ECONOMIC ANALYSIS:
Final Regulatory Impact Analysis
Final Rule

Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle Offered for Slaughter, and Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle during Slaughter
(FSIS Docket No.03-025F)

Updated from the
Preliminary Regulatory Impact Analysis

United States Department of Agriculture
Food Safety and Inspection Service

June 28, 2007

TABLE OF CONTENTS

LIST OF TABLES

Tables **Page**

GLOSSARY

Abbreviation/Acronym	Definition
AAMP	American Association of Meat Processors
ADRS	Animal Disposition Reporting System of FSIS
AFDO	Association of Food and Drug Officials
AMI	American Meat Institute
AMR	Advanced Meat/Bone Separation Machinery and Meat Recovery
AMS	Agricultural Marketing Service, U.S. Department of Agriculture
ANPR	Advance Notice of Proposed Rulemaking
APHIS	Animal and Plant Health Inspection Service, U.S. Department of Agriculture
BCA	Benefit-Cost Analysis
BSE	Bovine Spongiform Encephalopathy
CCP	Critical Control Points of a HACCP Plan
CDC	Centers for Disease Control and Prevention
CE	Carcass equivalent is the dressed weight of a carcass that is intact or in primary cuts
CEA	Cost-Effectiveness Analysis
CER	Cost-Effectiveness Ratio
CJD	Creutzfeldt-Jakob Disease
ERS	Economic Research Service, U.S. Department of Agriculture
FAS	Foreign Agricultural Service, U.S. Department of Agriculture
FDA	Food and Drug Administration of HHS
FR	Federal Register
FRIA	Final Regulatory Impact Analysis
FSIS	Food Safety and Inspection Service, U.S. Department of Agriculture
GMP	Good Manufacturing Practices

HACCP	Hazard Analysis and Critical Control Point
HCRA	Harvard Center for Risk Analysis
High cost estimates	Cost estimates that represent the maximum value of a triangular distribution of estimated values
HRA	Harvard Risk Assessment
HSS	U.S. Department of Health and Human Services
ICER	Incremental Cost-Effectiveness Ratio
ID50 (bovine)	bovine infectious dose level or quantity of infectious agents of BSE that will cause 50 percent of the exposed or challenged cattle to acquire a clinical disease of BSE
Low cost estimates	Cost estimates that represent the minimum value of a triangular distribution of estimated values
MARCIS	Microbiological and Residues Contamination Information System of FSIS
Maximum Value	The maximum or high value of a triangular distribution of estimated values of the cost analysis
Midpoint Value	Median value of a distribution of estimated values
Minimum Value	The minimum or low value of a triangular distribution of estimated values of the cost analysis
Most-likely Value	The most likely value of a triangular distribution of estimated values of the cost analysis
NA	Data or information not available
NAMP	National Association of Meat Processors
NASS	National Agricultural Statistical Service, U.S. Department of Agriculture
NCBA	National Cattlemen’s Beef Association
NR	Non-compliance record or report of PBIS generated by FSIS inspection program personnel documenting that an establishment was non-compliant with FSIS regulations
NRA	National Renderers Association
OIE	Office International des Epizooties,

	World Organization for Animal Health
PBIS	Performance Based Inspection System of FSIS
PHV	Public Health Veterinarian of FSIS
Prerequisite Programs	Prerequisite Programs are procedures that an establishment has voluntarily developed, documented, and implemented in order to enhance food safety in the production of its food products. These are procedures, including Good Manufacturing Practices (GMP), that address operational conditions providing the foundation for the HACCP system. These are steps or procedures that control the establishment's environmental conditions that provide a foundation for safe food production.
PRIA	Preliminary Regulatory Impact Analysis
RIA	Regulatory Impact Analysis
RTI	RTI International
SOP	Standard Operating Procedures
SRM	Specified Risk Material
SSOP	Sanitation Standard Operations Procedures
U.S.A.	United States of America
USDA	United States Department of Agriculture
vCJD	variant Creutzfeldt-Jakob Disease

Summary

This final regulatory impact analysis[1] (FRIA) of the final rule updates and modifies the preliminary regulatory impact analysis[2] (PRIA) that the Food Safety and Inspection Service (FSIS) conducted for three interim final rules.[3] The three rulemaking actions taken by FSIS were in response to the finding of a cow in Washington State positive for BSE on December 23, 2003. FSIS took these emergency actions to strengthen its BSE prevention programs designed to protect the public health. FSIS issued this series of interim final rules to minimize human exposure to materials that scientific studies have demonstrated contain the BSE infectious agent in cattle infected with that disease. Scientific and epidemiological studies have linked the human disease variant Creutzfeldt-Jakob (vCJD) to exposure to the BSE infectious agent, most likely through human consumption of beef products contaminated with the BSE infectious agent. In

[1] FSIS based the FRIA cost and benefit impact analysis of the Final Rule on a probabilistic model developed by FSIS. FSIS based the cost impacts of the final regulatory measures on the probabilistic values cited in the text of the FRIA analysis. FSIS based the benefit impacts of the final regulatory measures on probabilistic values of the Harvard Risk Assessment (HRA) cited in the text of the FRIA analysis.

[2] FSIS based the cost impact analysis of the Interim Final Rules on a probabilistic model developed by FSIS, excluding the prohibition on non-ambulatory disabled cattle from the food supply, and Hazard Analysis and Critical Control Points (HACCP) plan development, record keeping, and verification. FSIS based the cost impacts of these interim final regulatory measures on the deterministic values cited in the text of the PRIA analysis. In March 2004, the analysis was posted on the FSIS web pages: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/03-025N/BSE_Analysis.pdf .

[3] FSIS published in the Federal Register, on January 12, 2004, three interim final rules that also took effect on January 12, 2004: (a) "Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Cattle," (69 FR 1862, Jan 12, 2004), which was amended in September 2005 (70 FR 53043, Sep 7, 2005); (b) "Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter," (69 FR 1885, Jan 12, 2004); and (c) "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems" (69 FR 1874, Jan 12, 2004).

this final rule, FSIS is affirming, with changes, the interim final rule "Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Cattle," (also referred to as "the SRM interim final rule"). In addition, FSIS is affirming, without changes the interim final rule "Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter" (also referred to as the "air-injection stunning interim final rule."). Because the interim final rule "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR)" (also referred to as the "AMR interim final rule") contains several non-BSE related provisions, FSIS intends to affirm and, if necessary amend, the AMR interim final rule in a separate document that FSIS will publish in the Federal Register at a later date. Thus, unlike the PRIA, this FRIA does not directly analyze the impacts of the AMR interim final rule.

Section 1 of the FRIA is an introduction to the SRM Interim Final Rule and the SRM Final Rule. Section 2 of the FRIA is a discussion of the need for the SRM Final Rule. Section 3 of the FRIA is a preliminary assessment of the effectiveness of the SRM Interim Final Rule.

FSIS used existing data from the PRIA, and new and updated data sources in the FRIA. Section 4 of the FRIA has a discussion of these data sources. FSIS incorporated information about

affected establishments and the costs of compliance with the Final Rule into the FRIA from the following sources:

- surveys of industry (Cates, et al., June 2005 and Cates, et al., December 2005);
- survey of custom-exempt companies (Association of Food and Drug Officials (AFDO), 2005);
- communications with staff of the University of Minnesota (Thompson, September 2004), University of California Davis (Davidson, February 2004), and the Minnesota Extension Service (Kjome, July 2004); and
- surveys of FSIS' inspection program personnel (FSIS, 2002 and FSIS site visits of establishments, 2004).

In developing the FRIA, FSIS reviewed the public comments received on the SRM and air-injection stunners PRIA and the SRM and air-injection stunners interim final rules, excluding those received in response to the AMR interim final rule. In addition, FSIS reviewed the public comments on the Harvard Risk Assessment updated analysis. The PRIA is available on the FSIS web pages: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/03-025N/BSE_Analysis.pdf. In Section 5 of the FRIA, FSIS presents its responses to the public comments.

In addition, FSIS developed and analyzed a set of regulatory alternatives for the FRIA. Sections 6 and Section 7

of the FRIA discuss regulatory alternatives and the cost-effectiveness of the considered regulatory alternatives.

Table I compares in summary form this final regulatory impact analysis (FRIA) to the preliminary regulatory impact analysis (PRIA). A major difference between the FRIA and the PRIA is that the FRIA does not include the regulatory impact analysis of the AMR Interim Final Rule, as does the PRIA. Thus, FSIS narrowed the scope of the Final Rule and the FRIA. Other differences include the use of additional data sources and updated data, and changed or added regulations.

The methodology of the FRIA and the PRIA was the same. However, FSIS updated the regulatory impact analysis (RIA) model with new probability distributions and assumptions of the costs of the SRM Final Rule (see section 6 of the FRIA). Further, FSIS updated the probabilistic simulation models of the FRIA with new probability distributions and the assumptions set forth in the Harvard Risk Assessment (HRA) model that addresses benefits (see section 7 of the FRIA). In Section 8 of the FRIA, FSIS discusses the impact on small entities, and, in Section 9, unfunded mandates on firms, businesses, and industry.

Table I. Summary Comparisons of the PRIA of the Interim Final Rule and the FRIA of the Final Rule for Differences in the Final Rule Compared to the Interim Rule, and Comparison of the Interim Final Rule and the Final Rule.

A. Summary Comparison of the PRIA and the FRIA		
	PRIA of the Interim Rule	**FRIA of the Final Rule**
Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR):	Preliminary Regulatory Impact Analysis (PRIA) included for new AMR regulations in the AMR Interim Rule.	Scope of the Final Rule and FRIA narrowed: the Regulatory Impact Analysis (RIA) does not include the regulations of the AMR Interim Rule.
Data Sources:	Used existing data of 2002 and 2003: • Baseline data • FSIS employee surveys • FSIS AMR surveys • FSIS databases	Used existing 2003 baseline data, and new and updated data from: • Two industry surveys • State establishments • Updated FSIS databases and new information collected on non-ambulatory cattle • Custom-Exempt establishments (See Section 4 in this FRIA)
Methodology of the Regulatory Impact Analysis (RIA):	Probabilistic simulation models (with some deterministic components on the cost analysis): • Cost analysis (using @RISK software) • Benefits analysis based on the Harvard Risk Assessment of 2001/2003 • Cost-effectiveness analysis was deterministic.	Probabilistic simulation models: • Cost analysis (using @RISK software) • Benefits analysis based on the re-modeled Harvard Risk Assessment of 2005 • Cost-effectiveness analysis (used @RISK software) (See Sections 6 and 7 in this FRIA)

	PRIA of the Interim Rule (continued)	FRIA of the Final Rule (continued)
Assumptions of the Regulatory Impact Analysis (RIA):	the PRIA analysis was posted on the FSIS web pages: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/03-025N/BSE_Analysis.pdf (See the appendices of the PRIA)	Assumptions are discussed in Sections 6 and 7 in this FRIA.
Public Comments Received and Considered in the Regulatory Impact Analysis:	Public comments were not available because this was an interim final rule.	Public comments considered and included in the FRIA: • Exclusion of small intestine as SRM, except for the distal ileum • Allowed salvage of non-ambulatory veal calves presented for slaughter, r that are unable to stand because they are tired or cold and on a case by case basis cattle that pass ante-mortem inspection • Included effects of the final rule on custom-Exempt establishments that are prohibited from slaughtering non-ambulatory disabled cattle offered for slaughter for use as human food • Included costs for the establishments that use dentition methods to determine age of older cattle, and in some cases discounted the value of the older cattle still owned by cattle producers. (See Section 5 in this FRIA)

	PRIA of the Interim Rule (continued)	**FRIA of the Final Rule (continued)**
Annualized Average Cost at 7 percent rate (without the impact of the AMR Interim Final Rule)	$105.6 million annually ($81.6 (minimum) to $134.9 (maximum) million annually)	$171.2 million annually ($95.9 (minimum) to $244.0 (maximum) million annually) (See Section 6 in this FRIA)
Annualized Average Cost at 3 percent rate (without the impact of the AMR Interim Final Rule)	$105.2 million annually	$171.0 million annually ($95.7(minimum) to $243.8 (maximum) million annually) (See Section 6 in this FRIA)
Annual Benefit of average potential risk reduction for human exposure (without the impact of the AMR Interim Final Rule)	7,900 cattle oral ID50s (average) (500 imported cattle basis)	6,580 cattle oral ID50s (average) (500 imported cattle basis) (See Section 7 in this FRIA)
Cost-Effectiveness Ratio (average) at 7 percent rate (without the impact of the AMR Interim Final Rule)	$13,640 per unit of human exposure reduction of cattle oral ID50s ($5,490 lower bound to $32,311 upper bound) (500 imported cattle basis)	$31,899 per unit of human exposure reduction of cattle oral ID50s ($3,207 lower bound to $121,748 upper bound) (500 imported cattle basis) (See Section 7 in this FRIA)

	PRIA of the Interim Rule (continued)	**FRIA of the Final Rule (continued)**
Affect on Small Entities - Annualized Average Cost at 7 percent rate (without the impact of the AMR Interim Final Rule)	$30.3 million annually	$64.2 million annually (See Section 8 in this FRIA)
Affect on Small Entities - Annualized Average Cost at 3 percent rate (without the impact of the AMR Interim Final Rule)	This was not calculated for the Interim Final Rule.	$64.2 million annually (See Section 8 in this FRIA)

B. Summary Comparison of the Interim Final Rule and the Final Rule		
	Interim Rule	Final Rule
Non-ambulatory Disabled Cattle:	Defines “non-ambulatory disabled livestock” as livestock that cannot rise from a recumbent position or that cannot	Affirms without changes definition of non-ambulatory cattle.
	walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions (9 CFR 309.2(b)).	
	Interim Rule (continued)	**Final Rule (continued)**
Non-ambulatory Disabled Cattle (continued):	Requires that all non-ambulatory disabled cattle offered for slaughter be condemned (9 CFR 309.2(b)).	Affirms that all non-ambulatory disabled cattle offered for slaughter must be condemned. Clarifies that FSIS inspection program personnel will determine the disposition of cattle that become non-ambulatory after they have passed ante-mortem inspection on a case-by-case basis (9 CFR 309.3(e)). Changes reflects current practice in FSIS Notices 5-04 and 5-06: FSIS Notice 5-04, “Interim Guidance for Non-Ambulatory Disabled Cattle and Age Determination” and FSIS Notice 05-06, “Re-Examination of Bovines that Become Non-Ambulatory After They Have Passed Ante-mortem inspection”

	Preamble explains that prohibition of non-ambulatory disabled cattle is necessary because non-ambulatory disabled cattle present a risk of introducing the BSE agent into the human food supply.	Preamble explains that prohibition on the slaughter of non-ambulatory disabled cattle is still necessary to prevent potential human exposure to the BSE agent. Preamble also states that FSIS intends to initiate a separate action in which is will discuss measures that may be necessary to ensure that non-ambulatory cattle and other livestock are humane handled in connection with slaughter.
	Requires condemnation of veal calves presented for slaughter that cannot rise from a recumbent position or that cannot walk because they are tired or cold.	Adds veal calves that cannot rise from a recumbent position or that cannot walk because they are tired or cold to the list of conditions for which condemned livestock may be set aside and treated (9 CFR 309.13(b)). Amendment reflects current practice.
	Prohibits the slaughter for humane handling purposes of cattle in the absence of an inspector and prohibits for use as human food the carcasses and parts of cattle slaughtered in the absence of an inspector (9 CFR 311.27)	Affirms without changes prohibition on use for human food of animals slaughtered for humane reasons in the absence of an inspector.

	Interim Rule (continued)	**Final Rule (continued)**
Specified Risk Materials (SRMs):	Designates brain, skull, eyes, trigeminal ganglia, 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), and dorsal root ganglia of cattle 30 months of age and older; and the distal ileum and tonsils of all cattle as SRMs (9 CFR 310.22(a)). Declares that SRMs are inedible and requires that they be removed and disposed of as inedible (9 CFR 310.22(b), 9CFR 310.22(c))	Affirms list of materials designated as SRMs In Interim Rule. Adds a new provision that excludes from the definition of SRMs materials from cattle from foreign countries that can demonstrate that their BSE risk status can reasonably be expected to provide the same level of protection from human exposure to the BSE agent as prohibiting SRMs for human food does in the United States (9 CFR 310.22(a)). Also, adds a new provision that requires that spinal cord from cattle 30 months of age and older be removed in the establishment where the animal was slaughtered (9 CFR 310.22(c)).
	Does not permit use of entire small intestine for human food. After the PRIA, in 2005, the Interim Rule was amended (in response to comments) to permit small intestines to be used for human food if certain conditions are met (9 CFR 310.22(a)(3)).	Permits small intestines to be used for human food if certain conditions are met. Affirms amended interim rule and re-designates provision as 9 CFR 310.22(d).

	Requires that establishments develop, implement and maintain written procedures for the removal, segregation, and disposition of SRMs, and incorporate these procedures into their HACCP plans or Sanitation SOPs or other pre-requisite program. In addition, prescribes recordkeeping requirements (9 CFR 310.22(d).	Affirms and re-designates as 9 CFR 310.22(e), interim rule provisions in 9CFR 310.22(d). Adds new provision that clarifies that procedures must address potential contamination of edible materials with SRMs before, during, and after entry into the establishment (9CFR 310.22(e)(1)).
	Interim Rule (continued)	**Final Rule (continued)**
Specified Risk Materials (SRMs) (continued):	Specifies that materials that are SRMs if they are from cattle 30 months of age and older will be deemed to be from cattle 30 months of age and older unless the establishment can demonstrate that the materials are from an animal that was younger than 30 months of age at the time of slaughter (9 CFR 310.22(e)).	Affirms and re-designates provisions as 9 CFR 310.22(h).

	No codified requirements for sanitation of equipment used to cut through specified risk materials.	Adds new regulations that prescribe requirements for the sanitation of equipment used to cut through specified risk materials (SRMs) (9 CFR 310.22(f)). New requirements codify current practices in FSIS Notice 10-04. FSIS Notice 10-04, "Questions and Answers Regarding the Aging Determination of Cattle and Sanitation," describes procedures that FSIS inspection personnel are to use to verify that cross-contamination of edible tissue with SRMs is reduced to the maximum extent practical in facilities that slaughter cattle, and in facilities that process the carcasses or parts of cattle, both younger than 30 months of age and 30 months of age and older.
	Interim Rule (continued)	**Final Rule (continued)**
Specified Risk Materials (SRMs) (continued):	No codified requirement permitting the transporting of carcasses or parts that contain SRM vertebral columns from slaughter establishments to another federally inspected establishment for further processing.	Adds new regulations that specify the conditions under which slaughter establishments may ship beef carcasses or parts that contain vertebral columns from cattle 30 months of age and older to another federally-inspected facility for further processing (9 CFR 310.22(g)). New regulations strengthen and codify current practices. Changes reflect current practice in FSIS Notice 68-05

		FSIS Notice 68-05, “Verification Activities at Establishments that Transport or Receive Cattle Carcasses or Parts with Vertebral Columns that Contain Specified Risk Materials (SRMs),” provides instructions to FSIS inspection program personnel on how to verify that establishments that ship or receive beef carcasses and parts that contain vertebral columns from cattle 30 months of age and older have controls in place to ensure that the SRM portion of the vertebral column is removed by the receiving establishment.
	Prohibits MS(beef) for use as human food (9 CFR 319.5(b).	Affirms without change prohibition on use of MS(beef) as human food.
Air-injection Stunning	Prohibits the use of stunning devices that deliberately inject compressed air into the cranial cavity of cattle (9 CFR 313.15(b)(2) and 9 CFR 310.13(a)(2)(iv)(C)).	Affirms without change prohibition of use of stunning devices that deliberately inject compressed air into the cranial cavity of livestock.

The actions required in the final rule require about 3,512 establishments that slaughter cattle or process bone-in beef (i.e., beef with vertebrae) products (e.g., beef carcasses or parts) of cattle 30 months of age and older to take measures to minimize human exposure to cattle materials that could potentially contain the BSE agent. Table II indicates the number of beef slaughter and processing establishments, by type (e.g., federally inspected, state inspected, and custom-exempt establishments that are exempt from inspection), considered in the preliminary regulatory impact analysis (PRIA) compared to this final regulatory impact analysis (FRIA). The number of affected establishments considered in the PRIA increased for the FRIA because the FRIA considers more of the state-inspected and custom-exempt establishments (establishments exempt from inspection) that slaughter cattle or process bone-in beef products of cattle 30 months of age and older.

Table II: Summary: Number of Beef Slaughter and Processing Establishments Considered in the Preliminary Regulatory Impact Analysis (PRIA) and this Final Regulatory Impact Analysis (FRIA)

Establishments by Type	PRIA	FRIA
Federally Inspected	2,500[a]	768[b]
State Inspected	888[a]	1,430[b] [c]
Custom-Exempt (exempt from inspection)	NA[d]	1,314 [c]
Total Establishments	3,388	3,512

Sources:
[a] FSIS Animal Disposition and Reporting System (ADRS) 2003
[b] FSIS Performance Based Inspection System (PBIS) 2006
[c] Association of Food and Drug Officials (AFDO) 2005
[d] NA data not available to FSIS.

Table III categorizes the number of affected establishments by HACCP-size[4] categories. The FRIA addresses how the final rule affects about 3,278 very small, 197 small, and 37 large establishments for a total of about 3,512 establishments affected. Within the 197 HACCP-small category, the FRIA defines two sub-categories: small-class I establishments and small-class II establishments. The FRIA addresses how the final rule affects 138 small-class I, and 59 small-class II establishments. FSIS used these sub-categories to determine the regulatory

[4] FSIS defined small and very small establishments by its HACCP (Hazard Analysis and Critical Control Points) size definition. Establishments that have fewer than 10 employees or generate less than $2.5 million in annual sales are “very small” establishments; establishments that have between 10 and 499 employees or generate more than $2.5 million in annual sales are “small” establishments; and establishments that have 500 or more employees are “large” establishments. The size definition classification is different from the Small Business Administration’s categorization of small and large business due to the unique nature of the meat and poultry slaughter and processing industry.

impacts on small entities. FSIS did this because the HACCP-small category of establishments have significant variability in production and sales volumes, number of employees, capital investment, type of products, type of livestock slaughtered and meat processing, and operations. The sub-categories of small-class I and small-class II group establishments that slaughter and process less than 30,000 head of cattle and more than 30,000 head of cattle, respectively. This represents two significantly different groups of small entities. The number of establishments in each HACCP-category is different from the PRIA because FSIS used new data to identify more effects of the Final Rule on very small state inspected and custom-exempt establishments, and relatively fewer effects on large processing-only establishments.

Table III. Summary: Number of Beef Slaughter and Processing Establishments by Size and Class

Establishments by Size and Class	PRIA[a]	FRIA[b] [c]
Very Small	2,128	3,278
Small Small Class I Small Class II	1,203	197 138 59
Large	57	37
Total Establishments	3,388	3,512
Sources: [a] FSIS Performance Based Inspection System (PBIS) 2003 [b] FSIS Performance Based Inspection System (PBIS) 2006 [c] Association of Food and Drug Officials (AFDO) 2005		

Table IV summarizes data sources FSIS considered for the FRIA. Information from public comments received (see Section 5 of this FRIA), industry surveys, state surveys, FSIS databases, USDA databases, FSIS Employee (inspection program personnel) surveys, trade organizations, and publications were considered. The data sources are discussed in Section 4 of this FRIA. FSIS used the new and updated data for the FRIA to define further the population of affected establishments and the companies that own these establishments. In addition, FSIS used new and updated data for the FRIA to define the distribution of costs of compliance of the final rule. With respect to the benefits of the final rule, FSIS used information from a 2005 updated version of the 2001/2003 Harvard Risk Assessment (HRA) (referred to as the 2005 Harvard BSE Update) (Cohen et al., 2005) to estimate the distribution of cattle oral ID50s under alternative scenarios.

Table IV: Summary: Sources [a] of Data Used for the FRIA

FSIS Databases:	• Performance Based Inspection System (PBIS) • Animal Disposition Reporting System (ADRS) • Microbiologic and Residue Contamination Information System (MARCIS) • FAST/STOP/CAST – results of residue analyses
USDA Databases:	• Agricultural Marketing Service (AMS) • Foreign Agriculture Service (FAS) • Economic Research Service (ERS) • National Agricultural Statistics Service (NASS)
FSIS Employee Surveys:	• SRM Survey of 2002 • Site visits to establishments
Industry Surveys:	• Meat and Poultry Slaughter and Processing Industry • Meat and Poultry Processing-Only Industry
State Surveys:	• State-Inspected Meat and Poultry Slaughter and Processing Establishments • Meat and Poultry Custom-Exempt Establishments
Trade Organizations:	• National Cattleman's Beef Association (NCBA) • American Meat Institute (AMI) • National Renderers Association (NRA) • Association of Food and Drug Officials (AFDO)
Publications:	• Economic Research Service (ERS) • Informa Economics (formerly Sparks Company) • Universities (see References Section of FRIA)
Other sources:	• Personal communications with staff of the Minnesota State Extension Service • Personal communications with staff of the University of Minnesota and University of California Davis
Sources: [a] See References Section of FRIA for details	

The costs of the final rule are set for forth in Table V. The FRIA estimates that the total annual average cost of the actions required by the final rule is $171.2 million annualized over 5 years at an interest rate of 7 percent, and $171.0 million at an interest rate of 3 percent. The average present value is $702.0 at a discount rate of 7 percent and $783.13 at a discount rate of 3 percent.[5] The primary costs associated with the final rule are the:

- prohibition on the slaughter of non-ambulatory disabled cattle offered for slaughter,
- exclusion of SRMs from use in the human food supply,
- modifications that establishments must make to their HACCP plans or Sanitation SOPs or other prerequisite programs for the exclusion, disposition of the SRMs, and
- recordkeeping requirements.

The FRIA found that there is no cost associated with affirming the air-injection stunning interim final rule because these stunning devices are no longer in use in the United States.

[5] FSIS estimated higher costs in the FRIA than it did in the PRIA because more establishments will need to take measures than the number of establishments anticipated by the PRIA.

Table V: Summary: Costs for Establishment of the Requirements of the Final Rule ($millions)

Establishments by HACCP-Size	FRIA Annualized Average Costs by Type of Establishment, $millions							
	7 Percent Interest Rate				3 Percent Interest Rate			
	Non-ambulatory Cattle	SRMs	Air-injection Stunning	Totals	Non-ambulatory Cattle	SRMs	Air-injection Stunning	Totals
Very Small	$1.1	$7.9	0	$9.0	$1.1	$7.9	0	$9.0
Small Class I Small Class II	$1.9 $1.2	$5.9 $46.2	0	$7.8 $47.4	$1.9 $1.2	$5.9 46.2	0	$7.8 $47.4
Large	$1.7	$105.3	0	$107.0	$1.7	$105.1	0	$106.8
Totals	$5.9	$165.3	0	$171.2	$5.9	$165.1	0	$171.0

The FRIA assesses the benefits of the measures adopted in the final rule. The measures adopted in the final rule are reasonable and necessary measures to ensure food safety. They help to assure domestic and foreign consumers that the U.S. food supply is safe. In Table VI, the benefits and costs, and cost-effectiveness ratios of the Final Rule and the alternatives considered to the Final Rule are presented. An analysis conducted using the model from the 2005 Harvard BSE Update predicts an average potential risk reduction for human exposure of 6,580 cattle oral ID50, or 99.7 percent, relative reduction in potential human exposure to the BSE infectious agent associated with the measures adopted in the final rule.[6] While the percent risk reduction is more generally applicable, the total number of cattle oral ID50s avoided depends on the starting point assumptions in the Harvard Risk Assessment scenarios; they are not expectations of the actual number of BSE positive cattle in the food supply. However, because the amount of the BSE agent necessary to cause disease in humans is unknown, it is not possible at this time to estimate the potential human health benefits of these measures. No known cases of vCJD have been associated with consuming beef products

[6] FSIS made the original 2005 Harvard BSE Update available for public comment. The model was subsequently revised in response to comments from the public. The original and revised versions of the 2005 Harvard BSE Update are available on the FSIS Web site. Comments received in response to the original 2005 Harvard BSE update and FSIS responses to it are available on the FSIS Web site. FSIS used the results from the revised 2005 Harvard BSE Updated to estimate benefits in this FRIA.

in the United States. Consequently, FSIS has not estimated monetary values for reductions in human morbidity and mortality associated with this final rule.

The FRIA does estimate a benefit for the restoration of beef export markets (gross sales), which may, in part, have been affected by this final rule. However, because of the many other factors that are also relevant to re-gained market access, the affects on the restoration of beef export markets that may be attributed to the measures implemented in this final rule are difficult to determine. In pre-BSE 2003, beef export markets totaled $3,861.9 million annually for veal, beef, and beef variety meats. Then, in post-BSE 2004, these beef export market sales dropped about 79 percent or $3,053.8 million to $808.1 million. However, in 2005, the U.S. had restored its beef export market sales to a total of $1,365.3million. Compared to 2004, this is an increase of about 69 percent or $557.2 million in beef export market sales.

Table VI of the FRIA shows that the final rule is cost-effective when compared to other considered regulatory alternatives. Section 7 of the FRIA presents the cost-effectiveness analysis of the Final Rule, as well as the benefits analysis and the considered regulatory alternatives.

FSIS, in Section 6 of the FRIA, estimated based on the relatively small decrease in quantities of beef food products

and the relatively inelastic price elasticity of supply and of demand associated with affected beef food products, that the aggregate beef price impacts of the measures contained in the final rule are not significant: less than a 0.2 percent increase. Further, FSIS estimates that the affected establishments have a relatively insignificant increase in operating costs, given that this increase is typically a relatively small share, less than 0.4 percent, of the total Industrywide operating costs affected. In addition, the removal of specified risk materials (SRMs)(e.g., brains, detached spinal cords for export, eyes, and distal ileum) from the supply of variety meats is not expected to have a significant impact on prices, given the availability of substitutes (e.g., brains from cattle younger than 30 months of age, and the remaining small intestine excluding the distal ileum). Furthermore, FSIS estimates that only a relatively small share, about 0.2 percent, of the beef variety meat supply is affected. In addition, the removal of non-ambulatory disabled cattle from the food supply is not expected to have a significant impact on beef prices given the relatively small share of the beef supply affected (less than 0.15 percent).

Table VI: Summary: Benefits and Costs, and Cost-Effectiveness Ratios for Final Rule and Alternatives to it Considered

	Average Risk Reduction (Cattle Oral ID50)[b]	Incremental Average Risk Reduction (Cattle Oral ID50)	Annualized Average Cost ($millions)	Incremental Cost ($millions)	Incremental Cost-Effectiveness ($/Cattle Oral ID50)
Scenario 1: Ban on non-ambulatory cattle offered for slaughter for use as human food - – 100 percent compliance	200	-	$5.9	-	*
Scenario 4: Ban on use of SRMs from cattle 30 months of age and older for use as human food – 100 percent compliance	6,580	6,580	$164.8	$164.8	$25 thousand
Final Rule. Scenario 8: Ban on non-ambulatory disabled cattle offered for slaughter and use of SRMs from cattle 30 months of age and older for use as human food – 100 percent compliance	6,580	-	$171.2	-	**[a]
Scenario 3: Ban on use of SRMs from cattle 24 months of age and older for use as human food – 100 percent compliance	6,583	3	$504.0	$339.2	$113 million
Scenario 2: Ban on use of SRMs from cattle 12 months of age and older for use as human food – 100 percent compliance	6,583	-	$570.0	-	**

*- Weakly Dominated **-Dominated

[a] Note that the Final Rule is dominated by scenario 4, since the model assumed no quantifiable risk reduction from banning non-ambulatory disabled cattle offered for slaughter from the food supply. The analysis below explains why USDA thinks that the benefits of this ban justify the costs.

