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Docket No. FSIS-2006-0011
FSIS-2006-0011-7
R-Calf United Stockgrowers of America

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street, SW., Room 102
Cotton Annex, Washington, D.C., 20250

Sent Via Federal eRulemaking Portal

Re: R-CALF USA Comments in Docket No. FSIS-2006-0011E, Harvard Risk Assessment of Bovine Spongiform Encephalopathy (BSE) Update: Notice of Availability and Technical Meeting

Dear Administrator:

The Ranchers-Cattlemen Action Legal Fund – United Stockgrowers of America (R-CALF USA) appreciates this opportunity to submit comments regarding the Harvard Risk Assessment of Bovine Spongiform Encephalopathy (BSE) Update; Notice of Availability and Technical Meeting.

R-CALF USA is a non-profit cattle-producer association that represents 18,000 U.S. cattle producers in 47 states. R-CALF USA's mission is to ensure the continued profitability and viability of independent U.S. cattle producers. The demographics of R-CALF USA's membership are reflective of the demographics of the entire U.S. cattle industry, with membership ranging from the largest of U.S. cattle producers to the smallest. R-CALF USA's membership consists primarily of cow-calf operators, cattle backgrounders, and feedlot owners. Various main street businesses are associate members of R-CALF USA.

I. INTRODUCTION

R-CALF USA is concerned that given the nascent nature of BSE research and the potential impact of this disease on the U.S. cattle industry, the Harvard Risk Assessment of Bovine Spongiform Encephalopathy (BSE) Update (Harvard BSE Update)[1] is too limited in scope and too optimistic in its assumptions to accurately

[1] *Harvard Risk Assessment of Bovine Spongiform Encephalopathy Update, Phase IA*, Joshua T. Cohen, Ph.D., George M. Gray, Ph.D., Harvard Center for Risk Analysis, October 31, 2005.

assess the potential risks associated with the introduction of BSE into the United States.

II. COMMMENTS

A. The Harvard BSE Update Overlooks a Known, Direct Pathway of BSE Infectivity

The Harvard BSE Update, while it analyzes risks of mislabeling, contamination, and misfeeding events associated with feed ban compliance and enforcement, does not address the risks inherent to the feed ban's inadequacies. The Harvard BSE Update is silent on a known risk inherent to the U.S. feed ban – the risk of feeding poultry litter to cattle. This known risk was acknowledged but not addressed in the Revised Harvard Risk Assessment, which recommended that this risk be further investigated.[2] Despite recognition by the Food and Drug Administration (FDA) in 2004 that a ban on the use of poultry litter in cattle feed should be imposed, no such prohibition exists and poultry litter remains exempt from the U.S. feed ban.[3]

The Revised Harvard Risk Assessment stated:

> ". . . [T]he use of chicken litter as a feed supplement could pose a risk (Public Citizen 2001) that should be investigated further. It is possible that cattle-derived protein feed supplements administered to chicken could contain BSE infectivity, and that BSE infectivity could pass through chicken [sic] and become available in cattle feed supplemented with chicken litter."[4]

The omission of any analysis of risk associated with the ongoing practice of feeding poultry litter to cattle, a practice previously recognized by both the FDA and the Revised Harvard Risk Assessment as a pathway of BSE infectivity, is sufficiently profound to render the Harvard BSE Update fundamentally deficient.

The occurrence of mislabeling, contamination, or misfeeding can only occur if handlers knowingly or inadvertently violate the law, and, therefore, the Harvard BSE Update has determined that the frequency of such occurrences should be presumed isolated. This presumption is reflected in the Harvard BSE Update given that the rate factor for the worst case scenario for any of these violations is no higher than 4 percent.[5] However, the potential pathway of BSE infectivity from chicken litter identified in the Revised Harvard Risk Assessment is subject to no such constraints nor can it be afforded any such presumption. The practice of feeding poultry litter is lawful and is ongoing. The risk to cattle from BSE-infected poultry litter should be considered direct and BSE infection should be presumed to occur each time BSE-infected poultry litter is fed to cattle.

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[2] *Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States*, Joshua T. Cohen, Keith Duggar, George M. Gray, Sylvia Kreindel, Harvard Center for Risk Analysis, Harvard School of Public Health, Revised October 2003 (hereinafter "Revised Harvard Risk Assessment"), at 32.

[3] *Expanded "Mad Cow" Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission*, U.S. Department of Health and Human Services, News Release, January 26, 2006.

[4] *Revised Harvard Risk Assessment*, at 32.

[5] *Harvard Risk Assessment of Bovine Spongiform Encephalopathy Update, Phase IA*, Joshua T. Cohen, Ph.D., George M. Gray, Ph.D., Harvard Center for Risk Analysis, October 31, 2005, (hereinafter "Harvard BSE Update") at 18.

Importantly, the Harvard BSE Update found that the most influential assumption in its sensitivity analysis regarding animal feed was the misfeeding rate, which could lead to an R_0 of 1.0 or more with 5% probability if the most pessimistic value is used for the assumption.[6] Given the direct pathway of infectivity associated with the practice of feeding poultry litter to cattle, there is the possibility this pathway could result in the R_0 exceeding 1.0, suggesting a potential for the spread of BSE if it were introduced into the United States.

Because the Harvard BSE Update does not include any analysis of risk associated with the practice of feeding poultry litter to cattle, which poultry litter is acknowledged by the Revised Harvard Risk Assessment as possibly containing BSE infectivity, the Harvard BSE Update is incapable of accurately or otherwise realistically assessing the potential risk associated with the introduction of BSE into the United States.

B. The Harvard BSE Update Understates the Significance of Cross-Contamination in the Spread of BSE

The Harvard BSE Update acknowledges that both it and its predecessor studies suggest ". . . that cross-contamination of MBM and feed production lines is a relatively minor factor in the spread of BSE."[7] This statement suggests that the assumptions underpinning the base case, as well as the variables associated with subsequent sensitivity analyses, all presume that cross-contamination is a relatively minor factor in the spread of BSE. Recent facts, however, show that cross-contamination has been a significant factor in the spread of BSE in Canada.

The recent investigation completed by the Canadian Food Inspection Agency (CFIA) of the 50-month old BSE-infected Canadian cow that died on July 2, 2006, reveals that contamination has likely occurred between ruminant and non-ruminant feed in Canada. The investigation report states:

> Considering the feeding regime on the farm and specific production records reviewed, the most likely source of exposure to BSE infectivity appears to be the heifer ration referred to above, which could have become contaminated by prohibited material from the non-ruminant ration produced immediately before it. Because of incomplete or absent documentation, the possibility of cross-contamination during transportation being a contributing factor could not be ruled out.[8]

Moreover, the CFIA news release accompanying the issuance of the foregoing report additionally stated:

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[6] *Harvard Risk Assessment of Bovine Spongiform Encephalopathy (BSE)*, Slide Presentation, Joshua T. Cohen, Ph.D., July 25, 2006, Slide 45.

[7] *Harvard BSE Update*, at 36.

[8] *Report on the Investigation of the Seventh Case of Bovine Spongiform Encephalopathy (BSE) in Canada*, Canadian Food Inspection Agency, August 24, 2006, available online at http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2006/7investe.shtml.

> Nonetheless, the extremely small infective dose of BSE means that even very limited opportunities for contamination may permit periodic cases. The emergence of such cases is common to almost every country reporting the disease.[9]

This recent evidence shows that the risk of contamination should be considered a significant factor in the spread of BSE. This evidence is further reinforced by the epidemiological investigations conducted for the earlier BSE detections in Canada. The BSE infection of the 71 month-old cow detected in Canada in April 2006 was attributed to cross-contamination of ruminant and non-ruminant feed by the CFIA:

> The findings of this investigation indicate that compliance with the1997 feed ban regulations was largely achieved through adoption of dedicated manufacturing facilities. Despite this, it is evident that opportunities for cross-contamination remained where conveyances and equipment were cross-utilized.[10]

The CFIA also suspected cross-contamination as a factor in the BSE infection of the 69 month-old cow detected in Canada in January 2006:

> However, the findings indicate that a particular calf grower ration could have become contaminated during either manufacture or distribution. Furthermore, investigators could not rule out the somewhat remote possibility of residual pre feed ban materials persisting on the farm.[11]

Cross-contamination was implicated as a source of infection for each of the three Canadian cows detected in 2006 that were born after Canada implemented its 1997 feed ban. Based on the nine BSE cases detected in indigenous Canadian cattle since 2003, cross-contamination was officially implicated as a source of infectivity in a full one-third of all Canadian cases. This fact belies the Harvard BSE Update's conclusion that cross-contamination is a relatively minor factor in the spread of BSE.

To the extent that the base case of the Harvard BSE Update and its predecessor reports are underpinned by the assumption that cross-contamination is a relatively minor factor in the spread of BSE, any output from the models, conclusions, and predictions drawn therefrom will grossly understate the significance of cross-contamination in the spread of BSE, as well as the overall risk that BSE will spread if introduced into the United States.

R-CALF USA is concerned that this erroneous conclusion, perpetuated in this and previous Harvard reports, has the affect of misleading policy-makers into falsely believing that scientific evidence suggests it is unnecessary to require either dedicated facilities or dedicated production

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[9] *BSE Investigation Reaches Conclusion*, Canadian Food Inspection Agency, August 24, 2006, available online at http://www.inspection.gc.ca/english/corpaffr/newcom/2006/20060824e.shtml.
[10] *See BSE in North America*, Latest News, Canadian Food Inspection Agency, available online at http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/bccb2006/5investe.shtml.
[11] *Id.*

lines for plants producing ruminant feed, either in the United States or in countries from which the United States imports cattle and beef.

R-CALF USA recommends that the Harvard BSE Update be revised to reflect that cross-contamination of ruminant and non-ruminant feed in feed production lines is a significant factor in the spread of BSE.

C. The Harvard BSE Update's Prediction that Removing SRMs Reduces Human Exposure by 99 Percent on Average Is Not Supportable

The Harvard BSE Update does not purport to lessen the risk factors associated with any specified risk material (SRM). In fact, the Harvard BSE Update has inputted additional at-risk tissues not previously contemplated by the Revised Harvard Risk Assessment. These new at-risk tissues include tonsils and bone-in cuts of beef from animals 24 months of age or over. Further, the Harvard BSE Update does not purport to change the effectiveness of the SRM removal procedures previously established in the Revised Harvard Risk Assessment. Consequently, the effectiveness of SRM removal should not change from the rate determined in the Revised Harvard Risk Assessment, and if it changes at all, it should be less effective given the addition of new, potentially infectious tissues.

The Revised Harvard Risk Assessment found that:

> Prohibiting the rendering of animals that die, potentially from BSE, prior to being sent to slaughter (*i.e.*, animals that "die on the farm") substantially reduces the potential for contamination of cattle feed, decreasing the average predicted additional cases of BSE following introduction of ten infected cattle by more than 80%. Implementation of a UK style ban on specified risk material (*e.g.*, spinal cords, brains, vertebral columns) from both human food and animal feed reduces the predicted number of additional BSE cases in cattle by almost 90% and potential human exposure by 95%.[12]

The Harvard BSE Update, however, concludes that "Removing high risk tissues, often called specified risk materials or SRMs, from animals over 30 months of age reduces potential human exposure by more than 99% on average."[13] This conclusion is suspect. Because potential human exposure is dependent on the predicted number of additional BSE cases in cattle, and because the United States does not ban SRMs from animal feed, which would minimize infectivity in cattle caused by contamination, mislabeling and misfeeding, it is implausible that SRM removal alone could achieve a higher rate of effectiveness (99%) than that predicted when a more stringent SRM ban, which also includes a ban from animal feed, is in place (95%).

This incongruent finding is heightened by the Harvard BSE Update's related conclusion as to the effectiveness of modeling a "UK style" SRM ban that includes SRMs in cattle over 12 months of age and prohibits SRMs in animal feed. It states in regard to these additional measures, "Our evaluation suggests that this measure would reduce potential human exposure by more than 99%

[12] *Revised Harvard Risk Assessment*, at x.
[13] *Harvard BSE Update*, at 36.

and the number of new cases by 80% relative to the base case."[14] This stands in sharp contrast to the Revised Harvard Risk Assessment's conclusion above that contains a 90% to 95% relationship between the number of additional BSE cases in cattle and a reduction in human exposure. It is counterintuitive that a less effective reduction in additional BSE cases in cattle would improve the effectiveness in reducing human exposure.

Adding even further skepticism for the appropriateness of predicting that SRM removal would reduce human exposure by 99 percent is the recent study completed by the FSIS that evaluated mitigation options using the scientific findings of the Revised Harvard Risk Assessment.[15] The FSIS concluded that the combined SRM and AMR (automated meat recovery) rules implemented by FSIS can reduce human exposure to BSE by about 80 percent.[16]

The three aforementioned studies provide contradictory conclusions regarding what is perhaps the most important question to be asked by policy-makers regarding the level of protection needed to prevent human exposure to BSE. Consequently, FSIS should carefully and thoroughly reexamine this conclusion and provide a full explanation that describes the differing assumptions used in each of the three studies that led to the three different conclusions, as well as a justification for any assumptions used to arrive at a new effective rate for SRM removal.

D. The Harvard BSE Update Omits Significant Scientific Findings Regarding BSE Tissue Infection and Should be Revised

The Harvard BSE Update does not incorporate or mention the additional bovine tissues that researchers have found to harbor BSE infectivity. A German study completed last year by Buschmann and Groshup examined tissues from a cow naturally infected with BSE and found that the facial nerve and sciatic nerve of the BSE-infected cow contained sufficient BSE infectivity to cause BSE infection.[17]

The Animal and Plant Health Inspection Service (APHIS) was previously presented with this study but made a factual error when it improperly discounted its significance in its final rule on the importation of whole cuts of boneless beef from Japan. Therein APHIS stated:

> Given these factors, APHIS has determined that the finding of BSE infectivity in facial and sciatic nerves of the transgenic mice is not directly applicable to cattle naturally infected with BSE. Therefore, we do not consider it necessary to make any adjustments to the risk analysis for this rulemaking or to extend the comment period to solicit additional public comment on this issue.[18]

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[14] *Ibid.*
[15] *See Preliminary Analysis of Interim Final Rules and an Interpretive Rule to Prevent the BSE Agent from Entering the U.S. Food Supply*, USDA Food Safety and Inspection Service, at 47, attached hereto as Attachment A.
[16] *Id.* at 56. 57, attached hereto as Attachment A.
[17] *See* Anne Buschmann and Martin H. Gruschup, *Highly Bovine Spongiform Encephalopathy–Sensitive Transgenic Mice Confirm the Essential Restriction of Infectivity to the Nervous System in Clinically Diseased Cattle*, The Journal of Infectious Diseases, 192:934-42, September 1, 2005, Attached hereto as Attachment B.
[18] *Importation of Whole Cuts of Boneless Beef from Japan*, 9 CFR Part 94 [Docket No. 05-004-2] RIN 0579-AB93, Federal Register, Vol.70 No. 239 (December 14, 2005), at 73906.

It was incorrect for APHIS to state that the infectivity was found in the facial and sciatic nerves of the transgenic mice. The facial and sciatic nerves were harvested from the cow naturally infected with BSE and the transgenic mice, which were used as a bioassay model, developed infectivity from those bovine tissues.[19]

Before FSIS uses the Harvard BSE Update as support for policy decisions that would either relax current BSE mitigations or forestall implementation of proposed mitigations, the recent scientific findings of BSE infectivity in the sciatic nerve and facial nerve of bovines naturally infected with BSE should be fully incorporated and integrated into the Harvard BSE Update.

E. The Harvard BSE Update Assumes that BSE Testing Will Be Used to Enhance Food Safety – A Proposition that is Inconsistent with USDA's Practices and Policies

The Harvard BSE Update suggests that its base case assumes that animals that have reached the clinical stage of disease and display clinical signs consistent with BSE would be tested for the BSE agent, and the carcasses of all animals testing positive would be destroyed.[20] In regard to animals that have reached the clinical stage of the disease, the Harvard BSE Update states, "That is, as is effectively assumed in the simulation, the tissues from such animals could not be used in either human food or in animal feed."[21]

Thus it appears that the Harvard BSE Update relies upon BSE testing as a mitigation measure to support its assumption that the carcasses of all animals that have reached the clinical stage of BSE would be destroyed and completely removed from human food and animal feed, thereby presenting no risk of potential contamination to either human food or animal feed. However, the use of BSE testing as a mitigation measure is inconsistent with USDA's claim recently made in its final rule on the importation of whole cuts of boneless beef from Japan. In that rule, USDA stated, "A statistically and epidemiological valid surveillance plan is crucial to monitoring the success of risk mitigation measures, such as a feed ban, but surveillance is not a mitigation measure."[22]

USDA has even more recently reinforced its position that its BSE testing program is not a mitigation measure. The USDA stated in an agency news release on July 20, 2006:

> BSE surveillance is not a food safety program. Human and animal health is protected by a system of interlocking safeguards, including the removal of specified risk materials - those tissues that studies have demonstrated may contain

[19] *See* Anne Buschmann and Martin H. Gruschup, *Highly Bovine Spongiform Encephalopathy–Sensitive Transgenic Mice Confirm the Essential Restriction of Infectivity to the Nervous System in Clinically Diseased Cattle*, The Journal of Infectious Diseases, 192:934-42, September 1, 2005, Attached hereto as Attachment B.
[20] *Harvard BSE Update*, at 10, 11.
[21] *Id.* at 11.
[22] *Importation of Whole Cuts of Boneless Beef from Japan*, 9 CFR Part 94 [Docket No. 05-004-2] RIN 0579-AB93, Federal Register, Vol.70 No. 239 (December 14, 2005), at 73914.

> the BSE agent in infected cattle, along with the U.S. Food and Drug Administration's 1997 ruminant to ruminant feed ban.[23]

In addition to USDA's opposition to the use of BSE testing for purposes of removing potentially infected carcasses from either human food or animal feed, i.e., as a risk mitigation measure, the USDA Office of Inspector General (OIG) found that their were inherent limitations in the USDA surveillance program in identifying and testing high-risk cattle.[24] The OIG report issued in January 2006 stated:

> The U.S. program is voluntary and sampling is not random. The success of the program depends on the cooperation of industry and a variety of other conditions, including some that differ across geographical areas and other demographic attributes of the U.S. herd. Therefore, compared to the Europeans, USDA exerts less control over which animals can be tested for BSE, and is generally less able to assure that those tested represent the herd, their surveillance stream, or their age group within each surveillance stream.[25]

Due to the combination of the voluntary nature of the USDA BSE surveillance program, along with USDA's opposition to using BSE as a mitigation measure, it cannot be assumed that carcasses of all animals that have reached the clinical stage of BSE would be destroyed and completely removed from human food and animal feed. The use of such an unsupportable assumption would grossly understate the risks associated with carcasses of animals that have reached the clinical stage of BSE.

R-CALF USA recommends that this assumption be revised downward to reflect the fact that the USDA does not use BSE testing to remove potentially infected animals from the food supply and that the voluntary nature of the USDA testing program does not ensure that all animals that have reached the clinical stage of BSE would be tested or otherwise diagnosed with BSE.

F. The Harvard BSE Update's Base Case Overstates The Proportion Of Animals With Clinical Signs That Would Be Detected By Inspectors

R-CALF USA agrees with the recommendations presented by Peer Reviewer 1 regarding the necessity to significantly reduce the assumption that ante-mortem inspectors will detect 90% of animals with clinical signs. As indicated by Peer Reviewer 1, this detection rate is inconsistent with data from the United Kingdom (UK) and the European Union (EU). In addition, this detection rate is inconsistent with data from the cases of BSE detected in indigenous Canadian cattle. Both the Canadian BSE case detected in Canada in May 2003 and the Canadian-origin BSE case detected in the U.S. in December 2003 were presented for, and were slaughtered,

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[23] *USDA Announces New BSE Surveillance Program*, U.S. Department of Agriculture, Release No. 0255.06, July 20, 2006, available online at http://www.usda.gov/wps/portal/usdahome?contentidonly=true&contentid=2006/07/0255.xml.

[24] *Audit, Animal and Plant Health Inspection Service, Bovine Spongiform Encephalopathy (BSE) Surveillance Program – Phase II and Food Safety Inspection Service Controls over BSE Sampling, Specified Risk Materials, and Advanced Meat Recovery Products – Phase III*, U.S. Department of Agriculture, Office of Inspector General, (hereinafter "OIG Audit") at iii.

[25] *OIG Audit*, at 8.

without being identified as suspects at ante-mortem inspection. The CFIA stated in its report of the latter case only that: "Like the first Canadian case, the animal exhibited signs that placed it in one of the surveillance classes recommended by the OIE."[26]

Based on Harvard's response to Peer Reviewer 1 regarding this issue, it appears that Harvard acknowledges that its base case may overstate the ability of ante-mortem inspectors to detect animals with clinical signs for BSE. Harvard suggests that Sensitivity Analysis 5 addresses this issue because it lowers the detection rate to reflect that 50% of ambulatory clinical cases and 25% of non-ambulatory clinical cases are detected. The results of this sensitivity analysis increases the mean number of BSE infections from 180 to 190 animals over 20 years and increases human exposure by about 50%. Harvard suggests that this changed assumption could be applied to other scenarios by increasing the projected human exposure in each by approximately 50 percent.[27]

Given the validation of the concern that the base case overstates the detection rate of animals with clinical signs as well as the substantial increase to projected human exposure resulting from the lower rates, the Harvard BSE Update's base case should, itself, be revised to reflect the lower, i.e., 50% and 25%, rates of detection and the sensitivity analysis should likewise be revised to reflect the possibility of even more pessimistic probabilities. This important revision to the base case will add credibility and realism to the Harvard BSE Update and will prevent potential misunderstandings on the part of policy-makers about the predicted risks of introducing BSE into the United States.

G. The Harvard BSE Update Improperly Assumed a Likelihood of Smaller Exposures to BSE Infectivity than that Evidenced in the United Kingdom

In the closing paragraph of the Harvard BSE Update, the authors offer remarks inferring that the BSE risks identified in the base case may be overstated based on a theory that cattle in the U.S. could be subject to much smaller exposures to BSE infectivity, which would lead to longer BSE incubation periods. Presumably, the theoretical conclusion that BSE incubation periods would be longer in the U.S. than in the UK influenced the development of Sensitivity Analysis 6, which doubled the incubation period from about 50 months in the base case to about 100 months. The Revised Harvard Risk Assessment postulated a median incubation period of 4.2 years, which is comparable to the mean incubation period of 4.2 years calculated from UK data.[28]

The theory that the incubation period would be longer in the U.S. if additional BSE infectivity were to be introduced is contradicted by the incubation periods of the BSE cases detected in Canadian-origin cattle. Of the nine Canadian-origin BSE cases detected since 2003, seven died before reaching the age of 99 months. The ages of these seven cases at death were 50, 69, 70,

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[26] *Canada's Assessment of the North American BSE Cases Diagnosed from 2003 to 2005 (Part II)*, Canadian Food Inspection Agency, January 23, 2006, available online at http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/eval2005/evale.shtml#app.

[27] *Harvard BSE Update*, Appendix 4 – Revisions and Responses to Peer Review Comments, at 7.

[28] *See Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities, Final Rule*, U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Federal Register, Vol. 70, No. 2, January 4, 2005, at 470, 474.

71, 80, 81, and 98 months.[29] The Revised Harvard Risk Assessment references studies that estimate that susceptibility to BSE infection peaks when cattle reach the age of 1.31 years and between 0.5 and 1.5 years of age.[30] Subtracting 12 months from the age of each of the seven Canadian BSE cases referenced above, to factor the period during which these animals may have become infected, reveals potential incubation periods of 38, 57, 58, 59, 68, 69, and 86 months.

Given that over 75% of the Canadian-origin cattle with BSE died before reaching the age of 99 months, and the potential that their incubation periods were likely closer to 50 months than 100 months, the theory that the U.S. should expect a longer BSE incubation period than in the UK is unfounded. The Harvard BSE Update should be revised to eliminate any inference that the risks of BSE may be less than what its base case predicts because incubation periods would be longer in the U.S. than in the UK.

H. The Harvard BSE Update Appears to Incorporate an Industry Practice into the Base Case that is Not Required in the U.S.

The Harvard BSE Update purports to revise the original BSE simulation model used in the Revised Harvard Risk Assessment with the assumption that the SRM ban would apply to dead stock as well as to cattle that went to slaughter. It is unclear if this means that the model would assume that SRMs from dead stock could not be included in the production of non-ruminant animal feed, such as feed for poultry. If the BSE simulation model does adopt this assumption, then the model's output regarding the potential spread of BSE would be understated because the USDA does not ban the use of SRMs from dead stock in the production of non-ruminant animal feed.

The FDA proposed a rule on October 6, 2005 that would ban SRMs obtained from dead stock for use in animal food or feed. [31] However, this proposed rule has not been finalized or otherwise implemented.

The implication of incorporating a ban on the use of SRMs from dead stock for animal feed within the Harvard BSE Update when such a ban is not required is that the simulation model would understate the level of infectivity available from missfeeding, contamination, mislabeling, and the more direct pathway of BSE infectivity – the practice of feeding poultry litter to cattle.

If R-CALF USA's interpretation regarding this issue is correct, the Harvard BSE Update should not be used to support policy decisions that would relax existing BSE mitigation measures or forestall the implementation of additional BSE mitigations. Moreover, and again if R-CALF USA's interpretation is correct, the Harvard BSE Update should contain a clear and prominent

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[29] *See Canada's Assessment of the North American BSE Cases Diagnosed from 2003 to 2005 (Part II)*, Canadian Food Inspection Agency, January 23, 2006, available online at http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/eval2005/evale.shtml#app; *See also* BSE in North America, Latest Information, Canadian Food Inspection Agency, available online at http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/situatione.shtml.

[30] *Revised Harvard Risk Assessment*, at 10.

[31] *Substances Prohibited From Use in Animal Food or Feed; Proposed Rule*, Federal Register, Vol. 70, No. 193, October 6, 2005, at 58580.

disclaimer that its base case inputs contain mitigation measures not presently implemented in the United States.

I. The Scope of the Harvard BSE Update is Entirely Too Narrow to Support the Overreaching Conclusion of its Authors

According to the transcript accompanying the issuance of the Harvard BSE Update, the purpose of the Harvard BSE Update was *limited* to assessing risk ". . . associated with the introduction of BSE into the U.S. and to assess the impact of various risk management strategies."[32] Among their responses to concerns raised by Peer Reviewer 1, the authors further qualified the limited scope of the Harvard BSE Update stating, "Keep in mind that the purpose of this analysis has been to evaluate how different measures affect the spread of BSE in the U.S. following its introductions. It is not the purpose of this analysis to evaluate specific introduction scenarios."[33] And, again, when Peer Reviewer 1 recommended that a spatial risk assessment be conducted regarding risks that arise from previous imports of Canadian cattle and meat-and-bone meal, the authors stated, "Such an analysis is beyond the scope of this report."[34]

Thus, the scope of the Harvard BSE Update is much narrower than that of the original Harvard Risk Assessment, which was commissioned for the purpose of conducting a comprehensive investigation of the BSE risk in the United States.[35]

Despite its much narrower scope, as substantiated by the authors' acknowledged limitations and qualifications, the Harvard BSE Update nevertheless concluded:

> Qualitatively, our finding here are the same as in our earlier analysis, with the results indicating that the spread of BSE in the U.S. cattle population would be limited, that BSE would be eradicated from the U.S. over time, and that potential human exposure to BSE-contaminated food would be low.[36]

This conclusion overreaches the limited scope of the Harvard BSE Update. The Revised Harvard Risk Assessment identified two key mitigation measures that are most effective at reducing the spread of BSE in the United States.[37] These measures include 1) the ban on the import of ruminants from countries known to have BSE and 2) the feed ban. [38] However, the Harvard BSE Update does not factor in any risk associated with the United States' relaxation of its ban on imports from countries with BSE. In 2005, the United States imported over 1 billion pounds of beef from Canada, a BSE-affected country; and since the 2005 reopening of the Canadian border to Canadian live cattle, approximately 1.2 million head of live cattle have been

[32] *Harvard Bovine Spongiform Encephalopathy (BSE) Risk Assessment Technical Meeting*, U.S. Department of Agriculture, Food Safety and Inspection Service, July 25, 2006, at 14.
[33] *Harvard BSE Update*, Appendix 4 – Revisions and Responses to Peer Review Comments, at 9.
[34] *Id.* at 13.
[35] *Harvard Risk Assessment of Bovine Spongiform Encephalopathy (BSE) Update*; Notice of Availability and Technical Meeting, Federal Register, Vol. 71, No 133, July 12, 2006, at 39282.
[36] *Harvard BSE Update*, at 24.
[37] *See* Revised Harvard Risk Assessment at viii.
[38] *See Id.* at viii; *See also Id.* at 99.

imported into the United States.[39] The United States also imports beef from Japan, another BSE-affected country. Any BSE risks associated with these imports would be constant and ongoing, meaning the risks will persist year-after-year. Thus, the conclusions that BSE would be eradicated from the U.S. over time and that potential human exposure to BSE-contaminated food would be low cannot be supported by the Harvard BSE Update that does not consider this potentially persistent and cumulative risk.

