance, a carcass may be mis-split, which allows a portion of the spinal cord to remain encapsulated in the spinal canal of the vertebral column. In addition, the DRG is not removed along with the spinal cord. FSIS's follow-up to the Beef AMR Product Survey of 2002 shows that approximately 33 percent of

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[11] 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 Subcommittee Report, *Measures Relating to BSE in the United States*).

[12] FSIS, *Current Thinking on Measures That Could be Implemented to Minimize Human Exposure to Material That Could Potentially Contain the Bovine Spongiform Encephalopathy Agent* (updated Jan. 15, 2002), at p. 6, found at <*http://www.fsis.usda.gov/oa/topics/BSE_thinking.htm*>.

[13] 69 Fed. Reg. at 1876.

samples were positive for CNS tissues.[14]

The Harvard Risk Analysis commissioned by USDA concluded that the most important means by which low risk tissue could become contaminated with BSE material is through the use of AMR systems that can leave spinal cord and DRG in the AMR product.[15] In the interim final rule, FSIS agrees that "[t]he presence of spinal cord or other CNS-type tissue in AMR product, that is, in meat, particularly from cattle, represents a potential threat to the public health of the United States."[16]

Given the lack of scientific certainty concerning BSE's pathogenesis, the fact that it has been discovered, albeit rarely, in young cattle, and that compliance testing demonstrates that spinal cord and CNS tissue are still present in AMR beef product, FSIS's responsibility is to minimize the possibility that infective tissue can enter the food supply. The only way FSIS can do this is to ban skulls, vertebral columns and neck bones from cattle over 12 months, not just 30 months and older, from AMR systems. FSIS should not continue to treat the presence of spinal cord and other CNS tissue in beef produced from AMR systems as a mislabeling, rather than food safety, issue.

B. Spinal Cord and DRG in AMR-Pork, Sheep, and Goat Product

In the interim final rule, FSIS also addresses the presence of spinal cord and other CNS-type tissue in AMR product from swine, sheep and goats, providing that the definition of "meat"

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[14] 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.

[15] 69 Fed. Reg. at 1875.

[16] 69 Fed. Reg. at 1877.

cannot include brain, trigeminal ganglia, spinal cord or DRG from these animals.[17] As a result, AMR product containing these tissues is considered mislabeled.

Although there have been no reported cases of BSE-like illness occurring naturally in pigs, it has been produced experimentally by direct inoculation of infected bovine brain tissue into pigs' brains.[18] The possibility of emerging diseases that may be transmitted via infected CNS tissue also warrants keeping these tissues out of the human food supply.

According to the American Meat Institute, U.S. meat companies produce an estimated 45 million pounds of beef using AMR and 141 million pounds of pork using AMR each year.[19] FSIS's survey on pork AMR products has led the agency to believe "that the lack of process control regarding the presence of CNS-type tissues in pork product recovered from AMR systems also may be a concern."[20] Whether a safety or quality issue, consumers would not knowingly consent to eat spinal cord or other CNS tissue.[21] USDA should ban these parts from the food supply.

3. The Inadequacy of Current Testing Demonstrates the Need to Keep Skulls and Vertebrae Out of AMR Systems

The inadequacy of both establishment and FSIS testing also demonstrates the need to keep vertebral columns, neck bones, and DRG out of AMR systems. Under the interim rule, establishments using AMR systems are required to revise their HACCP plans, Sanitation

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[17] 7 C.F.R. § 301.2(1)(ii).

[18] *The BSE Inquiry: The Report*, Vol.11, 4. Advice on Animal Feed, § 4.296.

[19] American Meat Institute, *AMI Fact Sheet: Meat Derived by Advanced Meat Recovery* (Oct. 2002).

[20] 69 Fed. Reg. at 1877.

[21] Sheep in particular may harbor scrapie, a BSE-like illness.

Standard Operation Procedures (SSOPs), or other prerequisite programs to include testing of the product exiting the AMR system. They also must maintain daily records documenting the implementation and verification of the product production process.[22]

FSIS "expects that the establishment will ensure that each production lot is in compliance with the provisions of this regulation."[23] At the same time, the agency has recognized that tests used by most facilities are not as sensitive or specific as FSIS histological testing.[24] Until all establishments using AMR systems adopt sensitive and scientifically valid tests, they will be unable to verify on a routine basis that their systems are in control.