[b] Note that USDA also ran the model (explained in more detail below) assuming different numbers of cattle introduced into the U.S. The average potential risk faced by humans depends essentially linearly on the assumed number of cattle introduced. While the absolute cost-effectiveness of each scenario depends on this assumption, the relative ranking of scenarios by cost-effectiveness does not.

(This is a blank page.)

1.0 Introduction

On January 12, 2004, FSIS issued a series of three interim final rules to minimize human exposure to materials that scientific studies have demonstrated contain the BSE agent in cattle infected with that disease. Scientific and epidemiological studies have linked the human disease vCJD to exposure to BSE, most likely through human consumption of beef products contaminated with the BSE agent.

One of the interim final rules, "Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-ambulatory Disabled Cattle" (69 FR 1862, Jan. 12, 2004) is also referred to as "the SRM interim final rule." This interim final rule designates certain materials from cattle as SRMs, declares that SRMs are inedible, and prohibits the use of these materials for human food (9 CFR 310.22(a) and 9 CFR 310.22(b)). The SRM interim final rule also requires that establishments that slaughter cattle, and establishments that process the carcasses or parts of cattle, develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs and incorporate these procedures into their HACCP plans or Sanitation SOPs or other prerequisite programs (9 CFR 310.22(d)).

The materials identified as SRMs in the SRM interim final rule are the following: the brain, skull, eyes, trigeminal

ganglia, 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), and dorsal root ganglia (DRG) from cattle 30 months of age and older. In addition, the distal ileum of the small intestine and tonsils from all ages of cattle are designated as SRMs in the interim final rule (9 CFR 310.22(a)). The SRM interim final rule declares that SRMs are inedible because they present a sufficient risk of exposing humans to the BSE agent so as to render them "unfit for human food" within the meaning of section 1(m)(3) of the adulteration provisions of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601(m)(3)).

The SRM interim final rule designates the distal ileum from all cattle as a SRM. To ensure effective removal of the distal ileum, the SRM interim final rule originally required that the establishment remove and dispose of the entire small intestine as inedible. However, in the preamble to the SRM interim final rule, FSIS noted that beef processors might be able to remove effectively the distal ileum from the rest of the small intestine and requested comments on this issue (69 FR 1862, 69 FR 1869). FSIS again requested comments on this issue in an advance notice of proposed rulemaking published in July 2004 ("Federal Measures To Mitigate BSE Risks: Considerations for Further Action" (69 FR 42287, 69 FR 42296)).

In response to these requests, FSIS received several comments that described detailed procedures on how to remove the distal ileum from the small intestine. Based on the comments submitted on this issue, FSIS evaluated the issue and determined that processors have the technology to remove effectively the distal ileum from the rest of the small intestine. Therefore, on September 7, 2005, FSIS issued an amendment to the SRM interim final rule to permit, under specific conditions, the use of beef small intestine, excluding the distal ileum, for human food (70 FR 53043).

In addition to prohibiting SRMs for use as human food, the SRM interim final rule also prohibits the slaughter for human food of non-ambulatory disabled cattle offered for slaughter. FSIS prohibited the slaughter of these non-ambulatory cattle because surveillance data from European countries where BSE has been detected indicate that non-ambulatory cattle are among the cattle that have a greater incidence of BSE than do healthy slaughter cattle. Furthermore, because the typical clinical signs of BSE cannot always be distinguished from the typical clinical signs of other diseases and conditions that affect non-ambulatory cattle, FSIS determined that non-ambulatory disabled cattle offered for slaughter present a sufficient risk of introducing the BSE agent into the human food supply to render the carcasses of these animals unfit for human food under

section 1(m)(3) of the FMIA (21 U.S.C. 601(m)(3)). The SRM interim final rule requires that all non-ambulatory disabled cattle that are offered for slaughter be condemned (9 CFR 309.3(e)).

In addition to the SRM interim final rule, FSIS published two other interim final rules. One of the interim final rules, Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter (69 FR 1885)(also referred to as "the air-injection stunning interim final rule") prohibits the use of captive bolt stunning devices that deliberately inject air into the cranial cavity of cattle. In the final rule, FSIS is affirming without amendment the air-injection stunning interim final rule. The other interim final rule issued, "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems" (69 FR 1874), establishes requirements for meat produced using advanced meat/bone separation machinery and meat recovery (AMR) systems. Because the AMR interim final rule contains several non-BSE related provisions, FSIS intends to affirm and, if necessary amend, the AMR interim final rule in a separate document that will be published in the Federal Register at a later date.

2.0 Need for the Final Rule

FSIS is taking this action to make permanent interim measures implemented by FSIS to minimize human exposure to cattle materials that could potentially contain the BSE agent.

Before the SRM interim final rule and before the finding of a BSE infected cow in Washington State in 2003, FSIS surveyed its inspection program personnel in federally inspected beef establishments about the procedures establishments had implemented in regard to SRMs, and other slaughter and processing practices and activities (USDA, FSIS, 2002). This FSIS study showed that a significant portion of beef establishments (277 of 290 establishments surveyed, or 96 percent) were not addressing the possible contamination of edible beef products with products that could potentially contain the BSE agent (e.g., spinal cord tissues remaining in vertebral bone-in cuts of beef of cattle 30 months of age and older). Thus, beef establishments were not addressing this potential food safety hazard in their Hazard Analysis and Critical Control Point (HACCP) plans or Sanitation Standard Operating Procedures (Sanitation SOPs) or other prerequisite programs, or taking other measures to minimize human exposure to cattle materials that could potentially contain the BSE agent. The study found, however, that some establishments were removing the distal ileum of the small intestines of all ages of cattle

because export markets for beef small intestine products stipulated that this measure had to be taken (e.g., exports to Japan and South Korea).

After FSIS issued the SRM and air-injection stunners interim final rules described above, the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) confirmed a case of BSE in a beef cow in the United States in June 2005. That animal was a 12-year-old cow born and raised on a ranch in Texas. This was the first native case of BSE in the United States. Previously, APHIS, USDA had confirmed a case of BSE in 2003 in a cow that a U.S. livestock producer had imported from Canada. In March 2006, APHIS confirmed a third case of BSE, also involving a native-born cow, in Alabama that APHIS estimated to have been 10 years old. All three of the BSE-confirmed cattle in the United States were born prior to the Food and Drug Administration’s (FDA) 1997 feed ban put in place to prevent the spread of BSE. The 1997 feed ban prohibits the feeding of most mammalian protein to ruminants.

The Final Rule is needed because, in the absence of regulatory actions, the market might not provide the timely mitigation measures needed to maintain confidence in the safety of the beef supply. Beef slaughter and processing operations might not allocate needed resources and efforts to provide effective prevention measures for BSE agent contamination of

their products. Based on the SRM Survey of 2002, establishments were marketing, as human food products or variety meats, brains derived from cattle 30 months of age and older and the distal ileum of the small intestines derived from all ages of cattle (USDA, FSIS, 2002). However, these tissues are potentially sources of the BSE agent, and are SRMs under the SRM Interim Final Rule and the Final Rule.

The 2001/2003 Harvard risk assessment (HRA) model and the 2005 Harvard BSE Update indicate that beef products from establishments that are not taking preventive measures to remove SRMs from the human food supply can lead to increased risks of human exposure to the BSE agent. The 2005 Harvard BSE Update estimated the relative risk reductions that preventive measures of increasing intensity can achieve with regard to the removal of SRMs. The HRA model concluded that several measures to remove SRMs could be effective, but that some are relatively more effective than others are, and that a combination of measures appears to be much more effective in mitigating the potential exposure to the BSE agent than any single measure. This final rule affirms, and, in some instances, amends the measures that establishments are required to implement to minimize the potential human exposure to the BSE agent.

The 2005 Harvard BSE update shows that a combination of preventive measures is more effective than a single measure in

reducing or eliminating the potential risk of exposure to the BSE agent in beef products (Cohen et al. 2005). For example, spinal cord removal is relatively more effective in removing the potential risk of exposure than just the removal of the distal ileum of the small intestines. However, both spinal cord and distal ileum removal is relatively more effective than the removal of only the spinal cord or only the distal ileum.

3.0 Preliminary Assessment of the Effectiveness of the SRM and Air-injection Stunners Interim Final Rules

FSIS does not know of any reported human cases of vCJD in the U.S. that it can trace to U.S. sources of beef products. However, records of establishments' non-compliance with FSIS regulatory requirements (non-compliance records (NRs) maintained by FSIS) indicate that some establishments are more effective in minimizing the potential contamination of beef products with materials that could potentially contain the BSE agent than other establishments. FSIS reported the rate of non-compliance reflected in its NRs in August 2005, regarding SRMs and related concerns. It has been monitoring establishments' progress about SRM compliance since that time. This information is available on the FSIS web page: http://www.fsis.usda.gov/Fact_Sheets/BSE_Rules_Being_Strictly_Enforced/index.asp.

Since FSIS released its non-compliance information in August of 2005, FSIS has continued to assess the effectiveness of SRM removal and control by establishments. In August 2005, FSIS stated that the non-compliance action rate for control of SRMs by establishments (removal of SRMs from the human food supply) was approximately 1 percent of all non-compliance actions taken in beef establishments. By August 2006, the non-compliance rate dropped to just under 0.5 percent. FSIS believes that the level of non-compliance for SRM removal and control has always been low and continues to improve.

As discussed in the following Benefits Section 7 of this FRIA, the major positive effects of the SRM interim final rule are the maintenance of domestic consumer confidence and the regaining of international or foreign consumer confidence in the safety of the U.S. beef supply. The final rule will result in the continuation of this confidence in the safety of the U.S. beef supply. The cost of compliance with the final rule for the affected establishments and beef industry are discussed in Section 6 of this FRIA.

Table 3.1 shows the effects of non-compliance with certain types based on the results of the 2005 Harvard BSE Update. The 2005 Harvard BSE Update addresses the effects of non-compliance effects that change the costs and benefits for the Final Rule.

The added non-compliance effects suggested that there would be less than anticipated costs and benefits for the Final Rule.

Table 3.1: Effects of Non-Compliance on the Costs and Benefits of the Final Rule

Area of Non-Compliance Type	Incidence of all non-compliance reported by FSIS	Effects on Final Rule Costs and Benefits	
		Costs	Benefits: risk reduction for humans, in cattle oral ID50s
Non-compliance for prohibition on the use of non-ambulatory disabled cattle offered for slaughter prohibited for use as human food	Less than 0.5 percent	Lowers costs of compliance	Lowers benefits of compliance
Non-compliance for required disposition of SRMs – bone-in beef products	Less than 0.5 percent	Lowers costs of compliance	Lowers benefits of compliance
Total Non-compliance for the above areas of the Final Rule	Less than 0.5 percent	Lowers costs of compliance	Lowers benefits of compliance
Source: FSIS PBIS 2006			

4.0 Data Sources

Data from the PRIA, and new and updated data sources are used in the FRIA to estimate the impacts of the final rule. Some of this data came from surveys of FSIS employees (inspection program personnel), two surveys of industry, public and FSIS' databases, other databases, published research, and public comments received on the PRIA, the SRM and air-injection stunners interim final rules, the Harvard Risk Assessments. The

summaries of the FSIS surveys and copies of the public comments are available on the FSIS web page (http://www.fsis.usda.gov) and in the FSIS Docket Room, 300 12th Avenue SW, Room 101, Washington, DC.

One of the industry surveys from which the data obtained were used, in part, to estimate the impacts of the final rule was of beef slaughtering and processing establishments (Cates et al., June 2005). The second industry survey was of processing-only establishments ((Cates et al., December 2005). These two industry surveys were OMB-approved (OMB No. 0583-0125). The industry surveys were of slaughter and processing operations pre-BSE (i.e., prior to finding a case of BSE in a cow in Washington State in December of 2003), and measures adopted by establishments since the implementation of the SRM and air-injection stunners interim final rules.

In addition, the Association of Food and Drug Officials (AFDO) provided data on custom-exempt establishments that are exempt from FSIS' inspection requirements for slaughter and processing operations (AFDO, December 2005). A copy of this survey is available in the FSIS Docket Room and as a related document on the FSIS web page.

In addition, before the SRM and air-injection stunners interim final rules and pre-BSE, FSIS employees (inspection program personnel) responded to a data gathering initiative.

FSIS gathered data from its inspection program personnel in federally inspected establishments about slaughter and processing practices and activities (USDA, FSIS, 2002).

Additionally, FSIS' databases of 2003, 2004, 2005, and 2006 were a source of information about establishment activities, including their compliance with removal of SRMs from the human food supply, their slaughter volume, and non-ambulatory disabled cattle that were offered for slaughter (e.g., Performance Based Inspection System (PBIS), Animal Disposition Reporting System (ADRS) and Microbiological and Residues Contamination Information System (MARCIS)).

Further, the databases of the Agricultural Marketing Service (AMS), the National Agricultural Statistical Service (NASS), and the Foreign Agricultural Service (FAS) of USDA were sources of information about producer price discounts for older cattle, beef production, and domestic and export markets for cattle and beef food products.

Table 4.1 presents the areas for which data were collected for all of the surveys, used in the FRIA.

Table 4.1: Summary of Areas for which Data was Collected for All of the Surveys, used in the FRIA.

Sources	Surveys	Areas for which Data were Collected
FSIS Employees	SRM Survey of 2002	• Establishments slaughtering or processing beef • Disposition of non-ambulatory cattle • Disposition of Specified Risk Materials • Age of cattle at slaughter • AMR production practices
FSIS Employees	Site visits to establishments by DEAS (informal survey), 2003-2005	• Establishments slaughtering or processing beef • Disposition of non-ambulatory cattle • Disposition of Specified Risk Materials • Age of cattle at slaughter • AMR production practices
Industry	Meat and Poultry Slaughter and Processing Industry Survey of 2005[a]	• Establishments slaughtering or processing beef • Disposition of non-ambulatory cattle • Disposition of Specified Risk Materials • Age of cattle at slaughter
Industry	Meat and Poultry Processing-Only Industry Survey of 2005[b]	• Establishments processing beef • Disposition of Specified Risk Materials
State Officials	State-Inspected Meat and Poultry Slaughter and Processing Establishments of 2005[b]	• Establishments slaughtering or processing beef
State Officials	Meat and Poultry Custom-Exempt Establishments Survey of 2005[c]	• Establishments slaughtering or processing livestock

Notes:
[a] Cates et als., June 2005
[b] Cates et als., December 2005
[c] Association of Food and Drug Officials, 2005

Table 4.2 presents a summary of areas for which data were available and some assumptions of the FRIA and the PRIA. The table indicates how these assumptions affect the conclusions of the FRIA. The table compares assumptions in the PRIA to those in the FRIA. Assumptions are also discussed in Sections 7 and 8 of the FRIA.

Table 4.2: Summary of Areas for which Data were Available and Assumptions Made in the FRIA Compared to Assumptions of the PRIA

Topics	PRIA	FRIA	Change in the results of the FRIA because of change in the data or assumptions made in the FRIA compared to assumptions of the PRIA
Non-Ambulatory Disabled Cattle	Used industry estimate to assume deterministic values	Used FSIS database to determine probability distribution of values	Lowers costs of compliance
Specified Risk Materials	Establishments affected included only those that were federally or state inspected	Establishments affected included those federally inspected, state inspected, and custom-exempt establishments	Increases costs of compliance because of the increase in the number of affected establishments
Distal ileum	Assumes that the entire small intestine including the distal ileum was not allowed for human food	Assumes only the distal ileum is not allowed for human food. The rest of the small intestine is available for human food.	Lowers costs of compliance
Harvard Risk Assessment	2001/2003 HRA does not assume non-compliance effects of SRM removal	2005 Harvard BSE Update assumes non-compliance effects of SRM removal	Increases benefits of compliance

5.0 Response to Comments: Economic Impact Issues Received on the PRIA with Respect to SRMs and Air-injection Stunners and the SRM and Air-injection Stunners Interim Final Rules

FSIS received approximately 23,000 comments in response to the January 12, 2004 interim final rules, the March 2004 PRIA of the interim final rules, the APHIS/FSIS/FDA ANPR, and the September 7, 2005 amendment to the SRM interim final rule. The following are the economic impact issues raised by the comments on the SRMs and air-injection stunners FRIA and the SRM and air-injection stunners interim final rules, and FSIS' response.

Prohibition on the slaughter of non-ambulatory disabled cattle

Comment: Several comments from cattle farmers and ranchers asserted that the prohibition on the slaughter of non-ambulatory disabled cattle has placed a serious economic burden on livestock owners. Many of these comments, particularly those from dairy farmers, stated that prior to the implementation of the new regulations, when a healthy cow suffered an acute injury, farmers were able to send the animal to slaughter and receive compensation for it. According to the comments, because of the rule, a livestock owner not only incurs a loss when a healthy animal becomes non-ambulatory, but also incurs costs associated with destroying the animal and disposing of its carcass.

Several comments from small meat processors and custom operations said that the prohibition on the slaughter of non-ambulatory disabled cattle places a serious economic burden on them. These comments stated that because they do not slaughter or process a large number of animals they stand to lose a significant source of revenue and that the prohibition on the slaughter of non-ambulatory disabled cattle would cause them to go out of business.

Response: FSIS acknowledges that its prohibition on the slaughter of all non-ambulatory disabled cattle offered for slaughter has certain economic impacts on cattle producers, small meat processors, and custom-exempt operators (i.e., fee-for-service establishments). Cattle producers, small meat processors, and custom operators cannot use the carcasses of non-ambulatory disabled cattle offered for slaughter for human food because the carcasses are adulterated. Thus, cattle producers will not be able to salvage such cattle that are non-ambulatory because of an acute injury. Cattle producers will lose the opportunity to salvage the net value of the beef from an acutely injured animal offered for slaughter that is non-ambulatory, yet otherwise healthy. In addition, small meat processors and custom slaughter establishments will not be able to generate revenue from slaughtering or processing the carcasses of these animals. However, under the regulations, the

disposition of cattle that become non-ambulatory after they have passed ante mortem inspection is determined on a case-by-case basis. The economic impact of prohibiting the slaughter of non-ambulatory disabled cattle offered for slaughter is presented in Section 6.3 “Quantifying the Costs of this Final Rule and Assumptions.”

Age verification

If an establishment has accurate records that document the age of the cattle slaughtered in the facility, FSIS’ inspection program personnel will accept these records as verification of the age of the cattle. If the establishment does not have records that document the age of the cattle presented for slaughter, FSIS verifies age through dental examination. Under its age verification procedures, FSIS deems cattle to be 30 months of age and older if at least one of the second set of permanent incisors has erupted (the permanent incisors of cattle erupt from 24 through 30 months of age).

Comment: Some comments asserted that FSIS’ method for verifying the age of cattle frequently overestimates the age of cattle that are younger than 30 months of age, resulting in an economic loss to cattle producers or feeders. One comment stated that certain meatpackers have indicated that they intend to deduct 15 cents per pound per head for any animal that is determined to be 30 months of age and older by

dentition. According to the comment, the implementation of the rule is devaluing a group of cattle ("heiferettes") that previously returned a premium over their current class (cull cows). The comment also noted that after Canada implemented similar procedures for determining the age of cattle offered for slaughter, cattle producers or feeders sold cattle in Canada with more than two permanent incisors for a total price of 8 to 20 cents (Canadian) per pound liveweight.

This same comment stated that cattle feeders are losing nearly $200.00 per head for any animal found to have more than two permanent incisors, which is a per head loss of nearly 20 percent. Another comment also claimed that ranchers are losing up to $360.00 per head for any animal found to have more than two permanent incisors, which amounts to a per head loss of nearly 50 percent. The comment estimated that the costs associated with FSIS' method for verifying the age of cattle using dentition will cost the cattle producing industry in excess of $1,036 million. One comment submitted by a rancher indicated that he takes a discount of $60.00 to $100.00 per head on cattle deemed to be 30 months of age and older, which could force him to discontinue his business unless he is able to purchase cattle that have documentation of age.

Response: FSIS discusses in detail the economic impacts of this final rule on age verification in Section 6.3 "Quantifying

the Costs of this Final Rule and Assumptions." In the cattle industry, "heiferettes" are relatively young cows that have delivered their first calf (dead or alive). Generally, in any group of steers and heifers, some cattle will appear to be 30 months of age and older based on dentition even if all of the animals in the group are younger than 30 months of age. Estimates of the proportion of steers and heifers that will appear to be 30 months of age and older based on dentition range from 1 to 5 percent (Hodges and Seward, 2004).

After FSIS published the SRM and air-injection stunners interim final rules, the USDA Market News Service (of the Agricultural Marketing Service (AMS)) began to report discounts for cattle 30 months of age and older (including those determined by dentition). Weekly values have ranged from $35 to $50 per cwt (carcass weight), which translates to an approximate discount of $175 to $250 per head for a 500-pound cow or bull carcass (e.g., on the lower end, $35 per cwt times 5 cwt equates to $175). Thus, the comments on this issue demonstrate the advantage of using accurate records rather than dentition to determine the age of cattle.

Comment: One comment stated that while the sole impetus for FSIS' implementation of the SRM interim final rule was APHIS' finding of a BSE-positive cow in Washington State in

December 2003, neither the rule nor the PRIA acknowledge the fact that the animal was imported from Canada. According to the comment, because neither the rule nor the PRIA recognize that the United States has never had a native case of BSE, the PRIA fails to consider more effective alternative approaches to accomplishing FSIS' stated benefits of reducing human exposure to BSE infectivity and restoring beef exports. The comment asserted that FSIS' strategy for protecting consumers and the U.S. cattle herd from the BSE agent must include an immediate and coordinated effort to identify the higher-risk Canadian cattle currently interspersed, albeit in small numbers, within the U.S. beef and dairy cattle herds. The comment also argued that by failing to acknowledge the true origin of the BSE case detected in Washington State, FSIS unwittingly signaled the international community and any other interested party that the United States is among the countries known to have BSE.

Response: As noted earlier in this document, APHIS has detected two native cases of BSE in the United States since FSIS issued the SRM interim final rule, so the statement that the United States has never had a native BSE case is no longer accurate. In addition, in the summary section of the PRIA, FSIS states that "[t]he findings of a single cow with BSE 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 exports demand."[7] Thus, FSIS disagrees that the PRIA does not acknowledge the origin of the BSE positive cow found in 2003 in Washington State.

Comment: In the PRIA, 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 risk assessment (HRA) model, as revised by the Harvard Center for Risk Analysis (HCRA) in response to peer review comments and released in 2003 (also referred to as the 2001/2003 HRA). One comment stated that in the PRIA, FSIS mischaracterized the 2001/2003 HRA as both "an analysis and evaluation of the current measures implemented by the U.S. government to prevent the introduction and spread of BSE and to reduce the potential exposure to the BSE agent." The comment asserted that the scope of the HRA, as described by its authors, is limited to an analysis which evaluates the robustness of the U.S. measures to prevent the spread of bovine spongiform encephalopathy (BSE or "mad cow disease") if it were to arise in this country." According to the comment, FSIS' mischaracterization in the PRIA suggests that the HRA provides scientific evidence that measures implemented by the U.S. government are adequate to prevent the introduction of BSE into the United States.

[7] Food Safety and Inspection Service, Preliminary Analysis of Interim Final Rules and an Interpretive Rule to Prevent the BSE Agent from Entering the U.S. Food Supply, p.2-3. April 7, 2004. This is the PRIA that was posted on the FSIS web pages: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/03-025N/BSE_Analysis.pdf

Response: Although the PRIA did in one instance state that the HRA was “an analysis and evaluation of the current measures implemented by the U.S. government to prevent the introduction and spread of BSE and to reduce the potential exposure to the BSE agent,” in this document FSIS is clarifying that the objective of the 2001/2003 Harvard Study was to analyze and evaluate the measures implemented by the U.S. Government to prevent the spread of BSE in the United States. However, as noted in the PRIA, the 2001/2003 HRA concluded that if introduced, BSE is extremely unlikely to become established in the United States.

In May 2004, USDA contracted with the Harvard Center for Risk Analysis (HCRA) to revise the HRA model to reflect information available through December 2003. USDA also contracted with the HCRA to develop a new baseline for the risk assessment model, analyze the effects of the measures implemented by USDA and FDA in response to the confirmation of the BSE case in Washington State, and analyze recommendations made by an international expert BSE panel. At the request of the Secretary of Agriculture, this BSE panel was convened to review the actions taken by the United States in response the confirmation of the BSE case in Washington State.

The HRA authors submitted an updated risk assessment to FSIS in June 2005. Contracted reviewers completed a peer review of

the updated risk assessment in September 2005. FSIS submitted the final updated risk assessment and the revised risk assessment model to its web page, following the peer review.

On July 12, 2006, FSIS made the 2005 updated Harvard Risk Assessment (also referred to as the 2005 Harvard BSE Update) available to the public. On July 25, 2006, FSIS held a public technical meeting to provide information on the 2005 Harvard BSE Update. FSIS used the findings of the 2005 Harvard BSE Update to assess the benefits associated with the measures adopted in the final rule, as well as the alternatives considered.

6.0 Updated Final Regulatory Economic Analysis and Methodology

In this section, FSIS has updated the regulatory impact analysis of the SRM and Air-Injection Stunning Interim Final Rules. The primary objectives of the FRIA are to estimate the: costs and revenues changes (a partial budget analysis) associated with the final rule compared to the baseline; the net total monetary changes of decreased revenues and increased costs versus increased revenues and decreased costs; and the distribution of those net revenues and costs changes among producers. The methodology of the FRIA is the same as the methodology of the PRIA. The methodology used is set forth in the PRIA (USDA, FSIS, March 2004). FSIS used its probability simulation model to analyze the effects of the final rule. FSIS

ran its economic model with @RISK (Version 4.5) software (Palisade Corporation). This is quantitative analysis software using Monte-Carlo simulation. The inputs, the outputs, and the influential factors of the economic model are in the tables of Appendix B.

FSIS based the PRIA cost impact analysis of the SRM and Air-Injection Stunning Interim Final Rules on a probabilistic model developed by FSIS, excluding the prohibition on non-ambulatory disabled cattle from the food supply, and Hazard Analysis and Critical Control Points (HACCP) plan development, record keeping, and verification. FSIS based the PRIA cost impacts of the interim final regulatory measures on the deterministic values cited in the text of the PRIA analysis. In March 2004, FSIS posted the PRIA on the FSIS web pages: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/03-025N/BSE_Analysis.pdf.

FSIS based the FRIA cost and benefit impact analysis of the Final Rule on a probabilistic model developed by FSIS. FSIS based the cost impacts of the final regulatory measures on the probabilistic values cited in the text of the FRIA (see the rest of Section 6 below). FSIS fitted triangular distributions of values (minimum, most likely, maximum values of sources) for the probabilistic values of the compliance costs and associated biological parameters. The distributions of values were derived

from various data sources (see Section 4 above) of databases, surveys, trade organizations, and experts (e.g., FSIS employees, University staff, and State Extension Service staff). Minimum value of a distribution is the low value, and maximum value of a distribution is the high value. The “most likely” value is between the minimum and maximum values. FSIS based the benefit impacts of the final regulatory measures on the probabilistic values of the Harvard BSE Update cited in the text of the FRIA (see section 7 below). FSIS determined baseline conditions that represent pre-BSE conditions of the industry prior to confirmation diagnostically of a BSE-infected imported dairy cow in Washington State on December 23, 2003. Then, FSIS developed alternative actions or measures that potentially reduce the exposure of humans to the presence of BSE agents in beef food products. For each of the considered alternatives, including the Final Rule, FSIS estimated:

- compliance cost probability distributions based on its data sources, and
- potential risk reduction (to humans) probability distributions based on the 2005 Harvard BSE Update risk assessment model.

Then, FSIS calculated the cost-effectiveness ratio of each of the considered alternatives, including the final rule. In addition, FSIS calculated the incremental cost-effectiveness

ratios in order to evaluate the marginal changes between the alternatives (see Section 7 below).

6.1. The Baseline

Pre-BSE conditions of cattle production and beef markets in the livestock sector and meat industry during 2003, prior to confirmation diagnostically of a BSE-infected imported dairy cow in Washington State on December 23, 2003, comprise the baseline for assessing the economic impacts associated with the SRM interim final rule and related rulemaking. The FRIA for the final rule used the same baseline year of 2003, as did the PRIA for the interim final rule. In the FRIA, FSIS estimates that the final rule would affect 768 federally inspected establishments[8], about 1,430 state-inspected establishments[9] and about 1,314 custom-exempt slaughtering and processing establishments, or a total of about 3,512 establishments (see Tables II and III in the Summary Section and Table 6.1.1 below).

- **Baseline Industry Characterization**

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

[8]FSIS obtained these numbers by counting establishments with at least one FSIS Performance Based Inspection System (PBIS) code that corresponds to production of beef products, and by using the FSIS Animal Disposition Recording System (ADRS) database to select establishments that slaughtered cattle. For details, see the PRIA (USDA FSIS, March 2004).

[9]FSIS obtained these numbers by counting establishments with at least one FSIS Performance Based Inspection System (PBIS) code that corresponds to production of beef products. Some of the State information was obtained from State Agencies and marketing reports. For details, see the PRIA (USDA FSIS, March 2004).

markets. The USDA Agricultural Marketing Service (AMS) and its National Agricultural Statistics Service (NASS) estimated that beef production was 26.3 billion pounds from an annual slaughter of about 36.7 million cattle in 2003. Gross farm income from cattle and calf production totaled $44.1 billion in 2003.[10] U.S. exports of beef, veal, and beef variety meats in 2003 were 2.6 billion pounds valued at $3.8 billion.

FSIS estimates that, in 2003, federally inspected establishments slaughtered and processed 98.7 percent of all cattle.[11] Further, FSIS estimates that about 80 percent of the cattle slaughtered at federally inspected establishments are younger than 30 months of age. The remaining 20 percent are cows, bulls, or stags[12] and some steers and heifers that are estimated to be 30 months of age and older.[13] FSIS sought in the PRIA, but did not receive, comments on the age distribution of cattle sent to slaughter and, in particular, reliable information on the age distribution of cattle slaughtered at

[10] 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

[11] FSIS obtained this data from U. S. Department of Agriculture, Food Safety and Inspection Service, Animal Disposition and Reporting System (ADRS), 2003.

[12] Stags are male bovines castrated after maturity. This is not a common practice in the U.S. cattle industry.

[13] FSIS has found that some first-calf cows, and some juvenile (not mature) and mature bulls that go to slaughter may be younger 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. This can result because cattle producers feed these steers and heifers primarily grass pasture or forage crops while growing and then, after an extended period, finish them for grading on grain. In addition, cattle producers have removed heifers that have failed to conceive in the breeding season, or have lost their calves, from cattle herds. Cattle producers have placed these older heifers or young cows that have already matured in feedlots where the heifers or young cows have been finished for grading on grain. Thus, at slaughter, not all cows or bulls are 30 months of age and older, and not all heifers and steers are younger than 30 months.

establishments that specialize in market or fed cattle. FSIS assumes that no more than about 5 percent of fed cattle (i.e., steers and heifers that are finished on a high level of grain) for slaughter are 30 months of age and older. These steers and heifers are included in the 20 percent portion that represent cattle 30 months of age and older.