R-CALF USA recommends that the conclusions and predictions contained in the Harvard BSE Update be revised to more accurately reflect the limited scope of the analysis. It is detrimental to the interests of the U.S. cattle industry to have a BSE risk analysis that draws overreaching conclusions as they tend to undermine our industry's credibility when such overreaching conclusions are later proven false. Already, empirical evidence has disproved a number of overreaching conclusions contained in the Revised Harvard Risk Assessment. For example, the ongoing BSE epidemic in Canada has rendered the following Harvard conclusions erroneous:

- "Our analysis finds that the U.S. is highly resistant to any introduction of BSE or a similar disease."[40] However, BSE was introduced as evidenced by the December 2003 detection of a BSE-infected cow imported from Canada and the detection of two BSE cases in the United States.
- "These imports [referring to previously imported Canadian cattle] are extremely unlikely to pose a risk of introducing BSE to the U.S."[41] However, the first case detected in the United States was an imported Canadian cow detected in 2003.
- "Because APHIS has banned the import of cattle and feed from countries in which the presence of native BSE has been documented (see Section 2.3.2), the import of even a single infected animal is not highly likely."[42] However, the detection of an imported Canadian cow with BSE in 2003 raises the question of whether adequate surveillance is being conducted in all countries form which we continue to import cattle or beef.

R-CALF USA recommends that the conclusions and predictions contained in the Harvard BSE Update be revised to reflect a strict, conservative standard regarding the interpretation of the risks associated with the introduction of BSE into the United States. Research on and understanding of the BSE disease and its epidemiology is quite nascent and the potential impact of underestimating BSE risks could be devastating to the domestic live cattle industry.

III. CONCLUSION

R-CALF USA appreciates the opportunity to offer comments regarding the Harvard BSE Update and urges FSIS to consider the concerns, comments, and recommendations discussed above before using the Harvard BSE Update to support policy decisions that would relax the United States' current BSE mitigation measures or that would forestall the implementation of more stringent measures.

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[39] Livestock, Dairy, and Poultry Outlook, Cumulative U.S. Meat and Livestock Trade, Updated October 12, 2006, available online at http://www.ers.usda.gov/Publications/LDP/xlstables/cumulative_US_livestock_meat_trade.xls.
[40] Revised Harvard Risk Assessment, at vii.
[41] *Id.* at 23.
[42] *Id.* at 84.

Should the FSIS make revisions to the Harvard BSE Update based on these and other public comments received during this availability, R-CALF USA would appreciate the opportunity to further comment on any such revisions.

Sincerely,

Bill Bullard
CEO
R-CALF USA

Attachment A
Attachment B

PRELIMINARY ANALYSIS OF INTERIM FINAL RULES AND AN INTERPRETIVE RULE TO PREVENT THE BSE AGENT FROM ENTERING THE U.S. FOOD SUPPLY

I. Summary

In response to finding a cow in Washington State positive for Bovine Spongiform Encephalopathy (BSE) on December 23, 2003, FSIS has taken emergency actions to protect public health. These actions include: designating certain high-risk tissues as specified risk materials (SRMs) and prohibiting the use of such materials for human food; requiring the condemnation of non-ambulatory disabled cattle presented for slaughter and use in human food applications; not awarding the mark of inspection on cattle tested for BSE under the Animal and Plant Health Inspection Service (APHIS) surveillance program until the test results are received and the results are reported to be negative for BSE; ensuring that advanced meat recovery (AMR) systems do not process SRMs and that boneless "meat" does not contain central nervous system (CNS)–type tissues or excess levels of bone solids and bone marrow; and prohibiting the use of certain stunning methods. These actions are all science-based measures intended to further minimize potential human exposure to the BSE agent through the consumption of beef and beef food products.

The extent of the economic impact of the BSE finding on the livestock sector and meat processing industry depends on domestic and foreign consumer attitudes toward the safety of the U.S. beef supply and how beef consumption habits might change given this new situation. Consumer attitudes may vary depending on 1) whether the single case of a cow with BSE were imported or of domestic origin, 2) the extent of the disease, and 3) how many cattle infected with BSE were taken out of the national beef herd. The finding

of a single cow with BSE originating from a shipment of imported cattle from Canada has had a negative impact on the U.S. cattle sector, largely as a result of decreased export demand. The measures prescribed by the SRM interim final rule provide greater assurances to both domestic and foreign consumers that the U.S. beef supply is safe.

As will be shown in the analysis later in this document the total annual cost of the FSIS actions related to the SRM and AMR interim final rules is estimated at $110.3 to $149.1 million. The total cost of the SRM interim final rule is estimated at $99.9 to $136.6 million. The primary impacts of the SRM interim final rule are the exclusion of SRMs from use in the human food supply ($35.6 to $36.7 million); the prohibition on non-ambulatory disabled cattle ($35.6 to $71.3 million); and modifications of HACCP plan/procedures, sanitation SOPs, or other pre-requisite programs and record keeping requirements ($27.6 million).

The annual total cost of the AMR interim final rule is estimated at $10.7 to $12.5 million. The primary impacts of the AMR interim final rule are restrictions on incorporating certain non-meat components in AMR products ($4.4 to $5.6 million); testing AMR product for iron, protein, and CNS-type tissues ($4.7 to $6.2 million); and revisions to HACCP and other plans, and bookkeeping requirements ($1.0 to $1.3 million).[1] Most values are reported as averages for the analysis. Some values however are reported at the 5^{th} and 95^{th} percentiles of the distribution.

[1] The cost impact analysis of the SRM and AMR Interim Final rules is based on a probabilistic model developed by FSIS, excluding the prohibition on non-ambulatory disabled cattle from the food supply (p. 28) and HACCP plan development, record keeping, and verification (p.33). The cost impacts of these regulatory measures are based on the deterministic values cited in the text of the analysis.

The annual cost of additional inspection, testing, and surveillance by FSIS is estimated at $3 million[2]. This estimate does not include the impact of FSIS measures on programs administered by other USDA agencies. Nor does it include the impacts of changes in the programs of these agencies on FSIS program costs. These impacts are difficult to estimate at this time due to uncertainty about the provisions of the programs that may be implemented by other USDA agencies.[3] The action related to the prohibition on certain stunning devices is not expected to have any cost impacts as these devices are no longer in use.

The aggregate beef price impacts of the measures contained in the SRM and AMR interim final rules are not expected to be significant.[4] The measures affecting the removal of SRMs from the human food supply, excluding the condemnation of non-ambulatory cattle presented for slaughter, may have a minimal impact on consumer beef prices. Price impacts are expected to be primarily limited to products derived from beef small intestines such as sausages with natural casings and trepas for which substitutes are limited. Substitutes are available for other by-products, largely from cattle less than 30 months of age, although prices will likely be somewhat higher. For example, the prohibition on bone-in beef cuts from cattle 30 months of age and older will raise the

[2] United States Department of Agriculture, 2005, Explanatory Notes for the Committee on Appropriations, Volume 1, page 14-14.

[3] The impacts of the test and hold provision depend on the level of surveillance testing for BSE that will be conducted by the APHIS on cattle presented for slaughter at federally-and state-inspected establishments. Because non-ambulatory disabled cattle are prohibited for use in human food, APHIS surveillance testing for BSE may shift toward locations other than federally inspected establishments and thereby minimize the impacts of the new FSIS test and hold policy on establishments that slaughter cattle. However, a more extensive BSE surveillance program that focuses on all cattle 30 months of age and older may increase testing at these establishments, and consequently the impact of the test and hold provisions.

[4] FSIS is collecting additional information on cost impacts of the SRM and AMR interim final rules that may not be fully reflected in the current analysis. When this information is available, it will be used with existing information to estimate the beef price impacts, disaggregated by major market categories. This analysis, conducted by RTI, International, along with information from public comment; will be incorporated into the final regulatory impact analysis.

prices of these cuts from younger cattle. The removal of non-ambulatory cattle from the food supply is not expected to have a significant impact on beef prices given the very small share of beef supply affected (0.1 percent).

The costs associated with regulatory measures affecting the segregation and disposal of SRMs, and changes in process control practices including plan development and record keeping are not significant from an industry perspective. Consequently, the resulting impacts on beef and beef products, and both beef and pork AMR products are not expected to be significant.

Anecdotal information suggests that prices received for cattle 30 months of age and older are being significantly discounted from prices for cattle of equivalent grade that are less than 30 months. The amount of the discount may reflect a combination of costs due to product loss, segregation, SRM removal and disposal, and other related processing control costs. These impacts could be significant for cattle producers. The Agency requests comment on the effect of the SRM interim final rule provisions on cattle marketing practices and prices.

The following is a preliminary analysis of the major impacts of the measures contained in the SRM and AMR interim final rules. The Agency is seeking comment from the public on the types and magnitude of the impacts resulting from the SRM and AMR interim final rule measures to ensure that the final regulatory impact analysis is comprehensive.

II. Cattle and Meat Processing Industry.

The United States has the largest fed-cattle industry in the world, and is the world's largest producer of beef, primarily high-quality grain-fed beef, for domestic and

export markets. Beef production in 2003 is estimated at 26.3 billion pounds from an annual slaughter of about 36 million cattle. Gross farm income from cattle and calf production totaled $44.1 billion in 2003[5]. U.S. exports of beef, veal, and beef variety meats in 2003 were 2.6 billion pounds valued at $3.8 billion according to the most recent estimates.

In 2003, 98.7 percent of all cattle were slaughtered for food and processed in federally-inspected establishments.[6] About 80 percent of the cattle slaughtered at federally- inspected establishments are estimated to be less than 30 months of age. The remaining 20 percent are cows, bulls, or stags and some steers and heifers that are estimated to be 30 months of age and older[7]. FSIS seeks comments on the age distribution of cattle sent to slaughter and, in particular, reliable information on the age distribution of cattle slaughtered at establishments that specialize in market or fed cattle.

In 2003, cattle were processed for dress or further processing in an estimated 4,033 establishments that are federally- and State-inspected. Of the 4,033 establishments, FSIS estimates that about 84 percent or 3,388 were establishments that typically dealt with SRMs during carcass dressing, meat-cut fabrication, or further processing of carcasses or parts of carcasses. The remaining 16 percent, or 645, were establishments that did not receive SRMs of any type, or only received parts of beef carcasses derived

[5] U.S. Department of Agriculture, Economic Research Service, released on February 6, 2004 at ERS website: http://www.ers.usda.gov/briefing/farmincome/ See the following for more detailed information: http://www.ers.usda.gov/data/farmincome/finfidmu.htm

[6] U. S. Department of Agriculture, Food Safety and Inspection Service. Animal Disposition and Reporting System, 2003.

[7] FSIS has found that some first-calf cows, and some juvenile (not mature) and mature bulls that go to slaughter may be less than 30 months of age. Furthermore, FSIS has found that some steers and heifers that go to slaughter may be 30 months of age and older. These steers and heifers have been fed primarily grass pasture or forage crops while growing and then finished for grading on grain. Also, heifers that have failed to conceive in the breeding season, or have lost their calves, have been removed from cattle herds. These older heifers, that have already matured, have been placed in feedlots where the heifers have been finished for grading on grain. These practices affect the share of meat slaughter and processing establishments which may have to modify their practices in response to the proposed measures.

from cattle 30 months of age and older that did not include the vertebrae (e.g. boxed boneless trimmings for further processing). Furthermore, of the 3,388 establishment that typically dealt with SRMs, approximately 888 (26 percent) are State-inspected establishments and about 2,500 (74 percent) are federally-inspected establishments. Of these 3,388 establishments, about 2,128 (62.8 percent) were establishments that are classified by FSIS as "very small." About 1,203 (35.5 percent) of the establishments were classified as "small." The remaining 57 establishments (1.7 percent) were classified as "large." [8] These 57 large establishments slaughter or further process more than 94 percent of the cattle. All of the large establishments are federally-inspected. The 1,203 small establishments slaughter and process about 5 percent of the cattle. The 200 largest establishments slaughter or process about 98 percent of the cattle[9].

In 2003, about 56 establishments used AMR systems to produce beef and pork AMR products. AMR products derived from beef vertebrae were produced in about 30 establishments. Pork AMR products derived from pork vertebrae were produced in about 22 establishments. One establishment produced both beef and pork AMR products derived from vertebrae. At least four establishments produced beef or pork AMR products derived from non-vertebral bones. About 17 AMR establishments were small establishments, and the remaining were large. At least one establishment processed beef vertebrae from its operations and the operations of another establishment. About three AMR establishments only fabricated cuts or processed carcasses or parts of carcasses.

[8] The size classifications used by FSIS for very small, small, and large establishments are defined as establishments with fewer than 10, between 10 and 499, and 500 or more employees, respectively.
[9] U.S. Department of Agriculture. Animal Disposition and Reporting System, FSIS. 2003.

III. Scientific Findings

In April 1998, USDA commissioned the Harvard School of Public Health, Center for Risk Analysis, to conduct an analysis and evaluation of the current measures implemented by the U.S. government to prevent the introduction and spread of BSE in the United States and to reduce the potential human exposure to the BSE agent. The Harvard risk assessment reviewed available scientific information related to BSE and other Transmissible Spongiform Encephalopathies (TSEs), assessed pathways by which BSE could potentially occur in the United States, and identified measures that could be taken to protect human and animal health.[10]

The Harvard BSE risk assessment concluded that if introduced, BSE is extremely unlikely to become established in the United States and that should BSE enter the United States, only a small amount of potentially infective tissue would likely reach the human food supply and be available for human consumption. The Harvard study identified three pathways or practices that could contribute most to either increased human exposure to the BSE agent or to the spread of BSE should it be introduced. The three pathways are:

- Noncompliance with FDA regulations prohibiting the use of certain proteins in feed for cattle and other ruminants;
- Rendering of animals that die on the farm and use (through illegal diversion or cross-contamination) of the rendered product in ruminant feed;
- Inclusion of high-risk tissue from cattle, such as brain and spinal cord, in edible products.

The Harvard study concluded that, based on conditions as they existed in 2001, if 10 infected cows were introduced into the United States, on average, three additional new cases of BSE in cattle would be expected in a 20 year time period. The Harvard study

[10] Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, November 26, 2001. Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States.

predicted that there was a 75 to 95 percent chance that there would be no new cases at all. An extreme case (95th percentile of the distribution) predicted 11 new cases. However, the simulation studies showed that the animal health emergency management system, and other safeguards in place in 2001, was sufficient to ensure that the disease would be quickly cleared from the United States with virtually no chance that there would be any infected animals 20 years following the import of the 10 infected cattle.

The Harvard study concluded that the greatest sources of potential human exposure to the BSE agent would be human consumption of cattle brain (26 percent of the total potential exposure on average), cattle spinal cord (5 percent of the total potential exposure on average), and beef products derived from AMR systems (57 percent of the total potential exposure on average). The Harvard study also determined that other potential human exposure routes to the BSE agent include consumption of bone-in beef products (11 percent of the total potential exposure on average), and small intestine (2 percent of the total potential exposure on average). However, as stated in the Harvard study, these estimates are likely to overstate true human exposure because they represent the amount of infectivity presented for human consumption but do not take into account waste or actual consumption rate. The basic findings of the Harvard study were used to develop measures to address the food safety concerns arising from the finding of BSE in the United States. The Harvard BSE risk assessment model has been revised to include two additional scenarios since it was initially developed. The input parameters used in the Harvard BSE risk assessment model were further modified by FSIS to evaluate the impacts of various risk mitigation measures on the potential human exposure during the

development of the SRM interim final rules. A discussion of these modifications is provided in section IX. Benefits.

IV. Preventive Measures

Prior to the detection of the BSE case on December 23, 2003, the United States government had already implemented a number of measures to prevent BSE from entering the United States and to prevent the spread of the disease should it be introduced into this country. Since 1989, APHIS has prohibited the importation of live cattle and certain cattle products, including rendered protein products, from countries where BSE is known to exist. In 1997, due to concerns about widespread risk factors and inadequate surveillance for BSE in many European countries, these importation restrictions were extended to include all of the countries in Europe. In 1997, FDA prohibited the use of most mammalian protein in the manufacture of animal feeds given to cattle and other ruminants. However, compliance was not complete or immediate. In December 2000, APHIS prohibited all imports of rendered animal protein products, regardless of species, from BSE-restricted countries because of concern that feed intended for cattle may have been cross-contaminated with the BSE agent. In addition, APHIS leads an ongoing, comprehensive, interagency surveillance system for BSE in the United States and, in cooperation with FSIS, has drafted an emergency response plan to be used in the event that BSE is identified in the United States. This plan was activated when the BSE test for the cow in Washington State came back presumptive positive December 23, 2003. Other Federal agencies also have contingency plans that work in concert with the USDA plan.

On December 30, 2003, Agriculture Secretary Ann Veneman announced additional safeguards to bolster U. S. protection systems against BSE, and further protect

the public health from the consumption of the BSE agent. The documents that implement these policies were published in the Federal Register on January 12, 2004, and the policies became effective at that time. The policies require that non-ambulatory disabled cattle presented for slaughter be condemned; designate certain materials as SRMs, and prohibit the use of such materials for human food; require that establishments that produce boneless meat using AMR systems implement additional process controls; require that the carcasses of cattle that have been targeted for BSE surveillance testing be held until the test results are received and the results are reported to be negative for BSE; and prohibit the use of air-injection stunning of cattle. These policies were issued as three Interim Final Rules and a Federal Register Notice and are described below.

Interim final rule "Prohibition on the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle" (69 FR 1862):

- Designates that the brain, skull, eyes, trigeminal ganglia, dorsal root ganglia (DRG), spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age and older; and the tonsils and the distal ileum of all cattle as SRMs;
- Declares that SRMs are inedible and prohibits their use for human food;
- To ensure effective removal of the distal ileum, requires that the entire small intestine be removed and disposed of as inedible;
- Requires that establishments that slaughter cattle, or establishments that process the carcasses or parts of cattle, develop, implement, and maintain, written procedures for the removal, segregation, and disposition of materials designated as SRMs. Establishments must incorporate these procedures into their HACCP plans, Sanitation SOPs, or other prerequisite program;
- Prohibits Mechanically Separated (MS) (beef) food product for human food;
- Requires that all non-ambulatory disabled cattle presented for slaughter be condemned and prescribes requirements for the handling and disposition of such cattle.

Interim final rule, "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems" (69 FR 1874):

- Prohibits the use of vertebral columns and skulls of cattle 30 months of age and older in the production of AMR product (product derived from these materials is adulterated);
- Prohibits the incorporation of any brain, trigeminal ganglia, spinal cord, or DRG in AMR product identified as "meat";
- Finalizes restrictions related to bone solids and bone marrow (as measures by calcium and iron content);
- Requires establishments which produce AMR product to document their process controls in writing, and if the establishment processes cattle, the program must be in its HACCP plan Sanitation SOP, or other prerequisite program.

Interim final rule, "Prohibition on the Use of Certain Stunning Devices Used to Immobilize Cattle" (69 FR 1885):

- Prohibits the use of penetrative captive bolt stunning devoices that deliberately inject air into the cranial cavity of cattle.

Federal Register Notice, "Bovine Spongiform Surveillance Program" (69 FR 1892)

- Announces that FSIS inspection program personnel will no longer pass and apply the mark of inspection to the carcasses and parts of cattle that are selected for testing by APHIS for BSE testing until the test results are received and the results are reported negative for BSE.

State-inspected establishments must implement procedures that are equal to those prescribed in the new regulations (21 U.S.C 301). Foreign establishments that export meat food product to the United States also must implement procedures equal to those prescribed in the new regulations. FSIS intends to evaluate foreign "equivalency" on a case-by-case basis.

V. Baseline Regulatory Environment Prior to the Issuance of BSE Regulations.

The following describes regulatory conditions prior to the issuance of the above regulations.

Non-Ambulatory Disabled Cattle. Prior to December 30, 2003, the date that the Secretary announced the prohibition on the slaughter of non-ambulatory disabled cattle

for human food, non-ambulatory disabled cattle were not automatically condemned on antemortem inspection. However, these animals were automatically suspected of being affected with a disease or condition that may require condemnation of the animal, in whole or in part, and were identified as ``U.S. Suspects" (9 CFR 309.2(b)). All animals identified as "U.S. Suspects" are examined at ante-mortem inspection by an FSIS veterinarian, and a record of the veterinarian's clinical findings accompanies the carcass to post-mortem inspection if the animal is not condemned on ante-mortem inspection. Under FSIS' regulations, "U.S. Suspects," must be set apart and slaughtered separately (9 CFR 309.2(n)). If, on post-mortem inspection, the meat and meat food products from such cattle are found to be not adulterated, such products may be used for human food (9 CFR 311.1).

Specified Risk Materials. Prior to January 12, 2004, the date that the new FSIS policies to prevent human exposure to the BSE agent were issued, most of the materials designated as SRMs under the new regulations were permitted for use in human food. Thus, establishments were not required to develop, implement, and maintain written procedures for the removal, segregation, and disposition of these materials. Furthermore, U.S. companies were permitted to export these materials and to import these materials from foreign countries (provided that the regulatory requirements for importing or exporting meat food products were met):

- Brain, spinal cord: The brains of all livestock species, including the brains of cattle regardless of age, were permitted for human food. Cattle brains from cattle of all ages were also permitted to be used as a source material in edible rendering. Although detached spinal cords from all livestock species, including cattle, were, and still are, prohibited for use in the preparation of edible products, detached spinal cords from all livestock species, including those from cattle 30 months of age and older, were permitted to be used as a raw material in edible rendering (9 CFR 318.6(b)(4)).

- Vertebral column and DRG: Bones from the vertebral column of cattle of all ages, including bones that contain DRG, were permitted to be used for bone-in cuts of beef, as source materials in the production of processed products manufactured from edible rendering, as source materials in AMR systems, and in the production of MS (beef) meat food product. Furthermore, although DRG is not marketed as a consumer product, there were no restrictions on the incorporation of DRG into beef AMR product, products produced from edible rendering, or MS (beef) meat food product.

- Small intestine: For clarification, it is the distal ileum that is the SRM. However, to ensure effective removal of the distal ileum, FSIS requires the entire small intestine to be removed and designated as inedible. Thus, throughout this document the small intestine is referred to when ever discussing costs and benefit impacts. The entire small intestine from cattle of all ages was permitted for use as human food and were typically sold as "trepas." Casings made from the small intestine of all cattle regardless of age were permitted to be used as containers for meat food products. Cattle small intestines from cattle of all ages were also permitted for use as ingredients in meat food products provided that certain labeling requirements were met.

- Skull, eyes, trigeminal ganglia, tonsils: Although FSIS' regulations did not prohibit the use of cattle eyes for human food, direct consumption of such materials is uncommon in the United States. The tonsils of all livestock species, including cattle, were prohibited for use as ingredients of meat food products but could be used for edible rendering. The trigeminal ganglia of cattle are not sold directly as consumer products. However, the heads of cattle (commonly referred to as "market heads"') were permitted for use as human food regardless of the age of the animal. Cattle market heads contain skull, eyes, trigeminal ganglia, and fragments of brains.

Proportion of infectivity in certain tissues. In 2001, the European Commission's Scientific Steering Committee (SSC), a scientific advisory committee for the European Union, considered the amount and distribution of BSE infectivity in a typical case of BSE and estimated that, in an animal with clinical disease, the brain contains 64.1 percent of the total infectivity in the animal and the spinal cord contains 25.6 percent of the total infectivity.[11] Thus, the brain and spinal cord of cattle with clinical BSE are estimated to contain nearly 90 percent of the total infectivity in the animal. According to the SSC, the

[11] European Union Scientific Steering Committee (EU SSC), 2001. Opinion of 10 December 1999 of the Scientific Steering Committee on the Human Exposure Risk (HER) via Food with Respect to BSE,

remaining proportion of infectivity in a typical animal with clinical BSE is found in the DRG (3.8 percent) the trigeminal ganglia (2.6 percent), the distal ileum (3.3 percent), the spleen (0.3 percent), and the eyes (0.04 percent).[12] However, in experimentally infected cattle, BSE infectivity has been demonstrated in the distal ileum as early as 6 to 18 months post oral exposure to the BSE agent and in the tonsils as early as 10 months post exposure. Thus, in younger cattle infected with BSE, these materials apparently present the greatest risk of exposing humans to the BSE agent.

Advanced Meat Recovery (AMR). Under FSIS' former and current regulations, boneless comminuted beef from AMR systems can be labeled as "meat"' because it is comparable to meat derived from hand-deboning (9 CFR 301.2). Under the former and current FSIS regulations, spinal cord is not considered a component of meat, and therefore, product from AMR systems identified as "meat"' that contains spinal cord is misbranded. Prior to January 12, 2004, vertebral bones and skulls from cattle 30 months of age and older were permitted to be used as source materials in AMR systems and beef AMR product that contained spinal cord from cattle 30 months of age and older was not considered adulterated. Furthermore, AMR product that contained DRG was not misbranded or adulterated, even if the DRG were from cattle 30 months of age and older.

Under the former AMR rule, AMR product could not exceed a calcium content of 0.15 percent or 150 milligrams/100 grams of product (150 mg/100 g) within a tolerance of 0.03 percent or 30 mg per 100g of product for each sample analyzed. The rule also required that the bones emerging from the AMR machinery be comparable to those resulting from hand deboning. The new rule establishes a calcium content limit,

[12] For this study, low levels of infectivity were assumed for the spleen and eyes based on scrapie experiments. The spleen has not demonstrated infectivity in cattle.

measured by individual samples and rounded to the nearest 10^{th}, of 130 mg per 100 g, and establishes an iron content limit, measured by duplicate analyses on individual samples and rounded to the nearest 10^{th}, of 3.5mg per 100 g. These limits apply to AMR product derived from the bones of all livestock species.

Air Injection Stunning. FSIS' regulations specifically listed air-injection captive bolt stunning as an approved method for injecting air into the carcasses or parts of livestock. However, FSIS is not aware of any US establishments that are using this stunning technique.

Test and hold policy. Before FSIS issued the "test and hold" policy, FSIS inspection program personnel applied the mark of inspection to the carcasses of cattle tested for BSE under APHIS' surveillance program before the test results were known.

VI. Modeling Economic Impact of BSE Regulations.

The purpose of the economic model is to quantify the economic effect of the SRM and AMR interim final rules, which require the implementation of a number of mitigation measures that, would reduce the risk of infectivity that may be present if an infected animal was slaughtered from entering the food system. To account for uncertainty and variability with many of the key economic costs a stochastic model was developed[13] to generate tables 1, 2, 4, 5, 9, and 11. A non-stochastic model was developed and used to generated tables 6, 7, and 10. The numbers used in table 8 is a mixture of both types of models. To do the cost-effectiveness analysis a stochastic model was also developed to assess the risk and generate tables 13, 14, 15, and 16. The totals in the columns may disagree with sums of individual at times because of rounding.

[13] Variability reflects the natural differences between values. Uncertainty reflects the ability to accurately measure a parameter.

The distributions for the stochastic models were derived from various data, including survey data, laboratory results, expert opinion,[14] and scientific literature. The references for the data are shown in Appendix 1. Appendix 2 provides documentation of baseline values and assumptions used in the models to estimate the cost impacts of the SRM and AMR interim final rules. Appendix 3 contains the model for estimating the cost of the SRM interim final rule. Appendix 4 contains input and output values for the models used to estimate SRM and AMR interim final rule cost, including information on distributions. Appendix 5 contains the model for estimating the cost of the ARM interim final rule. These appendices will be available electronically at the FSIS website. Reference materials cited in this document and comments received will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 4:30 p.m.

The SRM Rule scenario estimates the annual amount of brain, spinal cord, vertebral column, small intestines and other SRMs affected by the rule. The AMR Rule scenario estimates the amount of AMR product affected by the rule. For the analysis of the SRM interim final rule, four scenarios were run, each with 50,000 iterations using @Risk® Version 4.5 (Palisade Corporation). The alternative scenarios are listed in Table 3.

An example of how the data, information, and the reference material are used by FSIS in the costs analysis is shown in the following example. Estimates of the quantity of beef SRMs affected by the SRM interim final rule are based on the following information:

[14] Note, while some variability may be inherent in the model, more intensive data collection can often reduce uncertainty. There are several places in this modeling effort where data currently are lacking. Because specific data were unavailable at this time "expert" opinion was sought and distributions used to capture the uncertainty. Given the modeling effort is a dynamic process, when more complete information becomes available it can be added to the model.