In addition, FSIS verification testing may be inadequate to identify when an establishment's system is not in control. Although FSIS has revised its regulatory sampling program and directs its inspection personnel to take samples on a "routine" basis to verify that spinal cord is not present in the final AMR product, it does not specify the sampling frequency for its inspectors. Accordingly, FSIS testing may not occur on a sufficient frequency to ensure that AMR product does not contain spinal cord or other high risk CNS tissue on a continuing basis.

Finally, even though establishments must maintain daily records documenting the implementation and verification of their production processes and make those records available to inspection program personnel, there is no requirement that establishments report positive samples to FSIS.[25] FSIS can only assure effective oversight of AMR systems and the resulting

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[22] 69 Fed. Reg. at 1882; 7 C.F.R. § 318.24(b).

[23] 69 Fed. Reg. at 1882.

[24] 69 Fed. Reg. at 1882.

[25] 69 Fed. Reg. at 1882; 7 C.F.R. § 318.24(b).

product if it imposes an affirmative obligation on establishments to report samples that yield positives for spinal cord and CNS tissue.

4. High Risk Tissues Should Not be Used in Edible Rendering

Although the rule does not allow AMR-derived products containing spinal cord or other CNS tissue to be labeled as meat, those products still may be used in the edible rendering process to produce foods destined for human consumption, such as beef bouillon. According to FSIS, it "is possible that, when vertebral column bones are used as a source material for products produced from edible rending, spinal cord and DRG could become dislodged from the vertebral bones and incorporated into the final product."[26] Given that BSE has been found in cattle under 30 months, and that an animal may be incubating BSE even if its tests negative, materials with the highest infectivity should be kept out of the human food chain. The only way to assure that high-risk materials such as the skull, spinal cord and DRG are not incorporated into beef products produced from the edible rendering process is to ban the use of skulls and vertebral columns from cattle older than 12 months from AMR systems.

Studies demonstrate that rendering processes may not completely inactivate the infectious agent. According to the United Kingdom's BSE Inquiry, tests have shown that neither the older-style batch atmospheric systems, the newer continuous systems, nor solvent extraction were, or are, capable of completely destroying either the scrapie or BSE agents. More significantly, the report found that "[t]he results of the experiments do not lend themselves, either, to a definitive conclusion on whether the change to continuous systems produced a significant change in

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[26] 69 Fed. Reg. at 1868.

deactivation."[27] FSIS also has noted that the infectious agent is highly resistant to heat, ultraviolet light, ionizing radiation, and common disinfectants that normally inactivate viruses or bacteria.[28]

5. In the Alternative, FSIS Should Strengthen Labeling Requirement on AMR-Derived Products

As set forth above, the most public-health protective approach would be for FSIS to ban the use of skulls, vertebrae and neck bones from cattle over 12 months of age in AMR systems. If FSIS does not take this action (including designating these materials as SRMs in cattle over 12 months), then it must take other action to protect consumers. In particular, it should strengthen requirements for labeling ARM-derived beef and pork products by requiring labels that advise consumers that the products may contain central nervous system tissue. Indeed, this is one of the recommendations made by the General Accounting Office in its report on improvements necessary to strengthen U.S. BSE-prevention and protection efforts.[29]

In response to that recommendation, USDA acknowledged its support for providing consumers with information on product contents and "for an open process that allows consumers to make choices."[30] However, at that time USDA stated that it did not believe labeling and warning statements were necessary since BSE was not in the United States. Now that it is, such labeling requirements are necessary and appropriate to, as the GAO stated, "allow American consumers to make more informed choices about the products they consume," as well as

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[27] *The BSE Inquiry: The Report, Volume 13: Industry Processes and Controls*, 6. Rendering and inactivation of BSE.

[28] 69 Fed. Reg. at 1863.

[29] General Accounting Office, *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. 38

[30] GAO, *Mad Cow Disease*, at p. 39.

"facilitate more timely removal of products that could pose a health risk if BSE were to appear."[31]

Conclusion

Although FSIS has taken some steps toward controlling the potential for high-risk materials, including brain and spinal cord, to enter the human food supply, additional action is needed. In particular, FSIS should ban the use of vertebral columns and skulls from cattle over 12 months of age from AMR systems. Alternately, the agency should require revised labeling on AMR-derived products advising consumers that the product may contain spinal cord and other central nervous system tissue.

Respectfully submitted,

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[31] GAO, *Mad Cow Disease*, at pp. 39, 57.