FSIS estimated that, in 2003, 3,512 establishments that were federally inspected, State inspected, or custom-exempt establishments processed cattle or parts of cattle for dress or further processing. Of these affected 3,512 establishments, about 3,278 (93.3 percent) were establishments that FSIS classified as “very small.” About 197 (5.6 percent) of the establishments were classified as “small.” Of the 197 small establishments, about 123 establishments slaughter from 1 to 30,000 cattle with an average of less than 5,000 cattle annually. Based on slaughter volume, FSIS classified these small establishments as “small–class I.” Another 52 slaughter establishments slaughter significantly more than cattle – an average of about 74,000 cattle annually. FSIS classified these small establishments as “small–class II.” In addition, of the 197 small establishments, based on FSIS estimate of beef volume, FSIS classified 15 small establishments that process-only as “small–class I,” and 7 small establishments as “small–class II,” FSIS estimated that of the 22 small processing-only

establishments, 12 small-class I establishments process an average of about 10,000 beef carcasses (CE) and 7 small-class II establishments process an average of about 19,000 carcasses (CE), annually. Of the total 3,512 establishments affected, the remaining 37 establishments (1.0 percent) FSIS classified as "large." These 37 large establishments slaughter or further process more than 94 percent of the cattle. FSIS inspects all of the large establishments. The 197 small establishments (class I and class II) slaughter and process about 4 percent of the cattle. The 200 largest establishments slaughter or process about 98 percent of the cattle.[14]

The final rule affects all establishments that slaughter cattle or that process the carcasses and parts from cattle. Specifically, the final rule affects all federally-inspected, state-inspected, and custom-exempt establishments that slaughter cattle. The term "cattle" refers to veal calves or calves, steers and heifers, and cows and bulls. The final rule also affects all inspected processing establishments that do not slaughter cattle but that receive carcasses or parts from cattle that contain vertebral columns from cattle 30 months of age and older. All establishments that process carcasses or bone-in parts of cattle with vertebral columns from cattle younger than 30 months are also affected because they must demonstrate

[14] U.S. Department of Agriculture FSIS Animal Disposition and Reporting System (ADRS) 2003

(through documentation provided by the supplier) that the materials received are from cattle that are younger than 30 months of age at the time of slaughter. Finally, the final rule also affects all custom-exempt slaughter and processing establishments that slaughter or process cattle on a fee-for-service basis because custom-exempt establishments that slaughter cattle must remove SRMs and custom-exempt establishments that slaughtered non-ambulatory cattle prior to the SRM interim final rule no longer are permitted to do so. Table 6.1.1 provides FSIS' estimates of the total population of potentially affected slaughter and processing establishments in each category, and the number of establishments affected by the requirements of the final rule. Using the best available data, FSIS estimates that the final rule affects the following 3,512 establishments:

768 federally inspected establishments,

1,430 state-inspected establishments, and

1,314 custom-exempt establishments.

By HACCP-size category, FSIS estimates that the final rule affects the following 3,512 establishments:

37 large establishments,

197 small establishments (138 small-class-I and 59 small-class-II), and

3,278 very small establishments.

Table 6.1.1 presents the pre-BSE 2003 estimated population of establishments potentially affected by this Final Rule.

Table 6.1.1: Pre-BSE 2003 Estimated Population of Establishments Potentially Affected by this Final Rule

Type of Inspection	Category[a]	Estimated Population of Establishments	Estimated Affected Establishments
Federal Inspection (2003)	Cattle slaughter—very small[g]	528	528
	Cattle slaughter—small class I[g]	100	100
	Cattle slaughter—small class II[g]	52	52
	Cattle slaughter—large[g]	36	36
	Total federal slaughter[g]	*716*	*716*
	Processing-only—very small[b]	1,609	29
	Processing-only—small class I[b]	698	15
	Processing-only---small class II[b]	360	7
	Processing-only—large[b]	59	1
	Total federal processing-only[b]	*2,726*	*52*
	Total federal inspection	3,442	768
State Inspection (2003/2004)[c]	Meat slaughter-only—very small[d]	795	731
	Meat processing-only—very small[e]	1,056	84
	Meat combination—very small[dg]	643	592
	Total state—very small	*2,494*	*1,407*
	Meat slaughter-only—small class I[d]	13	12
	Meat processing-only—small class I[e]	24	0
	Meat combination—small class I[dg]	12	11
	Total state—small	*49*	*23*
	Total state inspection	2,543	1,430
Custom-Exempt (2003/2004)	Meat slaughter-only—very small	40	34
	Meat processing-only—very small	1,473	0
	Meat combination—very small[g]	1,621	1,280
	Total custom-exempt[f]	3,134	1,314
Total Establishments		9,119	3,512

[a]Source: PBIS. 2003. FSIS Performance Based Inspection System Database. FSIS supplemented the PBIS with data from State agencies on state-inspected establishments and on custom-exempt establishments.

[b]Meat processing federally inspected establishments are included in the total inventory of *beef* processing establishments only if they have PBIS or HACCP codes representing beef carcasses and cuts or beef grinding. Meat processing-only establishments that process beef products but not beef carcasses, cuts, or ground product likely do not receive beef carcasses with SRMs. The numbers of federal processing-only establishments that are affected by the final rule (because they receive carcasses or parts of cattle containing vertebral column from cattle 30 months of age and older) were obtained from unpublished results of the FSIS processing-only establishments industry survey conducted in fall 2005.

[c]Twenty-eight (28) states operate state inspection systems for meat slaughter and processing, in addition to federal inspection systems. The remaining twenty-two (22) states do not operate state inspection systems but instead only have federal inspection systems for meat slaughter and processing.

[d]Based on results of the meat and poultry slaughter and processing industry survey, an estimated 92 percent of state-inspected meat slaughter establishments slaughter cattle (Cates et al., June 2005). FSIS categorized the vast majority of establishments as very small.

[e]The numbers of state-inspected processing-only establishments that are affected by the final rule (because they receive carcasses or parts of cattle containing vertebral column from cattle 30 months of age and older) were obtained from results of the processing-only industry survey (Cates et al., December 2005).

[f]Data on numbers of custom-exempt establishments are available only for states that operate state inspection systems. Custom-exempt operations occur in federally- and state-inspected establishments. However, these custom-exempt operations are accounted for in the analysis of federally- and state-inspected establishments. FSIS estimated the number of custom-exempt establishments in states without state inspection systems based on the proportion of custom-exempt establishments to total inspected establishments in states with state inspection systems. This calculation may possibly overstate the number of custom-exempt establishments if establishments operate under both state inspection and conduct custom processes. Data on custom-exempt establishments indicate only that the establishments handled meat species, based on data provided by the Association of Food and Drug Officials (AFDO) in December 2005. The analysis assumes that 84 percent of custom-exempt meat slaughter and processing establishments handle beef. FSIS assumed that all custom-exempt establishments employ fewer than 10 employees.

[g]Meat or cattle combination establishments are those that have both slaughter and processing operations.

FSIS estimated that the final rule might potentially affect a total population of 9,119 establishments, based on FSIS database information (e.g., PBIS, ADRS, and MARCIS). After making adjustments for meat slaughter establishments that likely do not slaughter cattle but slaughter other species (e.g., swine), for processing establishments that likely do not receive carcasses or vertebral bone-in parts of cattle 30 months of age and older, and custom-exempt establishments that do not

slaughter cattle or process vertebral bone-in parts of cattle 30 months of age and older, FSIS estimated that the total number of affected establishments is 3,512. This baseline of affected establishments is slightly more establishments than that used for the baseline in the PRIA (3,388 establishments), because of new information collected in surveys after the implementation of the SRM and Air-Injection Stunning Interim Final Rules.

Additional details on types of cattle slaughtered by size of establishment are available for establishments under federal inspection. In 2003, slaughter at these establishments comprised 98.7 percent of the total cattle slaughter volumes in the United States. FSIS assumed that the slaughter volumes for establishments that operate under state inspection are similar for each of the very small and small size categories for federally inspected establishments (no large establishments operate under state inspection). Table 6.1.2 presents the distribution of total slaughter volumes in each age category of cattle for very small, small, and large establishments. Most establishments slaughter cattle in one or more of the age categories. Thus, FSIS double counted many of these establishments in the total number of affected establishments. Of the 6.7 million bulls and cows slaughtered in 2003, small establishments slaughtered the majority (56 percent). In contrast, of the 28.2 million steers and heifers slaughtered,

large establishments slaughtered the vast majority (87 percent). Of the 1.0 million veal calves or calves slaughtered, very small and small establishments slaughtered all of these animals.

Note: The total volumes reported here are the total slaughter volumes reported by FSIS and adjusted to the National Agricultural Statistics Service (NASS) because of differences in the methods for recording establishment slaughter volumes in 2003.

Establishment Size	Bulls and Cows		Steers and Heifers		Veal Calves or Calves	
	Number of Estab-lishments	Slaughter Volume	Number of Estab-lishments	Slaughter Volume	Number of Estab-lishments	Slaughter Volume
Very small	473	172,597	521	492,238	176	68,375
Small class I	76	351,465	80	385,273	56	178,457
Small class II	39	3,068,300	41	3,465,258		729,107
Large	20	3,059,729	34	23,911,958	0	0
Total	608	6,652,091	676	28,254,726	232	975,939

Most establishments slaughter cattle in multiple age categories. Thus, the establishment totals are double counted.

Source: FSIS, Animal Disposition Reporting System (ADRS) Database, 2003.

Table 6.1.2: Federally Inspected Establishment that Slaughtered Cattle in Pre-BSE 2003, Categorized on Size and Slaughter Volumes

Table 6.1.3 shows another distribution of federally inspected establishments by the size and the type of cattle slaughtered at them. In this table, FSIS did not double count the affected establishments. The categories for the type of cattle slaughtered are: veal calves or calves only (i.e., cattle always younger than 30 months of age), market cattle only (i.e., mostly cattle younger than 30 months of age such as fed cattle (e.g., steers, heifers, young cows, and young bulls), culled

cattle only (e.g., cows and bulls), and those establishments that slaughter a mix or combination of cattle of all ages.

Table 6.1.3: Pre-BSE 2003 Classification of Federally Inspected Slaughter Establishments in 2003, Categorized by Size and Type of Cattle Slaughtered.

Establishment Size	Predominate Type of Cattle Slaughtered				Total
	Veal or Calves Immature Cattle Only (always younger than 30 months of age)	Market Cattle Only (mostly younger than 30 months of age)	Culled Mature Cattle Only (mostly cattle 30 months of age and older)	Mix Operations: all Classes of Cattle (cattle of all ages)	
Very Small	6	48	4	470	528
Small class I	7	6	1	86	100
Small class II	8	5	8	31	52
Large	0	16	1	19	36
Totals	21	75	14	606	716

Source: FSIS ADRS, 2003.

Table 6.1.4 presents the average live weights and dressed weight for each age category of cattle at Federally inspected establishments in 2003. Steers and heifers have both the highest average live weights and dressing percentages (dressed weight/live weight).

Table 6.1.4: Average Weight of Cattle at Federally Inspected Establishments, Pre-BSE 2003

Cattle Type	Average Live weight (lbs)	Average Dressed Weight (lbs)[a]
Steers	1,316	803
Heifers	1,200	732
Cows	967	590
Bulls	1,482	904
Veal and calves	318	194

[a]Dressed weight means the carcass amount used for primary-muscle meat cuts.

Steers/heifers and cows/bulls source of data: U.S. Department of Agriculture (USDA)/Agricultural Marketing Service (AMS). 2005. Various issues. "USDA Market News, By-product Drop Value Reports." Available from www.ams.usda.gov/mnreports/nw_ls441.txt.

Veal/calves source of data: U.S. Department of Agriculture (USDA)/National Agricultural Statistics Service (NASS). March 2004. "Livestock Slaughter 2003 Summary." Available from http://jan.mannlib.cornell.edu/reports/nassr/livestock/pls-bban/lsan0303.txt.

Table 6.1.5 shows the pounds and their value of beef and veal exports from the United States by year. FSIS used export values from the Foreign Agricultural Service (FAS) of USDA to complete table 6.1.5. This is USDA's official trade data. These data are accessible via the FAS website:

http://www.fas.usda.gov/ustrade.

Pre-BSE 2003 beef and veal exports were valued at $3,150.1 million dollars. The value of post-BSE 2004 beef and veal exports dropped $2,598.8 million to $551.3 million, or about an 82.5 percent drop in value, that represents lost export sales revenue. However, in 2005, the value of beef and veal exports increased $367.1 to $918.4 million, which is about a 66.6

percent increase from 2004. Thus, at that time, the U.S. was restoring its export markets toward pre-BSE levels.

Table 6.1.5: Pounds and Value of Beef and Veal Exports by Year

Year	Exports (Millions of Pounds)	Exports (Millions $)
Pre-BSE 2002	2,447	2,654.6
Pre-BSE 2003	2,523	3,150.1
Post-BSE 2004	462	551.3
Post-BSE 2005	689	918.4
Post-BSE 2006	NA	NA

Source: USDA's Foreign Agricultural Service (FAS)

- NA means data was not available to FSIS

Table 6.1.6 shows more details about the U.S. export trade. The table shows the same trend for beef variety meats, as shown for other beef products. The U.S. export trade almost doubled between 2004 and 2005, after a relatively large drop from the export trade in pre-BSE 2003.

Table 6.1.6: Value of Exports of Cattle and Beef Products by Year (Million Dollars)

Year	Beef & Veal	Variety Meats	Tallow	Hides	Live Cattle	Totals
Pre-BSE 2002	2,654.6	646.9	369.8	1,395.1	130.7	5,197.1
Pre-BSE 2003	3,150.1	711.8	373.9	1,455.0	42.7	5,733.5
Post-BSE 2004	551.3	256.8	354.8	1,407.7	5.5	2,576.1
Post-BSE 2005	918.4	446.9	336.4	1,314.0	7.3	3,023.0
Post-BSE 2006	NA	NA	NA	NA	NA	NA

Source: USDA's Foreign Agricultural Service (FAS)

- NA means data was not available to FSIS

- **Baseline Regulatory Conditions**

The following describes regulatory conditions pre-BSE and prior to the issuance of the SRM and air-injection stunners interim final rules on January 12, 2004:

Non-ambulatory Disabled Cattle Offered for Slaughter. Prior to December 30, 2003, the date that the Secretary of Agriculture announced the prohibition on the slaughter of non-ambulatory disabled cattle offered for slaughter for use as human food, non-ambulatory disabled cattle offered for slaughter were not automatically condemned on ante-mortem inspection. However, these animals were automatically suspected of being affected with a disease or condition that might require condemnation of

the animal, in whole or in part, and were identified as “U.S. Suspects” (9 CFR 309.2(b)). A FSIS veterinarian examines all animals identified as “U.S. Suspects” at ante-mortem inspection, and, if the animal is not condemned on ante-mortem inspection, a record of the veterinarian’s clinical findings accompanies the carcass to post-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 FSIS veterinarian finds the meat and meat food products from such cattle to be not adulterated, such products may be used for human food (9 CFR 311.1). Table 6.1.7 presents a comparison of the handling of non-ambulatory disabled cattle before the SRM Interim Final Rule (baseline year 2003), with the handling of such cattle after the Interim Final Rule (after January 12, 2004), and with the handling of such cattle as required by the Final Rule. In addition, Table I in the Summary Section compares the handling of non-ambulatory disabled cattle in the SRM Interim Final Rule (after January 12, 2004) with the handling of such cattle as required by the Final Rule.

Table 6.1.7: Comparison of the handling of non-ambulatory cattle before the SRM Interim Final Rule (baseline year 2003), to after the SRM Interim Final Rule (after January 12, 2004), and as set forth in the SRM Final Rule

	Before the SRM Interim Final Rule (baseline year 2003)	After the SRM Interim Final Rule (after January 12, 2004)	The SRM Final Rule
Definition	FSIS used the term “downer” for cattle that cannot rise from a recumbent position.	Defines “non-ambulatory disabled livestock” as livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions (9 CFR 309.2(b)).	Affirms without changes SRM interim rule’s definition of “non-ambulatory disabled livestock.”

Disposition	Non-ambulatory disabled cattle offered for slaughter were not automatically condemned on ante-mortem inspection. Non-ambulatory disabled cattle offered for slaughter were automatically suspected of being affected with a disease or condition that might require condemnation of the animal, in whole or in part, and were identified as "U.S. Suspects" (9 CFR 309.2(b)). The FSIS veterinarian examined all animals identified as "U.S. Suspects" at ante-mortem inspection, and, if the animal was not condemned on ante-mortem inspection, a record of the veterinarian's clinical findings accompanied the carcass to post-mortem inspection.	Non-ambulatory disabled cattle offered for slaughter are automatically condemned on ante-mortem inspection. Requires that all non-ambulatory disabled cattle offered for slaughter be condemned (9 CFR 309.2(b)).	Affirms without changes disposition required in SRM interim final rule for non-ambulatory disabled cattle offered for slaughter. Affirms that all non-ambulatory disabled cattle offered for slaughter must be condemned. Clarifies that FSIS inspection program personnel will determine the disposition of cattle that become non-ambulatory after they have passed ante-mortem inspection on a case-by-case basis (9 CFR 309.3(e)). Changes reflects current practice in FSIS Notices 05-04 and 05-06: FSIS Notice 05-04, "Interim Guidance for Non-Ambulatory Disabled Cattle and Age Determination" and FSIS Notice 05-06, "Re-Examination of Bovines that Become Non-Ambulatory After They Have Passed Ante-mortem inspection"
Disposition	The disposition of a "downer" animal is determined at post-mortem examination if the animal passes ante-mortem inspection as a U.S. Suspect. The animal is condemned if the examining FSIS veterinary medical officer determines that the animal has conditions that would affect the safety of food products derived from this animal.	Non-ambulatory disabled cattle offered for slaughter are required to be condemned. Preamble explains that prohibition of use as human food of non-ambulatory disabled cattle offered for slaughter is necessary because cattle present a risk of introducing the BSE agent into the human food supply.	Affirms without changes.

	The disposition of “downer” veal calves is determine at ante-mortem and at post-mortem examination if the animal passes ante-mortem inspection as a U.S. Suspect. The animal is condemned if the examining FSIS veterinary medical officer determines that the animal has conditions that would affect the safety of food products derived from this animal.	Required condemnation of veal calves presented for slaughter that cannot rise from a recumbent position or that cannot walk because they are tired or cold.	Permits veal calves that cannot rise from a recumbent position or that cannot walk because they are tired or cold to the list of conditions to be set aside and treated (9 CFR 309.13(b)). Amendment reflects current practice.
	Permits the emergency slaughter for humane handling purposes of cattle in the absence of an inspector and permits for use as human food the carcasses and parts of cattle slaughtered in the absence of an inspector.	Prohibits for use as human food the carcasses and parts of cattle slaughtered in the absence of an inspector (9 CFR 311.27)	Affirms without changes interim final rule’s prohibition on use as human food of the carcasses and parts of cattle slaughtered in the absence of an inspector.

Specified Risk Materials (SRMs). Pre-BSE in the United States and prior to January 12, 2004, the date that the FSIS' SRM and Air-Injection Stunning interim final rules were issued to strengthen FSIS' BSE programs designed to prevent human exposure to the BSE agent, most of the materials designated as SRMs under the SRM interim final rule 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, pre-BSE, FSIS permitted U.S. companies to export these materials and to import these materials from foreign countries (if the regulatory requirements for importing or exporting meat food products were met).

Brain and spinal cord: Pre-BSE and before the January 12, 2004 SRM interim final rule, FSIS regulations permitted the use of brains of all livestock species, including the brains of cattle regardless of age, for human food (a variety meat). In addition, FSIS regulations permitted the use of cattle brains from cattle of all ages as a source material in edible rendering. FSIS regulations did however prohibit the use of detached spinal cords from all livestock species, including cattle, in the preparation of meat food products. However, FSIS regulations permitted the use of detached spinal cords from all livestock species, including those from cattle 30 months of age and older, as a raw material in edible rendering as an edible food product (9 CFR 318.6(b)(4)). In addition, establishments exported detached spinal cords of all ages of cattle.

Vertebral column and DRG: Pre-BSE and before the January 12, 2004 SRM interim final rule, FSIS regulations permitted the use of bones from the vertebral column of

cattle of all ages, including bones that contained DRG, for bone-in cuts of beef, and as source materials in the production of processed products manufactured from edible rendering. In addition, FSIS regulations permitted the use of bones from the vertebral column of cattle of all ages, including bones that contained DRG, as source materials in AMR systems, and in the production of mechanically separated (MS) beef meat food products. Furthermore, although establishments did not market DRG as a consumer product, there were no restrictions on the incorporation of DRG into beef AMR products, products produced from edible rendering, or MS beef meat food products.

Distal ileum of the small intestine: The FSIS SRM interim final rule designated the distal ileum of the small intestine as a SRM. Pre-BSE and prior to the SRM interim final rule, FSIS regulations permitted the use of the entire small intestine from cattle of all ages for human food which was typically sold as a variety meat called "tripas" in Latin America (e.g., Mexico), and sold as a variety meat to Asian countries (e.g., Japan and South Korea). However, pre-BSE in the U.S., some establishments removed the distal ileum portion of the small intestine because of the export market requirements of Japan and South Korea. In addition, FSIS regulations permitted the use of casings made from the small intestine of all cattle regardless of age as containers for meat food products. Further, FSIS regulations permitted the use of cattle small intestines, including the distal ileum, from cattle of all ages for use as ingredients in meat food products if the establishment met certain labeling requirements.[15]

Skull, eyes, and trigeminal ganglia of the head, and tonsils of the neck: Pre-BSE and prior to the SRM interim final rule, although FSIS' regulations did not prohibit the use of cattle eyes for human food, direct consumption of such materials was uncommon in the United States. FSIS regulations prohibited the use of tonsils of all livestock species, including cattle, as ingredients of meat food products, but FSIS regulations permitted the use of tonsils for edible rendering for non-meat food

[15]The SRM interim final rule prohibited the use of the entire small intestine including the distal ileum. FSIS published an amendment to the SRM interim final rule on September 7, 2005 that now permits the use of small intestines excluding the distal ileum, if certain requirements are satisfied.

products. Establishments did not market directly, as consumer products, the trigeminal ganglia contained in the jaw (head) of cattle. FSIS regulations permitted the use of the heads of cattle (commonly referred to as "market heads"') for human food regardless of the age of the animal. Cattle market heads contain skull, eyes, trigeminal ganglia, and fragments of brain.

6.2. Regulatory Alternatives that were Assessed in the Regulatory Impact Analysis of the Final Rule

FSIS considered several regulatory alternatives for the final rule. In addition, before developing the regulatory alternatives, FSIS considered the following components:

- prohibition on the slaughter of non-ambulatory disabled cattle offered for slaughter;
- requirements for the disposition and handling of materials designated as SRMs, and age cutoffs for SRMs (e.g., 12, 24, or 30 months of age and older);
- requirements for the shipment of carcasses or parts of carcasses with vertebral column that contain SRM materials (i.e., the vertebral column (except for the vertebra of the tail, the transverse process of the thoracic and lumbar vertebra, and the wings of the sacrum) and DRG, but not the spinal cord that is to be removed at slaughter) for further processing if establishments have controls in place to ensure that SRMs are removed at processing in another federally inspected establishment prior to sale of meat and meat food products for human consumption;
- requirements for age verification of cattle received at slaughter establishments;
- requirements for sanitation of equipment that is used to cut through SRMs;
- requirements for imports of beef from countries that can demonstrate that their BSE risk status can reasonably be expected to provide the same level of protection from human exposure to the BSE agent as

excluding SRMs and non-ambulatory disabled cattle from the human food supply does in the United States; and

- prohibition on the use of certain stunning devices used to immobilize cattle during slaughter.

Before the presentation of the regulatory alternatives assessed and the provisions of the final rule that are discussed in Section 7 below, a discussion follows on each of the options considered about the above discussed components:

- **Prohibition on the slaughter of non-ambulatory disabled cattle offered for slaughter.**

  Option 1: Continue prohibition. This option is in the final rule. This option ensures that establishments do not slaughter for human food cattle that have clinical signs of BSE that FSIS may not detect due to their non-ambulatory status. Non-ambulatory disabled cattle that are offered for slaughter must be condemned. The final rule clarifies, however, that FSIS' inspection personnel will determine the disposition of cattle that become non-ambulatory after they have passed ante-mortem inspection on a case-by-case basis. This was the practice under the SRM interim final rule.

Option 2: Continue prohibition but provide exemption for custom slaughter of cattle that are non-ambulatory because of an acute injury. This option would provide relief for small businesses by allowing custom-exempt establishments or custom-exempt operations in federally- or state-inspected establishments to slaughter non-ambulatory disabled cattle and would provide producers an outlet for animals that would otherwise need to be disposed of. Owners of acutely injured cattle offered for slaughter in custom-exempt operations would be required to provide documentation that certifies the nature of the animal's injury, how the animal was injured, and the time that the injury occurred.

FSIS rejected this option because FSIS considers the carcasses of non-ambulatory disabled cattle offered for slaughter to be adulterated under the FMIA, and custom operations are subject to the adulteration and misbranding provisions of the FMIA. This option would also place additional burdens on the owner of the affected cattle and the custom operation regarding the documentation of the health of the animal.

- **Materials designated as SRMs and age cutoffs for SRMs.** FSIS considered making changes to the list of materials designated as SRMs.

  Option 1: Continue with current definition of SRMs. This option is in the final rule. Under this option, the brain, skull, spinal cord, trigeminal ganglia, vertebral column (except for the vertebra of the tail, the transverse process of the thoracic and lumbar vertebra, and the wings of the sacrum), and DRG tissues of cattle 30 months of age and older would continue to be SRMs. The tonsils and distal ileum of cattle of all ages would continue to be SRMs.

  Option 2: Lower age limit for SRMs to 24 months or 12 months. Designating certain tissues as SRMs only if they are from cattle 30 months of age and older removes tissues that present the highest risk of containing infective levels of the BSE agent, from the human food supply. This age cutoff is also consistent with international standards, including Canada's policy. Consistency with Canada's policy related to SRM mitigations was an important consideration because of the robust trade in animals and meat products with Canada. Adopting a lower age limit for SRMs would impart a

substantially greater economic burden without any appreciable risk reduction for exposure of humans to materials potentially containing the BSE-infectious agent.

- **Permit shipment of carcasses or parts of carcasses that contain vertebral columns from cattle that are 30 months of age and older at the time of slaughter to another federally-inspected establishments for further processing, if both establishments have controls in place to ensure that SRMs are removed and properly disposed of at the processing establishment.**

  Option 1: Continue to permit this practice. This option is in the final rule. The final rule, however, codifies that the spinal cord from cattle 30 months of age and older must be removed at the establishment where the animals were slaughtered.

  Option 2: Prohibit the practice permitted by option 1. Require that the establishments remove at slaughter all SRMs. This option reduces the possibility of SRMs reaching consumers because of errors at the processing establishment. However, it places an economic burden on establishments that slaughter cattle and ship carcasses

or bone-in parts with vertebral columns, which is the commercial practice in most of the United States.

- **Requirements for age verification of cattle received at slaughter establishments.**

  Option 1: Continue with current procedures (documentation or dentition). This option is in the final rule. SRMs will be deemed to be from cattle 30 months of age and older unless the establishment has accurate and reliable records to document the age of cattle offered for slaughter. If not, FSIS inspectors will use dentition to verify the age of the cattle offered for slaughter. The dentition procedure used by FSIS is consistent with procedures used in the international community. The dentition standards adopted by FSIS are based on data from veterinary anatomy texts and academic articles. They are also objective and simple to implement. Furthermore, according to one study, determining physiological maturity by the number of permanent incisors may be a more accurate technique of sorting beef carcasses into less variable age groups than the USDA bone ossification-based maturity system used for beef grading (Lawrence et al., 2001). Dental examination, however, under limited circumstances, is an unreliable indicator of age in some instances. Dentition will vary

from herd to herd and animal to animal because of genetics, diet, and the varied geographical locations in which cattle producers raise the animals. In these instances, cattle producers can provide accurate and reliable records to document the age of cattle offered for slaughter.

Option 2: Require documentation only. This option is currently not feasible given the practices used in the cattle industry. There is not a mandatory cattle identification program in the United States. Based on data available from the industry slaughter and processing survey (Cates et al., June 2005), an estimated 48,300 cattle arrived at slaughter establishments in 2004 with documentation for determining age. This represents approximately 1 percent of the cattle slaughtered. Thus, requiring establishments to use documentation for age verification of cattle in most cases is currently infeasible.

- **Requirements for sanitation of equipment that is used to cut through SRMs.**

  Option 1: Continue with and codify current sanitation verification procedures. Under FSIS' current sanitation verification procedures, if an establishment uses

separate equipment to cut through SRMs, or if the establishment segregates cattle 30 months of age and older from cattle younger than 30 months and processes the carcasses of the younger cattle first, routine operation sanitation procedures apply. This option is in the final rule. If an establishment does not use separate equipment to cut through SRMs or segregate the carcasses and parts of cattle 30 months of age and older from those from cattle younger than 30 months, and process the younger cattle first, the establishment must clean and sanitize equipment used to cut through SRMs before it is used on carcasses or parts from cattle younger than 30 months of age. The inadvertent slaughter of an animal 30 months of age and older during the slaughter production schedule for cattle younger than 30 months is the exception in the United States. Because the estimated prevalence of BSE in the United States is extremely low, these sanitation procedures minimize, to the maximum extent practical, cross-contamination of edible tissues with high-risk material.

Option 2: Require dedicated equipment for contact with SRMs (e.g., color-coded saws). Under this option, FSIS would require the use of dedicated equipment to cut through SRMs before it is used on carcasses and parts

from cattle younger than 30 months of age. FSIS rejected this option because, given the extremely low estimated prevalence of BSE in the United States, FSIS has determined that the current sanitation procedures described above, minimize, to the maximum extent practical, cross-contamination of edible tissues with high-risk material. However, the use of dedicated equipment to cut through SRMs is among the accepted sanitation procedures under the final rule and is the method employed by many establishments.

- Requirements for imports of beef from foreign countries

Option 1: Exempt from the definition of SRMs materials from cattle from foreign countries that can demonstrate that their BSE risk status can reasonably be expected to provide the same level of protection from human exposure to the BSE agent as does prohibiting SRMs for use as human food in the United States and exempt these countries from the prohibition on the slaughter of non-ambulatory disabled cattle.

This is the option that FSIS selected. Countries that believe that they are eligible to have materials from their cattle excluded from FSIS' definition of SRMs should notify FSIS' Office of International Affairs (OIA) and provide that office with sufficient scientific evidence to support its

claimed BSE risk status. FSIS will then develop criteria to evaluate the equivalence request.

In developing equivalence criteria, FSIS will consider evidence that the country proposes to submit in support of its BSE risk status, including a BSE risk status evaluation, if one was conducted, or any other supporting documentation. An exporting country may submit an evaluation of its BSE risk status conducted by the OIE, another country, or any other appropriate entity. Countries may also conduct their own evaluations. However, any evaluation and supporting documentation submitted by a country must contain sufficient scientific evidence to demonstrate that the country's BSE risk status can reasonably be expected to achieve the same level of protection from human exposure to the BSE agent as excluding SRMs from human food does in the United States.

Option 2: Continue to require that all foreign countries continue to comply with U.S. requirements for the removal, segregation, and disposition of SRMs and the prohibition on the slaughter of non-ambulatory disabled cattle regardless of their BSE risk status.

FSIS rejected this option because the Agency has concluded that it is possible for a country's BSE risk status to provide the same level of protection from human exposure to the BSE agent as excluding SRMs and non-ambulatory disabled cattle from

the human food supply does in the United States. The Agency also determined that restricting the importation of potentially infective materials on the basis of the BSE risk of the region of origin is more consistent with international guidelines than an approach that does not consider a country's BSE risk.