(1) Baseline used for analysis is 2003, before the BSE case reported on 23 December, 2003. The baseline specifies the number of beef establishments, beef establishment profiles of activities, beef slaughter numbers, beef carcasses and parts of carcasses production, beef by-products production, beef and beef variety meat exports, beef and beef variety meat prices. Data and information sources include: NASS; FSIS; AMS; ERS; U.S. Commerce Dept., Bureau of Census; and U.S. Meat Export Federation);

(2) Average fed-cattle live weight at slaughter was 1250 pounds, in 2003 (source: NASS 2004); and

(3) Beef products and by-products yields were expressed as percent of live weight (sources: NASS 2003 & 2004, AMS 2003 & 2004; FSIS Beef AMR Products Survey of 2002; Ockerman, 1988 & 2002; Pearson, 1988, 1992; and Jones, 1995).

Using these data, a model was developed which estimates the annual amount of brain, spinal cord, vertebral column, small intestines and other SRMs affected by the SRM interim final rule. The relationships forming the model are based on the following parameters.

N_s = 36 million head of cattle slaughtered, in 2003 (the average number of cattle slaughtered annually, in millions of cattle (including calves), from NASS 2004;

W_{lwt} = 1250 pounds per slaughtered fed-cattle, in 2003 (the average live weight of slaughtered fed-cattle, in pounds) from NASS 2004;

Y_{plwt} = average yield of SRM as a percent of average live weight of slaughter cattle (W_{lwt}), in percent, from NASS 2003 & 2004, AMS 2003 & 2004, the FSIS Beef AMR Products Survey of 2002; Ockerman, 1988 & 2002; and Pearson, 1988, 1992; and Jones, 1995; and

N_a = average number of affected cattle, annually, in millions of heads, from the FSIS BSE SRM Survey of 2002, and the FSIS beef AMR products regulatory test results of 2003 (FSIS MARCIS 2003).

Then:

Q_a = average quantity yield of SRM per head, in pounds, or

$Q_a = (Y_{plwt}) \times (W_{lwt})$;

P_a = average proportion of affected slaughtered animals calculated as a percent of the total U.S. cattle slaughtered, in percent, calculated average proportion of

affected slaughtered cattle (including calves) as a percent of the total U.S. cattle (including calves) slaughtered annually, (P_a), in percent, or

$P_a = (N_a/N_s)$; and

Q_t = Average total pounds of SRM affected, annually, in millions, or

$Q_t = (Q_a)(N_a)$, or

$Q_t = (Y_{plwt}W_{lwt})(P_aN_s)$

Baseline Conditions. Conditions in the livestock sector and meat and poultry industry during 2002-03, prior to the finding a BSE infected cow in Canada, comprise the baseline for assessing the economic analysis of impacts associated with SRM and AMR interim final rules and related rulemaking. This period is selected as the baseline because changes in product formulation, slaughter and processing practices, including age determination and segregation by age, took place in a variety of establishments, especially in the northern tier of States, following the May 20, 2003 finding of a BSE infected cow in Canada. This baseline was also selected because of the availability of comprehensive and reliable data on AMR production and the prevalence of SRMs in beef and pork products. These data sources include: Beef AMR Products Survey of 2002, BSE Specified Risk Material Survey of 2002, and Beef AMR product testing results for 2003, and the Pork AMR Product Survey of 2003. Also, the analytical framework developed for conducting regulatory impact analyses of the BSE and AMR regulatory alternatives being considered prior to the BSE finding can also be utilized in conjunction with a pre-BSE finding baseline.

Analytical Approach to Interim Final Rule. The cost analysis of the FSIS interim final rules should distinguish between responses beginning in early 2004 by the cattle and meat processing industries to comply with FSIS regulatory requirements and responses,

by the livestock sector and meat and poultry industries, to market forces associated with the finding of a BSE infected cattle in Canada and the United States. Market forces include changes in domestic and foreign consumer preferences, demand for new information such as the origin, product formulation, and process characteristics of beef that relate to food safety, changes in technology, and other factors. However, there is no clear dividing line between responses by the industry to the SRM and AMR interim final rules and related measures, and market forces resulting from the positive diagnosis of BSE infectivity in the North American cattle herd.

FSIS is aware of changes in cattle slaughter and processing practices that took place during 2003, in the United States, in response to the finding of a BSE infected cow in Canada. FSIS is also aware of measures being taken by some firms in the cattle and meat industries immediately following the December 23, 2003 notification of a BSE infected cow in Washington State. Some of the measures taken by meat industry were consistent with measures to comply with the SRM and AMR interim final rules announced January 14, 2004 by FSIS. These measures include the age determination of cattle and the segregation; separate slaughter and/or processing of cattle 30 months of age and older; and disposal of SRMs. In response to customer requests, some suppliers of AMR product became more selective with regard to the origin and age of the source animals. These changes were occurring in slaughter (animals), fabrication (product processing), and marketing activities prior to the onset of regulatory requirements. To the extent that meat processing establishments voluntarily undertake measures to prohibit the use of SRMs, and exclude their use in human food, the cost impacts of the regulatory requirements estimated in this analysis would be reduced accordingly. The available

information regarding voluntary measures is largely anecdotal and cannot be verified in a manner that would be useful for economic analysis. Consequently, the baseline for FSIS estimates of the compliance costs for the SRM and AMR interim final rules does not include voluntary measures meat slaughter and processing firms may have taken in response to the finding of BSE infectivity between May 20, 2003 and January 12, 2004. FSIS requests comment on the types of changes that took place in the U.S. livestock industry, and meat and poultry industry following the May 20, 2003 finding of a BSE infected cow in Canada.

VII. SRM Analysis

The model results for the total annual amount of brain, spinal cord, vertebral column used to produce AMR, and meat from non-ambulatory disabled cattle affected by the SRM interim final rule are shown in Table 1.

The total amount of beef and pork products and by-products affected by the domestic and export market as a result of the SRM and AMR interim final rules is estimated at 237 million pounds (Table 2). Nearly all the amount removed from human consumption is beef. Approximately 24 million pounds of these products are recovered as lower valued, edible products, leaving a net reduction of 213 million pounds. As shown in table 1 the exclusion of beef small intestines from the human food supply accounts for about the most significant (160 million pounds) of the total amount removed. A large amount of this product, which is now declared inedible, had been exported. The exclusion from the food supply of vertebral column from cattle 30 months of age and older also accounts for a significant amount (24.7 million pounds). The net amount of beef and edible beef by-products removed as a result of prohibiting non-

Table 1. Annual estimates of average SRM amounts affected by the SRM Interim final rule. /1 (All values are estimates of average distributions unless otherwise identified.)

Specified Risk Material (SRM)	(Y_{plwt}) Yield as percent of average live weight /2 of slaughter cattle (W_{lwt}) /3	(Q_a) Yield per animal (Y_{plwt})x(W_{lwt}	(N_a) Number of affected animals /4	(P_a) Affected animals, share of U.S. cattle slaughtered /5 (N_a/N_s)	(Q_t) Amount of SRM affected (Q_a) x (N_a)
	percent	Pounds	Thousand	percent	Thousand
Brain	0.08	1	373.0	1.036	373.0
Spinal Cord	0.03	0.375	161.0	0.447	60.0
Small Intestines (Incl. Distal Ileum)	0.88	11	14,535.0	40.375	159,885.0
Vertebral Columns for AMR Products (incl. DRG)	0.72	9	2,755.0	7.65	24,795.0
Non-ambulatory Disabled Cattle (Incl. calves)	18.7 /6	234	144.0 /7	0.4	33,700

/1 Estimated pounds of affected SRM from slaughtered cattle, and from non-ambulatory disabled cattle (including calves), in 2003.
/2 Live weight (W_{lwt}) of slaughtered fed cattle = 1250 pounds (NASS 2004)
/3 Yield as percent of average live weight of slaughter cattle (W_{lwt}), in percent (NASS 2003 & 2004, AMS 2003 & 2004; FSIS Beef AMR Products Survey of 2002; Ockerman, 1988 & 2002; Pearson, 1988, 1992; and Jones, 1995)
/4 Number of affected animals slaughtered (N_a), annually (FSIS BSE SRM Survey of 2002 and FSIS beef AMR products regulatory test results of 2003 (FSIS MARCIS 2003))
/5 calculated average proportion of affected slaughtered cattle (including calves) as a percent of the total U.S. cattle (including calves) slaughtered annually, (P_a), in percent. Number of cattle slaughtered (N_s) annually = 36 million cattle (including calves) (NASS 2004)
/6 29 percent of the live weight was removed as inedible e.g., fractured leg is removed; or that the animal was a thin cow that had lost 29 percent of its weight e.g., a live weight of 888 pounds instead of 1250 pounds live weight; or, in some cases, the non-ambulatory disabled animal was a 120 to 150 pound live weight veal calf
/7 Net 144,000 head of affected cattle (including calves) after a condemnations rate of 26% of 195,000 head of non-ambulatory disabled cattle (including calves)

ambulatory disabled cattle from human food is estimated at 33.7 million pounds. The measures contained in the AMR interim final rule will affect about 6.6 million pounds of beef and pork product from human consumption, 2.4 million of which is recovered as mechanically separated pork, MS(pork).

The short-term adjustment costs may be significant for establishments that processed cattle 30 months of age and older, or relied on edible by-products or cuts of

Table 2. Disposition of average amounts of beef and pork products affected by SRM and AMR interim final rules, product removed from human consumption./1

	Baseline Utilization /2	Post-rule Utilization /3	Net amount of product removed /4
	Thousand pounds		
SRM Interim Final Rule			
Non-ambulatory disabled cattle	33,700	0	33,700
Small intestine, incl. distal ileum	159,885	0	159,885
Brains	373.3	0	373.3
Spinal cord	60	0	60
Vertebral column	24,795	11,020	13,775
Edible Rendering	636		636
Bone-in cuts w/vertebrae	10,866	8,996	1,870
Skulls, eyes, TTG	424	157	267
Tonsils for edible rendering	42		42
Subtotal	230,825	20,173	210,652
AMR Interim Final Rule			
Beef due to yield loss derived from:			
Vertebral column	1,387	1,174	213
Non-vertebral column	0		0
Pork due to yield loss derived from			
Vertebral column	64		64
Non-vertebral column	0		0
Beef due to non-compliance derived from			
Vertebral column	1,920		1,920
Non-vertebral column	4		4
Pork due to non-compliance derived from			
Vertebral column	3,231	2,424	807
Non-vertebral column	7	7	0
Subtotal	6613	3,605	3,008
Total	237,038	23,778	213,260

/1 All values are estimates of average distributions unless otherwise identified.
/2 Product destined for domestic consumption prior to implementation of the SRM and AMR interim final rules and destined for the export market prior to the implementation of import bans by foreign countries. Excluded product used in inedible rendering or disposed.
/3 Product recovered through hand deboning.
/4 Recovered for industrial use typically in inedible rendering, i.e. feed, fuel, and fertilizer.

meat from these cattle. Brains, eyes, spinal cords, and the beef small intestines are primarily harvested and processed for export markets. Vertebral columns and skulls (market heads) are primarily used to produce meat and meat food products for domestic markets. The restrictions of the use of these materials may necessitate further

identification and segregation of cattle, beef, and by-products by age group in marketing, slaughter, and processing.

The major impacts of the SRM interim final rule are the exclusion of SRMs from the food supply, prohibition on non-ambulatory disabled cattle, modification of plans and record keeping, and SRM segregation. The economic impact of the interim final rule and alternatives are now analyzed.

SRMs excluded from the human food supply. The analysis conducted by FSIS examined the impacts of three alternatives for excluding SRMs from the human food supply. These alternatives and the SRM baseline are summarized in Table 3. The Alternatives considered by FSIS provide the following:

- Baseline. Baseline regulatory conditions for the SRM interim final rule are described in Section V. Baseline Regulatory Environment Prior to the Issuance of BSE Regulations.

- Alternative 1. Declaring that the brain, eyes, and spinal cords from cattle 30 months of age and older, and tonsils from cattle of all ages, are inedible and to prohibit these materials for human food.

- Alternative 2. Declaring that the brain, eyes, and spinal cords from cattle 30 months of age and older, and tonsils and the distal ileum (but require removal of the entire small intestine) from cattle of all ages are inedible and to prohibit these materials for human food.

- Alternative 3. (SRM removed from the human food supply under the SRM Interim final rule) Declaring that the brain, skull, eyes, trigeminal ganglia, DRG, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age and older; and the tonsils and the distal ileum (but require removal of the entire small intestine) of all cattle are inedible and to prohibit the use of these materials for human food.

Table 3. Inedible material under the SRM interim final rule and alternatives.

Alternatives & SRM interim final rule	Cattle aged 30 months or older								Cattle of all ages	
	Heads				Vertebrae				Heads	Intestines
	Skulls	Brain	TGG	Eyes	Spinal Cord /1	Dorsal Root Ganglia (DRG)			Tonsils /2	Small intestines (including distal ileum)
	Edible rendering &AMR, MSM					AMR MSM	Edible rendering	Bone-in cuts		
Baseline									•	
1		•		•	•				•	
2		•		•	•				•	•
3	•	•	•	•	•	•	•	•	•	•

/1 Spinal cords that are detached were already not allowed for direct use for human food but were allowed for indirect use for human food, and can be used for edible rendering.
/2 Tonsils are not allowed for direct use for human food but were allowed for indirect use for human food for cattle of any age.

Alternative 3 was the option selected for the interim final rule. Under the measures specified in the SRM interim final rule, the annual net cost[15] of excluding SRMs from the human food supply is estimated at $36.2 million (Table 4). The rule excludes beef small intestine from the human food supply, resulting in a net cost of about $28 million. A large share of this product had been supplied to foreign consumers. The net cost of removing the brains, spinal cords, skulls, and vertebral columns for bone-in processes accounts for the remaining $2 million in costs.

Alternative 1 for the exclusion of SRMs results in a net cost of $613.9 thousand ($128,100 plus $485,800 from Table 4). Alternative 2 results in a net cost of $28.2 million (Cost of alternative 1 plus $10,476,200 plus $17,098,000 from Table 4). If

[15] The net cost of excluding SRMs from the food supply reflects changes in production costs and the value of the product in other uses.

Alternative 2 allowed for the use of the beef small intestine, excluding the distal ileum, the loss in net revenue to the industry decline to about $17.2 million.

Table 4. Average net revenue losses due to exclusion of SRMs under the Interim Final Rule /1

SRM type	Amount of Product	Price	Revenue Loss	Offsets /2	Net Revenue Loss
	Thousand lbs.	$/lb.	$thousand	$thousand	$thousand
Brain	373.3	0.45	169.2	41.1	128.1
Spinal cord	60.3	0.30	18.1	(464.7) /2	485.8
Vertebral column	24,795.0	0.83	20,579.9	14,295.0	6,284.9
Edible rendering	636	0.25	158.9	44.5	114.4
Bone-in cuts w/ vertebrae	10,866	2.22	24,086.8	22,589.1	1,497.7
Skull, eyes, &TGG	424.1	0.36	152.7	62.6	90.1
Tonsils - edible rendering	42	0.25	10.5	3.0	7.5
Small intestine					
Casings	101,574	.18	18,791.2	8,315	10,476.2
Trepas /4	58,311	.37	21,575.0	4,477	17,098.0
Total					36,189.3

/1 All values are estimates of average distributions unless otherwise identified.
/2 Offsets includes measures which provide revenues from sales to optional markets, reduce operating costs, or increase costs, such as by-product disposal. If the value is positive, the offset reduces the revenue loss.
/3 Spinal cords have an offset that is largely the additional cost associated with removal.
/4 Trepas are that part of the small intestine used in the production of variety meats.

The prohibition on the use of vertebral columns from cattle 30 months of age and older is expected to have a significant impact on about 12 small establishments that produce AMR products using this material. FSIS estimates that about 40 percent of cattle 30 months or older are used to produce beef AMR products. Prohibiting vertebrae from cattle 30 months of age and older for use as human food is expected to have a significant impact on about 2,500 establishments that may need to remove the vertebrae or the body of the vertebrae from their beef meat cuts. FSIS notes that customers of establishments producing AMR products are placing restrictions on beef and pork AMR products that are consistent with this requirement.

Comparison of Exposure Reduction and Cost of SRM Removal Alternatives. A comparison of the cost and potential reduction in human exposure associated with different regulatory alternatives provides a general indication of the relative effectiveness of the alternatives. Table 5 provides such a comparison for the 3 alternative levels of SRM removal from the human food supply discussed above. The alternatives are ordered on the basis of the incremental amount of BSE infectivity removed from the human food supply. The derivation of the reduction in potential human exposure associated with each of the alternatives is described in Section IX. Benefits.

Alternative 1 prohibits brain, spinal cord, tonsils, and eyes from use in human food. This results in an average 30 percent reduction from the baseline in potential human exposure to BSE infectivity at a cost of $613.9 thousand. Alternative 2, which adds the beef small intestine from cattle of all ages to the SRMs prohibited in Alternative 1.

Table 5. Comparison of Average Change in Potential Human Exposure and Cost of Regulatory Alternatives. /1

Regulatory Alternative	Cumulative Reduction in Human Exposure	Incremental Reduction in Human Exposure	Incremental Cost /3
	percent	Percent	$thousand
Alternative 1	30	30	613.9
Alternative 2	30 + /2	Not significant /2	27,574.2
Alternative 3	80	50	8,615.1

/1 1 All values are estimates of average distributions unless otherwise identified.
/2 The additional reduction in risk of human exposure associated with the removal of beef small intestine is not significantly greater than the reduction in human exposure from Alternative 1.
/3 The incremental cost associated with Alternative 3 does not include the cost of prohibiting non-ambulatory disabled cattle from the human food supply.

(brain, spinal cord, eyes, tonsils), does not result in a significant reduction in potential human exposure beyond Alternative 1.[16] The incremental cost of this alternative is significant, however. Alternative 3 results in an average additional 50 percent reduction in potential human exposure with an incremental cost of $8.6 million over Alternative 2. In addition to the SRMs removed in Alternative 2, the spinal cord and DRG (vertebral column) from cattle 30 months of age and older, and MS(Beef) are removed from the human food supply.

Non-ambulatory disabled cattle can be separated into two groups: those displaying central nervous system (CNS) signs and those that do not (due to broken leg, etc). The reduction in potential human exposure to BSE from non-ambulatory disabled cattle that do not display clinical signs of CNS disorders is not reflected in the reductions in potential human exposure shown in Table 5. The Harvard BSE risk assessment model accounts for non-ambulatory disabled cattle that do display symptoms of CNS disorders by removing them from the human food supply during ante-mortem inspection at the time of slaughter.

The level of infectivity associated with non-ambulatory disabled cattle that do not display CNS disorders is not known. The proportion of total potential infectivity associated with this type of non-ambulatory disabled cattle is thought to be significant. Consequently, the reductions in potential human exposure shown in the table overestimate actual reductions. Removal of non-ambulatory cows from potential human

[16] The removal of the beef small intestine, including the distal ileum of all cattle from the human food supply is based on the risk characteristics of this SRM and consistency with international policy. Scientific evidence suggests that BSE infectivity is found in the distal ileum of all cattle in early stages of the incubation period (< 24 months post exposure). In cattle 18 months of age and younger the distal ileum is the only detectable source of BSE infectivity in experimentally infected animals. By nature of the long incubation period, infectivity levels, found only in the distal ileum, are still low (versus the amount of infectivity in an animal that has completed a 32+ month incubation cycle, with infectivity migrating to the CNS tissue) in the majority of finished cattle slaughtered in the simulation.

exposure reduces the total amount of potential human infectivity. This effectively reduces the proportion of un-mitigated potential human infectivity that can be reduced by further FSIS mitigations.

Removing the risk associated with non-clinical, non-ambulatory disabled cattle, reduces the level of infectivity in the cattle herd that would be addressed by the alternatives removing the remaining SRMs from the human food supply.

If the reduction in risk associated with non-clinical, non-ambulatory disabled cattle were known, the total average reduction in risk of potential human exposure associated with the measures required in the SRM and AMR interim final rules of 80 percent would change accordingly.

Prohibition of non-ambulatory disabled cattle. The estimated cost impact of condemning non-ambulatory disabled cattle presented for slaughter is based on baseline parameters for the value, number, and condemnation rates of these cattle. It is also based on the salvage value of these cattle following January 12, 2004. These values can differ by the type and condition of non-ambulatory disabled cattle, the extent of livestock and dairy production in a region, the proximity of rendering establishments and similar recovery activities, and other factors. The estimated impacts are based on the deterministic values shown in the text.

The baseline value of a non-ambulatory disabled animal is estimated at $475. This estimate is based on a price of 75 percent of the cull cow price ($48-50/cwt) prior to the BSE finding and an average live weight of 1,300 lbs.[17] The amount that a farmer or rancher would expect to receive for a "downer" cow prior to the FSIS prohibition on the

[17] Values provided by the USDA's World Agricultural Outlook Board. Telephone discussion, December, 2003

slaughter of non-ambulatory disabled cattle depends, in large part, on the general condition of the animal and the reason for the animal's non-ambulatory status. If the animal was an older dairy cow with a condition that would have required its condemnation on ante-mortem inspection, the farmer would have received very little for the animal or even have paid a nominal amount ($25 per stop) to have the animal picked up for rendering. If the animal was destined for slaughter as a market steer or heifer and became disabled during transportation or in a holding pen, the discount for the animal's condition would largely depend on the amount of trim resulting from the injury. The value of this type of animal presented for slaughter could be significantly more than $475. FSIS has selected this baseline value knowing that dairy farmers are likely to receive less and cattlemen more than the average amount. FSIS requests comment on the baseline value of non-ambulatory disabled cattle.

Non-ambulatory disable cattle are assumed to have zero value following their prohibition for use in human food. The information available to the agency suggests that dairy farmers and ranchers can have non-ambulatory disabled cattle removed from their farms and ranches at no cost. Firms recover the hides and use the remains for inedible rendered product, offsetting the pick up and hauling costs. Farmers and ranchers located in areas where these services are not available may have to pay to have non-ambulatory disabled cattle picked up and hauled away for disposal. Disposal at a landfill is estimated to cost $100, including fees.[18] FSIS requests comments on the assumed salvage values for non-ambulatory disabled cattle and disposal costs. The difference between the baseline value of a non-ambulatory disabled animal and its salvage value represents an average loss of $475 per head.

[18] Based on discussions with a representative of a regional rendering association, March 1-5, 2004.

The share of non-ambulatory disabled cattle that were condemned following ante-mortem and post mortem inspection are not attributed to the cost of the interim final rule. The share of non-ambulatory disabled cattle that were condemned following ante-mortem and post-mortem inspection is estimated to be between 25 and 50 percent. FSIS requests comment on condemnation rates used in the analysis.

A range of 150,000 to 200,000 cattle is used as the baseline value for non-ambulatory disabled cattle presented for slaughter. There are no reliable estimates of the number of non-ambulatory disabled cattle presented for slaughter prior to the January 14, 2004. The assumed value is based various sources of information. On the basis of a 1999 study that examined on-farm conditions, APHIS found that there were 195,000 "downer" cows[19]. The share of these cattle transported to a slaughter establishment is not known. Some of these cattle may have been custom slaughtered or marketed in some other manner. These cattle also may have been composted or buried on farm; processed by a renderer or other type of business that handled dead, diseased, and down cattle; or disposed of in some other manner. In addition, some cattle become non-ambulatory disabled in transit to the slaughter establishment, which adds to the on-farm number of non-ambulatory disabled cattle presented for slaughter.

The 1999 National Market Cow and Bull Beef Quality Audit[20] found that .8 percent of the 2001 cattle slaughter, or 280,000 cattle had "lameness serious enough to disable the animal" at the packing plant slaughter floor. About 60 percent of these animals were beef cattle, and the remaining were dairy cattle. Some share of these

[19] Hansen, Don and Victoria Bridges. "A survey description of down-cows and cows with progressive or non-progressive neurological signs compatible with a TSE from veterinary-client herd in 38 states." The Bovine Practitioner; 33(2) 179-187, 1999.
[20] D.L. Roeber, et al., "National Market Cow and Bull Beef Quality Audit-1999," 2000 Research Report, Department of Animal Sciences, Colorado State University.

animals may have become lame, seriously enough to disable the animal, after entering the establishment and may have continued through processing operations, subject to post-mortem inspection. Consequently, this estimate is considered to be high. FSIS requests comment on the baseline value for non-ambulatory disabled cattle presented for slaughter. The USDA has initiated efforts to obtain better estimates of the number on-farm non-ambulatory disabled cattle[21].

Based on these values, the cost of prohibiting non-ambulatory disabled cattle from entering the food supply is estimated to be $35.6 to $71.3 million (Table 6).

Table 6. Cost of prohibiting use of non-ambulatory disabled cattle from human food use.

	No. of non-ambulatory disabled animal	Value of non-ambulatory disabled animal	Salvage value	Loss per animal	Condemnation Rate	Cost of prohibition
Range	Thousand	Dollars	Dollars	Dollars	Percent	$thousand
Upper end	200	475	0	475	25	71,250
Lower end	150	475	0	475	50	35,625

The indirect effects on the cattle marketing system of the ban on the use of non-ambulatory disabled cattle are not expected to be significant from a national perspective. These animals are reported to comprise a very small share of the annual cattle slaughter, about 0.4 percent to 0.8 percent. However, the impacts of the ban on the use of non-ambulatory disabled cattle may be disproportionate for small, custom slaughter, and small cull cow slaughter establishments. Small, custom slaughter operations process cattle that may not be marketed through other commercial channels due to injury. In 2003, there were 568 establishments that slaughter less than 10 cattle per day, 79 percent of federally-inspected beef slaughter establishments. The share of revenues of these

[21] The National Agricultural Statistics Service of USDA is conducting a survey to obtain an annual estimate of the number of downed cattle and their disposition.

establishments derived from custom slaughter is not known and consequently the impact of the ban can not be estimated. It is also not known whether the number of custom slaughtered cattle is fully reflected in the range of 150,000 to 200,000 non-ambulatory disabled cattle slaughtered at federally-inspected establishments.

Renderers are establishments that process the by-products of the animal slaughter process. Firms in this industry are becoming more selective in the types of cattle that are accepted for processing. These changes are primarily a result of regulatory requirements in the SRM and AMR interim final rules restricting the use of non-ambulatory disabled cattle and SRMs from use in edible rendered product. For example, only carcasses may be accepted when the age of the animal can be determined. Rendering firms may require certification of the age of cattle from which materials for rendering are obtained, or reject the supply of these materials entirely. Due the lack of refrigerated storage at most rendering establishments, cattle that may be subject to APHIS test-and-hold requirements may generally be rejected. Other changes in rendering practices can be anticipated that may restrict the use of SRMs in the rendering industry. FSIS requests information on the types of changes in rendering practices that could be expected as a result of the SRM interim final rule.

The ban on the use of non-ambulatory disabled cattle could have disproportionate impact on the dairy sector as a large share of these cattle are dairy cows[22]. Surveys conducted by USDA show that 20-25 percent of the dairy herd is culled each year[23]. Culls (cows and bulls) represent about 38 percent of the total value of cattle sales on

[22] Hansen, Don and Victoria Bridges. "A survey description of down-cows and cows with progressive or non-progressive neurological signs compatible with a TSE from veterinary-client herd in 38 states". The Bovine Practitioner; 33(2) 179-187, 1999.

[23] The ARMS survey conducted by the Economic Research Service shows a cull rate of 20 percent. The NAHMS survey conducted by APHIS shows a cull rate of 25 percent.

dairy operations. However, cattle sales represent less than 4 percent, on average, of dairy farm receipts[24]. FSIS requests reliable information on the share of dairy culls that are non-ambulatory disabled at the time of slaughter to better assess the dairy sector impacts.

HACCP plan development, record keeping and certification. The SRM interim final rule requires that establishments that slaughter cattle, or establishments that process the carcasses or parts of cattle, develop, implement, and maintain, written procedures for the removal, segregation, and disposition of materials designated as SRMs. The cost to develop HACCP and other plans (prerequisite plans, Sanitation SOPS), implement and maintain monitoring/record keeping requirements, and verification is estimated at $27.6 million. The estimated impacts are based on the deterministic values shown in the text. (Table 7). There are about 3,388 federally-and State-inspected establishments that slaughter cattle or process beef carcasses or parts of beef carcasses that will be required to remove, segregate, and dispose of the materials prohibited for use as human food. Plan development costs are estimated at $1.6 million, based on the costs per plan and time requirement shown in the table. The time required for record keeping and other activities related to the age determination and proper segregation of cattle prior to slaughter, and to assure that processed products and SRMs are also properly segregated can vary significantly on the basis of plant size. Large plants, operating two shifts may employ full-time quality control technicians to conduct process controls activities established in HACCP and/or other plans. These activities at small and very small plants, whose average daily slaughter is significantly lower than at large plants, may apply to less complex systems for process control and segregation. The total annual costs associated with monitoring/record keeping are estimated at $22.8 million. Verification that records

[24] Information provided through correspondence with the Economic Research Service, December 31, 2003.

concerning process control activities are properly maintained is generally conducted by a quality control technician or quality assurance manager, depending on the size of the plant as shown in the table. Total verification costs are estimated at $3.3 million. The Agency seeks comment on the cost of plan development, record keeping, and verification.

Segregation of SRMs. The annual cost of segregating SRMs in slaughter, fabrication and further processing is estimated at $0.9 million (0.8 to $1.0 million). The Agency does not currently have reliable information to estimate the cost of segregating SRMs[25]. Some establishments currently segregate cattle 30 months of age and older prior to slaughter, minimizing further adjustments that may take place as a result of the rule. If this practice is not followed, carcasses may need to be segregated following slaughter. This can be accomplished by tagging the carcasses, segregating them from other carcasses, and processing them at the end of the day or shift, or in another shift.

Some establishments have established practices that treat all cattle as if they were 30 months of age and older. Consequently, there is no need to segregate carcasses following slaughter. The segregation of carcasses for very small establishments would be accomplished with minimal disruption given the slaughter methods employed. Segregation practices of SRMs will also depend on the accessibility of rendering facilities to the establishment. On-site rendering, which is available to most large establishments, would reduce the processing adjustments needed to segregate SRMs. For the purposes of

[25] FSIS has initiated a contract to obtain additional information on the segregation and disposal costs of SRMs. Data collection will take place in March, 2004.

this analysis, the cost of segregation is estimated at $0.20 to $0.30 per head for the estimated 7.2 million cattle that are identified as 30 months of age and older.[26]

Table 7. HACCP plan development, record keeping and verification.

Measure/Plant size					
Plan development	Time/1	Cost/plan /1	Labor Compen-sation /2	No. of plants	Cost
	Hours.	Dollars	$/hr.		$thousand
Very Small	4		31.20	2,128	265.6
Small		1,000		1,203	1,203.0
Large		2,000		57	114.0
Sub-Total					1,582.6
Monitoring/ Record keeping	Time/1	No. of days /3	Labor Compen-sation /1	No. of plants	Cost
	Hrs./day		$/hr.		$thousand
Very Small	.5	275	17.42	2,128	5,097.1
Small	2	275	17.42	1,203	11,525.9
Large	16	275	24.46	57	6,134.6
Sub-Total					22,757.6
Verification					
Very Small	.1	275	24.46	2,128	1,431.4
Small	.2	275	24.46	1,203	1,618.5
Large	.5	275	31.20	57	244.5
Sub-total					3,294.3
Total					27,634.5

/1 The time required for plan development, record keeping and verification; and the cost of plan development are based on expert opinion of FSIS personnel familiar with HACCP implementation and meat establishment operations. FSIS invites comment and reliable information on the values used for these parameters in the analysis.
/2 Compensation rates include an hourly wage rate and a 33 percent overhead cost that accounts for benefits, including insurance and retirement. The labor compensation rates used in the analysis are based on those reported for employees at meat and poultry processing establishments in the Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems. FR 61, 144.
/3 Average annual days of operation are based on expert opinion.

The Agency seeks comment and reliable information on practices and associated costs for segregating carcasses derived from cattle that are identified as 30 months or age and older and SRMs. The costs associated with the various measures of the SRM interim final rule are shown in Table 8.

AMR Interim Final Rule Impacts.

[26] Opinion of FSIS technical personnel.

The AMR interim final rule complements the SRM interim final rule by addressing the major sources of risk generated by the possible incorporation of brain, trigeminal ganglia, spinal cord, and DRG tissues in AMR products derived from beef skulls or vertebral columns. The rule also finalizes restrictions related to bone solids and bone marrow (as measures by calcium and iron content) and prohibits MS(beef) as a human food product.

Table 8. Summary: Cost impacts of the SRM interim final rule

	Annual Costs	
	Range /1	Average
Measure	$million	
SRM ban (net cost)	35.6-36.7	36.2
Segregation of SRMs	0.8-1.0	0.9
Modification of HACCP, sanitation SOP, or other prerequisite program plans and record keeping	27.6 /2	27.6
Ban on non-ambulatory, disabled animals	35.6-71.3	53.5
Total	99.6-136.6	118.2

/1 Values at the 5th and 95th percentiles except for ban on non-ambulatory, disable animals.
/2 A range was not estimated.

AMR yield loss and compliance modifications. Based on the 2002 Beef AMR product survey, FSIS found that about 29 percent of all final beef AMR product samples tested positive for spinal cord. More recent tests, based on regulatory sampling of beef AMR samples, conducted in 2003 show a much lower prevalence level of spinal cord tissue of 6.7 percent. In 2002, the prevalence rate for DRG tissue was found to be 10 percent. Based on FSIS estimated AMR production levels for 2003, about 45.6 million pounds of AMR products derived from beef vertebrae could be produced annually. FSIS

estimates that the yield loss from beef vertebral columns from cattle less than 30 months of age due to process modifications is about 1.4 million pounds (Table 9). The associated revenue loss is $1.4 million. The cost of these modifications, apart from product losses, is estimated at $0.9 million. Based on the available evidence, FSIS concludes that the amount of beef AMR product derived from cattle younger than 30 months that may contain brain, trigeminal ganglia, spinal cord, or DRG tissues would be significantly less than the levels shown in 2003. Prevalence levels of spinal cord tissue in beef AMR products declined significantly during 2003 and are likely to decline further in response to regulatory requirements and consumer concerns. However, the prevalence of DRG tissue in beef AMR products has not decreased from the 10 percent levels found in the 2002 Beef AMR product survey. The compliance cost to eliminate DRG tissue in beef AMR products, now only from cattle younger than 30 months, could be significant. Comments are solicited on the cost to eliminate the CNS-type tissues such as DRG. FSIS is currently estimating the compliance cost of this requirement to be $2.4 million.

If the prevalence rate of DRG, excess calcium, and excess bone marrow is 4 percent, about 1.9 million pounds of beef AMR product using the vertebral column of cattle less than 30 months of age would fail to comply with the new requirements (Table 8). The total amount of non-compliant beef and pork AMR products lost or diverted to alternative uses is estimated at about 6.6 million pounds. The documentation of the model used to estimate the quantity of AMR product affected by the AMR interim final rule is shown in Appendix 5. An example of how the model was used to estimate the amount of AMR product affected by the interim final rule is shown in Appendix 6.

Table 9. AMR yield loss and compliance modifications. /1

AMR Input Material	Yield/ animal	Animals	Product loss	Value of yield loss or process cost	Revenue loss/ Cost increase
	Lbs.	Thousand	Thousand lbs.	$/lb.	$thousand
Due to reduced prevalence of DRG, calcium, and iron					
Beef (<30 months) vertebral column	3.0				
Yield loss	0.5	2,720	1,387	0.98	1,364
Process modification cost /2	2.5	12,000	30,000	0.03	895
Revenue from alternative uses net of additional processing/disposal costs					210
Sub-total					2,049
Pork vertebral column	3.0				
Yield Loss	0.6	1,070	64	0.31	20
Process Modification	2.9	4,280	12,583	0.03	378
Sub-total					398
Total due to reduced prevalence					2,447
Due to non-compliant product					
Beef (<30 months) vertebral column					
Non-compliant	3	640	1,920	0.98	1,888
Revenue from alternative uses net of additional processing/disposal costs					26
Sub-total					1,862
Beef (< 30 months) non-vertebral					
Non-compliant	2	2	4	0.98	4
Revenue from alternative uses net of additional processing/disposal costs					.5
Sub-total					3.5
Pork Vertebral Column					
Non-compliant	3	1,100	3,300	0.31	1013
Revenue from alternative uses net of additional processing/disposal costs	3	802.5	2,424	0.11	250
Sub-total					763
Pork non-vertebral					
Non-compliant	2	3.4	6.8	0.31	2.1
Revenue from alternative uses net of additional processing/disposal costs					.6
Sub-total					1.5
Total due to non-compliant product					2,630
Total AMR yield loss and compliance modifications					5,077

/1 All values are estimates of average distributions unless otherwise identified.
/2 Process modification costs include adjustments to the establishment's AMR process, including equipment upgrades, changes in machine settings, changes in bone stock, and other changes.

The total annual cost, in terms of the lost value of beef and pork AMR products due to non-compliant products is estimated to be about $2.6 million when beef AMR

products are valued at an average of about 70 percent of the value of beef trimmings that are 90 percent lean, and pork AMR products are valued at an average of about 70 percent of the value of pork trimmings that are 72 percent lean. The net cost of the AMR interim final rule with regard to impacts on AMR yield loss and non-compliance is estimated at $5.0 million.

The pork AMR products survey of 2003 did not find any pork AMR products with DRG tissue, but 21.3 percent (or 23 of 108 samples tested) of the pork AMR products derived from vertebrae were found to contain spinal cord tissue. Furthermore, 55 percent, or 11 of 20, of the establishments that produced AMR products derived from pork vertebrae, were found to have at least one of their samples positive for the presence of spinal cord tissue. In addition, 25 percent, or 5 of 20, of the establishments were found to have more than one of their samples positive for the presence of spinal cord tissue.

Spinal cord tissue has not been permitted in AMR products prior to the publication of the SRM and AMR interim final rules. Therefore, the elimination of spinal cord tissue in AMR products is a part of the baseline conditions that are not affected by the new regulatory requirements. Consequently, the cost of eliminating spinal cord tissue in AMR products has already been realized by establishments that produce AMR product. Additional documentation of AMR Interim Final Rule Impacts are shown in Appendix 5.

Product testing. The AMR interim final rule will result in additional testing requirements of AMR products. The additional tests include a determination of the iron-to-protein ratio, and the tests for CNS-type tissues (spinal cord and DRG). Since skulls are not used in the United States, tests for brain and trigeminal ganglia are not anticipated

at this time and have not been factored into the cost estimates. The estimated costs for these tests are $5.4 million annually.

Modification of process control plans. There are additional costs for modifying process control plans and additional bookkeeping for the 56 establishments that are expected to continue producing AMR products. These costs are estimated at be $1.0 to 1.03 million annually.

Table 10. Additional Laboratory Testing Costs for Beef and Pork AMR Products /1

Laboratory Test /2	Affected establishments /3	Lots tested per test day	Number of test days per year	Average cost per test[27]	Increase in testing costs
				Dollars	Thousand dollars
CNS-type tissue tests	56	2	300	95	3,181
Iron and protein test (the dry-ash method with duplicate testing on the same sample)	56	2	300	67	2,240
Total					5,421

/1 All values are estimates of average distributions unless otherwise identified.
/2 A major portion of the laboratory is expected to be done by certified commercial laboratories. However, some of the testing is expected to be done on-site by the establishment;
/3 The average number of affected establishments was determined from the Beef AMR Products Survey of 2002, and the Pork AMR Products Survey of 2002;

The net cost of the AMR interim final rule is estimated at $10.7-$12.5 million (Table 11). The net cost of prohibiting the AMR processing of vertebral columns from cattle 30 months of age and older from use in human food is estimated at $6.3 million ($3.3 to $9.8 million). This provision applies to approximately 2.8 million cattle. The vertebral columns from cattle 30 months of age and older provide approximately 24.8 million pounds of beef product when processed in AMR systems.

[27] Based on estimates provided by as FSIS regional laboratory.

Table 11. Summary: Cost of the AMR interim final rule

Measure	Annual Cost	
	Range /1	Average
	$million	
Modifications of operations to achieve lower maximum calcium requirement, not exceed the bone marrow limit, and elimination of CNS-type tissues.[28]	2.0-2.7	2.4
Non-compliant beef and pork AMR products for excess levels of bone solids or bone marrow; or the incorporation of CNS-type tissues.	2.4-2.8	2.6
Testing for iron, protein, and CNS-type tissues	4.7-6.2	5.4
Process control plans, record keeping and product segregation, extra holding of AMR products, and extra packaging	1.0-1.3	1.2
Total Cost	10.7-12.5	11.6

/1 Values at the 5th and 95th percentiles.

Test and Hold Impacts.

The impacts of the test and hold provision are related to the number of surveillance tests that will be conducted within Federal establishments by APHIS and the length of time to complete each test and then to communicate the results to the inspection program personnel at the establishments. Typically, cattle carcasses or parts of carcasses are chilled and kept cool for about 24 to 36 hours before moving on for fabrication of cuts or further processing. Additional storage and carcass shrinkage (loss of moisture) costs may result if the test results are not available within about 24 to 36 hours of slaughter. APHIS has stated that it is working to approve a rapid screening test that will have results available within approximately 36-48 hours, contingent upon the order of operation at slaughter plants and sample pick-up time. BSE surveillance tests at

[28] Does not include SRM removal costs, which are shown in Table 1.

federally- and State-inspected plants may decline if it is more effective to test high risk cattle on the farm and at rendering establishments. However, if BSE surveillance testing increases significantly, more tests than are currently performed by APHIS may be conducted at slaughter establishments. Comments are solicited about the scope of these costs.

FSIS Program Costs

FSIS expects significant changes in inspection, testing, and surveillance programs in response to the three interim final rules and the interpretive rule. These changes include increased sampling and testing for excess bone solids and bone marrow in beef and pork AMR products, and CNS-type tissue (spinal cord and DRG) in beef and pork products. In addition, increased verification inspections would be expected in beef slaughter operations and in beef and pork processing operations, including any AMR systems or edible rendering systems. As part of the President's 2005 Budget, FSIS is requesting $4 million, an increase of $3 million, for in-plant verification of slaughter plant designs for controlling SRMs; in plant verification of proper holding of tested cattle that are part of the APHIS testing program; and increased testing of meat produced using AMR systems to help assure that SRMs are not entering the human food supply.

Total Costs

The total annual cost of the SRM and AMR interim final rules is estimated at $113.3 to $152.1 million, including FSIS costs for increased inspection, verification, and testing. This cost estimate does not include the following impacts:

- the costs to segregate, assemble, and transport cattle 30 months of age and older, or their carcasses or carcass parts to establishments that process these cattle;

- not awarding the mark of inspection on cattle tested for BSE until the test results are received and the results are report negative for BSE; and
- equivalence measures by foreign supplies and their impact on domestic beef supplies.

VIII. Domestic Economic Impacts

The impact of finding BSE in the United States is expected to have a minimal impact on U.S. meat production. Biological lags inherent in cattle production limit any significant change in the short term[29]. According to recent USDA estimates, the United States exported about 2.6 billion pounds of beef in 2003, accounting for 10 percent of U.S. beef production and the value of beef, veal, and variety meat exports is estimated at $3.9 billion.[30] In 2004, these products will be shifted to the domestic market. The loss of exports resulted in an immediate decrease in cattle prices of 15 to 20 percent.[31] As of late January, the cattle prices have strengthened and currently down by about 10 to 15 percent from pre-import ban levels.

The increase in beef supplies, due to reduced export demand, is expected to reduce 2004 cattle prices to $74 to $79 per cwt compared to USDA forecasts of $84 to $91 per cwt in December 2003[32].

The net amount of beef and pork product removed from human consumption due to the SRM and AMR interim final rules is estimated to be about 213 million pounds. This product is expected to be used in the production of in-edible rendered product. The amount removed from human consumption is a small share (0.5% or 0.005) of the total

[29] U.S. Department of Agriculture. World Agricultural Supply And Demand Estimates, WASDE-406. January 12, 2004.
[30] U.S. Department of Agriculture. Testimony of Keith Collins for House Committee on Appropriations, February 24, 2004.
[31] U.S. Department of Agriculture. AMS Daily Market News
[32] U.S. Department of Agriculture. World Agricultural Supply And Demand Estimates, WASDE-406. March 12, 2004.

46.0 billions (26.3 billion pounds of beef and 19.7 billion pounds of pork) produced annually.

The impacts of the measures contained in the SRM and AMR interim final rules on prices for beef and pork are not expected to be significant.[33] Price impacts are expected to be limited to beef by-products and variety meats which constitute a small share of domestic beef consumption. The measures affecting the removal of SRMs from the human food supply, excluding the condemnation of non-ambulatory disabled cattle presented for slaughter, are expected to have a minimal impact on beef prices to the consumer. The net amount of product removed from the human food supply as a result of the SRM interim final rule provisions is 177 million pounds, excluding that removed as a result of the prohibition on non-ambulatory disabled cattle from the food supply. This amount is about 0.7 percent of the total supply of beef. Price impacts largely would be limited to products derived from beef small intestines such as sausages with natural casings and trepas. Substitutes are available for other by-products, largely from cattle less than 30 months of age, although prices will likely be somewhat higher. For example, the prohibition on bone-in beef cuts from cattle 30 months of age and older will raise the prices of these cuts from younger cattle.

The removal of non-ambulatory disabled cattle from the food supply is not expected to have a significant impact on beef prices given the very small share of beef supply affected (0.1 percent). The impact of the condemnation of these cattle presented for slaughter is viewed as having an overall positive impact on consumer perceptions of

[33] FSIS is collecting additional information on cost impacts of the SRM and AMR interim final rules that may not be fully reflected in the current analysis. When this information is available, it will be used with existing information to estimate the beef price impacts, disaggregated by major market categories. This analysis will be provided in the final regulatory impact analysis.

the livestock and dairy industry.[34] The Agency requests comments on potential price impacts of the SRM interim final rule provisions affecting removal of this product from the human food supply.

The costs associated with other regulatory measures affecting the segregation and disposal of SRMs, and changes in process control practices, including plan development and record keeping, are not significant from an industry perspective. Beef price impacts resulting from higher industry per unit costs are expected to be minimal. The prohibition on the use of non-ambulatory disabled cattle for human food restricts the supply of cattle slaughtered and processed at custom slaughter establishments. The relative cost impacts of SRM interim final rule on these types of establishments is presumed to be significantly greater than those likely to occur for other types of meat slaughter and processing establishments.

The impacts of the AMR interim final rule on AMR product prices are also expected to be minimal. The amount of product removed from beef and pork supply is a very small share of total supplies. AMR product is generally used as an ingredient in processed products. FSIS has found that establishments producing AMR product began to make significant processing adjustments in 2003 to address concerns about the presence of spinal cord in AMR product. These changes largely were a result of customer requirements for product formulation.

Countries that import beef products into the U. S. must have requirements that are equivalent to the new regulatory requirements implemented by FSIS in response to the detection of a case of BSE in this country (9 CFR 327.2). The measures designating

[34] Based on numerous discussions with industry, university, and dairy farmers.

certain high-risk tissues as SRMs and prohibiting [35]their use for human food, and excluding non-ambulatory disabled cattle for slaughter and use in human food applications apply to registered establishments in foreign countries that export products to the United States. FSIS intends to evaluate equivalence standards on a case-by-case basis. It is not possible at this time to determine whether equivalency requirements will affect U.S. beef supplies.

The economic impact of a BSE case in the United States is more likely to mirror the market response experienced recently by Canada when one cow with BSE was detected in May 2003, rather than being associated with the magnitude of those experienced the U.K.[36] The measures in place prior to finding BSE in the United States, including those preventing infected feed from being widely distributed and consumed by cattle, limited the potential impact.

The impacts on livestock income, and cattle and meat prices and production described above do not include potential impacts on employment and other economic conditions in local economies. FSIS has observed changes in cattle marketing, transportation, and handling practices that can be attributed to finding BSE in the United States and to the SRM and AMR interim final rules. Over time, these changes could be significant and affect the spatial and structural characteristics of the livestock, dairy, and meat slaughter and processing industries in those regions that are most affected. FSIS requests comment on these types of changes and their potential impacts.

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[35] U.S. Department of Agriculture. World Agricultural Supply And Demand Estimates, WASDE-406. January 12, 2004.

[36] U.S. Department of Agriculture. Animal and Plant Health Inspection Service. Animal Disease Risk Assessment, Prevention, and Control Act of 2001. (PL 107-9) Final Report. January 2003. http://www.aphis.usda.gov/lpa/pubs/pubs/PL107-9_1-03.pdf

IX. Benefits

The benefits of the SRM and AMR interim final rules are primarily those resulting from the reduction in human exposure to BSE infectivity and the restoration of beef exports. The benefits of provisions of the AMR interim final rule concerning the amount of bone solids and bone marrow are not addressed in the analysis of benefits.

Reduction in Human Exposure to BSE

The following discusses the method by which the reduction in human exposure to BSE infectivity in the food supply is estimated and the reduction in human exposure resulting from the three alternatives discussed in the cost analysis.

FSIS evaluated possible mitigation options intended to prevent human exposure to the BSE agent in the United States using a modified version of the 2001 Harvard BSE risk assessment model (as revised by Harvard in response to peer review comments)[37]. In developing the baseline estimate of potential human exposure to the BSE agent, FSIS used similar assumptions to those used in a second risk assessment conducted by Harvard after the detection of the single case of BSE in Canada on May 20, 2003[38]. The 2003 Harvard analysis uses identical assumptions to the 2001 Harvard analysis to evaluate the potential for BSE to spread if it were introduced from Canada prior to May 20, 2003, when USDA banned all ruminant and ruminant products from Canada because of the discovery of the single case of BSE.

[37] Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, November 26, 2001. Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States,

[38] Harvard Center for Risk Analysis, Harvard School of Public Health, "Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada". 2003

For its baseline estimate of potential human exposure to the BSE agent, FSIS assumed that five BSE-infected bulls were imported from Canada into the United States in 2003, and then simulated the spread of BSE infectivity in the United States until 2020. Thus, the FSIS 2003 analysis assumes that measures implemented by the United States government to prevent the introduction and spread of BSE in this country, such as the FDA's mammalian to ruminant feed ban and APHIS' import restriction, were in place at the time that the infectivity was introduced. The simulations of the risk mitigation options were then run assuming that the FSIS mitigations would be implemented in 2004, which would allow infectivity to spread for approximately 12 months. Thus, because of these assumptions, the mitigation options can never remove all of the infectivity that could be available for human consumption over the model simulation timeframe. The maximum level of risk mitigation that could be achieved using these assumptions would be an average of approximately 90 percent. Risk mitigation scenarios were run for 50,000 iterations. The Harvard analyses conducted in 2001 and 2003 both ran 5,000 iterations per scenario.

FSIS determined that certain assumptions used in the FSIS analysis and the 2001 and 2003 Harvard analyses affect the results of the risk mitigation analyses. First, none of the analyses separate direct consumption of tissues by the age of the animal. Thus, although all of the options would prohibit the use of certain tissues, such as brain and spinal cord, from cattle 30 months of age and older, the models can only consider removal of these tissues from cattle of all ages. However, since most infectivity in the affected tissues is expected to manifest in older animals, the difference in modeling all animals versus only older animals is expected to be insignificant.

Another important assumption in the Harvard 2001 and 2003 analyses is that no animals older than 24 months go to the bone-in-beef pathway, which includes bone-in cuts of meat, such as T-bone steaks, roasts, and soup bones, as well as and bone-in materials that are used to produce edible rendered products. The reported infectivity via the bone-in-beef pathway in the 2001 and 2003 Harvard risk mitigation scenarios is attributable to infectivity found in cattle 24 months of age and younger. Although infectivity levels are much lower in these cattle, there is a high probability of human exposure via this pathway. Since some older animals may be used for bone-in-beef products, this assumption may cause the model to underestimate potential human exposure through this pathway, and thus overestimate the impact of some of the risk mitigation options.

FSIS changed this assumption in the FSIS analyses. Based on evidence available to the Agency, FSIS believes that vertebrae from cattle older that 24 months are used in bone-in cuts and processes (bone-in pathway). Therefore, model coefficients were changed in the FSIS 2003 baseline analysis to allow 20 percent of vertebrae from cattle 24 -29 months of age and 10 percent of vertebrae from cattle 30 months of age and older be used in the bone-in pathway. The estimates of the share of vertebrae from cattle in these two age categories that are used in the bone-in pathway is based on the opinion of FSIS technical specialists familiar with beef slaughter and processing operations. The Agency requests comment on the share of vertebrae that are used from animals in these two age categories for the bone-in pathway. As shown below, the proportion of vertebrae from cattle older than 24 months that enter the bone-in pathway does not substantially affect the total human baseline exposure to animal ID50s. Although the 2001 and 2003

Table 12. Comparison of assumptions: FSIS analysis with Harvard 2001 and 2003 analyses.

	Harvard 2001analysis	Harvard 2003 Canada analysis	FSIS analysis
Simulation time frame	20 years, beginning after 1999 policies in place	Simulation through 2020, various years for initiation of infection –starting in 1992	Simulation through 2020, with initiation of infectivity in 2003, mitigations in effect starting in 2004.
Number of infected animals as initiating event	10 cows	5 bulls	5 bulls
Number of simulation runs	5,000 iterations	5,000 iterations	50,000 iterations
Conditions simulated	Baseline only, all policy conditions/industry practices in place in 1999	Policy conditions vary over time, all policies/industry practices in place by 1999	a) Baseline 2003-2004 b) Baseline 2004-2020 c) Mitigation, effective in 2004 Average differences between the baseline and mitigation scenarios were determined.
Age distribution of animals going to bone-in-beef	< 24 months = 100% >24 months = 0%	< 24 months = 100% >24 months = 0%	Baseline: < 24 months = 70% 24-29 months = 20% > 29 months = 10% Mitigation: < 24 months = 70% 24-29 months = 30% > 29 months = 0%
Coefficients for industry practice	Representative of current industry practices prior to the USDA announcement in Jan. 2004.	Representative of current industry practices during the period of simulation.	Baseline: Representative of current industry practices prior to the USDA announcement in Jan. 2004. Mitigation: Coefficient values modified to reflect the removal of SRMs from human food and prohibition of >29 month cattle from AMR processes.

Harvard analyses and the FSIS baseline analysis assumed different bone-in beef exposure pathways from cattle aged greater than 24 months, the ultimate human exposure was substantially similar in all of the models. The following table compares the assumptions that were used by FSIS baseline analysis with the assumptions in the 2001 and 2003 Harvard analyses

FSIS 2003 baseline results for cumulative human exposure over 17 years when 5 infected animals are introduced into the United States show an average of 18.5 animal ID50s would potentially be available for human exposure (50,000 iterations). This has been compared to the 2001 Harvard analysis which showed an average cumulative human exposure of 39 animal ID50s when 10 infected animals were introduced into the United States (5,000 iterations)[39]. Harvard also modeled the introduction of 5 infected animals in the 2001 model, showing a cumulative human potential exposure of 18 animal ID50s.[40] Both of the Harvard analyses assumed that no vertebrae from animals greater than 24 months age entered the bone-in-beef pathway.

The 2001 Harvard analysis predicted a mean of 4 additional animals infected cumulatively over the 20-year period following the introduction of 10 infected animals into the United States[41]. When the 2001 Harvard model was used to analyze the introduction of 5 BSE infected cattle, a mean of 2 additional animals were infected during the next 20 years[42]. In the 2003 FSIS baseline and mitigation analyses in which 5 infected cattle are introduced into the United States, a mean of slightly less than 2 additional animals were affected during the 17 year simulation.

For the SRM and AMR interim final rules, FSIS estimated a baseline level of potential human exposure. This is the potential human exposure to the BSE agent through consumption of beef through the year 2020, should FSIS not implement any risk management options beyond those already in place. The Agency then estimated

[39] Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, November 26, 2001. Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States, Appendix 3A Section 1 – Base Case.
[40] Harvard Center for Risk Analysis, 2001. (Appendix 3A Section 3.2).
[41] Harvard Center for Risk Analysis, 2001. Appendix 3A Section 1 – Base Case.
[42] Harvard Center for Risk Analysis, 2001. Appendix 3A Section 3.2.

exposure with the FSIS risk management measures in place. The scenarios assume that infected animals are introduced into the U.S. in 2003, but that the FSIS rules take effect in 2004. This means that the actions taken previously by the government to prevent or reduce BSE are already in place (e.g., feed ban, import limitations, etc) for all of the scenarios that are run, but that BSE infectivity may enter human food for one year before the FSIS mitigations take effect.