- **Prohibition on the use of certain stunning devices used to immobilize cattle during slaughter.** No other option was considered. This option is in the final rule. This provision prohibits the use of certain stunning devices that deliberately inject air into the cranial cavity of cattle. The use of air injection stunning can force central nervous system (CNS) tissues into the circulatory system of stunned cattle, thereby causing pieces of CNS tissue, such as brain tissue, to lodge in edible tissues of the liver or heart.

In summary, using the above-considered components, FSIS, in its FRIA cost analysis, calculated the costs of the following provisions of the final rule:

Prohibition on the slaughter of non-ambulatory disabled cattle offered for slaughter: Continue prohibition, and provide no exemption for custom slaughter of cattle offered for slaughter that are non-ambulatory disabled because of an acute injury.

Requirements for handling and disposition of materials designated as SRMs: Continue current SRMs of the SRM interim final rule. Brain, skulls, eyes, spinal cord, trigeminal ganglia, vertebral column (except for the vertebra of the tail, the transverse process of the thoracic and lumbar vertebra, and the wings of the sacrum), and DRG of cattle 30 months of age and older. Tonsils and distal ileum of cattle of all ages would continue to be SRMs. The spinal cords from cattle 30 months of age and older must be removed in the establishment where the animal is slaughtered.

Requirements for the shipment of carcasses or parts of carcasses that contain vertebral columns to another federally-inspected establishment for further processing, if both establishments have controls in place to ensure that these SRMs are removed and properly disposed of at the processing establishment: Continue to permit this practice and codify and strengthen the requirements. If processing establishment cannot demonstrate that carcasses or parts of carcasses are from cattle younger than 30 months of age, the carcasses or parts of carcasses must be processed as if the carcasses and parts of carcasses are from cattle 30 months of age and older. In this final rule, FSIS is strengthening and codifying requirements for recordkeeping used to verify that suppliers and receivers of vertebral bone-in beef properly handle and dispose of the SRMs.

Requirements for age verification of cattle received at slaughter establishments: Continue with current procedures (documentation or dentition).

Requirements for sanitation of equipment that is exposed to SRMs. Continue with current sanitation verification procedures and codify these procedures. If an establishment does not segregate cattle 30 months of age and older from younger cattle, and process the younger cattle first, the establishment must either use dedicated equipment to cut through SRMs or it must clean and sanitize equipment used to cut through SRMs before it is used on carcasses or parts from cattle younger than 30 months of age.

Requirements for imports of beef from foreign countries. Provide exemption for foreign countries for materials

from cattle that are SRMs that can demonstrate that their BSE risk status provides the same level of protection from human exposure to the BSE agent as prohibiting SRMs and non-ambulatory disabled cattle for human food does in the United States.

Prohibition on the use of certain stunning devices used to immobilize cattle during slaughter. Without regard to the age of cattle, slaughtering establishments are prohibited from using these stunning devices.

Table 6.2.1 summarizes the primary alternatives analyzed in the 2005 Harvard BSE Update, in Section 7, each of which has several secondary options that are mutually exclusive that are summarized in the Table. FSIS selected, after considering all options for each primary alternative, one option and rejected the others for each of the primary alternative measures of the Final Rule. FSIS analyzed the primary alternatives, each with its selected option, which analysis is set forth in the cost-effectiveness analysis in Section 7.4.

Table 6.2.1: Primary Alternatives Analyzed in the Harvard BSE Update with Options

Primary Alternative	Secondary Considerations		Regulatory Alternative Configuration
	Option 1	Option 2	
1 - Prohibition on the slaughter of non-ambulatory disabled cattle offered for slaughter for use as human food	Non-ambulatory disabled cattle that are offered for slaughter must be condemned. However, the final rule clarifies that FSIS' inspection personnel will determine the disposition of cattle that become non-ambulatory after they have passed ante-mortem inspection on a case-by-case basis	Continue prohibition but provide exemption for custom slaughter of cattle that are non-ambulatory because of an acute injury.	Option 1
2 - Materials designated are SRMs and age cutoffs for SRMs	Continue with current definition of SRMs, as set forth in the Interim Final Rule	Lower age limit for materials that are designated as SRMs to 24 months or to 12 months	Option 1
3 – Permit shipment of carcasses or parts of carcasses that contain vertebral columns from cattle that were 30 months of age and older at the time of slaughter to another federally-inspected establishments for further processing, if both establishments have controls in place to ensure that SRMs are removed and properly disposed of at the processing establishment	Continue to permit practice set forth in primary alternative 3.	Prohibit practice set forth in primary alternative 3 and require that the establishments remove at slaughter all SRMs	Option 1
4 – Establishment of dentition and	Continue with current procedures	Permit documentation only to	Option 1

documentation requirements for age verification of cattle received at slaughter establishments	(documentation or dentition)	verify age of cattle.	
5 – Establish requirements for sanitation of equipment that is used to cut through SRMs	Continue with currently allowed sanitation procedures for equipment used to cut through SRMs, which permits sanitation of equipment or use of dedicated equipment.	Require only dedicated equipment be used to cut through SRMs (e.g., color-coded saws)	Option 1
6 – Establish requirements for imports of beef from foreign countries	Exempt from the definition of SRMs materials from cattle from foreign countries that can demonstrate their BSE risk status provides the same level of protection from human exposure to the BSE agent as does prohibiting SRMs for human food in the United States, and exempt these countries from the prohibition on the slaughter of non-ambulatory disabled cattle	Continue to require that all countries comply with U.S. requirements for the removal, segregation, and disposition of SRMs and the prohibition on the slaughter of non-ambulatory disabled cattle, regardless of the country's BSE risk status.	Option 1
7 - Prohibition on the use of certain stunning devices used to immobilize cattle during slaughter	None considered because these stunning devices are not in use.	None considered because these stunning devices are not in use.	Alternative 7

6.3. Quantifying the Costs of this Final Rule and Assumptions

The costs of the FSIS actions to prevent the BSE-infectious agent from entering the food supply result from the activities required to comply with the previously published SRM and Air-Injection Stunning interim final rules, as amended by the final rule. FSIS requested comments on the preliminary analysis of the costs for the SRM and Air-Injection Stunning interim final rules. FSIS received and incorporated the public comments into this final analysis, where appropriate. FSIS' analysis of the final rule includes many of the same assumptions that FSIS used in the PRIA of the SRM and Air-Injection Stunning interim final rules. However, FSIS made adjustments to account for new information. In Table 4.2, FSIS indicates the areas for which new data was available and assumptions that changed in the FRIA from the PRIA. In addition, FSIS indicates in this table the effect on the results of the FRIA compared to the results of the PRIA. The table shows the change in the results of the FRIA because of a change in the data or assumptions made in the FRIA compared to assumptions of the PRIA.

- **Cost Estimates for Establishments that Slaughter Cattle and that Use Air-injection Stunning Devices to Immobilize Cattle During Slaughter**

The air-injection stunning interim final rule, which this final rule affirms without changes, prohibits the use of certain

stunning devices to immobilize cattle during slaughter that inject air into the cranial cavity (69 FR 1885, January 12, 2004; “Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter”). The force of the injected air often forces visible pieces of CNS tissue into the vascular circulation where the CNS tissue can lodge in edible tissue, such as in the liver and heart. The PRIA found that there is no significant cost associated with this interim final rule because the beef packing industry and FSIS’ inspection program personnel (USDA, FSIS, 2002) report that beef establishments were not using these stunning devices pre-BSE in the United States, and there continues to be no significant cost associated with this prohibition.

- **Cost Estimates for Establishments that Slaughter Cattle under Federal or State Inspection**

Most of the costs of this final rule are associated with practices that occur at establishments that slaughter cattle, rather than at establishments that process vertebral bone-in parts from cattle that are 30 months of age and older at the time of slaughter. Requirements for federally and state-inspected establishments are the same; thus, similar size establishments under either type of inspection are expected to incur similar costs. Table 6.3.1 details the specific requirements for removal and control of SRMs and other

prohibited materials addressed in the cost analysis for establishments that slaughter cattle. In the SRM interim final rule, FSIS identified the following major requirements that establishments are required to address to ensure that SRMs, and the carcasses of non-ambulatory disabled cattle offered for slaughter, are excluded from the human food supply:

a. Removal and non use as human food of the following materials: brain, skull, eyes, trigeminal ganglia, 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) and dorsal root ganglia (DRG) of cattle 30 months of age and older; and

b. Removal and non-use as human food of the following materials: tonsils and the distal ileum from cattle of any age, and non-ambulatory disabled cattle of any age, offered for slaughter.

c. Written procedures for removal, segregation, and disposition of SRMs and sanitation.

d. Recordkeeping to document the implementation and monitoring of procedures for the removal, segregation, and disposal of SRMs and sanitation requirements.

To ensure effective removal of the distal ileum, the SRM interim final rule required that establishments remove and dispose of as inedible the entire small intestine. On September 7, 2005, FSIS amended the SRM interim final rule to permit the use as human food of the small intestines, excluding the distal ileum, if the establishments meet certain conditions.

Table 6.3.1: Summary of Requirements of the FSIS SRM Interim Final Rule Included in the Analysis

Non-ambulatory Disabled Cattle Offered for Slaughter
Non-ambulatory disabled cattle offered for slaughter must be condemned. Non-ambulatory disabled cattle are livestock that cannot rise from a recumbent position or that cannot walk because of injury or illness.
Age of Cattle (used to define when cattle carcasses or parts are SRMs)
Certain products (SRMs) of cattle 30 months of age and older are prohibited for use as human food. FSIS personnel will verify the age of cattle using documentation, or dental examinations, if documentation is not available or is questionable.
SRM Segregation and Disposal
Establishments must ensure that SRMs are completely removed from the carcass, segregated from edible products, and disposed of in an appropriate manner.
Vertebral Bone-In Cuts
Bone-in cuts that contain portions of the vertebral column designated as SRMs are prohibited. Spinal cord from cattle 30 months of age and older must be removed from the carcass at the establishment where the animal was slaughtered.
Written Plans
Establishments that slaughter cattle or that process the carcasses or parts of cattle must develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. An establishment must incorporate such procedures into its HACCP plan or Sanitation SOPs or other prerequisite programs.
Record Keeping
Establishments must maintain daily records sufficient to document the implementation and monitoring of procedures for the removal, segregation, and disposition of SRMs. The establishment must retain the records for at least 1 year.

Cost Data Collection Methodology. For the industry surveys, a contractor, RTI International (RTI) developed questionnaires, based on discussions with FSIS, to collect information from slaughter and processing establishments regarding the measures they took, and costs they incurred, in response to the SRM and Air-Injection Stunning interim final rules. Based on typical establishment responses and other information, FSIS then developed estimates of the costs of changes associated with the SRM and Air-Injection Stunning interim final rules.

After developing the questionnaires, RTI contacted several trade associations for the meat industries to seek comments on the questionnaires' content and their perspective on the effects of the regulations. RTI contacted representatives from the

American Association of Meat Processors (AAMP),

American Meat Institute (AMI),

National Association of Meat Processors (NAMP),

National Cattlemen's Beef Association (NCBA), and

National Renderers Association (NRA).

For the two industry surveys, RTI selected a large number of slaughter establishments, and processing only establishments, that were under federal inspection and representative of the industry. The details are available in the reports (Cates et al., June 2005 and Cates et al., December 2005), which are available at the FSIS web pages, and the FSIS Docket Room, Room 102, Cotton Annex, 300 12th St. NW, Washington, DC.

In addition to RTI's data collection obtained from the two industry surveys, FSIS also used the data presented in the PRIA of the SRM and Air-Injection Stunning interim final rules to assist with cost estimates. In particular, FSIS used PRIA estimates of the value of SRMs that the establishment can no longer use for human consumption. In addition, FSIS used the results of the FSIS employee survey of federally inspected beef

establishments that gathered pre-BSE information on SRMs (USDA FSIS, 2002).

Types of Costs. FSIS generally classified the costs of changes associated with this final rule as follows:

One-time noncapital expenditures. These costs include labor expenses and consulting fees associated with reassessing and modifying an establishment's HACCP plan, Sanitation SOPs, or other prerequisite program plans. Companies that own multiple establishments may develop these plans, as a one-time cost, at company headquarters.

One-time capital equipment expenditures. These costs include the costs of purchasing and installing new capital equipment within the establishment to address the requirements of this final rule. In making capital equipment changes, establishments, in some cases, may modify the layout of the establishment. For the final rule, capital equipment expenditures are associated with changes such as modified practices for handling of non-ambulatory disabled cattle offered for slaughter, dentition checks, segregation of cattle by age, and handling of vertebral bone-in cuts for cattle 30 months of age and older. When using capital equipment expenditure estimates in developing per-unit costs associated with the regulation, FSIS annualized the costs (using a 3 percent or 7 percent interest rate) over the expected useful life of the equipment to develop an annual cost estimate. This annualization accounts for the fact that once an establishment adds additional capital equipment, it will incur costs for replacing that capital equipment on a periodic basis throughout its operation.

Ongoing (or variable) expenses. Ongoing costs are the costs that generally vary by the number of cattle slaughtered in the establishment. These costs generally include labor and material expenses associated with additional processes conducted within the establishment. In addition, the costs of disposing of SRMs are another type of ongoing cost associated with the final rule.

Lost value of SRMs. For establishments that previously sold materials that are now classified as SRMs, they incur

losses associated with not selling these materials for human consumption. In compiling the cost estimates, FSIS treated the lost value of SRMs (i.e., the difference between the value of SRMs used in human food and the value of SRMs used in inedible rendering) as an additional category of ongoing costs associated with the final rule.

Whether each of these cost categories affects an individual establishment depends on the age of the cattle they slaughter. Establishments that slaughter only veal calves or calves will incur costs of only two types—reassessment of their written plans and the lost value of the distal ileum if the establishment was previously using distal ileum for human consumption.

In contrast, establishments that slaughter steers and heifers will incur costs in all categories because the establishment, using dentition, will likely classify at least some steers and heifers as 30 months of age and older. In general, establishments incur losses associated with removal and disposal of SRMs only for cattle that are 30 months of age and older (with the exception of the distal ileum of the small intestines and tonsils). However, not all establishments previously sold materials from cattle that are 30 months of age and older that are now classified as SRMs for human food.

There is likely a low cost associated with the prohibition on the use of tonsils for human food because FSIS regulations

did not allow the use of tonsils in meat food products prior to the January 2004 SRM interim final rule. However, tonsils may have been used in edible rendered products (e.g., beef stock and for flavorings). FSIS did not have sufficient information to estimate these costs.

FSIS characterized the changes that a typical establishment of each establishment type and size have made or will implement. Based on this typical characterization, FSIS identified costs attributable to those changes. FSIS assumed, in some cases, that a very small establishment addressed a specific requirement solely through changes that affect labor usage, while a large establishment addressed the same requirement through changes in capital equipment usage.

Changes in Practices Associated with Handling Non-Ambulatory Disabled Cattle. Under this final rule, establishments must euthanize, and dispose of all non-ambulatory disabled cattle offered for slaughter that FSIS Public Health Veterinarians (PHVs) condemn on ante-mortem inspection. However, the establishment can warm young veal calves or calves that cannot stand because they are hypothermal. Then, if these calves become ambulatory and pass ante-mortem inspection, the establishment can slaughter these animals.

In addition, ambulatory cattle that arrive at an establishment may become non-ambulatory at some point after passing ante-mortem inspection. In these relatively few cases, if the FSIS Public Health Veterinarian (PHV) determines that the animal became non-ambulatory as the result of an acute injury, FSIS will treat these cattle as U.S. Suspects in the same manner as cattle that arrived at the establishment in an ambulatory state.

Changes in Establishment Processes and Practices for Removal and Disposal of SRMs. Establishments have implemented a number of changes to comply with the SRM removal and disposal requirements. The types of changes made depend on whether an establishment slaughters steers and heifers or cows and bulls, or veal calves or calves. For example, establishments that slaughter only veal calves or calves need to make lesser changes than those for steers, heifers, bulls or cows because veal calves or calves are always younger than 30 months. Thus, their heads, skulls, and vertebral columns are not SRMs. Veal calf or calf operators, must, however, like other beef operators, now remove and dispose of the distal ileum and tonsils of all cattle because they are SRMs.

FSIS assumed that establishments that slaughter only cows and bulls treat all cattle as 30 months of age and older to

avoid the need for additional practices such as dentition and segregation of cattle by age.[16] By treating all cattle as 30 months of age and older, establishments avoid many of the steps that would be necessary if they chose to try to recover certain by-products of the occasional animal that was younger than 30 months of age (e.g., a first calf young cow or a heifer that was culled).

FSIS assumed that establishments that slaughter steers and heifers would use dentition to determine the age of each animal. FSIS did this because establishments and trade associations noted that documentation of the age of cattle is not yet generally available to establishments. In addition, the results of the meat and poultry slaughter industry survey indicated that 73.4 percent of establishments that slaughter cattle in multiple-age categories use dentition to determine age (Cates et al., June 2005). In addition, the survey results indicated that 80.5 percent of establishments that slaughter only steers and heifers use dentition to determine age.

Generally, in any group of steers and heifers, some cattle will appear to be 30 months of age and older based on dentition even if all of the animals in the group are younger than 30 months of age. Estimates of the proportion of steers and heifers

[16]Some establishments slaughter some fed cows and fed bulls. Thus, these establishments likely have different practices than those that slaughter only culled cows and culled bulls. For the purposes of the analysis, FSIS did not separately identify differences in practices for these types of establishments.

that will appear to be 30 months of age and older based on dentition range from 1 to 5 percent (Hodges and Seward, 2004). The results of the meat and poultry slaughter industry survey indicate that 40.3 percent of establishments estimate that less than 1 percent of fed steers or heifers are treated as 30 month of age and older based on dentition. In addition, 25.4 percent of establishments estimate 1 to 2 percent, 14.3 percent estimate 3 to 5 percent, and the remainder establishments estimate 6 percent or more (Cates et al., June 2005) of fed steers or heifers are treated as 30 months of age and older based on dentition.

Table 6.3.2 outlines typical changes that slaughter establishments are implementing in response to the SRM removal and disposal requirements. Some establishments may be implementing additional measures, but FSIS assumed for the purposes of the analysis that these measures are either not typical or do not have substantial cost implications when considered on a per-head basis. In establishments that slaughter only steers and heifers (or slaughter mixed ages of cattle), some practices apply to all cattle slaughtered in the establishment, and others apply only to cattle that are 30 months of age and older.

Table 6.3.2: Typical Changes in Cattle Slaughter Establishments in Response to the SRM Removal and Disposal Requirements

Process or Practice Change	Steer and Heifer Establishments[a]		Cow and Bull Establish-ments[b]
	Applies to Cattle Younger than 30 Months of Age	Applies to Cattle 30 Months of Age and Older	
Using methods to prevent brain seepage (e.g., plugging skull or supporting head)		•	•
Using dentition to determine age of cattle[c]	•	•	
Using separate equipment (or sanitizing equipment between age groups) for head removal		•	
Marking, tagging, or inking carcasses of cattle 30 months of age and older[d]		•	
Segregating and disposing of distal ileum	•	•	•
Segregating, denaturing, and disposing of skulls, eyes, and trigeminal ganglia		•	•
Using separate carcass splitting saw (or sanitizing the saw between age groups)		•	
Removing spinal cord before or after carcass splitting and disposing of spinal cord		•	•
Segregating carcasses by age in the cooler prior to fabrication		•	
Removing the vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum)		•	•
Segregating, denaturing, and disposing of vertebral column and DRG		•	•
Fabricating alternative cuts instead of t-bones, porterhouse steaks, bone-in rib roasts, and blade roasts (i.e., i-bone steaks)		•	•

[a]Includes establishments that slaughter steers and heifers or establishments that slaughter a combination of ages.

[b]Based on information provided in the industry surveys, FSIS assumed that establishments that slaughter only cows and bulls treat all animals as 30 months of age and older.

[c]All establishments are assumed to use dentition to determine age of cattle because records to verify age are rarely available.

[d]An establishment that slaughters mostly older cattle might tag the younger cattle for segregation, as opposed to tagging cattle 30 months of age and older.

Lost Value of SRMs. In developing estimates of the costs associated with the required removal and nonuse as human food of SRMs and non-ambulatory cattle offered for slaughter of the final rule, FSIS identified the lost value associated with SRM material. However, it is possible that establishments might reduce the lost value per animal when there are “alternative uses” for the products, such as the use in inedible rendering products or the use of a product with the SRMs removed (e.g., beef vertebral bone-out cuts). Thus, the total lost value per animal is the net of the value of the material in its “alternative uses” form. As indicated in Table 6.3.3, some establishments will incur lost product values from the following cattle parts:

Brains from cattle 30 months of age and older. Only some establishments used brains in edible products prior to the SRM interim final rule. To provide brains for the market, these establishments must now use brains from younger cattle.

Spinal cords from cattle 30 months of age and older. Prior to the SRM interim final rule, spinal cords were used only in edible rendering, inedible rendering, or were exported. Establishments now can use spinal cords from cattle younger than 30 months in edible or inedible rendering. Further, establishments now can use spinal cords from cattle 30 months of age and older only in inedible rendering.

Bone-in cuts from the vertebral column of cattle 30 months of age and older. Bone-in cuts include T-bone steaks, porterhouse steaks, rib roasts, and other cuts from the vertebral column. FSIS assumes that the establishment can recover 83 percent of the bone-in cut weight (63.75 of 77

pounds of bone-in cuts) without the vertebral column, from cattle 30 months of age and older.

Skull, eyes, and trigeminal ganglia of cattle 30 months of age and older. With the restrictions on the use of skull, eyes, and trigeminal ganglia, establishments can no longer sell market heads from older cattle. Based on the results of the meat and poultry slaughter industry survey, 27.9 percent of cattle slaughter establishments sold market heads from cattle 30 months of age and older in 2003 (Cates et al., June 2005). A copy of the survey is available on the FSIS web page (http://www.fsis.usda.gov) and in the FSIS Docket Room, 300 12th Avenue SW, Room 101, Washington, DC. Establishments can recover cheek meat, head meat, and tongues minus the tonsils from older cattle through hand deboning provided that the establishment uses a method to prevent brain seepage following stunning.

Distal ileum from cattle of any age. With the restrictions on the use of distal ileum in edible products, establishments can no longer produce products from the distal ileum for human consumption. However, few establishments ever used this material; thus, including its value may overstate the true lost values associated with this requirement.

Tonsils from cattle of any age. Prior to the SRM interim final rule, FSIS prohibited the use of tonsils in meat food products but FSIS permitted the use of tonsils in edible rendering for non-meat food products. With the restrictions now on the use of tonsils, establishments can now only use tonsils in inedible rendering. However, few establishments ever used tonsils in edible rendering prior to the SRM interim final rule.

In addition to the above discussed products, an establishment will have lost the value of all materials that the establishment could have derived from non-ambulatory cattle offered for slaughter. In addition, Table 6.3.3 includes totals – that is the total value of products based on the number of cattle affected.

Table 6.3.3: Summary of the Per-Animal Most-likely Cost Estimates for the SRM Products and Non-Ambulatory Disabled Cattle for the SRM Final Rule, Based on the Preliminary Regulatory Impact Analysis (PRIA) of the SRM Interim Final Rule

			$/Animal		All Cattle Affected	
Product or Process	$/lb	lbs/Animal	Lost Value	Less Alternative Use Value	Number of Cattle Affected	$/All Cattle Affected
Brains	$0.453	1.00	$0.453	–$0.030	393,000	$166,239
Spinal cords	$0.300	0.38	$0.114	–$0.011	7,200,000	$741,600
Edible rendering	$0.250	4.00	$1.000	–$0.120	168,000	$147,840
Bone-in cuts	$2.217	77.00	$170.709	–$169.575	144,000	$163,296
Skull, eyes, trigeminal ganglia (TGG) (market heads)	$0.363	16.25	$5.899	–$4.200	58,000	$98,542
Distal ileum of the small intestines[a]	$0.370	0.5	$0.185	–$0.015	17,100,000	$2,907,000
Tonsils	$0.250	2.50	$0.625	–$0.075	168,000	$92,400
Totals[b]			$178.985	–$174.026	NA	$4,316,917
Non-ambulatory cattle	$1.320	380.00	$501.600	–$24.000	112,,000	$5,923,000

[a]The preliminary analysis of the SRM interim final rule included the lost value associated with the small intestines; this value was adjusted for just the loss value of the distal ileum by assuming the distal ileum averages approximately 4 percent of the weight of the small intestines.

[b]Net costs are summed across all SRMs; however, many establishments did not use all SRMs prior to the SRM interim final rule.

Assumptions and notes:

Yields are for a 1,250-pound animal.

Alternative use values are 3 cents per pound for product used in inedible rendering.

Spinal cords from cattle 30 months of age and older are no longer used in human food, but a few establishments were selling spinal cord for human food (for export) prior to the SRM interim final rule.

An establishment can still recover about eighty-three percent of bone-in cut weight without the vertebral core (63.75/77 pounds).

An establishment can still recover about thirty-seven percent of meat (cheek meat, head meat, tongue) with hand deboning (6/16.25 pounds).

Changes for vertebral bone-in cuts include hand-deboning of cuts.

FSIS did not permit the use of tonsils for meat food products prior to the SRM interim final rule; but prior to the SRM interim final rule, FSIS permitted the establishment to use this product in edible rendering for non-meat food products. Currently, an establishment cannot use tonsils in edible rendering because of the interim final rule. This prohibition is continued in the final rule.

FSIS derived the non-ambulatory disabled cattle offered for slaughter value by assuming that the establishment will use 800 pounds of tissue per animal in inedible rendering.

Cost Estimates for Slaughter Establishments. Using the estimated lost by-product values in the PRIA, information from FSIS' inspection program personnel data gathering initiatives, and information from the two industry surveys, FSIS developed estimates of establishment costs associated with the SRM and non-ambulatory disabled cattle final rule and the FRIA and PRIA assumptions.[17] FSIS based these estimates on assumptions regarding each step of the slaughter and fabrication process that establishments have changed in response to the SRM interim final rule and to the amendments made to the interim final rule, and then developed estimates of the associated capital equipment, other one-time costs, ongoing costs, and lost by-product values associated with these changes. In developing the cost estimates, FSIS based the estimates on a per-head or per-animal basis to facilitate use of the estimates in the FRIA.

General Assumptions Used in Estimating Slaughter Establishment Costs. FSIS developed general assumptions for use in estimating costs to slaughter establishments of the final rule. These assumptions include those for typical operating schedules, wage rates, and slaughter volumes. FSIS refers to

[17]See the PRIA of the interim final rules, USDA, FSIS (March 2004) for an additional description of the data collection and cost estimation procedures.

these general assumptions throughout the discussion of establishment cost estimates.

FSIS assumptions about the most-likely number of hours of operation per shift per year for slaughter establishments are in Table 6.3.3.1. For example, the calculation for estimating the number of hours very small and small class I establishments operate per year is 8 hours per shift x 1 shift per day x 5 days per week x 51 weeks per year, which equals 2,040 hours per year. For large establishments, the number of hours of slaughter operations per year is 8 hours per shift x 2 shift per day x 5.5 days per week x 51 weeks per year, which equals 4,488 hours per year. In Table 6.3.3.1, FSIS presents the number of hours of operation for slaughter establishments, by type, based on FSIS PBIS data.

Table 6.3.3.1: Number of Hours (Most-Likely) of Operation per Workday for Slaughter Establishments, by Type, Based on FSIS PBIS Data

Slaughter Establishments	Very Small	Small Class I	Small Class II	Large
Federally-Inspected[a]	8	8	8	16 (2 shifts of 8 hours each)
State-Inspected	8	8	8	NA[b]
Custom-Exempt	8	8	NA	NA[b]

a Source: FSIS PBIS 2006

b NA data not applicable

FSIS obtained average wage rates, including benefits, for the baseline year of 2003 from the U.S. Department of Labor (2005). These rates are for the private manufacturing sector in general because the U.S. Department of Labor does not report rates specific to the meat slaughter industry.[18] FSIS assumed that the average wage rates with benefits are as follows: $38.92 per hour for a HACCP manager and $15.71 per hour for production workers.

Using slaughter volumes obtained from its Animal Disposition Reporting System (ADRS), FSIS calculated average slaughter volumes by age of cattle and by establishment size (see Table 6.3.4 below).

Table 6.3.4: Most-likely Slaughter Volumes, by Age of Cattle and Slaughter Establishment Size, Used for Calculating Compliance Costs of Federally-Inspected Establishments, Annually

Slaughter Establish-ment Size	Veal/Calf	Steers and Heifers	Cows and Bulls	Volume (All Ages)	No. of Head per Hour
Very small	388	945	365	1,698	0.8
Small class I	4,823	4,816	4,625	14,264	7
Small class II	38,374	84,518	78,674	201,567	99
Large	0	703,293	152,986	856,279	191

Source: FSIS based the calculations on data in the ADRS using the data for 2003.

[18]For comparison, *Meat & Poultry* magazine reported median total annual cash compensation of $66,000 without benefits for HACCP managers in 2002 (Troxel-Hellmer and Nunes, 2004). This equates to $30.00 per hour without benefits for 2,200 hours of work per year. If benefits equal 25 percent of wages, the total hourly wage with benefits would be $37.50. *Meat & Poultry* magazine's annual compensation survey does not report salaries for production workers.

Assumptions for Each Processing Step. For each of the following processing steps associated with the final rule described below, FSIS used assumptions for estimating the costs of compliance with the final rule:

- handling of non-ambulatory disabled cattle offered for slaughter,
- dentition for determining age of cattle,
- segregation of cattle and SRMs,
- disposal of SRMs,
- fabrication of vertebral cuts, and
- lost value of by-products.

For each processing step, slaughter and processing establishments may incur capital equipment costs, ongoing annual costs, or both. Establishments may use existing capital equipment, or in some cases, purchase new capital equipment.

Handling of Non-ambulatory Disabled Cattle Offered for Slaughter Assumptions for Estimating Costs to Slaughter Establishments. Whether a slaughter establishment incurs costs associated with the handling of non-ambulatory disabled cattle depends on what types of cattle the establishment slaughters, the size of the establishment, and when ownership of the cattle typically changes. For some types of establishments, the method of pricing cattle also affects who incurs these costs.

Establishments that slaughter steers and heifers typically will not bear costs associated with non-ambulatory disabled cattle offered for slaughter. Procurement departments at these establishments are cautious in their purchasing decisions, and they have told their producers not to ship non-ambulatory disabled cattle to the establishment. Therefore, either none arrive at the establishment, or the establishment does not bear the loss when one does arrive because grade and yield (grid) pricing is used. In grid pricing, the establishment pays prices for cattle based on the characteristics of the carcass. If the establishment does not slaughter the cattle, no carcass is produced; therefore, it cannot be priced.

Very small establishments that slaughter cows and bulls typically do not assume ownership of the animal prior to its arrival at the establishment. Therefore, FSIS assumed that very small establishments that slaughter cows and bulls no longer purchase or accept non-ambulatory disabled cattle and thus do not incur ongoing costs associated with these cattle.[19] However, FSIS assumed establishments have the necessary capital equipment to handle the occasional case that might occur (i.e., equipment for euthanasia of the animal and disposal of the animal).

[19]Prior to the interim final rules, some establishments specialized in slaughtering non-ambulatory disabled cattle (primarily non-fed cows and bulls). Some of these establishments have subsequently shut down or reorganized their operations; however, data on the numbers of these types of establishments are not available.