FSIS estimated the reduction in potential human exposure resulting from three different risk management alternatives. The alternatives are[43]:

- declare as SRMs: brain, eyes, trigeminal ganglia, and spinal cord from animals 30 months of age and older;
- declare as SRMs: brain, eyes, trigeminal ganglia, and spinal cord from animals 30 months of age and older, and distal ileum from cattle of all ages;
- declare as SRMs: brain, eyes, trigeminal ganglia, spinal cord from animals 30 months of age and older, distal ileum, and dorsal root ganglia,

To estimate the impact of the different risk management options, FSIS calculated potential human exposure when each of the three alternatives is implemented. The reduction in estimated potential human exposure for both the baseline and with the FSIS mitigation measures are shown below. Distributions of exposure were calculated

[43] These alternatives are not directly comparable to the alternatives analyzed in Section VII. SRM Analysis. However, the differences are inconsequential. Tonsils, tongue, and mechanically separated beef are not explicitly modeled in the risk assessment models. Therefore the amount of potential human exposure contributed by these materials is not included in overall potential human risk or in the risk reduction brought about by the mitigations as modeled. However the lost revenues resulting from their removal from the human food supply is reflected in the cost analysis. The information available to FSIS suggests that there is relatively low infectivity associated with these tissues. First, research conducted since the development of the Harvard BSE model suggest that small amounts of infectivity has been found in tonsils. However, tonsils were prohibited for use in meat food products before the new SRM regulations became effective, so human exposure to tonsils was limited. FSIS is not aware of any studies in which the tongue has demonstrated infectivity. Any infectivity attributed to the tongue is associated with a "long tongue," which may contain tonsils. Also, MS(beef) is not a "tissue." It represents contamination of low-risk tissues with high-risk tissues (i.e., spinal cord and DRG). However, very few, if any, establishments were intentionally producing MS(beef) before the SRM rules became effective, so human exposure to this product was also limited.

assuming 5 infected bulls were imported. Table 13 presents mean, 5%, median, and 95% estimates of exposure, as well as the incremental average reduction in potential exposure yielded by each alternative.

The two major sources of infectivity mitigated by the incremental risk reduction measures found in Alternative 3 are spinal cord and DRG from vertebral columns of cattle 30 months of age and older. Precise quantitative estimates of the relative share in the 50 percent reduction of potential human exposure that can be attributed to these two sources of infectivity in Alternative 3 have not been developed by the agency. The Agency has observed, based on experience from running the model and anecdotal

Table 13. Incremental change in potential human exposure for regulatory alternatives

	Potential human exposure (ID50) /1				
Regulatory alternative	Mean	5%	50%	95%	Incremental difference (means)
Baseline	18.5	0	5	70	--
1) Brain,spinal cord from animals > 30 months, eyes, and trigeminal ganglia	12.7	0	5	50	30%
2) Alternative 1 plus distal ileum from cattle of all ages	12.7	0	5	50	-- /2
3) Alternative 2, plus vertebral column from cattle >30 months (DRG and spinal cord from mis-split vertebral column).	4	0	0.08	20	50%

/1 The Harvard risk assessment expresses the amount of infectivity to which consumers might be exposed in terms of cattle oral ID50s. A cattle oral ID50 is the amount of infectious tissue that would be expected to cause 50% of exposed cattle to develop BSE.

/2 The additional reduction in risk of human exposure associated with the removal of beef small intestine is not significantly greater than the reduction in human exposure from Alternative 1.

information, that the contribution to estimated human exposure attributed to DRG far outweighs the contribution attributed to spinal cord.

Prior to measures taken by FSIS on January 14, 2004, under the incremental risk reduction measures identified in Alternative 3, human exposure to spinal cord resulted from mis-split vertebral column and spinal cord incompletely removed during slaughter of cattle 30 months of age and older. The 2001 Harvard analyses assumes that mis-splits occur 8 percent of the time during the slaughter of older cattle. When the AMR pathway is utilized, there is also a probability, 2 percent, that the spinal cord is not removed prior to AMR processing. When the AMR pathway is not utilized, there is a 50 percent probability of spinal cord removal.[44]

The baseline human exposure to DRG is likely higher through AMR than via the bone-in pathway. This is due to the dispersion of AMR product as an input for other beef products. The actual human consumption of DRG through the bone-in beef pathway is uncertain as the bone-in pathway includes edible rendered products, including bouillon, soup bases, and other products that may have higher probabilities of actual human consumption than tradition T-bone steak-type products in that pathway.

Results from the Alternative 3 simulation show a proportionally greater reduction in potential human exposure to ID50s from the AMR pathway. Table 14 shows an average exposure level of 9.5 animal ID50s in the FSIS baseline scenario versus less than an average of 1 animal ID50 in the mitigation scenario. There is an insignificant reduction in the contribution from this bone-in beef pathway in Alternative 3 versus the FSIS baseline analysis.

[44] Harvard Center for Risk Analysis, 200. Appendix 1, Table 2.18-1.

Table 14. Reduction in Human Exposure from AMR and Bone-in Beef

Product	Harvard 2003 /1, /2	FSIS 2003 /3	Alternative 3
	Number of ID50s (mean/5th percentile/95th percentile)		
AMR	10/0/38	9.5/0/40	.93/0/5
Bone-in –Beef	2.3/0/6.1	5.6/.001/20	5.5/0/20

/1 Harvard Center for Risk Analysis, 2001. Appendix 3A, Section 3.2. /2 20 year simulation. /3 17 year simulation.

Under the measures announced by FSIS on January 12, 2004, the spinal cord is required to be removed from the vertebral column of cattle 30 months of age and older. In addition, the vertebral column from cattle 30 months of age and older cannot be used for AMR systems. Thus, unless there is inadvertent use of this material in AMR systems or if cattle are not properly aged, components of the vertebral column may become incorporated into edible food, including steaks, meat from AMR systems, and edible rendered products. FSIS does not believe that the oxtail, used primarily for soups, is a source of potential infectivity because neither the spinal cord nor the DRG are present in the portion of the vertebral process that defines the tail area.

FSIS tested whether the model would predict linear increases in potential human exposure if the number of infected animals were changed. Table 15 summarizes the potential human exposure predicted by the baseline and mitigation scenarios (SRM and AMR rules) when different numbers of infected animals are imported.

The table shows that the average potential human exposure depends essentially linearly on the number of animals assumed to enter the U.S. The model predicts that the average amount of infectivity potentially available for human exposure from 2003 through 2020 would be about 43 cattle ID50s (95% CI: 2, 200). Since FSIS assumed that the SRM and AMR rules would not take effect until 2004, there is one year during which infectivity may enter the human food supply.

Table 15. Potential human exposure to the BSE agent (cattle oral ID50s)

Number of infected animals introduced	Mean	5%	50%	95%
	Baseline			
5 bulls	22	0.01	8	80
10 bulls	43	2	20	200
100 bulls	435	200	400	900
	With SRM and AMR rules in place one year after introduction of infectivity			
5 bulls	7	0	2	30
10 bulls	14	0	7	50
100 bulls	145	50	100	300

The model predicts that consumers could be exposed to about 7 cattle ID50s (95% CI: 0, 20) during that year. On average, the impact of the SRM and AMR rules would reduce the remaining 37 ID50s to about 14 ID 50s (or by about 80%). Thus, the analysis shows that during the 2004 through 2020 timeframe, consumers could potentially be exposed to an average of about 23 ID50s.

As noted earlier, the SRM and AMR rules implemented by FSIS (alternative 3) afford about an average of 80% reduction in potential human exposure at the mean. Since the number of infected animals that entered the United States is unknown, FSIS also considered whether the percent risk reduction predicted by the model would be sensitive to the amount of infectivity entering the U.S. cattle herd. Therefore, FSIS modeled the baseline potential human exposure the impact of implementing the SRM and AMR rules assuming 5, 10, or 100 infected bulls enter the United States. The percent reduction achieved by implementing the FSIS mitigations is relatively insensitive to the assumption about the number of imported infected animals.

The following table summarizes the impact of the rules and the impact of assuming different numbers of animals introducing BSE infectivity in 2003 on potential human exposure. The table presents both the baseline estimates and the impact of the SRM and AMR rules.

Table 16. Average potential human exposure to the BSE agent

No. of infected animals imported in 2003	baseline: 2003 – 2020	baseline: 2003 – 2004	baseline: 2004 – 2020	with SRM and AMR rules: 2004-2020	Percent reduction
5 bulls	22	3.5	18.5	7.5	80%
10 bulls	43	7	37	14	80%
100 bulls	435	70	365	145	80%

The measures include prohibiting certain SRMs from the human food supply and also requiring that AMR product not include spinal cord, DRG, or other CNS-type tissue. The analysis results show that the FSIS measures can reduce potential human exposure by 80 percent. These results reflect the implementation of the FSIS risk reduction measures one year after the introduction of infectivity into the U.S. cattle population. The fraction of the potential human exposure that can be prevented is consistent over a wide range in the assumed number of BSE infected cattle entering the livestock system.

The interim final rules and related measures will provide a substantial level of assurance to consumers that the U.S. food supply is safe. Because the exact quantitative relationship between human exposure to the BSE agent and the likelihood of human disease is unknown, the 2001 Harvard analysis did not evaluate the quantitative likelihood that humans will develop variant Creutzfeldt Jakob Disease (vCJD) if exposed to the BSE agent. Thus, the model predicts reduction in potential human exposure to the

BSE agent, but it is not possible at this time to estimate the potential human health benefits of these measures. The 2001 Harvard analysis also did not address potential human exposure to the BSE agent through products containing ingredients of bovine origin, such as some pharmaceuticals, gelatin, and beef stocks, extracts, and flavorings. Many of these products are derived through the edible rendering process. FSIS is working with FDA to address the impact of this issue.

Restoration of Beef Export Markets

About 40 countries have banned beef from the United States. The 2004 beef export demand forecast has been reduced by 90 percent.[45] In 2003, U.S. exports of beef, veal, and variety meats were valued at $3.8 billion. The value of exports of live cattle is small relative to the value of meat, and adds another $63 million.

There is no indication at this time when import bans on U. S. beef put in place by other countries will be lifted. The preventative measures announced by FSIS on January 14, 2004, in addition to other measures taken by the U.S. government, are intended to restore confidence in the U.S. beef supply and also to position the United States for reentry into the export market at the earliest possible date. These measures should also assure foreign consumers and eventually lead to the restoration of export markets for U.S. beef and beef by-products. Failure to assure consumer confidence in beef products could easily reduce cash receipts to the cattle sector by $5 to $10 billion annually. Net farm income could decline by $3 to $6 billion annually after taking into account changes in lower production costs.[46]

[45] U.S. Department of Agriculture. World Agricultural Supply And Demand Estimates, March, 2004.
[46] Based on analysis conducted by Economic Research Service, U. S. Department of Agriculture for FSIS. "Economic Impacts of the Discovery of BSE in the United States", January 6, 2004. The analysis is based

Appendix 1. References

The data used in establishing the baseline and estimating the impacts of the SRM and AMR interim final rules are derived from a number of sources. A number of scientific journal articles, studies, reports and other reference material, and expert opinion were used to analyze the impacts of the SRM and AMR interim final rules The references are shown in Appendix 1 of the FRIA (and below for this document). All references have been placed on display in the FSIS Docket Room (address above) and may be seen by interested persons between 8:30 a.m. and 4:30 p.m., Monday through Friday.

(1) Belay, E.D., et al, Relationship between transmissible spongiform encephalopathies in animals and humans. In: Task Force Report of the Council for Agricultural Science and Technology. Washington, DC: Council for Agricultural Science and Technology, October 2002, No. 136.

(2) MMWR, Probable Variant Creutzfeldt-Jakob Disease in a U.S. Resident—Florida, 2002, 51(41):927-929 October 18, 2002).

(3) Bruce, M.E., et al, Transmission to mice indicate that 'new variant CJD is caused by the BSE agent. Nature 389, 498-501 (1997).

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on the projected decline in beef exports, the subsequent decline in beef prices and prices of other meats. The analysis does not assume change in domestic demand resulting from lower meat prices.

(4) Cattle-Fax : National Cattlemen's Beef Association:, Economic Impact of BSE on the U.S. Beef Industry, a Power-Point presentation to the National Cattlemen's Beef Association, February 2003.

(5) Conninge, J., et al, Molecular analysis of prion strain variation and the aetiology of 'new variant' CJD. Nature 383, 685-690 (1996).

(6) European Union Scientific Steering Committee (EU SSC), 2001. Opinion of 10 December 1999 of the Scientific Steering Committee on the Human Exposure Risk (HER) via Food with Respect to BSE.

(7) European Union Scientific Steering Committee (EU SSC), 2002. Update on the Opinion of TSE infectivity distribution in ruminant tissues (initially adopted by the scientific steering committee at its meeting of 10-11 January 2002 and amended at its meeting of 7-8 November 2002) following the submission of (1) a risk assessment by the German Federal Ministry of Consumer Protection Food and Agriculture, and (2) new scientific evidence regarding BSE infectivity distribution in tonsils; European Commission, Scientific Steering Committee, Health and Consumer Protection Directorate General.

(8) Franco, D.A. & W. Swanson editors, The Original Recyclers, 1996.

(9) Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, November 26, 2001. Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States.

(9b) Harvard Center for Risk Analysis, Harvard School of Public Health, Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada 2003

(10 Jones, Morgan S. D., Quality and Grading of Carcasses of Meat Animals, 1995.

(11 Miller Publishing Co. Feedstuffs Ingredient Market, weekly reports in 2003.Ockerman, H. W. & C. L. Hansen, Animal By-Products Processing, 1988.

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(13) Pearson, A.M. & T.R. Dutson editors, Edible Meat By-Products: Advances in Meat Research, Vol. 5, 1988.

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(15) Scott, M.R., et al, Compelling transgenetic evidence for transmission of bovine spongiform encephalopathy prions to humans. Proc Natl Acad Sci USA 96, 15137-12142 (1997).

(16) Sparks Companies, Inc., Advanced Meat Recovery Systems – An Economic Analysis of proposed USDA Regulations, prepared for American Meat Institute. July 1999.

(17) Sparks Companies, Inc., Economic Analysis of FSIS Regulatory Options, prepared for American Meat Institute. June 2002.

(18) Tijskens, L. M., M. L. Hertog and B.M. Nicolai editors, Food Process Modeling, 2001.

(19) United Kingdom Food Standards Agency press release, Thursday, October 17, 2002.

(20) United States Department of Agriculture: Analysis of 2002 FSIS Bovine AMR Products Survey Results, prepared by the United States Department of Agriculture, Food Safety and Inspection Service, February 2003. Available on the internet at http://www.fsis.usda.gov/oa/topics/AMRAnalysis.pdf.

(21) United States Department of Agriculture: 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, prepared by the Food Safety and Inspection Service, February 2003. Available on the internet at http://www.fsis.usda.gov/OA/topics/AMRSurvey.pdf.

(22) United States Department of Agriculture: National Agricultural Statistics Service (NASS) Livestock Slaughter Summary 2002, March 2003.
(23) United States Department of Agriculture: National Agricultural Statistics Service (NASS) Livestock Slaughter Summary 2003, March 2004.

(24) United States Department of Agriculture: FSIS Animal Disposition Reporting System (ADRS 2003 & 2004).

(25) United States Department of Agriculture: FSIS Performance-Based Inspection System (PBIS 2003 & 2004), Washington, D.C.

(26) United States Department of Agriculture: Microbiological and Residue Contamination Information System (MARCIS 2003 & 2004), Washington, D.C. (note: This is FSIS data on regulatory test results of meat, poultry, and egg products, including beef and pork AMR products.)

(27) United States Department of Agriculture: FSIS Pork AMR Products Survey of 2003, Washington, D.C.

(28) United States Department of Agriculture: FSIS BSE Specified Risk Materials (SRMs) of BSE Survey of 2002, Washington, D.C.

(29) United States Department of Agriculture: FSIS Enhanced Facilities Database (EFD) of 2002, 2003, Washington, D.C.

(30) United States Department of Agriculture: Agricultural Marketing Service (AMS) in Livestock, Meat, Wool Market News, Weekly Summary, and Statistics, reports in 2003a, Des Moines, Iowa.

31) United States Department of Agriculture: Agricultural Marketing Service (AMS) in Livestock, Meat, Wool Market News, Daily Summary, and Statistics, reports in 2003b, Des Moines, Iowa.

32) United States Department of Agriculture: Economic Research Service, 2003 report released on February 6, 2004, Washington, D.C.

33) United States Department of Commerce Dept., Bureau of Census 2003 beef, veal, and beef variety meat exports in 2003, 2004, Washington, D.C.

34) United States Meat Export Federation (USMEF) data on beef and variety meat exports, 2002 & 2003, Washington, D.C.

(35) United States Department of Agriculture: Secretary of Agriculture, Ann Veneman speech of 30 December 2003.

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PRELIMINARY ANALYSIS OF INTERIM FINAL RULES AND AN INTERPRETIVE RULE TO PREVENT THE BSE AGENT FROM ENTERING THE U.S. FOOD SUPPLY

I. Summary

In response to finding a cow in Washington State positive for Bovine Spongiform Encephalopathy (BSE) on December 23, 2003, FSIS has taken emergency actions to protect public health. These actions include: designating certain high-risk tissues as specified risk materials (SRMs) and prohibiting the use of such materials for human food; requiring the condemnation of non-ambulatory disabled cattle presented for slaughter and use in human food applications; not awarding the mark of inspection on cattle tested for BSE under the Animal and Plant Health Inspection Service (APHIS) surveillance program until the test results are received and the results are reported to be negative for BSE; ensuring that advanced meat recovery (AMR) systems do not process SRMs and that boneless "meat" does not contain central nervous system (CNS)–type tissues or excess levels of bone solids and bone marrow; and prohibiting the use of certain stunning methods. These actions are all science-based measures intended to further minimize potential human exposure to the BSE agent through the consumption of beef and beef food products.

The extent of the economic impact of the BSE finding on the livestock sector and meat processing industry depends on domestic and foreign consumer attitudes toward the safety of the U.S. beef supply and how beef consumption habits might change given this new situation. Consumer attitudes may vary depending on 1) whether the single case of a cow with BSE were imported or of domestic origin, 2) the extent of the disease, and 3) how many cattle infected with BSE were taken out of the national beef herd. The finding

of a single cow with BSE originating from a shipment of imported cattle from Canada has had a negative impact on the U.S. cattle sector, largely as a result of decreased export demand. The measures prescribed by the SRM interim final rule provide greater assurances to both domestic and foreign consumers that the U.S. beef supply is safe.

As will be shown in the analysis later in this document the total annual cost of the FSIS actions related to the SRM and AMR interim final rules is estimated at $110.3 to $149.1 million. The total cost of the SRM interim final rule is estimated at $99.9 to $136.6 million. The primary impacts of the SRM interim final rule are the exclusion of SRMs from use in the human food supply ($35.6 to $36.7 million); the prohibition on non-ambulatory disabled cattle ($35.6 to $71.3 million); and modifications of HACCP plan/procedures, sanitation SOPs, or other pre-requisite programs and record keeping requirements ($27.6 million).

The annual total cost of the AMR interim final rule is estimated at $10.7 to $12.5 million. The primary impacts of the AMR interim final rule are restrictions on incorporating certain non-meat components in AMR products ($4.4 to $5.6 million); testing AMR product for iron, protein, and CNS-type tissues ($4.7 to $6.2 million); and revisions to HACCP and other plans, and bookkeeping requirements ($1.0 to $1.3 million).[1] Most values are reported as averages for the analysis. Some values however are reported at the 5^{th} and 95^{th} percentiles of the distribution.

[1] The cost impact analysis of the SRM and AMR Interim Final rules is based on a probabilistic model developed by FSIS, excluding the prohibition on non-ambulatory disabled cattle from the food supply (p. 28) and HACCP plan development, record keeping, and verification (p.33). The cost impacts of these regulatory measures are based on the deterministic values cited in the text of the analysis.

The annual cost of additional inspection, testing, and surveillance by FSIS is estimated at $3 million[2]. This estimate does not include the impact of FSIS measures on programs administered by other USDA agencies. Nor does it include the impacts of changes in the programs of these agencies on FSIS program costs. These impacts are difficult to estimate at this time due to uncertainty about the provisions of the programs that may be implemented by other USDA agencies.[3] The action related to the prohibition on certain stunning devices is not expected to have any cost impacts as these devices are no longer in use.

The aggregate beef price impacts of the measures contained in the SRM and AMR interim final rules are not expected to be significant.[4] The measures affecting the removal of SRMs from the human food supply, excluding the condemnation of non-ambulatory cattle presented for slaughter, may have a minimal impact on consumer beef prices. Price impacts are expected to be primarily limited to products derived from beef small intestines such as sausages with natural casings and trepas for which substitutes are limited. Substitutes are available for other by-products, largely from cattle less than 30 months of age, although prices will likely be somewhat higher. For example, the prohibition on bone-in beef cuts from cattle 30 months of age and older will raise the

[2] United States Department of Agriculture, 2005, Explanatory Notes for the Committee on Appropriations, Volume 1, page 14-14.

[3] The impacts of the test and hold provision depend on the level of surveillance testing for BSE that will be conducted by the APHIS on cattle presented for slaughter at federally-and state-inspected establishments. Because non-ambulatory disabled cattle are prohibited for use in human food, APHIS surveillance testing for BSE may shift toward locations other than federally inspected establishments and thereby minimize the impacts of the new FSIS test and hold policy on establishments that slaughter cattle. However, a more extensive BSE surveillance program that focuses on all cattle 30 months of age and older may increase testing at these establishments, and consequently the impact of the test and hold provisions.

[4] FSIS is collecting additional information on cost impacts of the SRM and AMR interim final rules that may not be fully reflected in the current analysis. When this information is available, it will be used with existing information to estimate the beef price impacts, disaggregated by major market categories. This analysis, conducted by RTI, International, along with information from public comment; will be incorporated into the final regulatory impact analysis.

prices of these cuts from younger cattle. The removal of non-ambulatory cattle from the food supply is not expected to have a significant impact on beef prices given the very small share of beef supply affected (0.1 percent).

The costs associated with regulatory measures affecting the segregation and disposal of SRMs, and changes in process control practices including plan development and record keeping are not significant from an industry perspective. Consequently, the resulting impacts on beef and beef products, and both beef and pork AMR products are not expected to be significant.

Anecdotal information suggests that prices received for cattle 30 months of age and older are being significantly discounted from prices for cattle of equivalent grade that are less than 30 months. The amount of the discount may reflect a combination of costs due to product loss, segregation, SRM removal and disposal, and other related processing control costs. These impacts could be significant for cattle producers. The Agency requests comment on the effect of the SRM interim final rule provisions on cattle marketing practices and prices.

The following is a preliminary analysis of the major impacts of the measures contained in the SRM and AMR interim final rules. The Agency is seeking comment from the public on the types and magnitude of the impacts resulting from the SRM and AMR interim final rule measures to ensure that the final regulatory impact analysis is comprehensive.

II. Cattle and Meat Processing Industry.

The United States has the largest fed-cattle industry in the world, and is the world's largest producer of beef, primarily high-quality grain-fed beef, for domestic and

export markets. Beef production in 2003 is estimated at 26.3 billion pounds from an annual slaughter of about 36 million cattle. Gross farm income from cattle and calf production totaled $44.1 billion in 2003[5]. U.S. exports of beef, veal, and beef variety meats in 2003 were 2.6 billion pounds valued at $3.8 billion according to the most recent estimates.

In 2003, 98.7 percent of all cattle were slaughtered for food and processed in federally-inspected establishments.[6] About 80 percent of the cattle slaughtered at federally- inspected establishments are estimated to be less than 30 months of age. The remaining 20 percent are cows, bulls, or stags and some steers and heifers that are estimated to be 30 months of age and older[7]. FSIS seeks comments on the age distribution of cattle sent to slaughter and, in particular, reliable information on the age distribution of cattle slaughtered at establishments that specialize in market or fed cattle.

In 2003, cattle were processed for dress or further processing in an estimated 4,033 establishments that are federally- and State-inspected. Of the 4,033 establishments, FSIS estimates that about 84 percent or 3,388 were establishments that typically dealt with SRMs during carcass dressing, meat-cut fabrication, or further processing of carcasses or parts of carcasses. The remaining 16 percent, or 645, were establishments that did not receive SRMs of any type, or only received parts of beef carcasses derived

[5] U.S. Department of Agriculture, Economic Research Service, released on February 6, 2004 at ERS website: http://www.ers.usda.gov/briefing/farmincome/ See the following for more detailed information: http://www.ers.usda.gov/data/farmincome/finfidmu.htm

[6] U. S. Department of Agriculture, Food Safety and Inspection Service. Animal Disposition and Reporting System, 2003.

[7] FSIS has found that some first-calf cows, and some juvenile (not mature) and mature bulls that go to slaughter may be less than 30 months of age. Furthermore, FSIS has found that some steers and heifers that go to slaughter may be 30 months of age and older. These steers and heifers have been fed primarily grass pasture or forage crops while growing and then finished for grading on grain. Also, heifers that have failed to conceive in the breeding season, or have lost their calves, have been removed from cattle herds. These older heifers, that have already matured, have been placed in feedlots where the heifers have been finished for grading on grain. These practices affect the share of meat slaughter and processing establishments which may have to modify their practices in response to the proposed measures.

from cattle 30 months of age and older that did not include the vertebrae (e.g. boxed boneless trimmings for further processing). Furthermore, of the 3,388 establishment that typically dealt with SRMs, approximately 888 (26 percent) are State-inspected establishments and about 2,500 (74 percent) are federally-inspected establishments. Of these 3,388 establishments, about 2,128 (62.8 percent) were establishments that are classified by FSIS as "very small." About 1,203 (35.5 percent) of the establishments were classified as "small." The remaining 57 establishments (1.7 percent) were classified as "large." [8] These 57 large establishments slaughter or further process more than 94 percent of the cattle. All of the large establishments are federally-inspected. The 1,203 small establishments slaughter and process about 5 percent of the cattle. The 200 largest establishments slaughter or process about 98 percent of the cattle[9].

In 2003, about 56 establishments used AMR systems to produce beef and pork AMR products. AMR products derived from beef vertebrae were produced in about 30 establishments. Pork AMR products derived from pork vertebrae were produced in about 22 establishments. One establishment produced both beef and pork AMR products derived from vertebrae. At least four establishments produced beef or pork AMR products derived from non-vertebral bones. About 17 AMR establishments were small establishments, and the remaining were large. At least one establishment processed beef vertebrae from its operations and the operations of another establishment. About three AMR establishments only fabricated cuts or processed carcasses or parts of carcasses.

[8] The size classifications used by FSIS for very small, small, and large establishments are defined as establishments with fewer than 10, between 10 and 499, and 500 or more employees, respectively.
[9] U.S. Department of Agriculture. Animal Disposition and Reporting System, FSIS. 2003.

III. Scientific Findings

In April 1998, USDA commissioned the Harvard School of Public Health, Center for Risk Analysis, to conduct an analysis and evaluation of the current measures implemented by the U.S. government to prevent the introduction and spread of BSE in the United States and to reduce the potential human exposure to the BSE agent. The Harvard risk assessment reviewed available scientific information related to BSE and other Transmissible Spongiform Encephalopathies (TSEs), assessed pathways by which BSE could potentially occur in the United States, and identified measures that could be taken to protect human and animal health.[10]

The Harvard BSE risk assessment concluded that if introduced, BSE is extremely unlikely to become established in the United States and that should BSE enter the United States, only a small amount of potentially infective tissue would likely reach the human food supply and be available for human consumption. The Harvard study identified three pathways or practices that could contribute most to either increased human exposure to the BSE agent or to the spread of BSE should it be introduced. The three pathways are:

- Noncompliance with FDA regulations prohibiting the use of certain proteins in feed for cattle and other ruminants;
- Rendering of animals that die on the farm and use (through illegal diversion or cross-contamination) of the rendered product in ruminant feed;
- Inclusion of high-risk tissue from cattle, such as brain and spinal cord, in edible products.

The Harvard study concluded that, based on conditions as they existed in 2001, if 10 infected cows were introduced into the United States, on average, three additional new cases of BSE in cattle would be expected in a 20 year time period. The Harvard study

[10] Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, November 26, 2001. Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States.

predicted that there was a 75 to 95 percent chance that there would be no new cases at all. An extreme case (95th percentile of the distribution) predicted 11 new cases. However, the simulation studies showed that the animal health emergency management system, and other safeguards in place in 2001, was sufficient to ensure that the disease would be quickly cleared from the United States with virtually no chance that there would be any infected animals 20 years following the import of the 10 infected cattle.

The Harvard study concluded that the greatest sources of potential human exposure to the BSE agent would be human consumption of cattle brain (26 percent of the total potential exposure on average), cattle spinal cord (5 percent of the total potential exposure on average), and beef products derived from AMR systems (57 percent of the total potential exposure on average). The Harvard study also determined that other potential human exposure routes to the BSE agent include consumption of bone-in beef products (11 percent of the total potential exposure on average), and small intestine (2 percent of the total potential exposure on average). However, as stated in the Harvard study, these estimates are likely to overstate true human exposure because they represent the amount of infectivity presented for human consumption but do not take into account waste or actual consumption rate. The basic findings of the Harvard study were used to develop measures to address the food safety concerns arising from the finding of BSE in the United States. The Harvard BSE risk assessment model has been revised to include two additional scenarios since it was initially developed. The input parameters used in the Harvard BSE risk assessment model were further modified by FSIS to evaluate the impacts of various risk mitigation measures on the potential human exposure during the

development of the SRM interim final rules. A discussion of these modifications is provided in section IX. Benefits.

IV. Preventive Measures

Prior to the detection of the BSE case on December 23, 2003, the United States government had already implemented a number of measures to prevent BSE from entering the United States and to prevent the spread of the disease should it be introduced into this country. Since 1989, APHIS has prohibited the importation of live cattle and certain cattle products, including rendered protein products, from countries where BSE is known to exist. In 1997, due to concerns about widespread risk factors and inadequate surveillance for BSE in many European countries, these importation restrictions were extended to include all of the countries in Europe. In 1997, FDA prohibited the use of most mammalian protein in the manufacture of animal feeds given to cattle and other ruminants. However, compliance was not complete or immediate. In December 2000, APHIS prohibited all imports of rendered animal protein products, regardless of species, from BSE-restricted countries because of concern that feed intended for cattle may have been cross-contaminated with the BSE agent. In addition, APHIS leads an ongoing, comprehensive, interagency surveillance system for BSE in the United States and, in cooperation with FSIS, has drafted an emergency response plan to be used in the event that BSE is identified in the United States. This plan was activated when the BSE test for the cow in Washington State came back presumptive positive December 23, 2003. Other Federal agencies also have contingency plans that work in concert with the USDA plan.

On December 30, 2003, Agriculture Secretary Ann Veneman announced additional safeguards to bolster U. S. protection systems against BSE, and further protect

the public health from the consumption of the BSE agent. The documents that implement these policies were published in the Federal Register on January 12, 2004, and the policies became effective at that time. The policies require that non-ambulatory disabled cattle presented for slaughter be condemned; designate certain materials as SRMs, and prohibit the use of such materials for human food; require that establishments that produce boneless meat using AMR systems implement additional process controls; require that the carcasses of cattle that have been targeted for BSE surveillance testing be held until the test results are received and the results are reported to be negative for BSE; and prohibit the use of air-injection stunning of cattle. These policies were issued as three Interim Final Rules and a Federal Register Notice and are described below.

Interim final rule "Prohibition on the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle" (69 FR 1862):

- Designates that the brain, skull, eyes, trigeminal ganglia, dorsal root ganglia (DRG), spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age and older; and the tonsils and the distal ileum of all cattle as SRMs;
- Declares that SRMs are inedible and prohibits their use for human food;
- To ensure effective removal of the distal ileum, requires that the entire small intestine be removed and disposed of as inedible;
- Requires that establishments that slaughter cattle, or establishments that process the carcasses or parts of cattle, develop, implement, and maintain, written procedures for the removal, segregation, and disposition of materials designated as SRMs. Establishments must incorporate these procedures into their HACCP plans, Sanitation SOPs, or other prerequisite program;
- Prohibits Mechanically Separated (MS) (beef) food product for human food;
- Requires that all non-ambulatory disabled cattle presented for slaughter be condemned and prescribes requirements for the handling and disposition of such cattle.

Interim final rule, "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems" (69 FR 1874):

- Prohibits the use of vertebral columns and skulls of cattle 30 months of age and older in the production of AMR product (product derived from these materials is adulterated);
- Prohibits the incorporation of any brain, trigeminal ganglia, spinal cord, or DRG in AMR product identified as "meat";
- Finalizes restrictions related to bone solids and bone marrow (as measures by calcium and iron content);
- Requires establishments which produce AMR product to document their process controls in writing, and if the establishment processes cattle, the program must be in its HACCP plan Sanitation SOP, or other prerequisite program.

Interim final rule, "Prohibition on the Use of Certain Stunning Devices Used to Immobilize Cattle" (69 FR 1885):

- Prohibits the use of penetrative captive bolt stunning devoices that deliberately inject air into the cranial cavity of cattle.

Federal Register Notice, "Bovine Spongiform Surveillance Program" (69 FR 1892)

- Announces that FSIS inspection program personnel will no longer pass and apply the mark of inspection to the carcasses and parts of cattle that are selected for testing by APHIS for BSE testing until the test results are received and the results are reported negative for BSE.

State-inspected establishments must implement procedures that are equal to those prescribed in the new regulations (21 U.S.C 301). Foreign establishments that export meat food product to the United States also must implement procedures equal to those prescribed in the new regulations. FSIS intends to evaluate foreign "equivalency" on a case-by-case basis.

V. Baseline Regulatory Environment Prior to the Issuance of BSE Regulations.

The following describes regulatory conditions prior to the issuance of the above regulations.

Non-Ambulatory Disabled Cattle. Prior to December 30, 2003, the date that the Secretary announced the prohibition on the slaughter of non-ambulatory disabled cattle

for human food, non-ambulatory disabled cattle were not automatically condemned on antemortem inspection. However, these animals were automatically suspected of being affected with a disease or condition that may require condemnation of the animal, in whole or in part, and were identified as ``U.S. Suspects" (9 CFR 309.2(b)). All animals identified as "U.S. Suspects" are examined at ante-mortem inspection by an FSIS veterinarian, and a record of the veterinarian's clinical findings accompanies the carcass to post-mortem inspection if the animal is not condemned on ante-mortem inspection. Under FSIS' regulations, "U.S. Suspects," must be set apart and slaughtered separately (9 CFR 309.2(n)). If, on post-mortem inspection, the meat and meat food products from such cattle are found to be not adulterated, such products may be used for human food (9 CFR 311.1).

Specified Risk Materials. Prior to January 12, 2004, the date that the new FSIS policies to prevent human exposure to the BSE agent were issued, most of the materials designated as SRMs under the new regulations were permitted for use in human food. Thus, establishments were not required to develop, implement, and maintain written procedures for the removal, segregation, and disposition of these materials. Furthermore, U.S. companies were permitted to export these materials and to import these materials from foreign countries (provided that the regulatory requirements for importing or exporting meat food products were met):

- Brain, spinal cord: The brains of all livestock species, including the brains of cattle regardless of age, were permitted for human food. Cattle brains from cattle of all ages were also permitted to be used as a source material in edible rendering. Although detached spinal cords from all livestock species, including cattle, were, and still are, prohibited for use in the preparation of edible products, detached spinal cords from all livestock species, including those from cattle 30 months of age and older, were permitted to be used as a raw material in edible rendering (9 CFR 318.6(b)(4)).

- Vertebral column and DRG: Bones from the vertebral column of cattle of all ages, including bones that contain DRG, were permitted to be used for bone-in cuts of beef, as source materials in the production of processed products manufactured from edible rendering, as source materials in AMR systems, and in the production of MS (beef) meat food product. Furthermore, although DRG is not marketed as a consumer product, there were no restrictions on the incorporation of DRG into beef AMR product, products produced from edible rendering, or MS (beef) meat food product.

- Small intestine: For clarification, it is the distal ileum that is the SRM. However, to ensure effective removal of the distal ileum, FSIS requires the entire small intestine to be removed and designated as inedible. Thus, throughout this document the small intestine is referred to when ever discussing costs and benefit impacts. The entire small intestine from cattle of all ages was permitted for use as human food and were typically sold as "trepas." Casings made from the small intestine of all cattle regardless of age were permitted to be used as containers for meat food products. Cattle small intestines from cattle of all ages were also permitted for use as ingredients in meat food products provided that certain labeling requirements were met.

- Skull, eyes, trigeminal ganglia, tonsils: Although FSIS' regulations did not prohibit the use of cattle eyes for human food, direct consumption of such materials is uncommon in the United States. The tonsils of all livestock species, including cattle, were prohibited for use as ingredients of meat food products but could be used for edible rendering. The trigeminal ganglia of cattle are not sold directly as consumer products. However, the heads of cattle (commonly referred to as "market heads"') were permitted for use as human food regardless of the age of the animal. Cattle market heads contain skull, eyes, trigeminal ganglia, and fragments of brains.

Proportion of infectivity in certain tissues. In 2001, the European Commission's Scientific Steering Committee (SSC), a scientific advisory committee for the European Union, considered the amount and distribution of BSE infectivity in a typical case of BSE and estimated that, in an animal with clinical disease, the brain contains 64.1 percent of the total infectivity in the animal and the spinal cord contains 25.6 percent of the total infectivity.[11] Thus, the brain and spinal cord of cattle with clinical BSE are estimated to contain nearly 90 percent of the total infectivity in the animal. According to the SSC, the

[11] European Union Scientific Steering Committee (EU SSC), 2001. Opinion of 10 December 1999 of the Scientific Steering Committee on the Human Exposure Risk (HER) via Food with Respect to BSE,

remaining proportion of infectivity in a typical animal with clinical BSE is found in the DRG (3.8 percent) the trigeminal ganglia (2.6 percent), the distal ileum (3.3 percent), the spleen (0.3 percent), and the eyes (0.04 percent).[12] However, in experimentally infected cattle, BSE infectivity has been demonstrated in the distal ileum as early as 6 to 18 months post oral exposure to the BSE agent and in the tonsils as early as 10 months post exposure. Thus, in younger cattle infected with BSE, these materials apparently present the greatest risk of exposing humans to the BSE agent.

Advanced Meat Recovery (AMR). Under FSIS' former and current regulations, boneless comminuted beef from AMR systems can be labeled as "meat"' because it is comparable to meat derived from hand-deboning (9 CFR 301.2). Under the former and current FSIS regulations, spinal cord is not considered a component of meat, and therefore, product from AMR systems identified as "meat"' that contains spinal cord is misbranded. Prior to January 12, 2004, vertebral bones and skulls from cattle 30 months of age and older were permitted to be used as source materials in AMR systems and beef AMR product that contained spinal cord from cattle 30 months of age and older was not considered adulterated. Furthermore, AMR product that contained DRG was not misbranded or adulterated, even if the DRG were from cattle 30 months of age and older.

Under the former AMR rule, AMR product could not exceed a calcium content of 0.15 percent or 150 milligrams/100 grams of product (150 mg/100 g) within a tolerance of 0.03 percent or 30 mg per 100g of product for each sample analyzed. The rule also required that the bones emerging from the AMR machinery be comparable to those resulting from hand deboning. The new rule establishes a calcium content limit,

[12] For this study, low levels of infectivity were assumed for the spleen and eyes based on scrapie experiments. The spleen has not demonstrated infectivity in cattle.

measured by individual samples and rounded to the nearest 10^{th}, of 130 mg per 100 g, and establishes an iron content limit, measured by duplicate analyses on individual samples and rounded to the nearest 10^{th}, of 3.5mg per 100 g. These limits apply to AMR product derived from the bones of all livestock species.

Air Injection Stunning. FSIS' regulations specifically listed air-injection captive bolt stunning as an approved method for injecting air into the carcasses or parts of livestock. However, FSIS is not aware of any US establishments that are using this stunning technique.

Test and hold policy. Before FSIS issued the "test and hold" policy, FSIS inspection program personnel applied the mark of inspection to the carcasses of cattle tested for BSE under APHIS' surveillance program before the test results were known.

VI. Modeling Economic Impact of BSE Regulations.

The purpose of the economic model is to quantify the economic effect of the SRM and AMR interim final rules, which require the implementation of a number of mitigation measures that, would reduce the risk of infectivity that may be present if an infected animal was slaughtered from entering the food system. To account for uncertainty and variability with many of the key economic costs a stochastic model was developed[13] to generate tables 1, 2, 4, 5, 9, and 11. A non-stochastic model was developed and used to generated tables 6, 7, and 10. The numbers used in table 8 is a mixture of both types of models. To do the cost-effectiveness analysis a stochastic model was also developed to assess the risk and generate tables 13, 14, 15, and 16. The totals in the columns may disagree with sums of individual at times because of rounding.

[13] Variability reflects the natural differences between values. Uncertainty reflects the ability to accurately measure a parameter.

The distributions for the stochastic models were derived from various data, including survey data, laboratory results, expert opinion,[14] and scientific literature. The references for the data are shown in Appendix 1. Appendix 2 provides documentation of baseline values and assumptions used in the models to estimate the cost impacts of the SRM and AMR interim final rules. Appendix 3 contains the model for estimating the cost of the SRM interim final rule. Appendix 4 contains input and output values for the models used to estimate SRM and AMR interim final rule cost, including information on distributions. Appendix 5 contains the model for estimating the cost of the ARM interim final rule. These appendices will be available electronically at the FSIS website. Reference materials cited in this document and comments received will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 4:30 p.m.

The SRM Rule scenario estimates the annual amount of brain, spinal cord, vertebral column, small intestines and other SRMs affected by the rule. The AMR Rule scenario estimates the amount of AMR product affected by the rule. For the analysis of the SRM interim final rule, four scenarios were run, each with 50,000 iterations using @Risk® Version 4.5 (Palisade Corporation). The alternative scenarios are listed in Table 3.

An example of how the data, information, and the reference material are used by FSIS in the costs analysis is shown in the following example. Estimates of the quantity of beef SRMs affected by the SRM interim final rule are based on the following information:

[14] Note, while some variability may be inherent in the model, more intensive data collection can often reduce uncertainty. There are several places in this modeling effort where data currently are lacking. Because specific data were unavailable at this time "expert" opinion was sought and distributions used to capture the uncertainty. Given the modeling effort is a dynamic process, when more complete information becomes available it can be added to the model.

(1) Baseline used for analysis is 2003, before the BSE case reported on 23 December, 2003. The baseline specifies the number of beef establishments, beef establishment profiles of activities, beef slaughter numbers, beef carcasses and parts of carcasses production, beef by-products production, beef and beef variety meat exports, beef and beef variety meat prices. Data and information sources include: NASS; FSIS; AMS; ERS; U.S. Commerce Dept., Bureau of Census; and U.S. Meat Export Federation);

(2) Average fed-cattle live weight at slaughter was 1250 pounds, in 2003 (source: NASS 2004); and

(3) Beef products and by-products yields were expressed as percent of live weight (sources: NASS 2003 & 2004, AMS 2003 & 2004; FSIS Beef AMR Products Survey of 2002; Ockerman, 1988 & 2002; Pearson, 1988, 1992; and Jones, 1995).

Using these data, a model was developed which estimates the annual amount of brain, spinal cord, vertebral column, small intestines and other SRMs affected by the SRM interim final rule. The relationships forming the model are based on the following parameters.

N_s = 36 million head of cattle slaughtered, in 2003 (the average number of cattle slaughtered annually, in millions of cattle (including calves), from NASS 2004;

W_{lwt} = 1250 pounds per slaughtered fed-cattle, in 2003 (the average live weight of slaughtered fed-cattle, in pounds) from NASS 2004;

Y_{plwt} = average yield of SRM as a percent of average live weight of slaughter cattle (W_{lwt}), in percent, from NASS 2003 & 2004, AMS 2003 & 2004, the FSIS Beef AMR Products Survey of 2002; Ockerman, 1988 & 2002; and Pearson, 1988, 1992; and Jones, 1995; and

N_a = average number of affected cattle, annually, in millions of heads, from the FSIS BSE SRM Survey of 2002, and the FSIS beef AMR products regulatory test results of 2003 (FSIS MARCIS 2003).

Then:

Q_a = average quantity yield of SRM per head, in pounds, or

$Q_a = (Y_{plwt}) \times (W_{lwt})$;

P_a = average proportion of affected slaughtered animals calculated as a percent of the total U.S. cattle slaughtered, in percent, calculated average proportion of

affected slaughtered cattle (including calves) as a percent of the total U.S. cattle (including calves) slaughtered annually, (P_a), in percent, or

$P_a = (N_a/N_s)$; and

Q_t = Average total pounds of SRM affected, annually, in millions, or

$Q_t = (Q_a)(N_a)$, or

$Q_t = (Y_{plwt}W_{lwt})(P_aN_s)$

Baseline Conditions. Conditions in the livestock sector and meat and poultry industry during 2002-03, prior to the finding a BSE infected cow in Canada, comprise the baseline for assessing the economic analysis of impacts associated with SRM and AMR interim final rules and related rulemaking. This period is selected as the baseline because changes in product formulation, slaughter and processing practices, including age determination and segregation by age, took place in a variety of establishments, especially in the northern tier of States, following the May 20, 2003 finding of a BSE infected cow in Canada. This baseline was also selected because of the availability of comprehensive and reliable data on AMR production and the prevalence of SRMs in beef and pork products. These data sources include: Beef AMR Products Survey of 2002, BSE Specified Risk Material Survey of 2002, and Beef AMR product testing results for 2003, and the Pork AMR Product Survey of 2003. Also, the analytical framework developed for conducting regulatory impact analyses of the BSE and AMR regulatory alternatives being considered prior to the BSE finding can also be utilized in conjunction with a pre-BSE finding baseline.

Analytical Approach to Interim Final Rule. The cost analysis of the FSIS interim final rules should distinguish between responses beginning in early 2004 by the cattle and meat processing industries to comply with FSIS regulatory requirements and responses,

by the livestock sector and meat and poultry industries, to market forces associated with the finding of a BSE infected cattle in Canada and the United States. Market forces include changes in domestic and foreign consumer preferences, demand for new information such as the origin, product formulation, and process characteristics of beef that relate to food safety, changes in technology, and other factors. However, there is no clear dividing line between responses by the industry to the SRM and AMR interim final rules and related measures, and market forces resulting from the positive diagnosis of BSE infectivity in the North American cattle herd.

FSIS is aware of changes in cattle slaughter and processing practices that took place during 2003, in the United States, in response to the finding of a BSE infected cow in Canada. FSIS is also aware of measures being taken by some firms in the cattle and meat industries immediately following the December 23, 2003 notification of a BSE infected cow in Washington State. Some of the measures taken by meat industry were consistent with measures to comply with the SRM and AMR interim final rules announced January 14, 2004 by FSIS. These measures include the age determination of cattle and the segregation; separate slaughter and/or processing of cattle 30 months of age and older; and disposal of SRMs. In response to customer requests, some suppliers of AMR product became more selective with regard to the origin and age of the source animals. These changes were occurring in slaughter (animals), fabrication (product processing), and marketing activities prior to the onset of regulatory requirements. To the extent that meat processing establishments voluntarily undertake measures to prohibit the use of SRMs, and exclude their use in human food, the cost impacts of the regulatory requirements estimated in this analysis would be reduced accordingly. The available

information regarding voluntary measures is largely anecdotal and cannot be verified in a manner that would be useful for economic analysis. Consequently, the baseline for FSIS estimates of the compliance costs for the SRM and AMR interim final rules does not include voluntary measures meat slaughter and processing firms may have taken in response to the finding of BSE infectivity between May 20, 2003 and January 12, 2004. FSIS requests comment on the types of changes that took place in the U.S. livestock industry, and meat and poultry industry following the May 20, 2003 finding of a BSE infected cow in Canada.

VII. SRM Analysis

The model results for the total annual amount of brain, spinal cord, vertebral column used to produce AMR, and meat from non-ambulatory disabled cattle affected by the SRM interim final rule are shown in Table 1.

The total amount of beef and pork products and by-products affected by the domestic and export market as a result of the SRM and AMR interim final rules is estimated at 237 million pounds (Table 2). Nearly all the amount removed from human consumption is beef. Approximately 24 million pounds of these products are recovered as lower valued, edible products, leaving a net reduction of 213 million pounds. As shown in table 1 the exclusion of beef small intestines from the human food supply accounts for about the most significant (160 million pounds) of the total amount removed. A large amount of this product, which is now declared inedible, had been exported. The exclusion from the food supply of vertebral column from cattle 30 months of age and older also accounts for a significant amount (24.7 million pounds). The net amount of beef and edible beef by-products removed as a result of prohibiting non-

Table 1. Annual estimates of average SRM amounts affected by the SRM Interim final rule. /1 (All values are estimates of average distributions unless otherwise identified.)

Specified Risk Material (SRM)	(Y_{plwt}) Yield as percent of average live weight /2 of slaughter cattle (W_{lwt}) /3	(Q_a) Yield per animal (Y_{plwt})x(W_{lwt}	(N_a) Number of affected animals /4	(P_a) Affected animals, share of U.S. cattle slaughtered /5 (N_a/N_s)	(Q_t) Amount of SRM affected (Q_a) x (N_a)
	percent	Pounds	Thousand	percent	Thousand
Brain	0.08	1	373.0	1.036	373.0
Spinal Cord	0.03	0.375	161.0	0.447	60.0
Small Intestines (Incl. Distal Ileum)	0.88	11	14,535.0	40.375	159,885.0
Vertebral Columns for AMR Products (incl. DRG)	0.72	9	2,755.0	7.65	24,795.0
Non-ambulatory Disabled Cattle (Incl. calves)	18.7 /6	234	144.0 /7	0.4	33,700

/1 Estimated pounds of affected SRM from slaughtered cattle, and from non-ambulatory disabled cattle (including calves), in 2003.
/2 Live weight (W_{lwt}) of slaughtered fed cattle = 1250 pounds (NASS 2004)
/3 Yield as percent of average live weight of slaughter cattle (W_{lwt}), in percent (NASS 2003 & 2004, AMS 2003 & 2004; FSIS Beef AMR Products Survey of 2002; Ockerman, 1988 & 2002; Pearson, 1988, 1992; and Jones, 1995)
/4 Number of affected animals slaughtered (N_a), annually (FSIS BSE SRM Survey of 2002 and FSIS beef AMR products regulatory test results of 2003 (FSIS MARCIS 2003))
/5 calculated average proportion of affected slaughtered cattle (including calves) as a percent of the total U.S. cattle (including calves) slaughtered annually, (P_a), in percent. Number of cattle slaughtered (N_s) annually = 36 million cattle (including calves) (NASS 2004)
/6 29 percent of the live weight was removed as inedible e.g., fractured leg is removed; or that the animal was a thin cow that had lost 29 percent of its weight e.g., a live weight of 888 pounds instead of 1250 pounds live weight; or, in some cases, the non-ambulatory disabled animal was a 120 to 150 pound live weight veal calf
/7 Net 144,000 head of affected cattle (including calves) after a condemnations rate of 26% of 195,000 head of non-ambulatory disabled cattle (including calves)

ambulatory disabled cattle from human food is estimated at 33.7 million pounds. The measures contained in the AMR interim final rule will affect about 6.6 million pounds of beef and pork product from human consumption, 2.4 million of which is recovered as mechanically separated pork, MS(pork).

The short-term adjustment costs may be significant for establishments that processed cattle 30 months of age and older, or relied on edible by-products or cuts of

Table 2. Disposition of average amounts of beef and pork products affected by SRM and AMR interim final rules, product removed from human consumption./1

	Baseline Utilization /2	Post-rule Utilization /3	Net amount of product removed /4
	Thousand pounds		
SRM Interim Final Rule			
Non-ambulatory disabled cattle	33,700	0	33,700
Small intestine, incl. distal ileum	159,885	0	159,885
Brains	373.3	0	373.3
Spinal cord	60	0	60
Vertebral column	24,795	11,020	13,775
Edible Rendering	636		636
Bone-in cuts w/vertebrae	10,866	8,996	1,870
Skulls, eyes, TTG	424	157	267
Tonsils for edible rendering	42		42
Subtotal	230,825	20,173	210,652
AMR Interim Final Rule			
Beef due to yield loss derived from:			
Vertebral column	1,387	1,174	213
Non-vertebral column	0		0
Pork due to yield loss derived from			
Vertebral column	64		64
Non-vertebral column	0		0
Beef due to non-compliance derived from			
Vertebral column	1,920		1,920
Non-vertebral column	4		4
Pork due to non-compliance derived from			
Vertebral column	3,231	2,424	807
Non-vertebral column	7	7	0
Subtotal	6613	3,605	3,008
Total	237,038	23,778	213,260

/1 All values are estimates of average distributions unless otherwise identified.
/2 Product destined for domestic consumption prior to implementation of the SRM and AMR interim final rules and destined for the export market prior to the implementation of import bans by foreign countries. Excluded product used in inedible rendering or disposed.
/3 Product recovered through hand deboning.
/4 Recovered for industrial use typically in inedible rendering, i.e. feed, fuel, and fertilizer.

meat from these cattle. Brains, eyes, spinal cords, and the beef small intestines are primarily harvested and processed for export markets. Vertebral columns and skulls (market heads) are primarily used to produce meat and meat food products for domestic markets. The restrictions of the use of these materials may necessitate further

identification and segregation of cattle, beef, and by-products by age group in marketing, slaughter, and processing.

The major impacts of the SRM interim final rule are the exclusion of SRMs from the food supply, prohibition on non-ambulatory disabled cattle, modification of plans and record keeping, and SRM segregation. The economic impact of the interim final rule and alternatives are now analyzed.

SRMs excluded from the human food supply. The analysis conducted by FSIS examined the impacts of three alternatives for excluding SRMs from the human food supply. These alternatives and the SRM baseline are summarized in Table 3. The Alternatives considered by FSIS provide the following:

- Baseline. Baseline regulatory conditions for the SRM interim final rule are described in Section V. Baseline Regulatory Environment Prior to the Issuance of BSE Regulations.

- Alternative 1. Declaring that the brain, eyes, and spinal cords from cattle 30 months of age and older, and tonsils from cattle of all ages, are inedible and to prohibit these materials for human food.

- Alternative 2. Declaring that the brain, eyes, and spinal cords from cattle 30 months of age and older, and tonsils and the distal ileum (but require removal of the entire small intestine) from cattle of all ages are inedible and to prohibit these materials for human food.

- Alternative 3. (SRM removed from the human food supply under the SRM Interim final rule) Declaring that the brain, skull, eyes, trigeminal ganglia, DRG, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) from cattle 30 months of age and older; and the tonsils and the distal ileum (but require removal of the entire small intestine) of all cattle are inedible and to prohibit the use of these materials for human food.

Table 3. Inedible material under the SRM interim final rule and alternatives.

Alternatives & SRM interim final rule	Cattle aged 30 months or older								Cattle of all ages	
	Heads				Vertebrae				Heads	Intestines
	Skulls	Brain	TGG	Eyes	Spinal Cord /1	Dorsal Root Ganglia (DRG)			Tonsils /2	Small intestines (including distal ileum)
	Edible rendering &AMR, MSM					AMR MSM	Edible rendering	Bone-in cuts		
Baseline									•	
1		•		•	•				•	
2		•		•	•				•	•
3	•	•	•	•	•	•	•	•	•	•

/1 Spinal cords that are detached were already not allowed for direct use for human food but were allowed for indirect use for human food, and can be used for edible rendering.
/2 Tonsils are not allowed for direct use for human food but were allowed for indirect use for human food for cattle of any age.

Alternative 3 was the option selected for the interim final rule. Under the measures specified in the SRM interim final rule, the annual net cost[15] of excluding SRMs from the human food supply is estimated at $36.2 million (Table 4). The rule excludes beef small intestine from the human food supply, resulting in a net cost of about $28 million. A large share of this product had been supplied to foreign consumers. The net cost of removing the brains, spinal cords, skulls, and vertebral columns for bone-in processes accounts for the remaining $2 million in costs.

Alternative 1 for the exclusion of SRMs results in a net cost of $613.9 thousand ($128,100 plus $485,800 from Table 4). Alternative 2 results in a net cost of $28.2 million (Cost of alternative 1 plus $10,476,200 plus $17,098,000 from Table 4). If

[15] The net cost of excluding SRMs from the food supply reflects changes in production costs and the value of the product in other uses.

Alternative 2 allowed for the use of the beef small intestine, excluding the distal ileum, the loss in net revenue to the industry decline to about $17.2 million.

Table 4. Average net revenue losses due to exclusion of SRMs under the Interim Final Rule /1

SRM type	Amount of Product	Price	Revenue Loss	Offsets /2	Net Revenue Loss
	Thousand lbs.	$/lb.	$thousand	$thousand	$thousand
Brain	373.3	0.45	169.2	41.1	128.1
Spinal cord	60.3	0.30	18.1	(464.7) /2	485.8
Vertebral column	24,795.0	0.83	20,579.9	14,295.0	6,284.9
Edible rendering	636	0.25	158.9	44.5	114.4
Bone-in cuts w/ vertebrae	10,866	2.22	24,086.8	22,589.1	1,497.7
Skull, eyes, &TGG	424.1	0.36	152.7	62.6	90.1
Tonsils - edible rendering	42	0.25	10.5	3.0	7.5
Small intestine					
Casings	101,574	.18	18,791.2	8,315	10,476.2
Trepas /4	58,311	.37	21,575.0	4,477	17,098.0
Total					36,189.3

/1 All values are estimates of average distributions unless otherwise identified.
/2 Offsets includes measures which provide revenues from sales to optional markets, reduce operating costs, or increase costs, such as by-product disposal. If the value is positive, the offset reduces the revenue loss.
/3 Spinal cords have an offset that is largely the additional cost associated with removal.
/4 Trepas are that part of the small intestine used in the production of variety meats.