Small and large establishments that slaughter cows and bulls, however, do receive non-ambulatory disabled cattle, despite their efforts to avoid them. Travel distances are typically greater for cows and bulls, and older animals are more susceptible to injury during travel. Thus, these establishments might incur costs associated with handling non-ambulatory disabled cattle.

Capital Equipment Cost Assumptions. Cow and bull slaughter establishments require the following equipment to handle and haul non-ambulatory disabled cattle:

Knives, aprons, and hooks for handling non-ambulatory disabled cattle. Many smaller establishments manually disassemble (remove head, skin, and quarter) of non-ambulatory disabled cattle outside of the establishment. Once disassembled, they dispose of the remains of the cattle either in a landfill or by inedible rendering. Typical costs for each set of knives, aprons, and hooks for manual disassembly range from $54 to $80. FSIS assumed a small establishment would have one set on hand and a large establishment would have two sets.

Equipment for hauling non-ambulatory disabled cattle. A typical very small establishment uses a chain and sled, and a typical small or large establishment uses a forklift for handling non-ambulatory disabled cattle. Typical costs for a chain and sled are approximately $300, and typical costs for a forklift are $5,000 to $9,000. FSIS assumed establishments already have this equipment in the establishment, although some establishments might choose to have segregated equipment for non-ambulatory disabled cattle.

Ongoing Cost Assumptions. Cow and bull slaughter establishments will incur ongoing costs with the arrival of each

non-ambulatory disabled animal. FSIS assumed, based on FSIS' inspection program personnel data gathering initiatives that a non-ambulatory disabled animal requires approximately 2 hours of labor. This involves removing the animal from the trailer or pen, euthanizing the animal, and then skinning the animal. Establishments also incur disposal costs. Some establishments send non-ambulatory disabled cattle to inedible rendering establishments that charge an average pickup fee of $50. In addition, some establishments send non-ambulatory disabled cattle to inedible rendering establishments that do not charge for pick up. Other establishments send non-ambulatory disabled cattle to a landfill, and may incur higher disposal costs than $50 a head.

Summary of Assumptions for Non-Ambulatory Disabled Cattle. Table 6.3.5 presents estimates of the number of non-ambulatory disabled cattle received on an annual and weekly basis, based on typical volumes reported in FSIS' ADRS database and a summary of the cost estimate assumptions. FSIS assumed these estimates refer to cattle that would have passed ante-mortem inspection prior to the SRM interim final rule. FSIS calculated the proportion of non-ambulatory disabled cattle offered for slaughter in relation to the number of cows and bulls slaughtered and then distributed the costs by this proportion to obtain the per-head cost increase by establishment size.

Table 6.3.5: Estimated Number and Cost Estimate Assumptions Associated with Non-ambulatory Disabled Cattle Offered for Slaughter, by Establishment Size: Slaughter Establishments

Establishment Size	Very Small	Small Class I	Small Class II	Large
Approximate Number of Non-ambulatory Disabled Cattle Arriving at Establishments, Based on Working 51 Weeks per Year				
Minimum	None purchased or accepted	51 per year (1 per week)	102 per year (2 per week	102 per year (2 per week)
Most-likely	None purchased or accepted	255 per year (5 per week)	510 per year (10 per week)	2,040 per year (40 per week)
Maximum	None purchased or accepted	408 per year (8 per week)	765 per year (15 per week)	4,080 per year (80 per week)
Number of Non-ambulatory Disabled Cattle Arriving as a Proportion of Total Calves, Cows and Bulls[a]				
Minimum	—	0.011	0.001	0.001
Most-likely	—	0.055	0.006	0.013
Maximum	—	0.086	0.010	0.025
Capital Equipment Costs	—	Dedicated knife, apron, hooks ($54–$80 per set)		
Labor Costs[b]	—	2 hours per non-ambulatory disabled animal[c]		
Disposal Costs[b]	—	$50 per non-ambulatory disabled animal		

Note: These estimates apply to establishments that slaughter calves, cows and bulls and assume non-ambulatory cattle offered for slaughter would have passed ante-mortem inspection prior to the SRM interim final rule. Based on FSIS data, 97,916 non-ambulatory cattle offered for slaughter passed ante-mortem inspection in 2003; this value is roughly consistent with the estimated number of non-ambulatory cattle offered for slaughter presented here.

[a]FSIS assumed for the analysis that most non-ambulatory cattle offered for slaughter are calves, cows and bulls because cattle in other age categories are much less likely to become non-ambulatory and because establishments are unlikely to incur the costs associated with their handling.

[b]Estimates assumed are the same for all establishment sizes.

[c]To determine the per-animal labor costs, FSIS multiplied the number of hours per animal by the average wage rate for production employees and then multiplied that by the proportion of non-ambulatory disabled cattle offered for slaughter relative to the total number of calves, cows and bulls. These costs apply only to small and large establishments that slaughter calves, cows and bulls. FSIS provides the specific estimates by type of establishment in the Appendix, Table A2.

Dentition for Determining Age in Slaughter Establishments. Slaughter establishments typically use dentition for determining whether cattle are younger than 30 months of age. Steers and heifers are typically younger than 30 months of age. However, some steers and heifers are 30 months of age and older. Veal calves, by their definition, are younger than 30 months of age, so there is no need for dentition. Furthermore, most cows and bulls are 30 months of age and older, so most establishments assume that all are 30 months of age and older when they are presented for slaughter and treat them accordingly. After the SRM and Air-Injection Stunning interim final rules were published, the USDA Market News Service began to report discounts for cattle 30 months of age and older (including those determined by dentition). Weekly values have ranged from $35 to $50 per cwt (carcass weight), which translates to an approximate discount of $175 to $250 per head for a 500-pound cow or bull carcass (e.g., on the lower end, $35 per cwt times 5 cwt equates to $175).

Capital Equipment Cost Assumptions for Slaughter Establishments. FSIS assumed that slaughter establishments did not typically purchase additional capital equipment for conducting dentition activities.

Ongoing Cost Assumptions for Slaughter Establishments. FSIS assumed that dentition examinations require approximately 1 minute per head. Workers who conduct dentition activities might also plug holes in the skull following stunning to prevent leakage of brain material; thus, the time estimate also includes these activities. Using the labor estimates presented above, this equals labor costs of $0.26 per head ($15.71 times 0.0167 hours).

Segregation of Cattle and SRMs for Slaughter Establishments. If the age of cattle can be determined prior to slaughter (e.g., through written documentation), establishments will segregate the cattle in the pens and slaughter the older cattle after slaughtering younger cattle. If the age of cattle cannot be determined prior to slaughter, which is typically the case, establishments will mark carcasses by age after slaughter and segregation.

Capital Equipment Cost Assumptions for Slaughter Establishments. Most slaughter establishments have purchased additional capital equipment to remove SRMs. Most establishments use color-coded knives to remove SRMs from cattle 30 months of age and older. Larger establishments have also purchased equipment such as spinal cord removers and dedicated splitting saws. SRMs are then stored in color-coded bins for disposal. The

types of capital equipment that slaughter establishments have purchased for segregation purposes include the following:

Dedicated knives. Generally, establishments that slaughter both younger and older cattle have purchased a second set of knives to allow the use of dedicated knives on cattle 30 months of age and older. Some establishments use color-coding or some other system to distinguish knives to be used on older cattle. However, while it is permitted, color-coding is not required by the final rule. The cost of an individual knife ranges from $28 to $36. Based on information from FSIS' inspection program personnel data gathering initiatives, FSIS assumed that very small establishments require 2 additional knives, small establishments require 10 additional knives, and large establishments require 20 additional knives.

Spinal cord remover. FSIS assumed that very small and small slaughter establishments typically use a specialized type of knife to remove spinal cords from cattle 30 months of age and older at a cost of approximately $100. Furthermore, FSIS assumed larger slaughter establishments have installed vacuum systems for removing spinal cords (which they may use for all ages of cattle or only for cattle 30 months of age and older). The typical cost of a spinal cord remover ranges from $2,500 to $5,500. The addition of the vacuum system (20 hp pump, tank, and control panel) typically brings the total cost of the system to a cost range of from $20,000 to $25,000. Spinal cord removers have a useful life of 4 to 7 years in many operations, but they may have a substantially shorter useful life in the highest volume establishments. With the exception of establishments that only slaughter veal calves or calves, the cost of a spinal cord remover applies to all establishments.

Carcass-splitting saw. A typical very small slaughter establishment uses a single carcass-splitting saw on cattle of all ages and sanitizes the saw between uses on cattle of different ages, as required by the final rule. A typical small or large slaughter establishment purchases a separate carcass-splitting saw to use on cattle 30 months of age and older. The cost of a carcass-splitting saw ranges from $2,300 to $3,300 for a saw that can split 65 carcasses per hour (small establishments) or

from $4,700 to $5,200 for a saw that can split 150 carcasses per hour (large establishments). Carcass-splitting saws have a useful life of 20 to 40 years if not in constant use (small establishments) or a useful life of 4 to 5 years if in constant use (large establishments).

Although some slaughter establishments may not have added cooler capacity to allow for the segregation of cattle by age, FSIS assumed that a typical establishment has sufficient cooler capacity for segregation activities. Thus, FSIS did not include capital equipment costs for expanding the cooler.

Ongoing Cost Assumptions for Slaughter. Slaughter establishments incur additional ongoing costs for both labor and materials in segregating cattle and SRMs. In terms of labor usage, very small establishments added responsibilities to existing employees, while small and large establishments hired additional employees. For very small and small class I establishments, FSIS calculated labor costs per head by multiplying an estimated additional 0.1 hours per head by the average $15.71 hourly loaded wage or $1.57 (0.1 hours x $15.71 per hour) per head. For small class II and large establishments, FSIS calculated labor costs per head by multiplying the additional number of employees by 2,200 hours and by the average $15.71 hourly loaded wage and then dividing by the most-likely number of head slaughtered per year for each establishment size.

For small class II establishments, 3 hires times 2,200 times $15.71, all divided by 78,674 head is $1.32 per head).

In terms of materials usage, most establishments of all sizes now purchase ink stamps or color-coded tags to mark carcasses that are from cattle 30 months of age and older. FSIS assumed that establishments mark cattle 30 months of age and older, but some establishments might instead mark cattle that are younger than 30 months of age. These identifiers must remain with the cattle throughout the slaughter process, so that SRMs are properly segregated. Establishments also plug the skulls after stunning to prevent seepage of brain material. FSIS estimated the most-likely costs for these materials at $0.05 per head for ink stamps, $0.01 per head for tags, and $0.30 per head for corks, for very small and small-class-I establishments. Volume purchases reduce these costs for small-class-II and large establishments.

Summary of Assumptions for Slaughter Establishments. Table 6.3.6 summarizes the capital and ongoing costs incurred by slaughter establishments that segregate cattle and SRMs.

Table 6.3.6: Assumptions and Most-likely Values Associated with Segregation of Cattle and SRMs, by Establishment Size: Slaughter Establishments

		Very Small	Small Class I	Small Class II	Large
Capital Equipment Purchases					
Minimum	Dedicated knives	$56	$56	$280	$560
	Spinal cord remover	$100	$100	$20,000	$20,000
	Carcass-splitting saw	$2,300	$2,300	$4,700	$4,700
Most-likely	Dedicated knives	$64	$64	$320	$640
	Spinal cord remover	$100	$100	$22,500	$22,500
	Carcass-splitting saw	$2,800	$2,800	$4,950	$4,950
Maximum	Dedicated knives	$72	$72	$360	$720
	Spinal cord remover	$100	$100	$25,000	$25,000
	Carcass-splitting saw	$3,300	$3,300	$5,200	$5,200
Most-likely Labor Costs		6 minutes per head $1.57 per head	6 minutes per head $1.57 per head	Three new hires $1.32 per head	Eight new hires $0.36 per head
Most-likely Materials Costs	Ink for stamps per head	$0.05	$0.05	$0.04	$0.03
	tags per head,	$0.01	$0.01	$0.009	$0.008
	corks per head	$0.30	$0.30	$0.25	$0.20

Disposal of SRMs for Slaughter Establishments. Slaughter establishments dispose of SRMs by sending them to an inedible rendering establishment or to a landfill. Inedible rendering is more common, so FSIS based the cost assumptions on this practice. Some independent renderers pay beef slaughter establishments for SRMs, while others charge a fee for pickup services. Many establishments have on-site inedible rendering facilities; thus, FSIS does not know the market prices or costs of disposal for their SRMs.

If establishments disposed of materials that FSIS now designates as SRMs and tonsils through inedible rendering prior to the interim final regulation or they did not pay for pick up of inedible rendering materials, then the additional costs of disposal associated with the regulation are zero. Thus, FSIS did not include costs of disposal for the low- and medium-cost estimates. Based on information from rendering companies (Informa Economics. National Renderers Association Economic Impact Report: The Disposal of Specified Risk Materials of BSE. December 2006.), FSIS used $0.02 per pound as the most-likely cost estimate for disposal.

FSIS multiplied these costs by the average weight of SRMs per head, detailed in Table 6.3.7. For veal or calves, and for steers and heifers younger than 30 months of age, the final rule

considers only the distal ileum and tonsils as SRMs, totaling an estimated 3 pounds per head. For cows and bulls, and for steers and heifers 30 months of age and older, SRMs account for an estimated 20.6 pounds per head (excluding the weight of SRMs associated with the vertebral column).

Table 6.3.7: Estimated Most-likely Weight of SRMs per Head at Slaughter Establishments

SRM	Weight per Head (lbs)
Brain	1.0
Spinal cord	0.4
Skull, eyes, and trigeminal ganglia[a]	16.2
Distal ileum of the small intestine	0.5
Tonsils	2.5
Total[b]	20.6

Note: FSIS obtained the values in this table from Table 6.3.3.

[a]If heads are deboned to use cheek meat, the weight of the SRMs associated with the head is approximately 10 pounds.

[b]Excludes the weight of SRMs associated with the vertebral column (addressed in the next section).

FSIS also assumed in its estimates that current methods for removing inedible rendering materials are adequate to meet the requirements of this final rule. Larger establishments have conveyer systems to remove materials for inedible rendering. Currently, larger establishments put all materials destined for inedible rendering on the conveyer without segregating by the

age of the cattle from which the establishment removed the materials.[20]

Fabrication of Vertebral Cuts. Establishments that slaughter cows and bulls or steers and heifers 30 months of age and older are no longer allowed to fabricate vertebral bone-in cuts from these cattle unless they exclude the vertebral column portion that contains DRG.[21] Although most cattle 30 months of age and older are deboned, some steers and heifers will appear to be 30 months of age and older based on dentition; thus, the final rule does not permit establishments to produce vertebral cuts from these animals without excluding the vertebral column portion that contains DRG. In addition, some establishments slaughter fed cows and bulls from which they previously produced vertebral bone-in cuts. According to the results of the meat and poultry slaughter industry survey, about half of establishments slaughtering some cattle 30 months of age and older produced bone-in cuts from these types of cattle in 2003 (Cates et al., June 2005).[22] FSIS assumed that all establishments slaughtering

[20]If FDA requires in the future that establishments segregate inedible rendering material by age of cattle, establishments would incur substantial costs in reconfiguring the establishment to add an additional inedible rendering conveyer system.

[21]Establishments may still produce vertebral bone-in cuts that contain the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum. Some establishments call these cuts "i-bone steaks."

[22]Specific estimates are as follows: 49.5 percent produced short-loins, 52.5 percent produced bone-in or standing rib roasts, 56.5 percent produced blade or chuck roasts, 57.1 percent produced porterhouse steaks, and 60.4 percent produced t-bone steaks from cattle 30 months of age and older (Cates et al., 2005).

cattle 30 months of age and older no longer are able to produce vertebral bone-in cuts from these cattle.

Capital Equipment Cost Assumptions for Slaughter and Processing Establishments. Because FSIS assumes that none of the establishments purchased new capital equipment for fabricating vertebral bone-in cuts, based on information from FSIS' inspection program personnel data gathering initiatives (without input from the industry), FSIS has not included the costs of capital equipment for this provision of the final rule.

Ongoing Cost Assumptions for Slaughter and Processing Establishments. Ongoing costs associated with fabrication of vertebral cuts from cattle 30 months of age and older include additional labor expenses for hand-deboning and the lost value of meat that cannot be recovered, because now the establishment can no longer process vertebral column bones in AMR systems to produce AMR products or MS(beef). Labor requirements have increased with the more time-consuming task of cutting around the vertebrae of the vertebral column. FSIS assumed that these additional labor costs are the same for all establishment sizes.

The lost value of bone-in meat cuts represents a significant cost to establishments that slaughter cows and bulls or steers and heifers 30 months of age and older. These establishments have adjusted by producing cuts without the

prohibited vertebral bone (e.g., New York strip steak or “i-bone” steak instead of t-bone steak). Although the boneless cuts weigh less than the bone-in cuts, their higher per-pound value may offset any losses. Based on FSIS’ inspection program personnel data gathering initiatives (without input from the industry), FSIS assumed $0.00 per head as the minimum lost value estimate, $17.50 (half of $35.00) per head as the most-likely estimate, and $35.00 per head as the maximum estimate for the lost value associated with vertebral bone-in cuts from cattle 30 months of age and older. FSIS then adjusted these estimates by assuming that the establishment used only 50 percent of these cattle to produce vertebral bone-in cuts; thus, the lost value estimates are $0.00, $8.75, and $17.50 per head.

The ongoing assumptions associated with vertebral bone-in cuts are in Table 6.3.8.

Table 6.3.8: Assumptions Associated with Vertebral Bone-In Cuts for Small-Class II and Large Establishments that Slaughter Cattle 30 Months of Age and Older: Slaughter Establishments

Labor Costs[a]		Labor per Head, in Minutes	Cost Per Head
Minimum	Establishments only produced boneless cuts and had no AMR system before the SRM interim final rule	0	$0
Most-Likely	Establishments produce in-bone cuts and no AMR meat or MS(beef) before the SRM interim final rule	15	$3.93
Maximum	Establishments produce in-bone cuts and AMR meat or MS(beef) before the SRM interim final rule	30	$7.86
Lost Value of Meat or Meat Cuts[a]		Pounds per Head	Cost Per Head
Minimum	Establishments only produced boneless cuts and had no AMR system before the SRM interim final rule	0	$0
Most-Likely	Establishments produce in-bone cuts and no AMR meat or MS(beef) before the SRM interim final rule	6.2	$8.75
Maximum	Establishments produce in-bone cuts and AMR meat or MS(beef) before the SRM interim final rule	15	$17.50

[a]Estimates are assumed to be the same for all establishment sizes.

Lost Value of SRM By-Products for Slaughter Establishments.

As noted above, slaughter establishments can no longer use or sell certain SRM by-products for human consumption. Instead, they must send them to inedible rendering or to a landfill. To determine the cost implications associated with the lost value of SRM by-products, FSIS used values and costs from the PRIA of the SRM interim final rule (see Table 6.3.3). FSIS measured lost value in dollars per head. For each by-product, FSIS included the lost value, subtracted the alternative use value, and added

in the disposal costs. FSIS assumed costs are the same for all establishment sizes, as indicated in Table 6.3.9. The minimum estimate assumes that establishments did not sell any SRM by-products prior to the SRM interim final rule, and the maximum estimate assumes that establishments sold all possible SRM by-products.[23] The most-likely estimate is the midpoint value between $0.00 and the total value of all possible by-products that the establishment can no longer sell.

Table 6.3.9: Assumptions for Lost Value, measured in dollars per head, of By-Products, by Age of Cattle: Slaughter Establishments[a]

	Veal/Calves and Steers and Heifers Under 30 Months		Cows and Bulls and Steers and Heifers 30 Months and Older	
Minimum	Establishment did not produce by-products	$0.00	Establishment did not produce by-products	$0.00
Most-Likely	Distal ileum of the small intestine Tonsils	$0.40	Distal ileum of the small intestine Brain Spinal cord Skull, eyes, and TGG Tonsils[c]	$1.62
Maximum	Distal ileum of the small intestine Tonsils Total per head	$0.19 $0.60 $0.79[b]	Distal ileum of the small intestine Brain Spinal cord Skull, eyes, and TGG Tonsils[c] Total per head	$0.19 $0.44 $0.11 $1.90 $0.60 $3.24

[a]These lost values, measured in dollars per head, exclude the lost values associated with vertebral bone-in cuts.

[b]The remaining by-products from cattle of this age can still be sold.

[c]Tonsils could only be used in edible rendering prior to the SRM interim final rule.

[c]Spinal cord could only be exported or used in edible or inedible rendering prior to the SRM interim final rule

[23]Based on the results of the FSIS' inspection program personnel data gathering initiative (USDA FSIS 2002), and the meat and poultry slaughter industry survey (Cates et al., June 2005): 9.4 percent of establishments that slaughter cattle of any age sold small intestines in 2003. In addition, 27.9 percent used market heads, 6.7 percent used brains, 1.4 percent used eyes, 1.3 percent used spinal cords, and 11.9 percent used vertebral columns from cattle 30 months of age and older in products for human consumption.

Other Slaughter and Processing Establishment *Costs*. In addition to the capital equipment and operating expenditures detailed above, establishments are expending resources to review and modify their written plans; perform monitoring and verification activities; and, in some instances, make other capital equipment changes. FSIS describes these other types of establishment costs below.

Written Plans Modification. The costs associated with modifying an establishment's written plans are one-time costs.

Table 6.3.10 shows FSIS assumptions for estimating the costs of modifying written plans based on information from FSIS' inspection-program-personnel data gathering initiatives. Most establishments slaughtering steers and heifers or cows and bulls, or processing-only operations reviewed their HACCP plan, Sanitation SOPs, and other prerequisite plans and made modifications to one of these. Veal or calf establishments of all sizes reviewed their written plans but generally did not need to make any changes unless they were selling distal ileum of cattle (which the final rule now prohibits). FSIS based the cost estimates on the hourly wages for a "HACCP manager" that would vary depending on the type of establishment. The hourly wage rate represents the average hourly costs for workers that might include the establishment manager, a HACCP manager, and

quality assurance technicians, depending on the type of establishment.

Table 6.3.10: Assumptions Associated with Written Plan Modifications, by Age of Cattle and Processing-Only and Slaughter Establishments

Type of Establishment	Establishment Size			
	Very Small	Small Class I	Small Class II	Large
Veal/Calves	HACCP manager for 1 hour	HACCP manager for 1 hour	HACCP manager for 1 hour	HACCP manager for 1 hour
Steers and heifers (all ages)	HACCP manager for 2 hours and hiring a consultant ($500)	HACCP manager for 20 hours and hiring a consultant ($750)	HACCP manager for 20 hours and hiring a consultant ($750)	HACCP manager for 40 hours and hiring a consultant ($1,000)
Cows and bulls	HACCP manager for 2 hours and hiring a consultant ($500)	HACCP manager for 20 hours and hiring a consultant ($750)	HACCP manager for 20 hours and hiring a consultant ($750)	HACCP manager for 40 hours and hiring a consultant ($1,000)
Processing-Only	HACCP manager for 2 hours and hiring a consultant ($500)	HACCP manager for 20 hours and hiring a consultant ($750)	HACCP manager for 20 hours and hiring a consultant ($750)	HACCP manager for 40 hours and hiring a consultant ($1,000)

In addition to using establishment or company employees, some establishments hire outside consultants to assist in reviewing and modifying plans.

Monitoring and Verification Activities. All processing establishments and establishments slaughtering steers and heifers or cows and bulls are required to monitor and verify activities associated with the final rule. Based on information from FSIS' inspection program personnel data gathering initiatives, FSIS assumed monitoring and verification activities of slaughter establishments require 0.1 minute (6 seconds) per

procedure per head. FSIS further assumed that this estimate of required time is approximately the same across all slaughter establishment sizes.

Table 6.3.11 presents FSIS' assumptions for the number of procedures monitored and verified and their associated costs. Examples of procedures that slaughter establishments monitor and verify include the following: dentition, dehorning, head dropping, head hooking, tonsil trimming (short tonguing), distal ileum of the small intestine removal, split saw sanitation and washing, spinal cord removal, miss-split carcass handling, processing equipment sanitizing and washing, and SRM disposal. According to the meat and poultry slaughter industry survey results, 46.3 percent of cattle slaughter establishments implemented one to two additional procedures in response to the SRM interim final rule, 26.5 percent implemented 3 to 4 additional procedures, and 11.3 percent implemented 5 or more additional procedures (Cates et al., June 2005). These results imply that establishments monitor different combinations of these procedures or that some establishments monitored some of these procedures prior to the SRM interim final rule (e.g., removal of the distal ileum, removal of tonsils, and removal of spinal cord).

Table 6.3.11: Assumptions Associated with Additional Monitoring and Verification Activities for Establishments that Slaughter Calves, Steers, Heifers, Cows, or Bulls

	Number of Procedures Monitored and Verified	Estimated Labor Cost per Head
Minimum	1	$0.03
Most-Likely	3	$0.08
Maximum	5	$0.13

Other Possible Capital Equipment Changes. In addition to the capital equipment changes outlined above, establishments might have made other capital equipment changes. For example, some establishments might alter the length of the chain on the slaughter line to allow additional activities to occur (e.g., dentition) or might alter the chain to allow railing out of cattle that are 30 months of age and older for separate handling. Some establishments now conduct the head deboning process online rather than on a table to prevent cross-contamination. Some establishments also might have built additional pen space to hold cattle for segregation by age prior to slaughter. Furthermore, some establishments might have added additional cooler capacity to have sufficient space to segregate carcasses from cattle 30 months of age and older prior to fabrication. The extent to which establishments have made these changes and the range of costs for making these changes are

currently uncertain and assumed to be highly variable; thus, costs for these changes are not included in FSIS' estimates.

Summary of One-Time Costs and Per-Head Ongoing Costs for Slaughter Establishments. Appendix Tables A1 and A2 summarize the capital equipment and one-time costs at the slaughter establishment level and the ongoing costs on a per-head level, respectively. Establishments that discount or reduce their purchase price of cattle that are 30 months of age and older may recoup some of the costs incurred because of the final regulation by paying less for these cattle when purchased from the producer. For the purposes of this analysis, FSIS examined the effects of the costs without making an adjustment for the methods by which establishments might "pass along" the costs to other segments of the industry. Establishments that slaughter older cattle incur higher costs than other establishment types because of SRM removal (e.g., spinal cords), segregation, and dentition costs to ensure that cattle 30 months of age and older are handled in accordance with the final rule. Large establishments that slaughter older cattle face the highest one-time costs, with a most-likely estimate of $33,866. Across all sizes of establishments that slaughter cows, bulls, steers and heifers, the largest one-time cost is the installation of a spinal cord remover to be used on cattle 30 months of age and older.

Most-likely estimates of ongoing costs of the final rule range from $0.46 to $16.86 per head, depending on cattle type and establishment size. Of all very small establishments, those that slaughter steers and heifers 30 months of age and older incur the highest ongoing costs. Of all small and large establishments, those that slaughter cows and bulls incur the highest ongoing costs. The lost value of beef cuts associated with vertebral bone-in cuts is the largest ongoing cost for establishments that slaughter cows and bulls, or steers and heifers 30 months of age and older.

Federally-Inspected, State-Inspected, and Custom-Exempt Slaughter Establishments Cost Estimates for the "Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle during Slaughter" Final Rule. The PRIA found that there is no significant cost associated with the final rule on the use of these stunning devices because the beef packing industry reported that slaughter establishments were not known to use these stunning devices to immobilize cattle pre-BSE in the United States (USDA, FSIS, March 2004). In addition, the information from FSIS' inspection program personnel data gathering initiatives of federally inspected slaughter establishments, in pre-BSE 2002, did not find any establishments that used these stunning devices to immobilize cattle (USDA, FSIS, 2002).

Federal Slaughter Establishment Cost Estimates for the “SRM and Non-ambulatory Disabled Cattle” Final Rule. To compute industry-wide cost estimates associated with the SRM interim final rule, FSIS multiplied per-establishment costs by the number of establishments in 2003 for capital equipment and other one-time costs, and per-head costs by the number of cattle slaughtered in 2003 for ongoing costs. Tables 6.3.12 and 6.3.13 present the resulting industry-wide capital expenditures and annual ongoing costs by establishment size for federally inspected slaughter establishments. Table 6.3.14 summarizes the total costs associated with the final rule by establishment size for federally inspected establishments. The estimated total annual cost of $162.2 million includes annualized capital expenditures and the annual ongoing costs of labor, materials, and lost value of product. The next section has the cost estimates for state-inspected establishments that slaughter cattle.

Table 6.3.12: Summary of Most-likely Industrywide Capital and Other One-Time Cost Estimates Associated with the Final Rule: Federally Inspected Slaughter Establishments

	Very Small	Small Class I	Small Class II	Large	Total
Veal/Calves Only					
Per-establishment costs	$78	$78	$97		—
Number of establishments	6	7	8	0	21
Total costs	$467	$545	$778	$0	$1,790
Steers and Heifers (including combination of ages)[a]					
Per-establishment costs	$781	$26,237	$27,148	$30,647	—
Number of establishments	518	92	36	35	681
Total costs	$404,434	2,423,782	$977,342	$1,072,638	$4,868,196
Cows and Bulls (including veal/calves)					
Per-establishment costs	$717	$23,184	$24,095	$25,191	—
Number of establishments	4	1	8	1	14
Total costs	$2,867	$23,184	$192,763	$25,191	$244,005
Total Number of Establishments[b]	528	100	52	36	716
Total Industrywide Capital Equipment Costs	$407,768	$2,437,511	$1,170,884	$1,097,829	$5,113,991

[a]Establishment numbers include establishments slaughtering any quantity of steers and heifers. FSIS assumed that all establishments that intend to slaughter only steers and heifers will also slaughter some cattle 30 months of age and older because dentition will indicate that some steers and heifers are in the older age category.

Table 6.3.13: Summary of Most-likely Industrywide Ongoing (Variable) Costs Associated with the Final Rule: Federally Inspected Slaughter Establishments

	Very Small	Small Class I	Small Class II	Large	Total
Veal/Calves					
Per-head cost	$0.46	$0.46	$0.46		—
Number of head[a]	68,375	178,457	729,107	0	975,939
Total industrywide costs	$31,224	$81,496	$332,959	$0	$445,679
Steers and Heifers (under 30 months)[b]					
Per-head cost	$2.73	$2.73	$2.64	$1.68	—
Number of head[a]	467,626	366,009	3,291,995	22,716,360	26,841,990
Total industrywide costs	$1,276,630	$999,213	$8,694,910	$38,227,813	$49,198,566
Steers and Heifers (30 months of age and older)					
Per-head cost	$11.50	$11.50	$15.56	$15.93	—
Number of head[a]	24,612	19,264	173,263	1,195,598	1,412,736
Total industrywide costs	$282,976	$221,484	$2,696,328	$19,050,257	$22,251,044
Cows and Bulls					
Per-head cost	$9.66	$11.45	$11.12	$16.09	—
Number of head[a]	172,597	351,465	3,068,300	3,059,729	6,652,091
Total costs	$1,668,009	$4,023,388	$34,127,660	$49,219,261	$89,038,318
Total Number of Head	733,210	915,195	7,262,665	26,971,687	35,882,757
Total Industrywide Ongoing Costs	$3,258,839	$5,325,582	$45,851,856	$106,497,331	$160,933,607

[a]FSIS adjusted the number of head slaughtered as reported in FSIS' ADRS so that the number of head in each category matches the number reported by NASS for 2003.

[b]FSIS assumed 95 percent of all steers and heifers slaughtered are younger than 30 months of age.