The prohibition on the use of vertebral columns from cattle 30 months of age and older is expected to have a significant impact on about 12 small establishments that produce AMR products using this material. FSIS estimates that about 40 percent of cattle 30 months or older are used to produce beef AMR products. Prohibiting vertebrae from cattle 30 months of age and older for use as human food is expected to have a significant impact on about 2,500 establishments that may need to remove the vertebrae or the body of the vertebrae from their beef meat cuts. FSIS notes that customers of establishments producing AMR products are placing restrictions on beef and pork AMR products that are consistent with this requirement.

Comparison of Exposure Reduction and Cost of SRM Removal Alternatives. A comparison of the cost and potential reduction in human exposure associated with different regulatory alternatives provides a general indication of the relative effectiveness of the alternatives. Table 5 provides such a comparison for the 3 alternative levels of SRM removal from the human food supply discussed above. The alternatives are ordered on the basis of the incremental amount of BSE infectivity removed from the human food supply. The derivation of the reduction in potential human exposure associated with each of the alternatives is described in Section IX. Benefits.

Alternative 1 prohibits brain, spinal cord, tonsils, and eyes from use in human food. This results in an average 30 percent reduction from the baseline in potential human exposure to BSE infectivity at a cost of $613.9 thousand. Alternative 2, which adds the beef small intestine from cattle of all ages to the SRMs prohibited in Alternative 1.

Table 5. Comparison of Average Change in Potential Human Exposure and Cost of Regulatory Alternatives. /1

Regulatory Alternative	Cumulative Reduction in Human Exposure	Incremental Reduction in Human Exposure	Incremental Cost /3
	percent	Percent	$thousand
Alternative 1	30	30	613.9
Alternative 2	30 + /2	Not significant /2	27,574.2
Alternative 3	80	50	8,615.1

/1 1 All values are estimates of average distributions unless otherwise identified.
/2 The additional reduction in risk of human exposure associated with the removal of beef small intestine is not significantly greater than the reduction in human exposure from Alternative 1.
/3 The incremental cost associated with Alternative 3 does not include the cost of prohibiting non-ambulatory disabled cattle from the human food supply.

(brain, spinal cord, eyes, tonsils), does not result in a significant reduction in potential human exposure beyond Alternative 1.[16] The incremental cost of this alternative is significant, however. Alternative 3 results in an average additional 50 percent reduction in potential human exposure with an incremental cost of $8.6 million over Alternative 2. In addition to the SRMs removed in Alternative 2, the spinal cord and DRG (vertebral column) from cattle 30 months of age and older, and MS(Beef) are removed from the human food supply.

Non-ambulatory disabled cattle can be separated into two groups: those displaying central nervous system (CNS) signs and those that do not (due to broken leg, etc). The reduction in potential human exposure to BSE from non-ambulatory disabled cattle that do not display clinical signs of CNS disorders is not reflected in the reductions in potential human exposure shown in Table 5. The Harvard BSE risk assessment model accounts for non-ambulatory disabled cattle that do display symptoms of CNS disorders by removing them from the human food supply during ante-mortem inspection at the time of slaughter.

The level of infectivity associated with non-ambulatory disabled cattle that do not display CNS disorders is not known. The proportion of total potential infectivity associated with this type of non-ambulatory disabled cattle is thought to be significant. Consequently, the reductions in potential human exposure shown in the table overestimate actual reductions. Removal of non-ambulatory cows from potential human

[16] The removal of the beef small intestine, including the distal ileum of all cattle from the human food supply is based on the risk characteristics of this SRM and consistency with international policy. Scientific evidence suggests that BSE infectivity is found in the distal ileum of all cattle in early stages of the incubation period (< 24 months post exposure). In cattle 18 months of age and younger the distal ileum is the only detectable source of BSE infectivity in experimentally infected animals. By nature of the long incubation period, infectivity levels, found only in the distal ileum, are still low (versus the amount of infectivity in an animal that has completed a 32+ month incubation cycle, with infectivity migrating to the CNS tissue) in the majority of finished cattle slaughtered in the simulation.

exposure reduces the total amount of potential human infectivity. This effectively reduces the proportion of un-mitigated potential human infectivity that can be reduced by further FSIS mitigations.

Removing the risk associated with non-clinical, non-ambulatory disabled cattle, reduces the level of infectivity in the cattle herd that would be addressed by the alternatives removing the remaining SRMs from the human food supply.

If the reduction in risk associated with non-clinical, non-ambulatory disabled cattle were known, the total average reduction in risk of potential human exposure associated with the measures required in the SRM and AMR interim final rules of 80 percent would change accordingly.

Prohibition of non-ambulatory disabled cattle. The estimated cost impact of condemning non-ambulatory disabled cattle presented for slaughter is based on baseline parameters for the value, number, and condemnation rates of these cattle. It is also based on the salvage value of these cattle following January 12, 2004. These values can differ by the type and condition of non-ambulatory disabled cattle, the extent of livestock and dairy production in a region, the proximity of rendering establishments and similar recovery activities, and other factors. The estimated impacts are based on the deterministic values shown in the text.

The baseline value of a non-ambulatory disabled animal is estimated at $475. This estimate is based on a price of 75 percent of the cull cow price ($48-50/cwt) prior to the BSE finding and an average live weight of 1,300 lbs.[17] The amount that a farmer or rancher would expect to receive for a "downer" cow prior to the FSIS prohibition on the

[17] Values provided by the USDA's World Agricultural Outlook Board. Telephone discussion, December, 2003

slaughter of non-ambulatory disabled cattle depends, in large part, on the general condition of the animal and the reason for the animal's non-ambulatory status. If the animal was an older dairy cow with a condition that would have required its condemnation on ante-mortem inspection, the farmer would have received very little for the animal or even have paid a nominal amount ($25 per stop) to have the animal picked up for rendering. If the animal was destined for slaughter as a market steer or heifer and became disabled during transportation or in a holding pen, the discount for the animal's condition would largely depend on the amount of trim resulting from the injury. The value of this type of animal presented for slaughter could be significantly more than $475. FSIS has selected this baseline value knowing that dairy farmers are likely to receive less and cattlemen more than the average amount. FSIS requests comment on the baseline value of non-ambulatory disabled cattle.

Non-ambulatory disable cattle are assumed to have zero value following their prohibition for use in human food. The information available to the agency suggests that dairy farmers and ranchers can have non-ambulatory disabled cattle removed from their farms and ranches at no cost. Firms recover the hides and use the remains for inedible rendered product, offsetting the pick up and hauling costs. Farmers and ranchers located in areas where these services are not available may have to pay to have non-ambulatory disabled cattle picked up and hauled away for disposal. Disposal at a landfill is estimated to cost $100, including fees.[18] FSIS requests comments on the assumed salvage values for non-ambulatory disabled cattle and disposal costs. The difference between the baseline value of a non-ambulatory disabled animal and its salvage value represents an average loss of $475 per head.

[18] Based on discussions with a representative of a regional rendering association, March 1-5, 2004.

The share of non-ambulatory disabled cattle that were condemned following ante-mortem and post mortem inspection are not attributed to the cost of the interim final rule. The share of non-ambulatory disabled cattle that were condemned following ante-mortem and post-mortem inspection is estimated to be between 25 and 50 percent. FSIS requests comment on condemnation rates used in the analysis.

A range of 150,000 to 200,000 cattle is used as the baseline value for non-ambulatory disabled cattle presented for slaughter. There are no reliable estimates of the number of non-ambulatory disabled cattle presented for slaughter prior to the January 14, 2004. The assumed value is based various sources of information. On the basis of a 1999 study that examined on-farm conditions, APHIS found that there were 195,000 "downer" cows[19]. The share of these cattle transported to a slaughter establishment is not known. Some of these cattle may have been custom slaughtered or marketed in some other manner. These cattle also may have been composted or buried on farm; processed by a renderer or other type of business that handled dead, diseased, and down cattle; or disposed of in some other manner. In addition, some cattle become non-ambulatory disabled in transit to the slaughter establishment, which adds to the on-farm number of non-ambulatory disabled cattle presented for slaughter.

The 1999 National Market Cow and Bull Beef Quality Audit[20] found that .8 percent of the 2001 cattle slaughter, or 280,000 cattle had "lameness serious enough to disable the animal" at the packing plant slaughter floor. About 60 percent of these animals were beef cattle, and the remaining were dairy cattle. Some share of these

[19] Hansen, Don and Victoria Bridges. "A survey description of down-cows and cows with progressive or non-progressive neurological signs compatible with a TSE from veterinary-client herd in 38 states." The Bovine Practitioner; 33(2) 179-187, 1999.
[20] D.L. Roeber, et al., "National Market Cow and Bull Beef Quality Audit-1999," 2000 Research Report, Department of Animal Sciences, Colorado State University.

animals may have become lame, seriously enough to disable the animal, after entering the establishment and may have continued through processing operations, subject to post-mortem inspection. Consequently, this estimate is considered to be high. FSIS requests comment on the baseline value for non-ambulatory disabled cattle presented for slaughter. The USDA has initiated efforts to obtain better estimates of the number on-farm non-ambulatory disabled cattle[21].

Based on these values, the cost of prohibiting non-ambulatory disabled cattle from entering the food supply is estimated to be $35.6 to $71.3 million (Table 6).

Table 6. Cost of prohibiting use of non-ambulatory disabled cattle from human food use.

	No. of non-ambulatory disabled animal	Value of non-ambulatory disabled animal	Salvage value	Loss per animal	Condemnation Rate	Cost of prohibition
Range	Thousand	Dollars	Dollars	Dollars	Percent	$thousand
Upper end	200	475	0	475	25	71,250
Lower end	150	475	0	475	50	35,625

The indirect effects on the cattle marketing system of the ban on the use of non-ambulatory disabled cattle are not expected to be significant from a national perspective. These animals are reported to comprise a very small share of the annual cattle slaughter, about 0.4 percent to 0.8 percent. However, the impacts of the ban on the use of non-ambulatory disabled cattle may be disproportionate for small, custom slaughter, and small cull cow slaughter establishments. Small, custom slaughter operations process cattle that may not be marketed through other commercial channels due to injury. In 2003, there were 568 establishments that slaughter less than 10 cattle per day, 79 percent of federally-inspected beef slaughter establishments. The share of revenues of these

[21] The National Agricultural Statistics Service of USDA is conducting a survey to obtain an annual estimate of the number of downed cattle and their disposition.

establishments derived from custom slaughter is not known and consequently the impact of the ban can not be estimated. It is also not known whether the number of custom slaughtered cattle is fully reflected in the range of 150,000 to 200,000 non-ambulatory disabled cattle slaughtered at federally-inspected establishments.

Renderers are establishments that process the by-products of the animal slaughter process. Firms in this industry are becoming more selective in the types of cattle that are accepted for processing. These changes are primarily a result of regulatory requirements in the SRM and AMR interim final rules restricting the use of non-ambulatory disabled cattle and SRMs from use in edible rendered product. For example, only carcasses may be accepted when the age of the animal can be determined. Rendering firms may require certification of the age of cattle from which materials for rendering are obtained, or reject the supply of these materials entirely. Due the lack of refrigerated storage at most rendering establishments, cattle that may be subject to APHIS test-and-hold requirements may generally be rejected. Other changes in rendering practices can be anticipated that may restrict the use of SRMs in the rendering industry. FSIS requests information on the types of changes in rendering practices that could be expected as a result of the SRM interim final rule.

The ban on the use of non-ambulatory disabled cattle could have disproportionate impact on the dairy sector as a large share of these cattle are dairy cows[22]. Surveys conducted by USDA show that 20-25 percent of the dairy herd is culled each year[23]. Culls (cows and bulls) represent about 38 percent of the total value of cattle sales on

[22] Hansen, Don and Victoria Bridges. "A survey description of down-cows and cows with progressive or non-progressive neurological signs compatible with a TSE from veterinary-client herd in 38 states". The Bovine Practitioner; 33(2) 179-187, 1999.

[23] The ARMS survey conducted by the Economic Research Service shows a cull rate of 20 percent. The NAHMS survey conducted by APHIS shows a cull rate of 25 percent.

dairy operations. However, cattle sales represent less than 4 percent, on average, of dairy farm receipts[24]. FSIS requests reliable information on the share of dairy culls that are non-ambulatory disabled at the time of slaughter to better assess the dairy sector impacts.

HACCP plan development, record keeping and certification. The SRM interim final rule requires that establishments that slaughter cattle, or establishments that process the carcasses or parts of cattle, develop, implement, and maintain, written procedures for the removal, segregation, and disposition of materials designated as SRMs. The cost to develop HACCP and other plans (prerequisite plans, Sanitation SOPS), implement and maintain monitoring/record keeping requirements, and verification is estimated at $27.6 million. The estimated impacts are based on the deterministic values shown in the text. (Table 7). There are about 3,388 federally-and State-inspected establishments that slaughter cattle or process beef carcasses or parts of beef carcasses that will be required to remove, segregate, and dispose of the materials prohibited for use as human food. Plan development costs are estimated at $1.6 million, based on the costs per plan and time requirement shown in the table. The time required for record keeping and other activities related to the age determination and proper segregation of cattle prior to slaughter, and to assure that processed products and SRMs are also properly segregated can vary significantly on the basis of plant size. Large plants, operating two shifts may employ full-time quality control technicians to conduct process controls activities established in HACCP and/or other plans. These activities at small and very small plants, whose average daily slaughter is significantly lower than at large plants, may apply to less complex systems for process control and segregation. The total annual costs associated with monitoring/record keeping are estimated at $22.8 million. Verification that records

[24] Information provided through correspondence with the Economic Research Service, December 31, 2003.

concerning process control activities are properly maintained is generally conducted by a quality control technician or quality assurance manager, depending on the size of the plant as shown in the table. Total verification costs are estimated at $3.3 million. The Agency seeks comment on the cost of plan development, record keeping, and verification.

Segregation of SRMs. The annual cost of segregating SRMs in slaughter, fabrication and further processing is estimated at $0.9 million (0.8 to $1.0 million). The Agency does not currently have reliable information to estimate the cost of segregating SRMs[25]. Some establishments currently segregate cattle 30 months of age and older prior to slaughter, minimizing further adjustments that may take place as a result of the rule. If this practice is not followed, carcasses may need to be segregated following slaughter. This can be accomplished by tagging the carcasses, segregating them from other carcasses, and processing them at the end of the day or shift, or in another shift.

Some establishments have established practices that treat all cattle as if they were 30 months of age and older. Consequently, there is no need to segregate carcasses following slaughter. The segregation of carcasses for very small establishments would be accomplished with minimal disruption given the slaughter methods employed. Segregation practices of SRMs will also depend on the accessibility of rendering facilities to the establishment. On-site rendering, which is available to most large establishments, would reduce the processing adjustments needed to segregate SRMs. For the purposes of

[25] FSIS has initiated a contract to obtain additional information on the segregation and disposal costs of SRMs. Data collection will take place in March, 2004.

this analysis, the cost of segregation is estimated at $0.20 to $0.30 per head for the estimated 7.2 million cattle that are identified as 30 months of age and older.[26]

Table 7. HACCP plan development, record keeping and verification.

Measure/Plant size					
Plan development	Time/1	Cost/plan /1	Labor Compen-sation /2	No. of plants	Cost
	Hours.	Dollars	$/hr.		$thousand
Very Small	4		31.20	2,128	265.6
Small		1,000		1,203	1,203.0
Large		2,000		57	114.0
Sub-Total					1,582.6
Monitoring/ Record keeping	Time/1	No. of days /3	Labor Compen-sation /1	No. of plants	Cost
	Hrs./day		$/hr.		$thousand
Very Small	.5	275	17.42	2,128	5,097.1
Small	2	275	17.42	1,203	11,525.9
Large	16	275	24.46	57	6,134.6
Sub-Total					22,757.6
Verification					
Very Small	.1	275	24.46	2,128	1,431.4
Small	.2	275	24.46	1,203	1,618.5
Large	.5	275	31.20	57	244.5
Sub-total					3,294.3
Total					27,634.5

/1 The time required for plan development, record keeping and verification; and the cost of plan development are based on expert opinion of FSIS personnel familiar with HACCP implementation and meat establishment operations. FSIS invites comment and reliable information on the values used for these parameters in the analysis.
/2 Compensation rates include an hourly wage rate and a 33 percent overhead cost that accounts for benefits, including insurance and retirement. The labor compensation rates used in the analysis are based on those reported for employees at meat and poultry processing establishments in the Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems. FR 61, 144.
/3 Average annual days of operation are based on expert opinion.

The Agency seeks comment and reliable information on practices and associated costs for segregating carcasses derived from cattle that are identified as 30 months or age and older and SRMs. The costs associated with the various measures of the SRM interim final rule are shown in Table 8.

AMR Interim Final Rule Impacts.

[26] Opinion of FSIS technical personnel.

The AMR interim final rule complements the SRM interim final rule by addressing the major sources of risk generated by the possible incorporation of brain, trigeminal ganglia, spinal cord, and DRG tissues in AMR products derived from beef skulls or vertebral columns. The rule also finalizes restrictions related to bone solids and bone marrow (as measures by calcium and iron content) and prohibits MS(beef) as a human food product.

Table 8. Summary: Cost impacts of the SRM interim final rule

	Annual Costs	
	Range /1	Average
Measure	$million	
SRM ban (net cost)	35.6-36.7	36.2
Segregation of SRMs	0.8-1.0	0.9
Modification of HACCP, sanitation SOP, or other prerequisite program plans and record keeping	27.6 /2	27.6
Ban on non-ambulatory, disabled animals	35.6-71.3	53.5
Total	99.6-136.6	118.2

/1 Values at the 5th and 95th percentiles except for ban on non-ambulatory, disable animals.
/2 A range was not estimated.

AMR yield loss and compliance modifications. Based on the 2002 Beef AMR product survey, FSIS found that about 29 percent of all final beef AMR product samples tested positive for spinal cord. More recent tests, based on regulatory sampling of beef AMR samples, conducted in 2003 show a much lower prevalence level of spinal cord tissue of 6.7 percent. In 2002, the prevalence rate for DRG tissue was found to be 10 percent. Based on FSIS estimated AMR production levels for 2003, about 45.6 million pounds of AMR products derived from beef vertebrae could be produced annually. FSIS

estimates that the yield loss from beef vertebral columns from cattle less than 30 months of age due to process modifications is about 1.4 million pounds (Table 9). The associated revenue loss is $1.4 million. The cost of these modifications, apart from product losses, is estimated at $0.9 million. Based on the available evidence, FSIS concludes that the amount of beef AMR product derived from cattle younger than 30 months that may contain brain, trigeminal ganglia, spinal cord, or DRG tissues would be significantly less than the levels shown in 2003. Prevalence levels of spinal cord tissue in beef AMR products declined significantly during 2003 and are likely to decline further in response to regulatory requirements and consumer concerns. However, the prevalence of DRG tissue in beef AMR products has not decreased from the 10 percent levels found in the 2002 Beef AMR product survey. The compliance cost to eliminate DRG tissue in beef AMR products, now only from cattle younger than 30 months, could be significant. Comments are solicited on the cost to eliminate the CNS-type tissues such as DRG. FSIS is currently estimating the compliance cost of this requirement to be $2.4 million.

If the prevalence rate of DRG, excess calcium, and excess bone marrow is 4 percent, about 1.9 million pounds of beef AMR product using the vertebral column of cattle less than 30 months of age would fail to comply with the new requirements (Table 8). The total amount of non-compliant beef and pork AMR products lost or diverted to alternative uses is estimated at about 6.6 million pounds. The documentation of the model used to estimate the quantity of AMR product affected by the AMR interim final rule is shown in Appendix 5. An example of how the model was used to estimate the amount of AMR product affected by the interim final rule is shown in Appendix 6.

Table 9. AMR yield loss and compliance modifications. /1

AMR Input Material	Yield/ animal	Animals	Product loss	Value of yield loss or process cost	Revenue loss/ Cost increase
	Lbs.	Thousand	Thousand lbs.	$/lb.	$thousand
Due to reduced prevalence of DRG, calcium, and iron					
Beef (<30 months) vertebral column	3.0				
Yield loss	0.5	2,720	1,387	0.98	1,364
Process modification cost /2	2.5	12,000	30,000	0.03	895
Revenue from alternative uses net of additional processing/disposal costs					210
Sub-total					2,049
Pork vertebral column	3.0				
Yield Loss	0.6	1,070	64	0.31	20
Process Modification	2.9	4,280	12,583	0.03	378
Sub-total					398
Total due to reduced prevalence					2,447
Due to non-compliant product					
Beef (<30 months) vertebral column					
Non-compliant	3	640	1,920	0.98	1,888
Revenue from alternative uses net of additional processing/disposal costs					26
Sub-total					1,862
Beef (< 30 months) non-vertebral					
Non-compliant	2	2	4	0.98	4
Revenue from alternative uses net of additional processing/disposal costs					.5
Sub-total					3.5
Pork Vertebral Column					
Non-compliant	3	1,100	3,300	0.31	1013
Revenue from alternative uses net of additional processing/disposal costs	3	802.5	2,424	0.11	250
Sub-total					763
Pork non-vertebral					
Non-compliant	2	3.4	6.8	0.31	2.1
Revenue from alternative uses net of additional processing/disposal costs					.6
Sub-total					1.5
Total due to non-compliant product					2,630
Total AMR yield loss and compliance modifications					5,077

/1 All values are estimates of average distributions unless otherwise identified.
/2 Process modification costs include adjustments to the establishment's AMR process, including equipment upgrades, changes in machine settings, changes in bone stock, and other changes.

The total annual cost, in terms of the lost value of beef and pork AMR products due to non-compliant products is estimated to be about $2.6 million when beef AMR

products are valued at an average of about 70 percent of the value of beef trimmings that are 90 percent lean, and pork AMR products are valued at an average of about 70 percent of the value of pork trimmings that are 72 percent lean. The net cost of the AMR interim final rule with regard to impacts on AMR yield loss and non-compliance is estimated at $5.0 million.

The pork AMR products survey of 2003 did not find any pork AMR products with DRG tissue, but 21.3 percent (or 23 of 108 samples tested) of the pork AMR products derived from vertebrae were found to contain spinal cord tissue. Furthermore, 55 percent, or 11 of 20, of the establishments that produced AMR products derived from pork vertebrae, were found to have at least one of their samples positive for the presence of spinal cord tissue. In addition, 25 percent, or 5 of 20, of the establishments were found to have more than one of their samples positive for the presence of spinal cord tissue.

Spinal cord tissue has not been permitted in AMR products prior to the publication of the SRM and AMR interim final rules. Therefore, the elimination of spinal cord tissue in AMR products is a part of the baseline conditions that are not affected by the new regulatory requirements. Consequently, the cost of eliminating spinal cord tissue in AMR products has already been realized by establishments that produce AMR product. Additional documentation of AMR Interim Final Rule Impacts are shown in Appendix 5.

Product testing. The AMR interim final rule will result in additional testing requirements of AMR products. The additional tests include a determination of the iron-to-protein ratio, and the tests for CNS-type tissues (spinal cord and DRG). Since skulls are not used in the United States, tests for brain and trigeminal ganglia are not anticipated

at this time and have not been factored into the cost estimates. The estimated costs for these tests are $5.4 million annually.

Modification of process control plans. There are additional costs for modifying process control plans and additional bookkeeping for the 56 establishments that are expected to continue producing AMR products. These costs are estimated at be $1.0 to 1.03 million annually.

Table 10. Additional Laboratory Testing Costs for Beef and Pork AMR Products /1

Laboratory Test /2	Affected establishments /3	Lots tested per test day	Number of test days per year	Average cost per test[27]	Increase in testing costs
				Dollars	Thousand dollars
CNS-type tissue tests	56	2	300	95	3,181
Iron and protein test (the dry-ash method with duplicate testing on the same sample)	56	2	300	67	2,240
Total					5,421

/1 All values are estimates of average distributions unless otherwise identified.
/2 A major portion of the laboratory is expected to be done by certified commercial laboratories. However, some of the testing is expected to be done on-site by the establishment;
/3 The average number of affected establishments was determined from the Beef AMR Products Survey of 2002, and the Pork AMR Products Survey of 2002;

The net cost of the AMR interim final rule is estimated at $10.7-$12.5 million (Table 11). The net cost of prohibiting the AMR processing of vertebral columns from cattle 30 months of age and older from use in human food is estimated at $6.3 million ($3.3 to $9.8 million). This provision applies to approximately 2.8 million cattle. The vertebral columns from cattle 30 months of age and older provide approximately 24.8 million pounds of beef product when processed in AMR systems.

[27] Based on estimates provided by as FSIS regional laboratory.

Table 11. Summary: Cost of the AMR interim final rule

Measure	Annual Cost	
	Range /1	Average
	$million	
Modifications of operations to achieve lower maximum calcium requirement, not exceed the bone marrow limit, and elimination of CNS-type tissues.[28]	2.0-2.7	2.4
Non-compliant beef and pork AMR products for excess levels of bone solids or bone marrow; or the incorporation of CNS-type tissues.	2.4-2.8	2.6
Testing for iron, protein, and CNS-type tissues	4.7-6.2	5.4
Process control plans, record keeping and product segregation, extra holding of AMR products, and extra packaging	1.0-1.3	1.2
Total Cost	10.7-12.5	11.6

/1 Values at the 5th and 95th percentiles.

Test and Hold Impacts.

The impacts of the test and hold provision are related to the number of surveillance tests that will be conducted within Federal establishments by APHIS and the length of time to complete each test and then to communicate the results to the inspection program personnel at the establishments. Typically, cattle carcasses or parts of carcasses are chilled and kept cool for about 24 to 36 hours before moving on for fabrication of cuts or further processing. Additional storage and carcass shrinkage (loss of moisture) costs may result if the test results are not available within about 24 to 36 hours of slaughter. APHIS has stated that it is working to approve a rapid screening test that will have results available within approximately 36-48 hours, contingent upon the order of operation at slaughter plants and sample pick-up time. BSE surveillance tests at

[28] Does not include SRM removal costs, which are shown in Table 1.

federally- and State-inspected plants may decline if it is more effective to test high risk cattle on the farm and at rendering establishments. However, if BSE surveillance testing increases significantly, more tests than are currently performed by APHIS may be conducted at slaughter establishments. Comments are solicited about the scope of these costs.

FSIS Program Costs

FSIS expects significant changes in inspection, testing, and surveillance programs in response to the three interim final rules and the interpretive rule. These changes include increased sampling and testing for excess bone solids and bone marrow in beef and pork AMR products, and CNS-type tissue (spinal cord and DRG) in beef and pork products. In addition, increased verification inspections would be expected in beef slaughter operations and in beef and pork processing operations, including any AMR systems or edible rendering systems. As part of the President's 2005 Budget, FSIS is requesting $4 million, an increase of $3 million, for in-plant verification of slaughter plant designs for controlling SRMs; in plant verification of proper holding of tested cattle that are part of the APHIS testing program; and increased testing of meat produced using AMR systems to help assure that SRMs are not entering the human food supply.

Total Costs

The total annual cost of the SRM and AMR interim final rules is estimated at $113.3 to $152.1 million, including FSIS costs for increased inspection, verification, and testing. This cost estimate does not include the following impacts:

- the costs to segregate, assemble, and transport cattle 30 months of age and older, or their carcasses or carcass parts to establishments that process these cattle;

- not awarding the mark of inspection on cattle tested for BSE until the test results are received and the results are report negative for BSE; and
- equivalence measures by foreign supplies and their impact on domestic beef supplies.

VIII. Domestic Economic Impacts

The impact of finding BSE in the United States is expected to have a minimal impact on U.S. meat production. Biological lags inherent in cattle production limit any significant change in the short term[29]. According to recent USDA estimates, the United States exported about 2.6 billion pounds of beef in 2003, accounting for 10 percent of U.S. beef production and the value of beef, veal, and variety meat exports is estimated at $3.9 billion.[30] In 2004, these products will be shifted to the domestic market. The loss of exports resulted in an immediate decrease in cattle prices of 15 to 20 percent.[31] As of late January, the cattle prices have strengthened and currently down by about 10 to 15 percent from pre-import ban levels.

The increase in beef supplies, due to reduced export demand, is expected to reduce 2004 cattle prices to $74 to $79 per cwt compared to USDA forecasts of $84 to $91 per cwt in December 2003[32].

The net amount of beef and pork product removed from human consumption due to the SRM and AMR interim final rules is estimated to be about 213 million pounds. This product is expected to be used in the production of in-edible rendered product. The amount removed from human consumption is a small share (0.5% or 0.005) of the total

[29] U.S. Department of Agriculture. World Agricultural Supply And Demand Estimates, WASDE-406. January 12, 2004.
[30] U.S. Department of Agriculture. Testimony of Keith Collins for House Committee on Appropriations, February 24, 2004.
[31] U.S. Department of Agriculture. AMS Daily Market News
[32] U.S. Department of Agriculture. World Agricultural Supply And Demand Estimates, WASDE-406. March 12, 2004.

46.0 billions (26.3 billion pounds of beef and 19.7 billion pounds of pork) produced annually.

The impacts of the measures contained in the SRM and AMR interim final rules on prices for beef and pork are not expected to be significant.[33] Price impacts are expected to be limited to beef by-products and variety meats which constitute a small share of domestic beef consumption. The measures affecting the removal of SRMs from the human food supply, excluding the condemnation of non-ambulatory disabled cattle presented for slaughter, are expected to have a minimal impact on beef prices to the consumer. The net amount of product removed from the human food supply as a result of the SRM interim final rule provisions is 177 million pounds, excluding that removed as a result of the prohibition on non-ambulatory disabled cattle from the food supply. This amount is about 0.7 percent of the total supply of beef. Price impacts largely would be limited to products derived from beef small intestines such as sausages with natural casings and trepas. Substitutes are available for other by-products, largely from cattle less than 30 months of age, although prices will likely be somewhat higher. For example, the prohibition on bone-in beef cuts from cattle 30 months of age and older will raise the prices of these cuts from younger cattle.

The removal of non-ambulatory disabled cattle from the food supply is not expected to have a significant impact on beef prices given the very small share of beef supply affected (0.1 percent). The impact of the condemnation of these cattle presented for slaughter is viewed as having an overall positive impact on consumer perceptions of

[33] FSIS is collecting additional information on cost impacts of the SRM and AMR interim final rules that may not be fully reflected in the current analysis. When this information is available, it will be used with existing information to estimate the beef price impacts, disaggregated by major market categories. This analysis will be provided in the final regulatory impact analysis.

the livestock and dairy industry.[34] The Agency requests comments on potential price impacts of the SRM interim final rule provisions affecting removal of this product from the human food supply.

The costs associated with other regulatory measures affecting the segregation and disposal of SRMs, and changes in process control practices, including plan development and record keeping, are not significant from an industry perspective. Beef price impacts resulting from higher industry per unit costs are expected to be minimal. The prohibition on the use of non-ambulatory disabled cattle for human food restricts the supply of cattle slaughtered and processed at custom slaughter establishments. The relative cost impacts of SRM interim final rule on these types of establishments is presumed to be significantly greater than those likely to occur for other types of meat slaughter and processing establishments.

The impacts of the AMR interim final rule on AMR product prices are also expected to be minimal. The amount of product removed from beef and pork supply is a very small share of total supplies. AMR product is generally used as an ingredient in processed products. FSIS has found that establishments producing AMR product began to make significant processing adjustments in 2003 to address concerns about the presence of spinal cord in AMR product. These changes largely were a result of customer requirements for product formulation.

Countries that import beef products into the U. S. must have requirements that are equivalent to the new regulatory requirements implemented by FSIS in response to the detection of a case of BSE in this country (9 CFR 327.2). The measures designating

[34] Based on numerous discussions with industry, university, and dairy farmers.

certain high-risk tissues as SRMs and prohibiting [35]their use for human food, and excluding non-ambulatory disabled cattle for slaughter and use in human food applications apply to registered establishments in foreign countries that export products to the United States. FSIS intends to evaluate equivalence standards on a case-by-case basis. It is not possible at this time to determine whether equivalency requirements will affect U.S. beef supplies.

The economic impact of a BSE case in the United States is more likely to mirror the market response experienced recently by Canada when one cow with BSE was detected in May 2003, rather than being associated with the magnitude of those experienced the U.K.[36] The measures in place prior to finding BSE in the United States, including those preventing infected feed from being widely distributed and consumed by cattle, limited the potential impact.

The impacts on livestock income, and cattle and meat prices and production described above do not include potential impacts on employment and other economic conditions in local economies. FSIS has observed changes in cattle marketing, transportation, and handling practices that can be attributed to finding BSE in the United States and to the SRM and AMR interim final rules. Over time, these changes could be significant and affect the spatial and structural characteristics of the livestock, dairy, and meat slaughter and processing industries in those regions that are most affected. FSIS requests comment on these types of changes and their potential impacts.

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[35] U.S. Department of Agriculture. World Agricultural Supply And Demand Estimates, WASDE-406. January 12, 2004.

[36] U.S. Department of Agriculture. Animal and Plant Health Inspection Service. Animal Disease Risk Assessment, Prevention, and Control Act of 2001. (PL 107-9) Final Report. January 2003. http://www.aphis.usda.gov/lpa/pubs/pubs/PL107-9_1-03.pdf

IX. Benefits

The benefits of the SRM and AMR interim final rules are primarily those resulting from the reduction in human exposure to BSE infectivity and the restoration of beef exports. The benefits of provisions of the AMR interim final rule concerning the amount of bone solids and bone marrow are not addressed in the analysis of benefits.

Reduction in Human Exposure to BSE

The following discusses the method by which the reduction in human exposure to BSE infectivity in the food supply is estimated and the reduction in human exposure resulting from the three alternatives discussed in the cost analysis.

FSIS evaluated possible mitigation options intended to prevent human exposure to the BSE agent in the United States using a modified version of the 2001 Harvard BSE risk assessment model (as revised by Harvard in response to peer review comments)[37]. In developing the baseline estimate of potential human exposure to the BSE agent, FSIS used similar assumptions to those used in a second risk assessment conducted by Harvard after the detection of the single case of BSE in Canada on May 20, 2003[38]. The 2003 Harvard analysis uses identical assumptions to the 2001 Harvard analysis to evaluate the potential for BSE to spread if it were introduced from Canada prior to May 20, 2003, when USDA banned all ruminant and ruminant products from Canada because of the discovery of the single case of BSE.

[37] Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, November 26, 2001. Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States,

[38] Harvard Center for Risk Analysis, Harvard School of Public Health, "Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada". 2003

For its baseline estimate of potential human exposure to the BSE agent, FSIS assumed that five BSE-infected bulls were imported from Canada into the United States in 2003, and then simulated the spread of BSE infectivity in the United States until 2020. Thus, the FSIS 2003 analysis assumes that measures implemented by the United States government to prevent the introduction and spread of BSE in this country, such as the FDA's mammalian to ruminant feed ban and APHIS' import restriction, were in place at the time that the infectivity was introduced. The simulations of the risk mitigation options were then run assuming that the FSIS mitigations would be implemented in 2004, which would allow infectivity to spread for approximately 12 months. Thus, because of these assumptions, the mitigation options can never remove all of the infectivity that could be available for human consumption over the model simulation timeframe. The maximum level of risk mitigation that could be achieved using these assumptions would be an average of approximately 90 percent. Risk mitigation scenarios were run for 50,000 iterations. The Harvard analyses conducted in 2001 and 2003 both ran 5,000 iterations per scenario.

FSIS determined that certain assumptions used in the FSIS analysis and the 2001 and 2003 Harvard analyses affect the results of the risk mitigation analyses. First, none of the analyses separate direct consumption of tissues by the age of the animal. Thus, although all of the options would prohibit the use of certain tissues, such as brain and spinal cord, from cattle 30 months of age and older, the models can only consider removal of these tissues from cattle of all ages. However, since most infectivity in the affected tissues is expected to manifest in older animals, the difference in modeling all animals versus only older animals is expected to be insignificant.

Another important assumption in the Harvard 2001 and 2003 analyses is that no animals older than 24 months go to the bone-in-beef pathway, which includes bone-in cuts of meat, such as T-bone steaks, roasts, and soup bones, as well as and bone-in materials that are used to produce edible rendered products. The reported infectivity via the bone-in-beef pathway in the 2001 and 2003 Harvard risk mitigation scenarios is attributable to infectivity found in cattle 24 months of age and younger. Although infectivity levels are much lower in these cattle, there is a high probability of human exposure via this pathway. Since some older animals may be used for bone-in-beef products, this assumption may cause the model to underestimate potential human exposure through this pathway, and thus overestimate the impact of some of the risk mitigation options.

FSIS changed this assumption in the FSIS analyses. Based on evidence available to the Agency, FSIS believes that vertebrae from cattle older that 24 months are used in bone-in cuts and processes (bone-in pathway). Therefore, model coefficients were changed in the FSIS 2003 baseline analysis to allow 20 percent of vertebrae from cattle 24 -29 months of age and 10 percent of vertebrae from cattle 30 months of age and older be used in the bone-in pathway. The estimates of the share of vertebrae from cattle in these two age categories that are used in the bone-in pathway is based on the opinion of FSIS technical specialists familiar with beef slaughter and processing operations. The Agency requests comment on the share of vertebrae that are used from animals in these two age categories for the bone-in pathway. As shown below, the proportion of vertebrae from cattle older than 24 months that enter the bone-in pathway does not substantially affect the total human baseline exposure to animal ID50s. Although the 2001 and 2003

Table 12. Comparison of assumptions: FSIS analysis with Harvard 2001 and 2003 analyses.

	Harvard 2001analysis	Harvard 2003 Canada analysis	FSIS analysis
Simulation time frame	20 years, beginning after 1999 policies in place	Simulation through 2020, various years for initiation of infection –starting in 1992	Simulation through 2020, with initiation of infectivity in 2003, mitigations in effect starting in 2004.
Number of infected animals as initiating event	10 cows	5 bulls	5 bulls
Number of simulation runs	5,000 iterations	5,000 iterations	50,000 iterations
Conditions simulated	Baseline only, all policy conditions/industry practices in place in 1999	Policy conditions vary over time, all policies/industry practices in place by 1999	a) Baseline 2003-2004 b) Baseline 2004-2020 c) Mitigation, effective in 2004 Average differences between the baseline and mitigation scenarios were determined.
Age distribution of animals going to bone-in-beef	< 24 months = 100% >24 months = 0%	< 24 months = 100% >24 months = 0%	Baseline: < 24 months = 70% 24-29 months = 20% > 29 months = 10% Mitigation: < 24 months = 70% 24-29 months = 30% > 29 months = 0%
Coefficients for industry practice	Representative of current industry practices prior to the USDA announcement in Jan. 2004.	Representative of current industry practices during the period of simulation.	Baseline: Representative of current industry practices prior to the USDA announcement in Jan. 2004. Mitigation: Coefficient values modified to reflect the removal of SRMs from human food and prohibition of >29 month cattle from AMR processes.

Harvard analyses and the FSIS baseline analysis assumed different bone-in beef exposure pathways from cattle aged greater than 24 months, the ultimate human exposure was substantially similar in all of the models. The following table compares the assumptions that were used by FSIS baseline analysis with the assumptions in the 2001 and 2003 Harvard analyses

FSIS 2003 baseline results for cumulative human exposure over 17 years when 5 infected animals are introduced into the United States show an average of 18.5 animal ID50s would potentially be available for human exposure (50,000 iterations). This has been compared to the 2001 Harvard analysis which showed an average cumulative human exposure of 39 animal ID50s when 10 infected animals were introduced into the United States (5,000 iterations)[39]. Harvard also modeled the introduction of 5 infected animals in the 2001 model, showing a cumulative human potential exposure of 18 animal ID50s.[40] Both of the Harvard analyses assumed that no vertebrae from animals greater than 24 months age entered the bone-in-beef pathway.

The 2001 Harvard analysis predicted a mean of 4 additional animals infected cumulatively over the 20-year period following the introduction of 10 infected animals into the United States[41]. When the 2001 Harvard model was used to analyze the introduction of 5 BSE infected cattle, a mean of 2 additional animals were infected during the next 20 years[42]. In the 2003 FSIS baseline and mitigation analyses in which 5 infected cattle are introduced into the United States, a mean of slightly less than 2 additional animals were affected during the 17 year simulation.

For the SRM and AMR interim final rules, FSIS estimated a baseline level of potential human exposure. This is the potential human exposure to the BSE agent through consumption of beef through the year 2020, should FSIS not implement any risk management options beyond those already in place. The Agency then estimated

[39] Harvard Center for Risk Analysis, Harvard School of Public Health, and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, November 26, 2001. Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States, Appendix 3A Section 1 – Base Case.
[40] Harvard Center for Risk Analysis, 2001. (Appendix 3A Section 3.2).
[41] Harvard Center for Risk Analysis, 2001. Appendix 3A Section 1 – Base Case.
[42] Harvard Center for Risk Analysis, 2001. Appendix 3A Section 3.2.

exposure with the FSIS risk management measures in place. The scenarios assume that infected animals are introduced into the U.S. in 2003, but that the FSIS rules take effect in 2004. This means that the actions taken previously by the government to prevent or reduce BSE are already in place (e.g., feed ban, import limitations, etc) for all of the scenarios that are run, but that BSE infectivity may enter human food for one year before the FSIS mitigations take effect.

FSIS estimated the reduction in potential human exposure resulting from three different risk management alternatives. The alternatives are[43]:

- declare as SRMs: brain, eyes, trigeminal ganglia, and spinal cord from animals 30 months of age and older;
- declare as SRMs: brain, eyes, trigeminal ganglia, and spinal cord from animals 30 months of age and older, and distal ileum from cattle of all ages;
- declare as SRMs: brain, eyes, trigeminal ganglia, spinal cord from animals 30 months of age and older, distal ileum, and dorsal root ganglia,

To estimate the impact of the different risk management options, FSIS calculated potential human exposure when each of the three alternatives is implemented. The reduction in estimated potential human exposure for both the baseline and with the FSIS mitigation measures are shown below. Distributions of exposure were calculated

[43] These alternatives are not directly comparable to the alternatives analyzed in Section VII. SRM Analysis. However, the differences are inconsequential. Tonsils, tongue, and mechanically separated beef are not explicitly modeled in the risk assessment models. Therefore the amount of potential human exposure contributed by these materials is not included in overall potential human risk or in the risk reduction brought about by the mitigations as modeled. However the lost revenues resulting from their removal from the human food supply is reflected in the cost analysis. The information available to FSIS suggests that there is relatively low infectivity associated with these tissues. First, research conducted since the development of the Harvard BSE model suggest that small amounts of infectivity has been found in tonsils. However, tonsils were prohibited for use in meat food products before the new SRM regulations became effective, so human exposure to tonsils was limited. FSIS is not aware of any studies in which the tongue has demonstrated infectivity. Any infectivity attributed to the tongue is associated with a "long tongue," which may contain tonsils. Also, MS(beef) is not a "tissue." It represents contamination of low-risk tissues with high-risk tissues (i.e., spinal cord and DRG). However, very few, if any, establishments were intentionally producing MS(beef) before the SRM rules became effective, so human exposure to this product was also limited.

assuming 5 infected bulls were imported. Table 13 presents mean, 5%, median, and 95% estimates of exposure, as well as the incremental average reduction in potential exposure yielded by each alternative.

The two major sources of infectivity mitigated by the incremental risk reduction measures found in Alternative 3 are spinal cord and DRG from vertebral columns of cattle 30 months of age and older. Precise quantitative estimates of the relative share in the 50 percent reduction of potential human exposure that can be attributed to these two sources of infectivity in Alternative 3 have not been developed by the agency. The Agency has observed, based on experience from running the model and anecdotal

Table 13. Incremental change in potential human exposure for regulatory alternatives

	Potential human exposure (ID50) /1				
Regulatory alternative	Mean	5%	50%	95%	Incremental difference (means)
Baseline	18.5	0	5	70	--
1) Brain,spinal cord from animals > 30 months, eyes, and trigeminal ganglia	12.7	0	5	50	30%
2) Alternative 1 plus distal ileum from cattle of all ages	12.7	0	5	50	-- /2
3) Alternative 2, plus vertebral column from cattle >30 months (DRG and spinal cord from mis-split vertebral column).	4	0	0.08	20	50%

/1 The Harvard risk assessment expresses the amount of infectivity to which consumers might be exposed in terms of cattle oral ID50s. A cattle oral ID50 is the amount of infectious tissue that would be expected to cause 50% of exposed cattle to develop BSE.

/2 The additional reduction in risk of human exposure associated with the removal of beef small intestine is not significantly greater than the reduction in human exposure from Alternative 1.

information, that the contribution to estimated human exposure attributed to DRG far outweighs the contribution attributed to spinal cord.

Prior to measures taken by FSIS on January 14, 2004, under the incremental risk reduction measures identified in Alternative 3, human exposure to spinal cord resulted from mis-split vertebral column and spinal cord incompletely removed during slaughter of cattle 30 months of age and older. The 2001 Harvard analyses assumes that mis-splits occur 8 percent of the time during the slaughter of older cattle. When the AMR pathway is utilized, there is also a probability, 2 percent, that the spinal cord is not removed prior to AMR processing. When the AMR pathway is not utilized, there is a 50 percent probability of spinal cord removal.[44]

The baseline human exposure to DRG is likely higher through AMR than via the bone-in pathway. This is due to the dispersion of AMR product as an input for other beef products. The actual human consumption of DRG through the bone-in beef pathway is uncertain as the bone-in pathway includes edible rendered products, including bouillon, soup bases, and other products that may have higher probabilities of actual human consumption than tradition T-bone steak-type products in that pathway.

Results from the Alternative 3 simulation show a proportionally greater reduction in potential human exposure to ID50s from the AMR pathway. Table 14 shows an average exposure level of 9.5 animal ID50s in the FSIS baseline scenario versus less than an average of 1 animal ID50 in the mitigation scenario. There is an insignificant reduction in the contribution from this bone-in beef pathway in Alternative 3 versus the FSIS baseline analysis.

[44] Harvard Center for Risk Analysis, 200. Appendix 1, Table 2.18-1.

Table 14. Reduction in Human Exposure from AMR and Bone-in Beef

Product	Harvard 2003 /1, /2	FSIS 2003 /3	Alternative 3
	Number of ID50s (mean/5th percentile/95th percentile)		
AMR	10/0/38	9.5/0/40	.93/0/5
Bone-in –Beef	2.3/0/6.1	5.6/.001/20	5.5/0/20

/1 Harvard Center for Risk Analysis, 2001. Appendix 3A, Section 3.2. /2 20 year simulation. /3 17 year simulation.

Under the measures announced by FSIS on January 12, 2004, the spinal cord is required to be removed from the vertebral column of cattle 30 months of age and older. In addition, the vertebral column from cattle 30 months of age and older cannot be used for AMR systems. Thus, unless there is inadvertent use of this material in AMR systems or if cattle are not properly aged, components of the vertebral column may become incorporated into edible food, including steaks, meat from AMR systems, and edible rendered products. FSIS does not believe that the oxtail, used primarily for soups, is a source of potential infectivity because neither the spinal cord nor the DRG are present in the portion of the vertebral process that defines the tail area.

FSIS tested whether the model would predict linear increases in potential human exposure if the number of infected animals were changed. Table 15 summarizes the potential human exposure predicted by the baseline and mitigation scenarios (SRM and AMR rules) when different numbers of infected animals are imported.

The table shows that the average potential human exposure depends essentially linearly on the number of animals assumed to enter the U.S. The model predicts that the average amount of infectivity potentially available for human exposure from 2003 through 2020 would be about 43 cattle ID50s (95% CI: 2, 200). Since FSIS assumed that the SRM and AMR rules would not take effect until 2004, there is one year during which infectivity may enter the human food supply.

Table 15. Potential human exposure to the BSE agent (cattle oral ID50s)

Number of infected animals introduced	Mean	5%	50%	95%
	Baseline			
5 bulls	22	0.01	8	80
10 bulls	43	2	20	200
100 bulls	435	200	400	900
	With SRM and AMR rules in place one year after introduction of infectivity			
5 bulls	7	0	2	30
10 bulls	14	0	7	50
100 bulls	145	50	100	300

The model predicts that consumers could be exposed to about 7 cattle ID50s (95% CI: 0, 20) during that year. On average, the impact of the SRM and AMR rules would reduce the remaining 37 ID50s to about 14 ID 50s (or by about 80%). Thus, the analysis shows that during the 2004 through 2020 timeframe, consumers could potentially be exposed to an average of about 23 ID50s.

As noted earlier, the SRM and AMR rules implemented by FSIS (alternative 3) afford about an average of 80% reduction in potential human exposure at the mean. Since the number of infected animals that entered the United States is unknown, FSIS also considered whether the percent risk reduction predicted by the model would be sensitive to the amount of infectivity entering the U.S. cattle herd. Therefore, FSIS modeled the baseline potential human exposure the impact of implementing the SRM and AMR rules assuming 5, 10, or 100 infected bulls enter the United States. The percent reduction achieved by implementing the FSIS mitigations is relatively insensitive to the assumption about the number of imported infected animals.

The following table summarizes the impact of the rules and the impact of assuming different numbers of animals introducing BSE infectivity in 2003 on potential human exposure. The table presents both the baseline estimates and the impact of the SRM and AMR rules.

Table 16. Average potential human exposure to the BSE agent

No. of infected animals imported in 2003	baseline: 2003 – 2020	baseline: 2003 – 2004	baseline: 2004 – 2020	with SRM and AMR rules: 2004-2020	Percent reduction
5 bulls	22	3.5	18.5	7.5	80%
10 bulls	43	7	37	14	80%
100 bulls	435	70	365	145	80%

The measures include prohibiting certain SRMs from the human food supply and also requiring that AMR product not include spinal cord, DRG, or other CNS-type tissue. The analysis results show that the FSIS measures can reduce potential human exposure by 80 percent. These results reflect the implementation of the FSIS risk reduction measures one year after the introduction of infectivity into the U.S. cattle population. The fraction of the potential human exposure that can be prevented is consistent over a wide range in the assumed number of BSE infected cattle entering the livestock system.

The interim final rules and related measures will provide a substantial level of assurance to consumers that the U.S. food supply is safe. Because the exact quantitative relationship between human exposure to the BSE agent and the likelihood of human disease is unknown, the 2001 Harvard analysis did not evaluate the quantitative likelihood that humans will develop variant Creutzfeldt Jakob Disease (vCJD) if exposed to the BSE agent. Thus, the model predicts reduction in potential human exposure to the

BSE agent, but it is not possible at this time to estimate the potential human health benefits of these measures. The 2001 Harvard analysis also did not address potential human exposure to the BSE agent through products containing ingredients of bovine origin, such as some pharmaceuticals, gelatin, and beef stocks, extracts, and flavorings. Many of these products are derived through the edible rendering process. FSIS is working with FDA to address the impact of this issue.

Restoration of Beef Export Markets

About 40 countries have banned beef from the United States. The 2004 beef export demand forecast has been reduced by 90 percent.[45] In 2003, U.S. exports of beef, veal, and variety meats were valued at $3.8 billion. The value of exports of live cattle is small relative to the value of meat, and adds another $63 million.

There is no indication at this time when import bans on U. S. beef put in place by other countries will be lifted. The preventative measures announced by FSIS on January 14, 2004, in addition to other measures taken by the U.S. government, are intended to restore confidence in the U.S. beef supply and also to position the United States for reentry into the export market at the earliest possible date. These measures should also assure foreign consumers and eventually lead to the restoration of export markets for U.S. beef and beef by-products. Failure to assure consumer confidence in beef products could easily reduce cash receipts to the cattle sector by $5 to $10 billion annually. Net farm income could decline by $3 to $6 billion annually after taking into account changes in lower production costs.[46]

[45] U.S. Department of Agriculture. World Agricultural Supply And Demand Estimates, March, 2004.
[46] Based on analysis conducted by Economic Research Service, U. S. Department of Agriculture for FSIS. "Economic Impacts of the Discovery of BSE in the United States", January 6, 2004. The analysis is based

Appendix 1. References

The data used in establishing the baseline and estimating the impacts of the SRM and AMR interim final rules are derived from a number of sources. A number of scientific journal articles, studies, reports and other reference material, and expert opinion were used to analyze the impacts of the SRM and AMR interim final rules The references are shown in Appendix 1 of the FRIA (and below for this document). All references have been placed on display in the FSIS Docket Room (address above) and may be seen by interested persons between 8:30 a.m. and 4:30 p.m., Monday through Friday.

(1) Belay, E.D., et al, Relationship between transmissible spongiform encephalopathies in animals and humans. In: Task Force Report of the Council for Agricultural Science and Technology. Washington, DC: Council for Agricultural Science and Technology, October 2002, No. 136.

(2) MMWR, Probable Variant Creutzfeldt-Jakob Disease in a U.S. Resident—Florida, 2002, 51(41):927-929 October 18, 2002).

(3) Bruce, M.E., et al, Transmission to mice indicate that 'new variant CJD is caused by the BSE agent. Nature 389, 498-501 (1997).

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on the projected decline in beef exports, the subsequent decline in beef prices and prices of other meats. The analysis does not assume change in domestic demand resulting from lower meat prices.

(4) Cattle-Fax : National Cattlemen's Beef Association:, Economic Impact of BSE on the U.S. Beef Industry, a Power-Point presentation to the National Cattlemen's Beef Association, February 2003.

(5) Conninge, J., et al, Molecular analysis of prion strain variation and the aetiology of 'new variant' CJD. Nature 383, 685-690 (1996).

(6) European Union Scientific Steering Committee (EU SSC), 2001. Opinion of 10 December 1999 of the Scientific Steering Committee on the Human Exposure Risk (HER) via Food with Respect to BSE.

(7) European Union Scientific Steering Committee (EU SSC), 2002. Update on the Opinion of TSE infectivity distribution in ruminant tissues (initially adopted by the scientific steering committee at its meeting of 10-11 January 2002 and amended at its meeting of 7-8 November 2002) following the submission of (1) a risk assessment by the German Federal Ministry of Consumer Protection Food and Agriculture, and (2) new scientific evidence regarding BSE infectivity distribution in tonsils; European Commission, Scientific Steering Committee, Health and Consumer Protection Directorate General.

(8) Franco, D.A. & W. Swanson editors, The Original Recyclers, 1996.

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(15) Scott, M.R., et al, Compelling transgenetic evidence for transmission of bovine spongiform encephalopathy prions to humans. Proc Natl Acad Sci USA 96, 15137-12142 (1997).

(16) Sparks Companies, Inc., Advanced Meat Recovery Systems – An Economic Analysis of proposed USDA Regulations, prepared for American Meat Institute. July 1999.

(17) Sparks Companies, Inc., Economic Analysis of FSIS Regulatory Options, prepared for American Meat Institute. June 2002.

(18) Tijskens, L. M., M. L. Hertog and B.M. Nicolai editors, Food Process Modeling, 2001.

(19) United Kingdom Food Standards Agency press release, Thursday, October 17, 2002.

(20) United States Department of Agriculture: Analysis of 2002 FSIS Bovine AMR Products Survey Results, prepared by the United States Department of Agriculture, Food Safety and Inspection Service, February 2003. Available on the internet at http://www.fsis.usda.gov/oa/topics/AMRAnalysis.pdf.

(21) United States Department of Agriculture: 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, prepared by the Food Safety and Inspection Service, February 2003. Available on the internet at http://www.fsis.usda.gov/OA/topics/AMRSurvey.pdf.

(22) United States Department of Agriculture: National Agricultural Statistics Service (NASS) Livestock Slaughter Summary 2002, March 2003.
(23) United States Department of Agriculture: National Agricultural Statistics Service (NASS) Livestock Slaughter Summary 2003, March 2004.

(24) United States Department of Agriculture: FSIS Animal Disposition Reporting System (ADRS 2003 & 2004).

(25) United States Department of Agriculture: FSIS Performance-Based Inspection System (PBIS 2003 & 2004), Washington, D.C.

(26) United States Department of Agriculture: Microbiological and Residue Contamination Information System (MARCIS 2003 & 2004), Washington, D.C. (note: This is FSIS data on regulatory test results of meat, poultry, and egg products, including beef and pork AMR products.)

(27) United States Department of Agriculture: FSIS Pork AMR Products Survey of 2003, Washington, D.C.

(28) United States Department of Agriculture: FSIS BSE Specified Risk Materials (SRMs) of BSE Survey of 2002, Washington, D.C.

(29) United States Department of Agriculture: FSIS Enhanced Facilities Database (EFD) of 2002, 2003, Washington, D.C.

(30) United States Department of Agriculture: Agricultural Marketing Service (AMS) in Livestock, Meat, Wool Market News, Weekly Summary, and Statistics, reports in 2003a, Des Moines, Iowa.

31) United States Department of Agriculture: Agricultural Marketing Service (AMS) in Livestock, Meat, Wool Market News, Daily Summary, and Statistics, reports in 2003b, Des Moines, Iowa.

32) United States Department of Agriculture: Economic Research Service, 2003 report released on February 6, 2004, Washington, D.C.

33) United States Department of Commerce Dept., Bureau of Census 2003 beef, veal, and beef variety meat exports in 2003, 2004, Washington, D.C.

34) United States Meat Export Federation (USMEF) data on beef and variety meat exports, 2002 & 2003, Washington, D.C.

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