Table 6.3.14: Summary of Most-likely Total Industrywide Costs Associated with the Final Rule: Federally Inspected Slaughter Establishments

	Very Small	Small Class I	Small Class II	Large	Total
Capital equipment costs	$407,768	$2,437,511	$1,170,884	$1,097,829	$5,113,991
Annualized capital equipment costs[a]	$99,451	$594,486	$285,568	$267,750	$1,247,255
Annual ongoing costs	$3,258,839	$5,325,582	$45,851,856	$106,497,331	$160,933,607
Total annual costs[b]	$3,358,289	$5,920,068	$46,137,424	$106,765,081	$162,180,862

[a]FSIS assumed capital equipment is replaced every 5 years on average, annualized using a 7 percent interest rate.

[b]Total annual costs equal annualized equipment plus annual ongoing costs.

- **Cost Estimates for State-Inspected Establishments that Slaughter Cattle**

State-inspected establishments that slaughter cattle must comply with the same requirements as federally inspected establishments. Thus, FSIS applied the cost estimates presented in Appendix Tables A1 and A2 to estimate the compliance costs for state-inspected establishments assuming that compliance costs are similar for federal and state inspected establishments in the same size category. That is, for example, very small (or small) state-inspected establishments are assumed to have the same average compliance costs as very small (or small) federally inspected establishments.

FSIS estimated the number of state-inspected establishments that slaughter cattle to be 1,346 including both establishments that only slaughter and establishments that slaughter and process (see Table 6.1.1). Based on agricultural statistics from National Agricultural Statistical Service (NASS), the estimated number of cattle slaughtered at state-inspected establishments is 612,000 head. FSIS assigned the state-inspected slaughter establishment slaughter quantities to each type of state-inspected slaughter establishment and age of cattle, assuming that the distributions for federally inspected establishments (as shown in Table 6.3.13) are similar to those for state-inspected slaughter establishments. FSIS used the resulting estimates to create the summary cost tables presented below.

Tables 6.3.15 and 6.3.16 present the estimated industry-wide capital expenditures and annual ongoing costs by establishment size for state-inspected establishments. Table 6.3.17 summarizes the total costs associated with the final rule by establishment size for state-inspected establishments. The estimated annual cost of $4.5 million includes annualized capital expenditures and annual ongoing costs of labor, materials, and lost value of product.

Table 6.3.15: Summary of Most-likely Industry-wide Capital and Other One-Time Cost Estimates Associated with the Final Rule: State-Inspected Slaughter Establishments

	Very Small	Small Class I	Small Class II	Total
Veal/Calves Only				
Per-establishment costs	$78			—
Number of establishments	15	0	0	15
Total costs	$1,170	0	0	$1,170
Steers and Heifers (including combination of ages)[a]				
Per-establishment costs	$781	$27,150		—
Number of establishments	1,293	23	0	1,321
Total costs	$1,013,382	$613,193	0	$1,626,576
Cows and Bulls Only (including veal/calves)				
Per-establishment costs	$717	$23,184	0	—
Number of establishments	10	0	0	10
Total costs	$7,184	0	0	$9,966
Total Number of Establishments	1,323	23	0	1,346
Total Industrywide Capital Equipment Costs	$1,021,736	$615,975	0	$1,637,712

[a]Establishment numbers include establishments slaughtering any quantity of steers and heifers. FSIS assumed that all establishments that intend to slaughter only steers and heifers will also slaughter some cattle 30 months of age and older because dentition will indicate that some steers and heifers are in the older age category.

Table 6.3.16: Summary of Most-likely Industrywide Ongoing (Variable) Costs Associated with the Final Rule: State-Inspected Slaughter Establishments

	Very Small	Small Class I	Small Class II	Total
Veal/Calves				
Per-head cost	$0.46	$0.46	0	—
Number of head[a]	21,416	3,694	0	25,110
Total industrywide costs	$9,780	$1,687	0	$11,467
Steers and Heifers (under 30 months)[b]				
Per-head cost	$2.73	$2.73	0	—
Number of head[a]	222,627	15,995	0	238,622
Total industrywide costs	$607,777	$43,666	0	$651,443
Steers and Heifers (30 months of age and older)				
Per-head cost	$11.50	$11.50		—
Number of head[a]	11,717	842	0	12,559
Total industrywide costs	$134,719	$9,679	0	$144,398
Cows and Bulls				
Per-head cost	$9.66	$11.45		—
Number of head[a]	282,622	52,827	0	335,449
Total costs	$2,731,303	$604,735	0	$3,336,038
Total Number of Head	538,382	73,357	0	611,739
Total Industrywide Ongoing Costs	$3,483,579	$659,767	0	$4,143,346

[a]The number of head or animals slaughtered by state-inspected establishments was estimated by assuming very small establishments slaughter an average 1,300 cattle per year and small establishments slaughter an average of 71,000 cattle per year.

[b]FSIS assumed 95 percent of all steers and heifers slaughtered are under 30 months of age.

Table 6.3.17: Summary of Most-likely Total Industrywide Costs Associated with the Final Rule: State-Inspected Slaughter Establishments

	Very Small	Small Class I	Small Class II	Total
Capital equipment costs	$1,021,736	$615,975	--	$1,637,712
Annualized capital equipment costs[a]	$249,192	$150,231	--	$399,423
Annual ongoing costs	$3,483,579	$659,767	--	$4,143,346
Total annual costs[b]	$3,732,771	$809,998	--	$4,542,768

[a]FSIS assumed capital equipment is replaced every 5 years on average, annualized using a 7 percent interest rate.

[b]Total annual costs equal annualized equipment plus annual ongoing costs.

- **Cost Estimates for Establishments that Slaughter Cattle on a Fee-for-Service Basis (Custom-Exempt Establishments)**

Establishments that slaughter cattle on a fee-for-service (custom exempt) basis are required to remove SRMs during the slaughter process. Custom-exempt operations occur in federally- and state-inspected establishments. However, FSIS accounted for these custom-exempt operations in the analysis of federally- and state-inspected establishments. Based on NASS data and on state-level custom-exempt establishment data provided by AFDO in December 2005, custom-exempt establishments slaughter about 192,000 cattle per year at an average of 146 per establishment.

The AFDO data is available on-line on the FSIS web site http://www.fsis.usda.gov and in the FSIS Docket Room (300 12th Street SW, Room 102, Washington, DC). Thus, their slaughter volumes are substantially less than the average slaughter volume of 1,698 for federally inspected slaughter establishments. However, the per-head cost of SRM removal for very small federally inspected establishments provides an upper-bound estimate of the per-head costs of SRM removal for custom exempt establishments.

Based on the distribution of very small federally-inspected establishments, FSIS assumed that 98 percent of custom slaughter establishments slaughter steers and heifers or a combination of cattle ages, 1 percent slaughter only veal calves or calves, and 1 percent slaughter only cows and bulls. Using the estimated one-time per establishment and ongoing per-head costs for federally inspected slaughter establishments, custom-exempt slaughter establishments are estimated to incur up to $215,496 in one-time costs and $1.67 million in annual ongoing costs. The estimated annual costs that include annualized capital expenditures and annual ongoing costs, equal $1.73 million.

In addition to the establishment incurring the costs of SRM removal during slaughter, FSIS prohibits custom-exempt slaughter establishments from slaughtering non-ambulatory disabled cattle

offered for slaughter under the SRM interim final rule. Under the final rule, FSIS also will not permit these establishments to slaughter such cattle. The lack of change in this provision results in custom-exempt slaughter establishments continuing to lose the revenue associated with the slaughtering of these animals. Based on information from FSIS' inspection-program-personnel data gathering initiatives, custom-exempt establishments slaughtered non-ambulatory disabled cattle offered for slaughter, prior to the SRM interim final rule. By FSIS not allowing slaughter of these non-ambulatory disabled animals, custom-exempt slaughter establishments will not be able to generate revenue from slaughtering these animals. In addition, cattle producers will not be able to salvage cattle that are non-ambulatory when offered for slaughter because they suffered an acute injury. The cattle producer will lose the opportunity to salvage the beef from an acutely injured animal that is non-ambulatory, even if the animal is otherwise healthy.

FSIS assumed, based on information from FSIS' inspection-program-personnel data gathering initiatives, custom-exempt establishments slaughtered between zero and 15 non-ambulatory disabled cattle that were offered for slaughter per year prior to the SRM interim final rule, with an average of four per establishment. Further, FSIS assumed that prior to the SRM interim final rule, establishments charged an average of $32 to

slaughter a cow and $0.36 per pound to cut, grind, and wrap (process) beef from a cow carcass. In addition, establishments obtained an average of $21 in revenue from the sale of the cowhide. Assuming an average carcass weight of 517 pounds (the average reported carcass weight for a cow), a custom-exempt establishment earned an average of $239 per cow. Thus, a typical establishment earned $956 from slaughtering non-ambulatory disabled cows prior to the SRM interim final rule ($239 per animal multiplied by 4 animals). This equates to $1.2 million of total revenue on an annual basis ($956 per custom-exempt establishment multiplied by 1,314 custom-exempt establishments that slaughter cattle).

Table 6.3.18 presents a summary of the most-likely total industrywide costs associated with the Final Rule, for custom-exempt slaughter establishments.

Table 6.3.18: Summary of the Most-likely Total Industrywide Costs Associated with the Final Rule: Custom-Exempt Slaughter Establishments

	Very Small	Small Class I	Small Class II	Total
Capital equipment costs	$215,496	$0	$0	$215,496
Annualized capital equipment costs[a]	$52,557	$0	$0	$52,557
Annual ongoing costs	$1,674,977	$0	$0	$1,674,977
Total annual costs[b]	$1,727,534	$0	$0	$1,727,534

[a]FSIS assumed capital equipment is replaced every 5 years on average, annualized using a 7 percent interest rate.

[b]Total annual costs equal annualized equipment plus annual ongoing costs.

- **Cost Estimates for Federally-Inspected Processing-Only Establishments that Receive, for Further Processing, Beef Carcasses or Vertebral Bone-In Parts of Carcasses from Cattle 30 Months of Age and Older**

FSIS made allowance for the shipment of carcasses or parts of carcasses that contain SRM materials (i.e., vertebral column containing the DRG, but not the spinal cord) for further processing only in federally inspected establishments, if these establishments have controls in place to ensure that the establishment removes SRMs at processing prior to distribution of beef for human consumption. FSIS used the cost estimates outlined above as the basis for estimating the cost estimates for these federally-inspected processing-only establishments that receive carcasses or vertebral bone-in parts of carcasses from cattle 30 months of age and older. FSIS derived the specific estimates for each category of costs as follows:

Capital equipment and other one-time costs

Written plan development. Costs per establishment were assumed to be half of the cost estimated for cattle slaughter establishments because the plans are expected to require less information and have a corresponding reduction in the number of hours necessary for developing the plan. This corresponds to a most likely value of $308 for very small and small-class-I establishments, $764 for small-class-II establishments, and $1,278 for large establishments. In many cases, FSIS used the midpoint as the most likely value of a triangular probability distribution of values.

Dedicated knives. FSIS assumed that establishments receiving SRMs would acquire separate knives for use on carcasses and vertebral bone-in parts of carcasses from cattle 30 months of age and older. Establishments that process carcasses and vertebral bone-in parts of carcasses from cattle younger than 30 months of age would not likely use separate knives. The most likely costs per establishment were assumed to be equal to the midpoint of those for cattle slaughter establishments, which are $64 for very small establishments, $320 for small-class I and II establishments, and $640 for large establishments.

Per-head ongoing (variable) costs

Segregation. FSIS assumed that the same amount of labor per head would be required for segregating carcasses and vertebral bone-in parts of carcasses based on whether they are from cattle younger than 30 months of age or not in processing-only establishments as for slaughter establishments. The most likely values for labor costs are $1.57 per carcass for very small and small-class I establishments that receive carcasses from cattle both under 30 months and 30 months and older that contain SRMs. Further, the most likely value for labor cost is $1.54 per carcass for small establishments, and $0.65 per carcass for large establishments that receive carcasses from cattle both under 30 months and 30 months and older that contain SRMs. Material costs are incurred to cover the costs of stamps and tags to identify carcasses from cattle 30 months and older. FSIS reduced these costs from about $0.36 per head for cattle slaughter establishments to $0.06 per head for processing-only establishments because corks to plug the head (valued at $0.30 per head) are not needed.

Vertebral bone-in cuts. FSIS assumed that the incremental cost of labor for preparing vertebral bone-in cuts would be the same as for cattle slaughter establishments. The most likely value of these costs is $2.88 for very small and small-class I establishment sizes, and 3.93 for small-class I and large establishment sizes. The lost value of meat cuts incurred by the processing establishments was assumed to be half of that for the cattle slaughter

establishments to reflect likely discounting of the carcasses and parts from cattle 30 months of age and older because of the lost value of meat cuts. The most likely value of this cost is $2.16 per carcass for very small and small-class I establishment sizes, $3.71 per carcass for small-class II establishment sizes, and $4.37 per carcass for large establishment sizes.

Monitoring and verification. Processing-only establishments that receive carcasses and bone-in parts of carcasses with vertebral columns from cattle 30 months of age and older will undertake monitoring and verification activities. Based on information from FSIS' inspection-program-personnel data gathering initiatives in federally inspected establishments, FSIS assumed that these activities would require as much time as for cattle slaughter operations because there are about the same number of steps to monitor. FSIS assumed the most likely value of this cost was $0.08 per carcass for all establishment sizes.

FSIS allows only state-inspected processing-only establishments to receive, for further processing only, carcasses or vertebral bone-in parts of carcasses of cattle 30 months of age or older that were slaughtered in state-inspected establishments. In addition, FSIS allows only federally-inspected processing-only establishments to receive, for further processing only, carcasses or vertebral bone-in parts of carcasses of cattle 30 months of age or older that were slaughtered in federally-inspected establishments. Since data on state inspected processing-only establishments is not readily available, FSIS cannot estimate how many of these establishments now will no longer be able to process federally-inspected carcasses or vertebral bone-in parts of carcasses from cattle 30

months of age and older. These state inspected establishments would now have to substitute state-inspected carcasses or vertebral bone-in parts of carcasses from cattle younger than 30 months of age that might be a higher cost than federally-inspected carcasses or vertebral bone-in parts of carcasses from cattle 30 months of age and older. This change in practice might result in lower profits for these state inspected processing-only establishments because their markets might not bear any increased costs of state-inspected carcasses or vertebral bone-in parts of carcass from cattle 30 months of age and older. The expected result might be a lowering of profit for these establishments. Tables 6.3.19 and 6.3.20 present the resulting estimated capital and other one-time costs and the annual ongoing costs by establishment size, for federally inspected establishments. FSIS obtained the establishment numbers used for estimating capital and other one-time costs from the results of the processing-only industry survey of industry conducted in fall 2005 (Cates, et al., December 2005). FSIS obtained the numbers of carcasses and parts of carcasses used for estimating ongoing costs by summing the weighted reported beef input purchases for these federally inspected establishments as reported in the industry survey and dividing by 517 pounds. This estimate likely overstates the number of affected carcasses and parts of carcasses from cattle 30 months

of age and older because some carcasses and parts of carcasses received by these processing-only establishments are from cattle younger than 30 months of age. Further, this estimate likely overstates the number of affected carcasses and parts of carcasses from cattle 30 months of age and older because some parts of carcasses would likely not contain vertebral column material.

Table 6.3.19: Summary of Most-likely Industrywide Capital and Other One-Time Cost Estimates Associated with the Final Rule: Federally-Inspected and State-Inspected Beef Processing-Only Establishments

	Very Small	Small Class I	Small Class II	Large	Total
Federally-Inspected Processing-Only Establishments					
Per-establishment costs	$372	$628	$1,084	$1,918	—
Number of establishments	29	15	7	1	52
Total costs	$10,799	$9,426	$7,589	$1,918	$29,733
State-Inspected Processing-Only Establishments					
Per-establishment costs	$372			—	—
Number of establishments	84	0	0	—	84
Total costs	$31,280	$0	$0	—	$31,280
Total Number of Establishments	113	15	7	1	136
Total Industrywide Capital Equipment Costs	$42,079	$9,426	$7,589	$1,918	$61,012

Table 6.3.20: Summary of Most-likely Industrywide Ongoing (Variable) Costs Associated with the Final Rule: Federally and State Inspected Beef Processing-Only Establishments

	Very Small	Small Class I	Small Class II	Large	Total
Federally Inspected Processing-Only Establishments					
Per-carcass cost	$6.81	$6.81	$9.43	$9.21	—
Number of carcasses received	1,329	150,770	131,145	27,079	310,323
Total federally-inspected	$9,054	$1,027,121	$1,236,353	$249,379	$2,521,906
State-Inspected Processing-Only Establishments					
Per-carcass cost	$6.81	—	—	—	—
Number of carcasses received	28,785	0	0	—	28,785
Total state-inspected	$196,098	$0	$0	—	$196,098
Total Number of Carcasses Received	30,114	150,770	131,145	27,079	339,108
Total Industrywide Ongoing Costs	$205,152	$1,027,121	$1,236,353	$249,379	$2,718,004

Based on these calculations, the total annual costs of compliance with the final rule for federally inspected processing-only establishments is $2.5 million. The total annual cost of compliance for state-inspected processing-only establishments is $203,727. FSIS provided the distribution by establishment size in Table 6.3.21. Table 6.3.21 summarizes the costs of compliance with the final rule for federally- and state-inspected processing-only establishments.

- **Summary of Cost Estimates for the Final Rule**

Table 6.3.22 summarizes the costs of compliance with the final rule including the following types of affected establishments: federally inspected slaughter establishments, state-inspected slaughter establishments, federally inspected processing-only establishments, and state-inspected processing-only establishments. Based on FSIS' estimates, the total annual average costs of the rule, including annual ongoing costs and annualized capital costs, is estimated at $171.2 million at a 7 percent interest rate. Approximately 99 percent of these costs are annual ongoing costs, and the remainder is capital costs.

Table 6.3.21: Summary of Most-likely Total Industrywide Costs Associated with the Final Rule: Federally and State Inspected Beef Processing-Only Establishments

	Very Small	Small Class I	Small Class II	Large	Total
Federally Inspected Processing –Only Establishments					
Capital equipment costs	$10,799	$9,426	$7,589	$1,918	$29,733
Annualized capital equipment costs[a]	$2,634	$2,299	$1,851	$468	$7,251
Annual ongoing costs	$9,054	$1,027,121	$1,236,353	$249,379	$2,521,906
Total annual costs for federally-inspected processing-only establishments[b]	$11,688	$1,029,419	$1,238,204	$249,847	$2,529,157
State-Inspected Processing-Only Establishments					
Capital equipment costs	$31,280	—	—	—	$31,280
Annualized capital equipment costs[a]	$7,629	—	—	—	$7,629
Annual ongoing costs	$196,098	—	—	—	$196,098
Total annual costs for state-inspected processing-only establishments[b]	$203,727	—	—	—	$203,727

[a]FSIS assumed capital equipment is replaced every 5 years on average, annualized using a 7 percent interest rate.

[b]Total annual costs equal annualized equipment plus annual ongoing costs.

The estimates in Table 6.3.22 are based on the assumption that 5 percent of steers and heifers are 30 months of age and older and would be classified as 30 months of age and older based on dentition. In the cost-effectiveness analysis, FSIS analyzed alternative scenarios with different age cutoffs for use of SRMs. For each different age cutoff (i.e., 12 months or 24 months), a different proportion of steers and heifers will be included in the older age category, thus affecting the estimated costs of the final rule. FSIS assumed that the per-head or per animal cost estimates for each age category are constant regardless of the age cutoff. However, by altering the proportion of cattle in each age category, FSIS obtained estimates of the total costs of compliance using existing cost information.

Table 6.3.22: Summary of Most-likely Total Industrywide Costs Associated with the Final Rule: All Inspected Establishment Types and Sizes. (Thousands Dollars)

	Slaughter Establishments			Processing-Only Establishments		Total
	Federal	State	Custom-Exempt	Federal	State	
Capital equipment costs	$5,114	$1,637	$215	$29.7	$31	$7,028
Annualized capital equipment costs[a]	$1,247	$399	$53	$7	$8	$1,714
Annual ongoing costs	$160,934	$4,143	$1,675	$2,522	$196	$1,714
Total annual costs[b]	$162,181	$4,543	$1,728	$2,529	$204	$171,184

[a]FSIS assumed capital equipment is replaced every 5 years on average, annualized using a 7 percent interest rate.

[b]Total annual costs equal annualized equipment plus annual ongoing costs.

6.4. Possible Indirect and Unintended Cost Impacts

The focus of the cost discussion thus far has been mainly on industry-wide direct compliance costs. These costs, on an annual basis, were estimated at about $171.2 million (at the mean), about 0.5 of one percent of the total annual value of about $33,000 million in beef carcass-equivalent (CE) industry sales ($171.2 million divided by $33,000 million). In addition, FSIS understands that the final rule may have other impacts such as changing beef-steak products characteristics, and forcing some establishments to exit the industry. However, these impacts are hard to quantify. Two other possible indirect cost impacts are on consumers and other sectors of the economy. However, necessary and sufficient market product quantity data are generally not available for SRMs (e.g., brains, market heads of cattle 30 months of age and older, and the distal ileum of the small intestine) to calculate the potential social costs of shifts in supply and demand in a consumer- and producer-surplus framework. Another confounding factor in estimating possible market supply reductions is the extent that the market could substitute imported or domestic products (e.g., imported or domestic brains from young cattle) for any U.S. SRM production cutbacks. Without such information, FSIS can only say that higher industry compliance costs and lower market supplies would likely raise consumer prices to some extent. From the information provided in this analysis

(the expected small cost impacts of regulatory compliance relative to total value of production and the likely small quantity cut-backs), FSIS expects that these regulatory impacts would be minimal.

In addition, a related issue is the possible impact on other sectors of the economy. Agricultural Census data show that the beef and dairy producer industries supply significant amounts of cattle product to the beef packing industry. Because, however, FSIS expects the quantity effect to be minimal, these upstream suppliers of cattle (raw material) are likely not to be significantly affected by the final rule. However, in Table 6.4.1, FSIS shows the shift from the baseline year to slaughtering a larger proportion of younger cattle (e.g., steers and heifers) excluding calves after the Interim Final Rule, based on FSIS Slaughter Data (NASS) from 2003 to 2006.

Table 6.4.1: The Shift from the Baseline Year (2003) to Slaughtering a Larger Proportion of Younger Market Fed-Cattle (e.g., Steers and Heifers), Excluding Calves after the Interim Final Rule, Based on Data from 2003 to 2006.

Year	Steers thousands	Heifers thousands	Total[a] Steers and Heifers thousands	Total[a] Cattle, excluding calves thousands	Proportion[a] of Steers and Heifers Percent
2003	17,177	11,079	28,256	34,908	80.9
2004	16,192	10,945	27,137	32,756	82.8
2005	16,348	11,288	27,636	33,310	83.0
2006	16,411	11,933	28,344	34,043	83.3

Sources: National Agricultural Statistical Service, Agriculture Statistics, 2005
FSIS Animal Disposition and Reporting System (ADRS) 2005/2006
Note: [a] Totals and percentages are based on unrounded data and may not equal the sum of class due to rounding.

6.5. Final Regulatory Impact Analysis (FRIA) Results

The results of the economic impact model of the final rule are detailed in the tables of the Appendices. In addition, the Summary Section of this FRIA presents summary results in Table V, and Table VI. In Table 6.5.1, FSIS compares the distribution (minimum, maximum, 5th percentile, median (50th percentile), average, 95th percentile, and standard deviation) of annualized cost of compliance values in the PRIA and the FRIA.

Table 6.5.1: Comparison of the Distribution (Minimum, Maximum, 5th Percentile, Median (50th Percentile), Average, 95th Percentile, and Standard Deviation) of Annualized Cost of Compliance Values in the PRIA (without the AMR impact) and the FRIA

Measure	Annualized Cost of Compliance, $millions			
	PRIA		FRIA	
	7 Percent	3 Percent	7 Percent	3 Percent
Minimum	81.6	NA	95.9	95.7
5th Percentile	94.2	NA	138.0	137.8
Median	105.0	NA	171.1	170.9
Average	105.6	NA	171.2	171.0
95th Percentile	118.5	NA	204.9	204.7
Maximum	134.9	NA	244.0	243.8
Standard Deviation	7.4	NA	20.2	20.2
Notes: 7 percent interest rate and 3 percent interest rate NA not available				

If the necessary and sufficient data (product volumes and prices) on markets of SRM products (e.g., brains, spinal cords,

market heads, distal ileum of small intestines, etc.) were available to FSIS, then the FRIA would estimate the costs to society associated with the final rule and the distribution of those costs among producers and consumers. The final rule requires establishments in the cattle slaughter industry to modify their production processes and thus increase their production costs. It is important to recognize that directly affected establishments are likely to respond to this change in the market environment by modifying their production rate or altering their input mix. The impacts of these adjustments on equilibrium prices and quantities will likely result in establishments at least partially transmitting the compliance costs to other entities through market relationships.

7.0. Benefits Analysis and Cost-Effectiveness Analysis of this Final Rule

This section examines benefits resulting from the final rule in terms of the potential reduction in human exposure to the BSE infectious agent. FSIS estimated the public health benefits of the final rule about the potential relative risk reduction of human exposure to the BSE agent. In addition, this section examines benefits from the restoration of beef export markets. Then, FSIS compares the benefits with the estimated costs reported in the last section.

7.1. Potential Relative Risk Reduction of Human Exposure

FSIS' analysis of benefits uses the results of the 2005 Harvard BSE Update model runs of scenarios that evaluate the relative reduction in human exposure to BSE agent infectivity effects that result from removing certain cattle materials (e.g., SRMs) from the human food supply chain (Cohen et al., 2005). The benefits of the final rule primarily result from the relative reduction in human exposure to BSE (agent) infectivity and the restoration of beef exports. FSIS modified the FRIA benefits analysis from the PRIA to account for the scenarios considered in the 2005 Harvard BSE Update. Furthermore, this final analysis assumes that establishments are adequately meeting the requirements of the AMR interim final rule that are in place. Therefore, the benefit estimates reported below for the provisions of the SRM interim final rule and air-injection stunning interim final rule must be interpreted as benefits that are separate from and, in addition to, the benefits associated with the provisions of the AMR interim final rule.

- **Reduction in Human Exposure to the BSE Agent**

The following discusses the methods used in this analysis to estimate the reduction in human exposure to BSE agent infectivity in the human food supply.

FSIS evaluated baseline human exposure and possible mitigation options intended to prevent human exposure to the BSE agent in the United States using a modified version of two previous risk assessment models developed by the Harvard Center for Risk Assessment (HCRA) of the Harvard School of Public Health and the Center for Computational Epidemiology at Tuskegee University. These two previous models are referred to here as the Harvard 2001 Analysis (as revised by Harvard in response to peer-review comments) (Cohen et al., 2001) and the Harvard 2003 Canada Analysis (Cohen et al., 2003). Harvard conducted the latter analysis after the detection of the single case of BSE in Canada on May 20, 2003. Using similar assumptions to the 2001 Harvard Analysis, the Harvard 2003 Analysis evaluated 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.

To develop baseline and mitigation estimates of potential human exposure to the BSE agent for this final rule, FSIS used a third and further modified version of the Harvard risk assessment models (Cohen and Gray, 2005). Table 7.1.1 compares the assumptions that FSIS used in this FSIS analysis with the assumptions in the 2001 and 2003 Harvard analyses. The data in Table 7.1.1 are from the FSIS 2005 analysis (October 2005 model)

and are the results of 30 months ban on AMR. For its baseline estimate of potential human exposure to the BSE agent, FSIS assumed that cattle producers imported 500 BSE-infected cows 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 analysis assumes that measures implemented by the U.S. 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. FSIS ran the risk mitigation scenarios for 50,000 iterations. In contrast, the Harvard 2001 analysis assumed that cattle producers imported 10 infected cows, and the Harvard 2003 analysis assumed cattle producers imported 5 BSE-infected bulls. Both of these analyses ran 5,000 iterations per scenario.

Another main assumption in the Harvard 2001 and 2003 analyses that differs from the FSIS assumptions 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 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 some possibility of human exposure via this pathway. Since some establishments may inadvertently use some older animals for bone-in-beef products, this assumption may cause the risk assessment model to underestimate potential human exposure through this pathway and thus overestimate the impact of some of the risk mitigation options.

Table 7.1.1: Comparison of Assumptions: Harvard 2005 Analysis, and Harvard 2001 and 2003 Analyses

	Harvard 2001 Analysis	Harvard 2003 Canada Analysis	Harvard 2005 Analysis
Simulation time frame	20 years, beginning after 1999 policies in place	Simulation through 2020, various years for initiation of infection—starting in 1992	Baseline reflects status up to 2003. Simulation for a 20-year period post-2003.
Number of infected animals as initiating event	10 cows	5 bulls	10 cows (baseline) 500 cows (baseline and mitigations)
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, 10 cows b) Baseline 2003, 500 cows c) Mitigations against the baseline of 500 cows./1 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 = 50% > 29 months = 25% Mitigation: FSIS ran a number of mitigations based on age categories (12, 24, 30 months) and non-ambulatory status.
Coefficients for industry practice	Representative of current industry practices prior to the USDA announcement in Jan. 2004, which stated pre-BSE conditions.	Representative of current industry practices during the period of simulation.	Baseline: Representative of industry practices prior to the USDA announcement in January 2004, which stated pre-BSE conditions. Mitigation: A number of mitigations based on age categories (12, 24, 30 months) and non-ambulatory status. Coefficient values modified to reflect the removal of SRMs from human food.

Footnote:

1. Mitigations begin one year after the 500 bse-infected cows are introduced into the U.S. herd or cattle population.
2. Simulated over 20 years after the introduction of BSE-infected cattle

To address this potential overestimation of mitigation impacts, FSIS used different assumptions regarding the age distribution of animals going to the bone-in-beef pathway. Based on evidence available to FSIS, FSIS has determined that establishments use vertebrae from cattle older than 24 months in bone-in cuts and processes (bone-in-beef pathway). Therefore, model coefficients were changed in the FSIS baseline analysis to allow 50 percent of vertebrae from cattle 24 to 29 months of age and 25 percent of vertebrae from cattle 30 months of age and older to 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. Although the 2001 and 2003 Harvard analyses and the FSIS baseline analysis assumed different bone-in beef exposure pathways from cattle older than 24 months, the ultimate human exposure was substantially similar in all of the risk assessment models.

To compare results using the different modeling assumptions, FSIS generated baseline results for cumulative human exposure over 20 years under two assumptions regarding the number of infected animals introduced into the United States—10 and 500 animals. To make them

comparable to the Harvard 2001 and 2003 baselines, these particular estimates do *not* assume that the requirements of the AMR interim final rule are in place. Under the first assumption (10 animals), which is closer to the assumptions used in the Harvard analyses, for the baseline over 20 years, FSIS estimates that an average of 75 cattle oral ID50s would potentially be available for cumulative human exposure (50,000 iterations). This has been compared to the 2001 Harvard analysis, which showed an average cumulative human exposure of 39 cattle oral ID50s when 10 infected animals were introduced into the United States (5,000 iterations).[24] Harvard also modeled the introduction of 5 infected animals in the 2001 model, showing a cumulative human potential exposure of 17 cattle oral ID50s over 20 years.[25] Both of the Harvard analyses assumed that no vertebrae from animals older than 24 months of age entered the bone-in-beef pathway.

Because FSIS is interested in how changes in the BSE SRM final rule might affect the contribution of specific tissues to potential human exposure, FSIS took steps to ensure greater numerical stability in the risk assessment model. In addition, FSIS took these steps in the risk

[24]Cohen et al., 2001. See Appendix 3A, Section 1—Base Case.
[25]Cohen et al., 2001. See Appendix 3A, Section 3.2.

assessment model to ensure a more reliable representation of low probability events. To achieve a sufficient degree of numerical stability and precision for evaluating the proposed SRM rule and other interventions considered in the 2005 Harvard BSE Risk Assessment Update, FSIS first asked Harvard to conduct 750,000 trials of our standard base case scenario. That scenario models the U.S. cattle population and contamination of the human food supply for 20 years following the introduction of 10 BSE-infected cattle. It took about 28 days to complete this base care scenario on a personal computer started with 10 infected cattle with 750,000 simulation trials.

There are about 20 scenarios to be evaluated by Harvard in the 2005-updated report. In addition, FSIS needs to use the 2005-updated model to run a number of scenarios to evaluate the effect of lower than perfect compliance and alternative age cut-off (12- and 24-month) in SRM removal. Each of these scenarios needs about a month to complete. For computational convenience, Harvard decreased the number of trials conducted (from 750,000 to 50,000 per scenario) and increased the number of infected animals introduced (from 10 to 500). FSIS recognize that an introduction of 500 infected cattle into the U.S. is unlikely. However, simulation of 50,000 trials of 500 infected animals being

introduced takes approximately one-tenth the time needed to run 750,000 trials of 10 infected animals being introduced.

Effectively, the numerical precision of a set of trials (expressed as the standard error of the mean divided by the estimated mean) depends on the product of the number of trials run and the number of infected animals introduced. Hence, the 50,000 trials of the base case with 500 infected animals introduced (25 million infected animals introduced in total) yielded even more precise estimates than the 750,000 trials of the base case with 10 infected animals introduced (7.5 million infected animals introduced in total). Results indicate that the arithmetic mean of the resulting projections can be scaled by the ratio of the number of infected animals introduced (i.e., by 500 divided by 50). Therefore, for evaluating relative reduction in potential human exposure to BSE infectivity, because of SRM removal or other measures, the concluding results are expected to be nearly the same as long as the product of the number of trials run and the number of infected animals introduced is large. This is true regardless that the model started with 10 or 500 animals.

Although the introduction of 500 BSE infected cattle into the U.S. is unlikely, it allowed FSIS to achieve satisfactory numerical stability in the risk assessment

model using far less computer time. For this reason, all alternative scenarios and sensitivity analyses in the 2005 Harvard BSE risk assessment update and the revision after the public meeting in 2006 assumed the hypothetical introduction of 500 infected cattle.

For this analysis of the final rule, FSIS assumed that 500 infected animals are introduced into the United States and that the requirements of the AMR interim final rule are being met (no AMR systems are allowed to operate using SRMs). Based on these assumptions, FSIS estimated the reduction in potential human exposure resulting from eight different risk management alternatives. The eighth risk management alternative is the final rule. The risk management alternative scenarios and the final rule scenario are as follows:

Scenario 1: (A100): Ban on non-ambulatory cattle for use as human food;

Scenario 2: (B12100): Ban on SRMs from cattle 12 months of age and older at slaughter for use as human food – 100 percent compliance;

Scenario 3: (B24100): Ban on SRMs from cattle 24 months of age and older at slaughter for use as human food – 100 percent compliance;

Scenario 4: (B30100): Ban on SRMs from cattle 30 months of age and older at slaughter for use as human food – 100 percent compliance;

Scenario 5: (B3090): Ban on SRMs from cattle 30 months of age and older at slaughter for use as human food – 90 percent compliance;

Scenario 6: (B3095): Ban on SRMs from cattle 30 months of age and older at slaughter for use as human food – 95 percent compliance;

Scenario 7: (B3099): Ban on SRMs from cattle 30 months of age and older at slaughter for use as human food – 99 percent compliance;

Final Rule or Scenario 8: (AB30100): Ban on non-ambulatory cattle and SRMs from cattle 30 months of age and older at slaughter for use as human food – 100 percent compliance.

To estimate the impact of the different risk management options, the potential human exposure resulting from each of the eight risk management alternatives was calculated. FSIS shows the estimated potential human exposure for both the baseline and the FSIS eight risk management alternatives in Table 7.1.2. Table 7.1.2 is the result of the FSIS 2006 analysis (December 2006 revised model), including the base case scenario. This table presents mean, standard deviation, 5 percent, median, 95 percent, 99 percent, 99.5 percent, 99.9 percent, and maximum estimates of potential exposure, as well as the incremental reduction in mean potential exposure yielded by each alternative.

Under baseline conditions of 500 imported cattle and the assumptions shown in Table 7.1.1, FSIS estimates that an average of 6,600 cattle oral ID50s would potentially be available for human exposure, with a range of 3,000 to 13,000 ID50s in the 5 to 95 percent interval and a median

of 5,700 ID50s. The major sources of infectivity are AMR (2,900 ID50s, 43.9 percent), beef-on-bone (1,500 ID50s, 22.7 percent), brain (1,300 ID50s, 19.7 percent), spinal cord (470 ID50s, 7.1 percent), and distal ileum (420 ID50s, 6.4 percent).

Table 7.1.2: Levels and Incremental Reductions in Potential Human Exposure to the BSE Agent for the Risk Management Alternatives Scenarios

Regulatory Alternative Scenarios	Potential Human Exposure (cattle oral ID50s) (Total Potential to Humans – for base case of 500 imported cattle)									Incremental Reduction of mean potential human exposure from the base case
	Mean	Standard Deviation	5%	50%	95%	99.0%	99.5%	99.9%	Maximum	
Base Case: baseline of 500 imported cattle	6,600	3,200	3,000	5,700	13,000	17,000	19,000	22,000	28,000	-
(1) Scenario 1: Ban non-ambulatory cattle for use as human food	6,400	3,200	2,900	5,500	13,000	17,000	19,000	22,000	28,000	3.03%
(2) Scenario 2: Ban SRMs from cattle 12 months of age and older at slaughter for use as human food – 100% compliance	17	7.6	6.3	16	31	39	43	51	66	99.74%
(3) Scenario 3: Ban SRMs from cattle 24 months of age and older at slaughter for use as human food – 100% compliance	17	12	6.3	16	31	39	43	53	1,500	99.74%
(4) Scenario 4: Ban SRMs from cattle 30 months of age and older at slaughter for use as human food – 100% compliance	20	58	6.5	16	34	72	170	450	7,300	99.70%
(5) Scenario 5: Ban SRMs from cattle 30 months of age and	670	970	49	430	1,900	6,700	7,000	8,400	15,000	89.85%

older at slaughter for use as human food – 90% compliance										
(6) Scenario 6: Ban SRMs from cattle 30 months of age and older at slaughter for use as human food – 95% compliance	350	700	16	210	1,100	3,200	6,600	7,000	9,600	94.70%
(7) Scenario 7: Ban SRMs from cattle 30 months of age and older at slaughter for use as human food – 99% compliance	83	290	7.7	22	270	910	1,500	6,400	7,300	98.74%
(8) Final Rule. Scenario 8: Ban non-ambulatory cattle for use as human food and SRMs from cattle 30 months of age and older at slaughter for use as human food – 100% compliance	20	53	6.1	15	33	84	180	630	3,200	99.70%

The Harvard risk assessment expresses the amount of infectivity to which consumers might be exposed in terms of cattle oral ID50s (Cohen et al., 2005).
- The risk assessment baseline assumes that cattle producers introduce 500 BSE-infected cows in year 2004. FSIS implemented regulatory alternative in the same year.
- The risk analysis assumes that FSIS has restrictions on AMR products.
- FSIS based the incremental reductions on the means – percentage reduction in mean potential exposure compared to previous regulatory alternative.
- 50,000 simulation runs
- FSIS 2006 Analysis (December 2006)

Scenario 1 (A100), the first risk management alternative—a ban on non-ambulatory disabled cattle offered for slaughter–is estimated to reduce mean potential exposure by a negligible amount (200 cattle oral ID50s), with small reductions in infectivity via the beef-on-bone and contaminated muscle meat pathways.

FSIS estimated that each of the other seven scenarios or risk management alternatives to reduce mean exposure between 5,930 and 6,583 cattle oral ID50s, which is a 89.85 to 99.74 percent reduction compared to the baseline (base case), respectively. They are all estimated to reduce mean potential from the main non-AMR sources of infectivity–brain, beef-on-bone, distal ileum, and spinal cord–to very close to zero. In each case, a majority of the remaining infectivity (roughly 1 to 10 percent) is associated with the contaminated muscle meat pathway and non-compliance issues of SRM removal.

Comparing the seven scenarios or risk management alternatives involving SRM removal (Scenarios 2 through 8), the main difference in reduced infectivity is between the options using a 30-month age cutoff and those using a lower age cutoff. FSIS estimated imposing a 24- or 12-month age cutoff to reduce mean potential human exposure compared to

a 30-month cutoff. However, these additional reductions are small (less than 0.1 percent) compared to the baseline.

For the results shown in Table 7.1.2, FSIS separated non-ambulatory disabled cattle offered for slaughter into two groups: those displaying CNS signs and those that do not (for example, due to a broken leg). The BSE risk-assessment model accounts for non-ambulatory disabled cattle offered for slaughter that do display signs 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 offered for slaughter is unknown but this is potentially real. Consequently, the reductions in potential human exposure shown in Table 7.1.2 most likely underestimate the reduction in exposure that results from the ban on non-ambulatory cattle offered for slaughter. This consequently overestimates the remaining infectivity. The effect of subsequent mitigations is therefore somewhat overestimated.

To evaluate the sensitivity of model results reported in Table 7.1.2, FSIS tested whether the model would predict linear increases in potential human exposure if the number

of infected animals were changed. Table 7.1.3 summarizes the potential human exposure predicted by the baseline when different numbers of infected animals are imported.

Table 7.1.3: Potential Human Exposure to the BSE Agent (cattle oral ID50s) under Alternative Baseline Assumptions Regarding Number of Infected Animals Cattle Producers Introduced[a]

Number of Infected Cattle Introduced	Potential Human Exposure (cattle oral ID50s) (Total Potential to Humans – for base case of 10 imported animal or 500 imported animals)							
	Mean	5%	50%	95%	99.0%	99.5%	99.9%	Maximum
	Baseline							
10 imported animals (750,000 simulations)	130	64	110	260	330	380	430	550
500 imported animals (50,000 simulations)	6,600	3,200	5,700	13,000	17,000	19,000	22,000	28,000

[a]All estimates assume no restrictions on AMR.

The table shows that the average potential human exposure depends (essentially linearly) on the number of animals assumed to enter the United States. Increasing the number of infected animals introduced by a factor of 50 (only at the mean) from 10 to 500 increased the mean exposure estimate by a factor of 50.7. It is important to note that both of these baseline estimates shown in Table 7.1.3 assume no restrictions on AMR; however, this

assumption should not affect the main conclusion regarding the proportionality of human exposure with respect to the number of infected animals.

Based on the results summarized in this section, FSIS has concluded that this final rule 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 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 cattle origin, such as some pharmaceuticals; gelatin; and beef stocks, extracts, and flavorings. Establishments derive many of these products through the edible rendering process.

In Table 7.1.4, FSIS presents a summary of the difference between the PRIA and the FRIA and the effect of those differences on the benefits of the final rule.

Table 7.1.4: Summary of Areas of Differences between the Results of the PRIA Compared to the Results of the FRIA and the Impact of those Differences on the Benefits of the Final Rule

Topic	PRIA	FRIA	Change in the results of the FRIA of the Final Rule because of change in the data or assumptions made in the FRIA compared to assumptions of the PRIA
Non-Ambulatory Disabled Cattle	Used industry estimate to assume deterministic values	Used FSIS database to determine probability distribution of values	Lowers costs of compliance. No change in the benefits of compliance.
Specified Risk Materials	Establishments affected included only those that were federally or state inspected	Establishments affected included those federally inspected, state inspected, and custom-exempt establishments	Increases costs of compliance because of the increase in the number of affected establishments. Increases benefits of compliance.
Distal ileum	Assumes that the entire small intestine including the distal ileum was not allowed for human food	Assumes only the distal ileum is not allowed for human food. The rest of the small intestine is available for human food.	Lowers costs of compliance. No change in the benefits of compliance.
Harvard Risk Assessment	2001/2003 HRA does not assume non-compliance effects	2005 Harvard BSE Update assumes non-compliance effects	Increases benefits of compliance.

7.2. Restoration of Beef Export Markets

In 2003, U.S. exports of beef, veal, and beef variety meats were valued at $3,861.9 million (see Tables 6.1.5 and 6.1.6, in Section 6). After the discovery of BSE in Washington State, in December 2003, U.S. beef exports declined dramatically. About 63 countries initially banned U.S. beef from entering their borders.

The FRIA does estimate a benefit for the restoration of beef export markets (gross sales), which may, in part,

have been affected by this final rule. However, because of the many other factors that are also relevant to re-gained market access, the affects on the restoration of beef export markets that may be attributed to the measures implemented in this final rule are difficult to determine. In pre-BSE 2003, beef export markets totaled $3,861.9 million annually for veal, beef, and beef variety meats. Then, in post-BSE 2004, these beef export market sales dropped about 79 percent or $3,053.8 million to $808.1 million. However, in 2005, the U.S. had restored its beef export market sales to a total of $1,365.3million. Compared to 2004, this is an increase of about 69 percent or $557.2 million in beef export market sales.

7.3. The Benefits of the Final Regulations - Summary of Costs and Benefits

The benefits of this final rule occur through reductions in potential human exposure to the BSE agent. Because the amount of the BSE agent necessary to cause disease in humans is unknown, FSIS has not estimated monetary values for reductions in human morbidity and mortality associated with these measures. However, FSIS estimates that the total annualized average cost of the final rule is about $171.2 million over five years at an

interest rate of 7 percent.[26] In addition, FSIS estimates that the total annualized average cost of the final rule is about $171.0 million over five years at an interest rate of 3 percent. Furthermore, FSIS estimated beef, veal, and beef variety meat export benefits increased from $808.1 million in 2004 to $1,365.3 million in 2005. This U.S. restoration of beef export market sales is a result of the SRM interim final rule and related measures that provide a substantial level of assurance to foreign consumers that the U.S. beef food supply is safe.

The benefits of this final rule are likely to be underestimated for several reasons. First, the benefit figures do not include any estimates of human lives saved from vCJD. Second, the benefit figures do not include any estimate of the growth in beef domestic consumption due to increased confidence in U.S. beef products being free of the BSE agent.

7.4. Cost-effectiveness Analysis

An important approach to evaluate regulatory impact is a cost-effectiveness analysis (CEA), which offers a slightly different perspective of the economic impact from

[26] FSIS estimated higher costs compared with those estimated for the PRIA of the interim final rule because more establishments needed to take measures than what the PRIA anticipated. However, the PRIA accounted for the removal of the entire small intestine instead of just the distal ileum portion of the small intestine. The savings of only removing the distal ileum offset partially the extra costs of more establishments (state-inspected and custom-exempt) needing to take the measures required by the final rule.

a benefit-cost analysis (BCA) and does not require monetization of all relevant benefits.

Comparison of Relative Exposure Reduction and Cost of SRM Removal Alternative Scenarios

A comparison of the cost and potential reduction in human exposure associated with different regulatory alternative scenarios for the final rule provides a general indication of the relative effectiveness of the scenarios. Table 7.4.1 provides such a comparison for the regulatory alternative scenarios discussed in the final benefit analysis. FSIS examined each of the regulatory scenarios based on their total cost for achieving the reduction of potential human exposure to the BSE agent. FSIS described the derivation of the reduction in potential human exposure associated with each of the regulatory scenarios in the final benefits analysis.

Table 7.4.1: Comparison of Average Change in Potential Human Exposure to the BSE Agent and the Average Cost of the Regulatory Alternative Scenarios[a]

Regulatory Alternative Scenarios	Cumulative Mean Reduction in Potential Human Exposure to Cattle Oral ID50s (percent reduction)	Incremental Mean Reduction in Potential Human Exposure to Cattle Oral ID50s (percent reduction)	Cumulative Cost[b] (thousand$)	Incremental Cost[b] (thousand$)
Scenario 1: A100: Ban non-ambulatory cattle offered for slaughter for use as human food	200 (3.03%)	200 (3.03%)	$5,923	$5,923
Scenario 5: B3090: Ban SRMs from cattle 30 months of age and older at slaughter for use as human food – 90% compliance	5,930 (89.85%)	5,730 (86.82%)	$150,677	$144,754
Scenario 6: B3095: Ban SRMs from cattle 30 months of age and older at slaughter for use as human food – 95% compliance	6,250 (94.70%)	520 (7.88%)	$157,717	$7,040
Scenario 7: B3099: Ban SRMs from cattle 30 months of age and older at slaughter for use as human food – 99% compliance	6,517 (98.74%)	267 (0.04%)	$163,348	$5,631
Scenario 4: B30100: Ban SRMs from cattle 30 months of age and older at slaughter for use as human food – 100% compliance	6,580 (99.70%)	63 (0.96%)	$164,756	$1,408
Scenarios 8: AB30100: Ban non-ambulatory cattle offered for slaughter for use as human food and SRMs from cattle 30 months of age and older at slaughter for use as human food – 100% compliance	6,580 (99.70%)	0 (0.00%)	$171,184	$6,428
Scenario 3: B24100: Ban SRMs from cattle 24 months of age and older at slaughter to human food – 100% compliance	6,583 (99.74%)	3 (0.04%)	$503,973	$332,789
Scenario 2: B12100: Ban SRMs from cattle 12 months of age and older at slaughter to human food – 100% compliance	6,583 (99.74%)	0 (0.00%)	$569,973	$66,000

[a]All values are estimates of average distributions and 7% interest rate unless otherwise identified.

[b]The cost calculations assume that 5 percent of steers and heifers are 30 months of age and older or would be classified as 30 months of age and older based on dentition, 10 percent of steers and heifers are 24 months of age and older, and 95 percent of steers and heifers are 12 months of age and older.

As previously reported in Section 7.1, FSIS estimated Scenario 1 — the ban on the use for human food of disabled non-ambulatory cattle offered for slaughter — to reduce mean exposure by about 200 cattle oral ID50s, or 3 percent. FSIS estimates the average cost of this ban scenario to be $5.9 million. Relative to Scenario 1, each of the remaining seven scenarios would further reduce exposure by approximately 5,930 to 6,583 cattle oral ID50s, or 89.8 to 99.7 percent. The additional average costs of these seven scenarios relative to the ban only on the use as human food of non-ambulatory disabled cattle offered for slaughter alternative are estimated to vary from $150.7 million (Scenario 5 — SRM removal with a 30-months age cutoff and 90 percent compliance) to $570.0 million (Scenario 2 — SRM removal with a 12-months age cutoff).

For the SRM removal scenarios or alternatives, lowering the age cutoff from 30 months to 24 months increases average costs by about $164.8 million, and lowering the cutoff from 24 to 12 months increases average costs by another $66.0 million. Adding a ban on non-

ambulatory disabled cattle offered to slaughter to the SRM removal scenarios adds costs of roughly $6 million in each case.

The alternative selected by FSIS — Scenario 8 — reduces estimated mean exposure from the baseline by about 6,580 cattle oral ID50s, or 99.7 percent, at an average cost of $171.2 million. Compared to Scenario 4, which does not include the ban on non-ambulatory disabled cattle offered for slaughter, it reduces estimated mean exposure by the same amount of cattle oral ID50s or percent of the baseline level and adds about $6.4 million in average costs.

As noted in Section 7.1, FSIS did consider the reduction in potential human exposure to BSE from non-ambulatory disabled cattle offered for slaughter that do not display clinical signs of CNS disorders in its determination of the reductions in potential human exposure to the BSE agent. Removal of non-ambulatory cattle offered for slaughter for use as human food reduces the total amount of potential human infectivity. This effectively reduces the proportion of unmitigated potential human infectivity that can be reduced by further FSIS mitigations.

In Table 7.4.2, FSIS presents a summary of the differences between the PRIA and the FRIA, and the impacts of the changes resulting from the updated HRA (Harvard Risk Assessment). In Table 7.4.3, FSIS compares the distribution (minimum, maximum, 5^{th} percentile, median (50^{th} percentile), average, 95^{th} percentile, and standard deviation) of cost-effectiveness ratio values in the PRIA and the FRIA.

Table 7.4.2: Summary of the Differences Between the PRIA that Used the Results of the 2002 Harvard Risk Assessment and the FRIA that Used the updated and re-modeled 2005 Harvard Risk Assessment, and the Impacts of the Changes Resulting from the 2005 Harvard BSE Update

Topic	PRIA used 2002 Harvard Risk Assessment	FRIA used updated and re-modeled 2005 Harvard Risk Assessment	Impacts of the Changes Resulting from the Updated and Re-modeled Harvard Risk Assessment
Non-compliance Issues	Not considered	Considered	Lowers costs of compliance and lowers benefits
Reduction in potential human exposure to BSE from non-ambulatory disabled cattle offered for slaughter that do not display clinical signs of CNS disorders	Not considered	Considered	Reduces the possible overestimate of the risk reduction to human exposure
Base Case	10 imported cattle	500 imported cattle	The scale was changed by a factor of about 50. However, scaling is linear. The risk assessments results can be interpolated to 10 imported cattle or any other number of imported cattle.
Some of the risk management alternative scenarios were changed or omitted	7 risk management alternative scenarios	8 risk management alternative scenarios: The new alternatives or scenarios included differences in compliance for the final rule – 90 to 100 percent compliance	The new alternative scenarios allowed for an evaluation (sensitivity analysis) of the differences in compliance for the final rule – 90 to 100 percent compliance

Table 7.4.3: Comparison of the Distribution (Minimum, Maximum, 5th percentile, Median (50th percentile), Average, 95th percentile, and Standard Deviation) of Cost-Effectiveness Ratio Values in the PRIA and the FRIA

Measure	Cost-Effectiveness Ratio of Average Cost of Compliance to the Final Rule to Mean Potential to Humans Exposure Reduction of Cattle Oral ID50s (for 500 imported cattle)			
	PRIA		FRIA	
	7 Percent	3 Percent	7 Percent	3 Percent
Minimum	$5,490	NA[a]	$3,207	$3,203
5th Percentile	$9,383	NA	$13,033	$13,018
Median	$13,522	NA	$29,738	$29,707
Average	$13,642	NA	$31,899	$31,866
95th Percentile	$29,741	NA	$58,207	$58,147
Maximum	$32,311	NA	$121,748	$121,643
Standard Deviation	$2,839	NA	$14,005	$13,992

[a] NA data not available

8.0. Compliance with Regulatory Flexibility Act of 1996

The Regulatory Flexibility Act (RFA) requires that FSIS conduct a final regulatory flexibility analysis (FRFA) to determine if the final rule will have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). The Act defines small entities as businesses that have less than 500 employees that are full-time equivalent. If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory

options or alternatives that would lesson the economic effect of the rule on small entities.

8.1. Number and Type of Small Businesses Affected

Table 8.1.1 presents estimates of the number of small businesses or small entities affected by the final rule. FSIS derived these numbers from Table 6.1.1 that indicates estimated numbers of establishments affected by the final rule. Although many affected companies own multiple establishments, the vast majority of affected companies own a single establishment. For federally inspected slaughter establishments, available information allowed us to provide direct counts of the number of affected small entities. However, for state-inspected and custom-exempt establishments, FSIS assumed that all very small establishments (with 9 or fewer employees) and small (class-I and class-II) establishments (with 10 to 499 employees) are owned by small businesses that own a single establishment.

Thus, based on the available data, the final rule affects an estimated 3,475 small establishments in some manner. Of these, 731 are under federal inspection and 1,430 are under state inspection. The final rule affects an estimated 1,314 small establishments that own custom-exempt

establishments because they can no longer slaughter or process non-ambulatory disabled cattle of livestock producers, and they must remove SRMs during the slaughter process or in processing operations.

Table 8.1.1: Estimated Population of Small Establishments Potentially Affected by the SRM and Non-Ambulatory Disabled Cattle Final Rule's Requirements

Type of Inspection	Category	No. of Establishments
Federal Inspection (2003)	Cattle slaughter and processing	680
	Beef processing-only	51
	Total Federal Inspection	731
State Inspection (2003/2004)	Meat slaughter only	743
	Meat processing-only	84
	Meat combination	603
	Total State Inspection	1,430
Custom-Exempt[a] (2003/2004)	Meat slaughter only	34
	Meat combination	1,280
	Total Custom-Exempt	1,314
	Total Small Entities	3,475

[a]Small entities that own custom-exempt establishments are affected to the extent that they must remove SRMs and that they can no longer slaughter or process non-ambulatory cattle of livestock producers. Custom-exempt operations occur in federally- and state-inspected establishments. However, these custom-exempt operations are accounted for in the analysis of federally- and state-inspected establishments.

8.2. Costs to Small Entities

FSIS measured the effects on small entities or small businesses in terms of the direct costs of the regulation and in terms of the estimated resulting effects on

establishment or firm closures and profitability of small companies.

- **Effects on Small Businesses that Slaughter Cattle**

The economic impact model presented in Section 6.5 compares the costs of compliance for beef slaughter establishments that operate under federal inspection. FSIS provides this comparison in Table 8.2.1. Small entities own 95 percent of the establishments but slaughter 25 percent of the industry volume for federally inspected establishments. Because their per-unit costs of compliance are higher than for large entities, their total compliance costs comprise 34 percent of the total compliance costs for federally inspected slaughter establishments.

Table 8.2.1: Capacity and Compliance Costs Comparisons for Small and Large Entities, Annually, 2003: Federally Inspected Slaughter Establishments

Entity Size	Number of Companies	Number of Establish-ments	Share of Establish-ments	Beef and Veal Production (CE/year)[a]		Total Compliance Costs, per Year, 7% Interest Rate	
				Total Carcasses	Share	Total ($thousand)	Share
Very Small	451	528	74%	733,210	2.0%	$3,358	3.5%
Small Class I	79	100	14%	915,195	2.6%	$5,920	8.5%
Small Class II	38	52	7%	7,262,665	20.2%	$46,137	29.7%
All of Above Small Entities	568	680	95%	8,911,070	24.8%	$55,415	34.2%
Large	21	36	5%	26,971,687	75.2%	$106,765	65.8%
Total	589	716	100%	35,882,757	100%	$162,181	100%

[a] Note: CE = carcass equivalent.

FSIS provides the comparison in Table 8.2.2 of the beef and veal capacity (slaughter volume), the dressed carcass equivalent (CE) value, and compliance costs for small and large entities. The dressed carcass equivalent (CE) value of beef ranged from $1.00 to $1.25 per pound, and of veal and heavy-calf beef ranged from $1.20 to $2.25 per pound. FSIS calculates the compliance costs as a proportion of dressed carcass equivalent (CE) value for federally-inspected slaughter establishments. The very small establishments have compliance costs at about 7 tenths of one percent (0.66%) of the value of beef sales. Further, the small-class I and II establishments have proportions of about 8 to 7 tenths of one percent (0.77% to 0.72%), respectively. In addition, the large establishments have compliance costs at about 4 tenths of one percent (0.42%). Thus, the low ratio values of the compliance costs of small entities compared to the value of their beef and veal production indicate that the rule does not have a significant economic impact on a substantial number of small entities.

Table 8.2.2: Capacity and Compliance Costs Comparisons for Small and Large Entities, Annually, 2003: Compliance Cost as a Proportion of Dressed Carcass Equivalent (CE) Value of Beef and Veal, for Federally Inspected Slaughter Establishments

Entity Size	Number of Establ-ishments	Production of Beef and Veal (CE/year)[a]			Total Compliance Costs, per Year, 7% Interest Rate			
		Total Carcasses (CE)	Dressed Carcasses (CE), millions of pounds	Dressed Carcass (CE) Value, $millions	Total, $millions	Share	Per Establishment	Compliance cost as a proportion of dressed carcass (CE) value
Very Small	528	733,210	509.2	$511.9	$3.4	2.1%	$6,439	0.66%
Small Class I	100	915,195	584.2	$764.9	$5.9	3.7%	$5,900	0.77%
Small Class II	52	7,262,665	5,015.5	$6,410.8	$46.1	28.7%	$886,538	0.72%
All above small entities	680	8,910,070	6,108.9	$7,687.6	$55.4	34.2%	$81,470	0.72%
Large	36	26,971,687	20,120.9	$25,151.1	$106.8	65.8%	$2,966,667	0.42%
Total	716	35,882,757	26,229.8	$32,838.7	$162.2	100%	$226,536	0..49%

[a] Note: CE = carcass equivalent.

FSIS assumed that small entities own all cattle slaughter establishments that are under state inspection. As presented in Section 6.3, FSIS assumed that the total annual costs of compliance for state-inspected cattle slaughter establishments, including both annual ongoing costs and annualized capital equipment costs, is $4.5 million. In addition, the annual compliance cost for custom-exempt slaughter establishments is $1.7 million. Although the total compliance costs for state-inspected and custom-exempt slaughter establishments owned by small entities are substantially less than for federally inspected slaughter establishments, the number of affected establishments is substantially greater. However, because of insufficient data on state-inspected and custom-exempt slaughter establishments, it is not possible to estimate the number of small entity closures for these other establishment types.

In addition to slaughter establishments that might have closed because of the costs of compliance with the SRM interim final rule, some establishments closed because they slaughtered mostly non-ambulatory cattle prior to the SRM interim final rule and, thus, can no longer operate without a change in the type of cattle or livestock slaughtered. FSIS does not have a reliable method of estimating the

number of establishments that slaughtered mostly non-ambulatory cattle prior to publication of the SRM interim final rule.

FSIS provides the comparison in Table 8.2.3 of the beef and veal capacity (slaughter volume), the dressed carcass equivalent (CE) value, and compliance costs for small entities that are state inspected. The dressed carcass equivalent (CE) value of beef ranged from $1.00 to $1.25 per pound, and of veal and heavy-calf beef ranged from $1.20 to $2.25 per pound. FSIS calculates the compliance costs as a proportion of dressed carcass equivalent (CE) value for state-inspected slaughter establishments. The very small establishments have compliance costs at about one percent (0.96%) of the value of beef and veal sales. Further, the small-class I have a proportion of about one percent (1.23%). There were no small-class II establishments and large establishments affected by this final rule. In addition, these small state-inspected establishments slaughtered and processed other species. Therefore, the value of sales from these establishments was more than just the beef and veal sales. The ratio values of the compliance costs of small entities compared to the value of their total production would be even lower than that for just the value of the beef and

veal sales. Thus, the low ratio values of the compliance costs of small entities compared to the value of their total production indicate that the rule does not have a significant economic impact on a substantial number of small entities that are state inspected.

Table 8.2.3: Capacity and Compliance Costs Comparisons for Small and Large Entities, Annually, 2003: Compliance Cost as a Proportion of Dressed Carcass Equivalent (CE) Value of Beef and Veal, for State Inspected Slaughter Establishments

Entity Size	Number of Establishments	Production of Beef and Veal (CE/year)[a]			Total Compliance Costs, per Year, 7% Interest Rate			
		Total Carcasses (CE)	Dressed Carcasses (CE), millions of pounds	Dressed Carcass (CE) Value, $millions	Total, $millions	Share	Per Establishment	Compliance cost as a proportion of dressed carcass (CE) value
Very Small	1,323	516,966	385.6	$482.0	$3.7	82%	$2,797	0.96%
Small Class I	23	69,663	52.0	$65.0	$0.8	18%	$34,783	1.23%
Small Class II	0	0	0	$0	$0	0%	$0	0.0%
All above small entities	1,430	586,629	437.6	$547.0	$4.5	100%	$3,147	0.82%
Large	0	0	0	$0	$0	0%	$0	0.0%
Total	1,430	586,629	437.6	$547.0	$4.5	100%	$3,147	0..82%

[a] Note: CE = carcass equivalent.

FSIS provides the comparison in Table 8.2.4 of the beef and veal capacity (slaughter volume), the dressed carcass equivalent (CE) value, and compliance costs for small entities that are custom exempt from inspected. The dressed carcass equivalent (CE) value of beef ranged from $1.00 to $1.25 per pound, and of veal and heavy-calf beef ranged from $1.20 to $2.25 per pound. FSIS calculates the compliance costs as a proportion of dressed carcass equivalent (CE) value for custom-exempt establishments. The very small establishments have compliance costs at about one percent (1.19%) of the value of beef and veal sales. There were no small-class I, small-class II, and large establishments affected by this final rule. In addition, these small custom-exempt establishments slaughtered and processed other species. Therefore, the value of sales from these establishments was more than just the beef and veal sales. The ratio values of the compliance costs of small entities compared to the value of their total production would be even lower than that for just the value of the beef and veal sales. Thus, the low ratio values of the compliance costs of small entities compared to the value of their total production indicate that the rule does not have a significant economic impact on a

substantial number of small entities that are custom exempt.

Table 8.2.4: Capacity and Compliance Costs Comparisons for Small and Large Entities, Annually, 2003: Compliance Cost as a Proportion of Dressed Carcass Equivalent (CE) Value of Beef and Veal, for Custom-Exempt Establishments

Entity Size	Number of Establishments	Production of Beef and Veal (CE/year)[a]			Total Compliance Costs, per Year, 7% Interest Rate			
		Total Carcasses (CE)	Dressed Carcasses (CE), millions of pounds	Dressed Carcass (CE) Value, $millions	Total, $millions	Share	Per Establishment	Compliance cost as a proportion of dressed carcass (CE) value
Very Small	1,314	153,496	114.5	$143.1	$1.7	100%	$1,294	1.19%
Small Class I	0	0	0	$0	$0	0%	$0	0.0%
Small Class II	0	0	0	$0	$0	0%	$0	0.0%
All above small entities	1,314	153,496	114.5	$143.1	$1.7	100%	$1,294	1.19%
Large	0	0	0	$0	$0	0%	$0	0.0%
Total	1,314	153,496	114.5	$143.1	$1.7	100%	$1,294	1.19%

[a] Note: CE = carcass equivalent.

- **Effects on Small Entities that Process-Only Beef**

As noted in Table 8.1.1, an estimated 51 small entities own federally inspected beef processing-only establishments and 84 small entities own state-inspected beef processing-only establishments. Beef processing-only establishments are affected by the final rule if they receive carcasses or parts of cattle containing vertebral columns from cattle 30 months of age and older. The final rule affects other beef processing-only establishments only to the extent that they must verify that incoming beef shipments do not contain these SRMs materials. If FSIS assumes that small entities own all very small and small beef processing establishments, then FSIS estimates that the total annual costs of compliance for very small and small beef processing-only entities is $2.5 million. Large entities incur the remaining $0.2 million. Based on the results of the FRIA presented in Section 6.5, FSIS estimates that the cost of compliance with the final rule results in relatively small impacts on small entities. Thus, the estimated impacts of the regulation on small entities that own beef processing-only establishments are small.

FSIS provides the comparison in Table 8.2.5 of the beef and veal capacity (processing-only volume of carcasses or parts of carcasses), the carcass equivalent (CE) value, and compliance costs for small and large entities that were federally inspected. The carcass equivalent (CE) value of further processed beef and veal was $1.75 per pound. FSIS calculates the compliance costs as a proportion of carcass equivalent (CE) value for federally-inspected processing-only establishments. The very small establishments have compliance costs at about 7 tenths of one percent (0.69%) of the value of further processed beef and veal sales. Further, the small-class I and II establishments have proportions of about 5 to 7 tenths of one percent (0.52% to 0.72%), respectively. In addition, the large establishments have compliance costs at about 7 tenths of one percent (0.71%). Thus, the low ratio values of the compliance costs of small entities compared to the value of their beef and veal processing-only production/fabrication indicate that the rule does not have a significant economic impact on a substantial number of federally-inspected small entities that have process-only operations to further process and add value to beef and veal carcasses or parts of carcasses.

Table 8.2.5: Capacity and Compliance Costs Comparisons for Small and Large Entities, Annually, 2003: Compliance Cost as a Proportion of Dressed Carcass Equivalent (CE) Value of Beef and Veal, for Federally-Inspected Processing-Only Establishments

Entity Size	Number of Establishments	Processing-Only Production/Fabrication of Beef and Veal (CE/year)[a]			Total Compliance Costs, per Year, 7% Interest Rate			
		Total Carcasses (CE)	Dressed Carcasses (CE), millions of pounds	Dressed Carcass (CE) Value, $millions	Total, $millions	Share	Per Establishment	Compliance cost as a proportion of dressed carcass (CE) value
Very Small	29	1,329	0.991	$1.735	$0.012	0.5%	$403	0.69%
Small Class I	15	150,770	112.474	$196.830	$1.029	40.7%	$68,628	0.52%
Small Class II	7	131,145	97,834	$171.210	$1,238	48.9%	$176,886	0.72%
All above small entities	51	281,915	210.308	$369.775	$2,279	90.1%	$44,692	0.62%
Large	1	27,079	20.201	$35.352	$0.250	9.9%	$249,847	0.71%
Total	52	308,994	230.510	$405.1	$2.529	100%	$48,638	0.62%

[a] Note: CE = carcass equivalent.

FSIS provides the comparison in Table 8.2.6 of the beef and veal capacity (processing-only volume of carcasses or parts of carcasses), the carcass equivalent (CE) value, and compliance costs for small entities that were state inspected. The carcass equivalent (CE) value of further processed beef and veal was $1.75 per pound. FSIS calculates the compliance costs as a proportion of carcass (CE) value for state-inspected processing-only establishments. The very small establishments have compliance costs at about 6 tenths of one percent (0.64%) of the value of beef and veal sales. There were no small-class I, small-class II, and large establishments that were state inspected, affected by this final rule. Thus, the low ratio values of the compliance costs of small entities compared to the value of their beef and veal processing-only production/fabrication indicate that the rule does not have a significant economic impact on a substantial number of state-inspected small entities that have process-only operations to further process and add value to beef and veal carcasses or parts of carcasses.

Table 8.2.6: Capacity and Compliance Costs Comparisons for Small and Large Entities, Annually, 2003: Compliance Cost as a Proportion of Dressed Carcass Equivalent (CE) Value of Beef and Veal, for State-Inspected Processing-Only Establishments

Entity Size	Number of Establishments	Processing-Only Production/Fabrication of Beef and Veal (CE/year)[a]			Total Compliance Costs, per Year, 7% Interest Rate			
		Total Carcasses (CE)	Dressed Carcasses (CE), millions of pounds	Dressed Carcass (CE) Value, $millions	Total, $millions	Share	Per Establishment	Compliance cost as a proportion of dressed carcass (CE) value
Very Small	84	28,785	21.5	$37.6	$0.204	100.0%	$2,428	0.64%
Small Class I	0	0	0	$0	$0	0.0%	$0	0.0%
Small Class II	0	0	0	$0	$0	0.0%	$0	0.0%
All above small entities	84	28,785	21.5	$37.6	$0.204	100.0%	$2,428	0.64%
Large	0	0	0	$0	$0	0.0%	$0	0.0%
Total	84	28,785	21.5	$37.6	$0.204	100%	$2,428	0.64%

[a] Note: CE = carcass equivalent.

In Table 8.2.7, FSIS shows the shift in burden or costs between establishment sizes from the PRIA to the FRIA. The table has the proportion or share of costs for small entities. In addition, in Table 8.2.8, FSIS presents the summary of the findings for cost-effectiveness and the impact on small entities. The discussion on the cost-effectiveness ratios of small entities when compared to large entities is to follow.

Table 8.2.7: The Shift in Burden or Costs for Establishments of Different Sizes from the PRIA to the FRIA Annually (Million Dollars)

	PRIA of the Interim Rule (without the impact of the AMR Interim Final Rule): Effect by Establishment Size					FRIA of the Final Rule: Effects by Establishment Size					
	Very Small	Small	Large	All Entities[a]	Proportion of Costs for All Small Entities[b]	Very Small	Small Class I	Small Class II	Large	All Entities[a]	Proportion of Costs for All Small Entities[b]
Annualized Cost at 7 percent rate	$7.8	$22.5	$75.3	$105.6	28.7%	$9.0	$7.8	$47.4	$107.0	$171.2	38%
Annualized Cost at 3 percent rate	$7.7	$22.4	$75.1	$105.2	28.6%	$9.0	$7.8	$47.4	$106.8	$171.0	38%

[a] all entities are very small, small, and large establishments combined
[b] small entities are very small and small establishments combined
[c] NA data not available

Table 8.2.8: Summary of the Findings of the FRIA Regarding Cost-Effectiveness and the Impact on Small Entities for Federally Inspected Slaughter Establishments, Annually (Thousand Dollars)

Company Size	Number of Companies	Number of Establishments	Share of Establishments	Benefits (mean risk reduction in cattle oral ID50s/year)		Total Compliance Costs, per Year, 7% Interest Rate ($thousands)		Cost-Effectiveness Ratios (Total annual compliance cost per unit of average risk to humans reduction in cattle oral ID50s per year)	
				Total	Share	Total	Share	Ratios	Share
Very Small	451	528	74%	NA[a]	NA	$3,358	2.1%	NA	NA
Small Class I	79	100	14%	NA	NA	$5,920	3.7%	NA	NA
Small Class II	38	52	7%	NA	NA	$46,137	28.4%	NA	NA
All of Above Small Entities	568	680	95%	NA	NA	$55,415	34.2%	NA	NA
Large	21	36	5%	NA	NA	$106,765	65.8%	NA	NA
Total	589	716	100%	6,580	100%	$162,181	100%	$24,648	100%

[a] NA data not available

8.3. Regulatory Options or Alternatives

The Regulatory Flexibility Act requires that FSIS consider options or alternatives for regulatory relief for small entities. In section 6.2 above, FSIS discusses regulatory options and alternatives that FSIS assessed in this analysis of the impacts of the Final Rule. In addition, FSIS is providing relief to small (and large) entities by allowing the use of the small intestine other than the distal ileum, thus allowing companies to recover lost revenues associated with not being able to sell small intestines. However, few small entities rely on revenue from the sale of by-products to operate profitably. FSIS considered other types of relief for small entities, such as permitting then to slaughter acutely injured non-ambulatory cattle that a veterinarian would certify to be otherwise healthy.

Since FSIS issued the SRM and Air-Injection Stunning interim final rules, FSIS has implemented a number of programs to train its inspection personnel and help establishments comply with new requirements. FSIS has issued 12 notices to its inspection personnel that detail specific aspects of the regulations, including BSE surveillance activities in cooperation with USDA’s Animal

and Plant Health Inspection Service (APHIS). In 2004, FSIS held 5 teaching workshops around the country to help primarily small and very small establishments understand the regulations and help ensure compliance. As part of a continuing outreach effort to small and very small establishments, FSIS produced workshop-training materials, (as obtained in December 2006) which remain available on the FSIS Web site. Additionally, FSIS developed and released a training CD and accompanying materials called "The ABC's of BSE," as part of FSIS' distance learning program.

8.4 Conclusion – Final Rule Effect on Small Businesses

Based on the economic analysis above, FSIS has made a final determination that this final rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601).

9.0. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires cost-benefit and other analyses for rules that would cost more than $100 million in a single year. The final rule qualifies as a significant rule under the statute. FSIS has carried out the benefit-cost analysis as

described in Section 7 of this document. The requirements of the Unfunded Mandates Act of 1995 include assessing the rule's effects on the following:

- future costs;
- particular regions, communities, or industrial sectors;
- national productivity and economic growth;
- full employment and job creation; and
- exports.

9.1. Future Costs

The costs of this final rule will recur on an annual basis.

9.2. Particular Regions, Communities, or Industrial Sectors

The final rule applies to establishments that slaughter cattle or process beef using carcasses or parts of cattle received with a vertebral column. It also affects other industrial sectors such as cattle producers and renderers. The cost for a producer is the opportunity lost to salvage a non-ambulatory bovine that becomes acutely injured but is otherwise healthy.

9.3. National Productivity and Economic Growth

FSIS does not expect this final rule to affect substantially productivity or economic growth. Any effects

on productivity and economic growth are confined to the directly regulated industries.

9.4. Full Employment and Job Creation

This final rule affects employment and job creation because some slaughter establishments will not be able to operate any more because they only slaughter non-ambulatory disabled cattle offered for slaughter, but it represents an increase in employment for companies that comply with its requirements.

9.5. Exports

As described in Section 7.2, USDA reported that U.S. veal, beef, and beef variety meat exports increased 69 percent to $1,365.3 million, in 2005, but the exports remain below pre-BSE levels (USDA, FAS, 2006). When export markets are fully open to U.S. beef products, FSIS expects that the value of beef food exports will return to at least the pre-BSE level of $3,800 million annually.

References

- Antle, John. 1995. Choice and Efficiency in Food. Safety Policy, American Enterprise Institute Press. Washington, DC.

- Association of Food and Drug Officials (AFDO) survey of custom-exempt establishments, December 2005. The AFDO web pages are at http://www.afdo.org/

- Cates, S.C., C.L. Viator, S.A. Karns, and P. Siegel. June 2005. "Survey of Meat and Poultry Slaughter and Processing Plants." Prepared for the U.S. Department of Agriculture, Food Safety and Inspection Service. Research Triangle Park, NC: RTI International.

- Cates, S.C., C.L. Viator, S.A. Karns, and P. Siegel. December 2005. "Survey of Processing-Only Plants." Prepared for the U.S. Department of Agriculture, Food Safety and Inspection Service. Research Triangle Park, NC: RTI International.

- Cohen, J.T., K. Duggar, G.M. Gray, and S. Kreindel, Harvard Center for Risk Analysis (HCRA), Harvard School of Public Health and H. Abdelrahman, T. Habtemariam, D. Oryang, and B. Tameru, 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."

- Cohen, J.T., K. Duggar, G.M. Gray, and S. Kreindel, Harvard Center for Risk Analysis (HCRA), Harvard School of Public Health and H. Abdelrahman, T. Habtemariam, D. Oryang, and B. Tameru, Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University. October 2003. "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States."

- Cohen, J.T., and G.M. Gray. October 31, 2005. "Harvard Risk Assessment (HRA) of Bovine Spongiform Encephalopathy Update Phase 1A." Cambridge, MA: Harvard Center for Risk Analysis (HCRA).

- Cohen, J.T., and G.M. Gray. July 2006. "Harvard Risk Assessment (HRA) of Bovine Spongiform Encephalopathy Update Phase 2A." Cambridge, MA: Harvard Center for Risk Analysis (HCRA).

- Cohen, J.T., and G.M. Gray. January 2007. "Harvard Risk Assessment (HRA) of Bovine Spongiform Encephalopathy Update Phase 3A." Cambridge, MA: Harvard Center for Risk Analysis (HCRA).

- Davidson, John. University of California, Davis. February 19, 2004. Personal communications with Dr. James Wilkus, FSIS.

- Doud, G. 2004a. "BSE Economics." Washington, DC: National Cattlemen's Beef Association (NCBA).

- Doud, G., National Cattlemen's Beef Association (NCBA). Teleconference with Mary Muth and Catherine Viator, RTI International, Research Triangle Park, NC. April 15, 2004.

- Food and Drug Administration (FDA). Use of Materials Derived from Cattle in Human Food and Cosmetics. Federal Register. 70 FR 53063, July 14, 2004. http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2004_register&docid=fr14jy04-9.

- Hodges, J., and S. Seward, American Meat Institute (AMI). Teleconference with Mary Muth and Catherine Viator, RTI International, Research Triangle Park, NC. March 31 2004.

- Kjome, David. Minnesota Extension Service. July 10, 2004. Personal communications with Dr. James Wilkus, FSIS.

- Informa Economics (formerly Sparks Company). National Renderers Association Economic Impact Report: The Disposal of Specified Risk Materials of BSE. December 2006. http://www.renderers.org/economic_impact/index.htm.

- Lawrence, T.E. 2001. A comparison of the USDA ossification-based maturity system to a system based on dentition, J. Anim. Sci., 79:1683-1690.

- Mathews, Kenneth H., Jr., Monte Vandeveer, and Ronald A. Gustafson. An Economic Chronology of Bovine Spongiform Encephalopathy in North America. USDA ERS Outlook Report No. (LDPM-14301) 18 pp, June 2006. http://www.ers.usda.gov/publications/ldp/2006/06Jun/ldpm14301/ldpm14301.pdf.

- Schrader, M., U.S. Department of Agriculture, Agricultural Marketing Service. November 13, 2003. Personal communication with Catherine Viator, RTI International.

- Thompson, Roy. University of Minnesota. September 21, 2004. Personal communications with Dr. James Wilkus, FSIS.

- U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS). Economic Analysis: Proposed Rule: Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities. October 24, 2003. http://www.aphis.usda.gov/lpa/issues/bse/bsecan_econ_anal.doc .

- U.S. Department of Agriculture, Foreign Agricultural Service (FAS). March 2004. “Livestock and Poultry: World Markets and Trade.”

- U.S. Department of Agriculture, Foreign Agricultural Service (FAS). March 2005. “Livestock and Poultry: World Markets and Trade.”

- U.S. Department of Agriculture, Foreign Agricultural Service (FAS). March 2006. “Livestock and Poultry: World Markets and Trade.”

- U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS). 2002. Summary Results of the BSE SRMs and Trimmings Survey. Washington, DC: FSIS.

- U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS). January 12, 2004. “Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Cattle” Interim Final Rule. Federal Register. Washington, DC.

- U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS). January 12, 2004. “Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery {AMR) Systems” Interim Final Rule. Federal Register. Washington, DC.

- U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS). January 12, 2004. “Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter” Interim Final Rule. Federal Register. Washington, DC.

- U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS). March 2004. Preliminary Regulatory Impact Analysis of BSE Interim Final Rules: “Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Cattle”; “Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter”; and “Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery {AMR) Systems”. In March 2004, FSIS published the PRIA in its web pages: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/03-025N/BSE_Analysis.pdf.

- U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS). November 2005. Summary results of the state-inspected and custom-exempt establishment survey. Washington, DC: FSIS.

- U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS). December 2003. Summary results of the non-ambulatory disabled cattle survey. Washington, DC: FSIS.

- U.S. Department of Agriculture (USDA), Grain Inspection, Packers and Stockyards Administration (GIPSA). 2003. "Packers and Stockyards Statistical Report: 2001 Reporting Year." SR-03-1. Washington, DC: USDA.

- U.S. Department of Agriculture (USDA), Grain Inspection, Packers and Stockyards Administration (GIPSA). 2004. "Packers and Stockyards Statistical Report: 2002 Reporting Year." SR-04-1. Washington, DC: USDA.

- U.S. Department of Agriculture (USDA), Grain Inspection, Packers and Stockyards Administration (GIPSA). 2005. "Packers and Stockyards Statistical Report: 2003 Reporting Year." SR-05-01. Washington, DC: USDA.

- U.S. Department of Commerce, Economics and Statistics Administration, U.S. Census Bureau. September 2004. "Animal (Except Poultry) Slaughtering: 2002." 2002 Economic Census: Manufacturing. EC02-311-311611. Washington, DC: U.S. Department of Commerce.

- U.S. Department of Labor, Bureau of Labor Statistics. "Employer Cost for Employee Compensation." Available at http://www.bls.gov/ces/home.htm. Data extracted July 27, 2004.

- U.S. International Trade Commission. Interactive Tariff and Trade DataWeb. http://dataweb.usitc.gov/.

Appendices

Appendix A: Establishments-Level and Per-Head Costs of Compliance by Type of Cost

Appendix B: The Inputs, Outputs, and Influential Factors of the Economic Model

Table A1. Summary of Establishment Capital Equipment and Other One-Time Costs Associated with this Final Rule: Federally- and State-Inspected Slaughter Establishments

One-time costs include written plan development (e.g., HACCP, Sanitation SOPs, and other prerequisite programs) and new capital equipment.

	Very Small Establishments								
	Veal/Calves Only			Steers and Heifers[a]			Cows and Bulls Only		
Type of Cost	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum
Written plan development	$39	$78	$117	$578	$617	$656	$578	$617	$656
Capital equipment—non-ambulatory disabled cattle									
• knives, apron, hooks	—	—	—	—	—	—	—	—	—
Capital equipment—segregation									
• dedicated knives	—	—	—	$56	$64	$72	—	—	—
• spinal cord remover	—	—	—	$100	$100	$100	$100	$100	$100
• carcass-splitting saw[b]	—	—	—	—	—	—	—	—	—
Total per Establishment	$39	$78	$117	$734	$781	$828	$678	$717	$756

(continued)

Table A1. Summary of Establishment Capital Equipment and Other One-Time Costs Associated with this Final Rule: Federally- and State-Inspected Slaughter Establishments (continued)

	Small Class I Establishments								
	Veal/Calves Only			Steers and Heifers[a]			Cows and Bulls Only		
Type of Cost	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum
Written plan development	$39	$78	$117	$578	$617	$656	$578	$617	$656
Capital equipment—non-ambulatory disabled cattle									
• knives, apron, hooks	—	—	—	—	—	—	$54	$67	$80
Capital equipment—segregation									
• dedicated knives	—	—	—	$280	$320	$360	—	—	—
• spinal cord remover	—	—	—	$20,000	$22,500	$25,000	$20,000	$22,500	$25,000
• carcass-splitting saw[b]	—	—	—	$2,300	$2,800	$3,300	—	—	—
Total per Establishment	$39	$78	$117	$23,158	$26,237	$29,316	$20,632	$23,184	$25,736

(continued)

Table A1. Summary of Establishment Capital Equipment and Other One-Time Costs Associated with this Final Rule: Federally- and State-Inspected Slaughter Establishments (continued)

Type of Cost	Small Class II Establishments								
	Veal/Calves Only			Steers and Heifers[a]			Cows and Bulls Only		
	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum
Written plan development	$58	$97	$136	$1,139	$1,528	$1,918	$1,139	$1,528	$1,918
Capital equipment—non-ambulatory disabled cattle									
• knives, apron, hooks	—	—	—	—	—	—	$54	$67	$80
Capital equipment—segregation									
• dedicated knives	—	—	—	$280	$320	$360	—	—	—
• spinal cord remover	—	—	—	$20,000	$22,500	$25,000	$20,000	$22,500	$25,000
• carcass-splitting saw[b]	—	—	—	$2,300	$2,800	$3,300	—	—	—
Total per Establishment	$58	$97	$136	$23,719	$27,148	$30,578	$21,193	$24,095	$26,998

(continued)

Table A1. Summary of Establishment Capital Equipment and Other One-Time Costs Associated with this Final Rule: Federally- and State-Inspected Slaughter Establishments (continued)

	Large Establishments								
	Veal/Calves Only			Steers and Heifers[a]			Cows and Bulls Only		
Type of Cost	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum
Written plan development	$78	$117	$156	$2,168	$2,557	$2,946	$2,168	$2,557	$2,946
Capital equipment—non-ambulatory disabled cattle									
• knives, apron, hooks	—	—	—	—	—	—	$108	$134	$160
Capital equipment—segregation									
• dedicated knives	—	—	—	$560	$640	$720	—	—	—
• spinal cord remover	—	—	—	$20,000	$22,500	$25,000	$20,000	$22,500	$25,000
• carcass-splitting saw[b]	—	—	—	$4,700	$4,950	$5,200	—	—	—
Total per Establishment	$78	$117	$156	$27,428	$30,647	$33,866	$22,276	$25,191	$28,106

[a]The estimates for steers and heifers apply to establishments slaughtering steers and heifers only or steers and heifers in addition to other ages of cattle.

[b]FSIS assumed that establishments slaughtering only veal/calves or only cows and bulls do not require a separate carcass-splitting saw.

Table A2. Summary of Per-Head Ongoing (Variable) Costs Associated with this Final Rule: Federally- and State-Inspected Slaughter Establishments

Ongoing costs include labor costs, materials, and value of lost products.

	Very Small Establishments											
	Veal/Calves			Steers and Heifers Under 30 Months			Steers and Heifers 30 Months and Older			Cows and Bulls		
Type of Cost	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum
Non-ambulatory disabled cattle												
• Labor	—	—	—	—	—	—	—	—	—	—	—	—
• Transportation and disposal	—	—	—	—	—	—	—	—	—	—	—	—
Dentition												
• Labor	—	—	—	$0.26	$0.26	$0.26	$0.26	$0.26	$0.26	—	—	—
Segregation												
• Labor	—	—	—	$0.79	$1.57	$2.36	$0.79	$1.576	$2.36	—	—	—
• Materials	—	—	—	$0.30	$0.36	$0.42	$0.30	$0.36	$0.42	$0.30	$0.36	$0.42
Disposal	$0.06	$0.06	$0.06	$0.06	$0.06	$0.06	$0.41	$0.41	$0.41	$0.41	$0.41	$0.41
Vertebral bone-in cuts												
• Labor	—	—	—	—	—	—	$0.00	$3.93	$4.71	$0.00	$3.93	$4.71
• Lost value of meat cuts	—	—	—	—	—	—	$0.00	$4.22	$8.71	$0.00	$4.22	$8.71
Monitoring and verification	—	—	—	$0.03	$0.08	$0.13	$0.03	$0.08	$0.13	$0.03	$0.08	$0.13
Lost value of by-products	$0.00	$0.40	$0.79	$0.00	$0.40	$0.79	$0.00	$1.62	$3.24	$0.00	$1.62	$3.24
Total Per Head	$0.06	$0.46	$0.85	$1.44	$2.73	$4.02	$1.79	$12.46	$20.25	$0.74	$10.624	$17.63

(continued)

Table A2. Summary of Per-Head Ongoing (Variable) Costs Associated with this Final Rule: Federally- and State-Inspected Slaughter Establishments (continued)

	Small Class I Establishments											
	Veal/Calves			Steers and Heifers Under 30 Months			Steers and Heifers 30 Months and Older			Cows and Bulls		
Type of Cost	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum
Non-ambulatory disabled cattle[a]												
• Labor	—	—	—	—	—	—	—	—	—	$0.13	$0.56	$0.84
• Transportation and disposal	—	—	—	—	—	—	—	—	—	$0.20	$1.50	$2.50
Dentition												
• Labor	—	—	—	$0.26	$0.26	$0.26	$0.26	$0.26	$0.26	—	—	—
Segregation												
• Labor	—	—	—	$0.79	$1.57	$2.36	$0.79	$1.57	$2.36	—	—	—
• Materials	—	—	—	$0.30	$0.36	$0.42	$0.30	$0.36	$0.42	$0.36	$0.36	$0.36
Disposal	$0.06	$0.06	$0.06	$0.06	$0.06	$0.06	$0.41	$0.41	$0.41	$0.00	$0.00	$0.62
Vertebral bone-in cuts												
• Labor	—	—	—	—	—	—	$0.00	$3.93	$4.71	$0.00	$3.93	$7.86
• Lost value of meat cuts	—	—	—	—	—	—	$0.00	$4.22	$8.71	$0.00	$8.75	$17.50
Monitoring and verification	—	—	—	$0.03	$0.08	$0.13	$0.03	$0.08	$0.13	$0.03	$0.08	$0.13
Lost value of by-products	$0.00	$0.40	$0.79	$0.00	$0.40	$0.79	$0.00	$1.62	$3.24	$0.00	$1.62	$3.24
Total Per Head	$0.06	$0.46	$0.85	$1.44	$2.73	$4.02	$1.79	$12.46	$20.25	$0.71	$16.80	$33.06

(continued)

Table A2. Summary of Per-Head Ongoing (Variable) Costs Associated with this Final Rule: Federally- and State-Inspected Slaughter Establishments (continued)

	Small Class II Establishments											
	Veal/Calves			Steers and Heifers Under 30 Months			Steers and Heifers 30 Months and Older			Cows and Bulls		
Type of Cost	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum
Non-ambulatory disabled cattle[a]												
• Labor	—	—	—	—	—	—	—	—	—	$0.0.04	$0.20	$0.30
• Transportation and disposal	—	—	—	—	—	—	—	—	—	$0.07	$0.32	$0.48
Dentition												
• Labor	—	—	—	$0.26	$0.26	$0.26	$0.26	$0.26	$0.26	—	—	—
Segregation												
• Labor	—	—	—	$1.54	$1.54	$1.54	$1.54	$1.54	$1.54	—	—	—
• Materials	—	—	—	$0.24	$0.30	$0.36	$0.24	$0.30	$0.36	$0.24	$0.30	$0.36
Disposal	$0.06	$0.06	$0.06	$0.06	$0.06	$0.06	$0.41	$0.41	$0.41	$0.41	$0.41	$0.41
Vertebral bone-in cuts												
• Labor	—	—	—	—	—	—	$0.00	$3.93	$7.86	$0.00	$3.93	$7.86
• Lost value of meat cuts	—	—	—	—	—	—	$0.00	$8.75	$13.54	$0.00	$4.22	$8.71
Monitoring and verification	—	—	—	$0.03	$0.08	$0.13	$0.03	$0.08	$0.13	$0.03	$0.08	$0.13
Lost value of by-products	$0.00	$0.40	$0.79	$0.00	$0.40	$0.79	$0.00	$1.62	$3.24	$0.00	$1.62	$3.24
Total Per Head	$0.06	$0.46	$0.85	$2.13	$2.64	$3.15	$2.49	$16.86	$27.34	$0.79	$11.09	$21.49

(continued)

Table A2. Summary of Per-Head Ongoing (Variable) Costs Associated with this Final Rule: Federally- and State-Inspected Slaughter Establishments (continued)

	Large Establishments											
	Veal/Calves			Steers and Heifers Under 30 Months			Steers and Heifers 30 Months and Older			Cows and Bulls		
Type of Cost	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum	Minimum	Most-Likely	Maximum
Non-ambulatory disabled cattle[a]												
• Labor	—	—	—	—	—	—	—	—	—	$0.02	$0.42	$0.79
• Transportation and disposal	—	—	—	—	—	—	—	—	—	$0.04	$0.67	$1.25
Dentition												
• Labor	—	—	—	$0.26	$0.26	$0.26	$0.26	$0.26	$0.26	—	—	—
Segregation												
• Labor	—	—	—	$0.65	$0.65	$0.65	$0.65	$0.65	$0.65	—	—	—
• Materials	—	—	—	$0.18	$0.24	$0.30	$0.18	$0.24	$0.30	$0.18	$0.24	$0.30
Disposal	$0.06	$0.06	$0.06	$0.06	$0.06	$0.06	$0.41	$0.41	$0.41	$0.41	$0.41	$0.41
Vertebral bone-in cuts												
• Labor	—	—	—	—	—	—	$0.00	$3.93	$7.86	$0.00	$3.93	$7.86
• Lost value of meat cuts	—	—	—	—	—	—	$0.00	$8.71	$17.53	$0.00	$8.71	$17.53
Monitoring and verification	—	—	—	$0.03	$0.08	$0.13	$0.03	$0.08	$0.13	$0.03	$0.08	$0.13
Lost value of by-products	$0.00	$0.40	$0.79	$0.00	$0.40	$0.79	$0.00	$1.62	$3.24	$0.00	$1.62	$3.24
Total Per Head	$0.06	$0.46	$0.85	$1.18	$1.69	$2.19	$1.53	$15.90	$30.38	$0.68	$16.08	$31.51

[a]Costs associated with non-ambulatory disabled cattle are proportioned over all cows and bulls received at a typical establishment that slaughters cows and bulls.