



Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

December 20, 2005

**RE: Docket No. 2002N-0273, Substances Prohibited From Use in
Animal Food or Feed**

Cargill, Incorporated appreciates this opportunity to comment on the FDA's proposed rule to further reduce the risk of BSE exposure through animal feed by prohibiting specific substances from use in feed for all animals.

Cargill is an international marketer, processor and distributor of agricultural, food, financial and industrial products and services with over 100,000 employees in 61 countries.

In the area of meat and poultry, Cargill and its subsidiaries have extensive operations in the U.S. and Canada. These include beef, pork, turkey, chicken and egg production and processing. Cargill is also a large producer of animal nutrition products including commercial animal feed and pet food. Within the beef sector we operate cattle feedlots and process over 8 million head of cattle each year at our 7 USDA inspected establishments. This includes 2 facilities that primarily process older dairy and beef animals. Additionally, our beef processing facilities typically include dedicated edible and inedible rendering operations.

Cargill has a critical interest in this matter as it impacts the producers, processors, related businesses and domestic and export customers upon whom our business depends. Our broad diversification of potentially affected businesses provides us the opportunity to take a comprehensive look at the North American BSE situation. We have attempted to propose reasoned solutions to significantly enhance existing animal feed controls that are effective, systematic in nature, environmentally sustainable, relatively easy to verify and that have minimal economic impact to U.S. and Canadian beef and dairy producers.

**CARGILL SUPPORTS AGGRESSIVE ACTIONS
TO ENSURE PROMPT ERADICATION OF BSE IN NORTH AMERICA**

Cargill supports the intent and general direction of feed rule enhancements that the FDA is currently proposing. Past exposure of some cattle in the North American herd to BSE infectivity cannot be disputed. The detection of 5 native cases in North America over the past several years demonstrates that BSE infectivity was at times recycled within the U.S. and Canadian cattle herds through contaminated animal feed. From this knowledge, it is reasonable to assume that multiple undetected BSE infected cattle, at various stages of

disease progression, entered the North American animal feed supply both before and after the 1997 feed regulation. The National Cattlemen's Beef Association estimates that approximately 12 million beef cattle born prior to the 1997 feed regulation are still alive in the U.S. cattle population at this time.

Enhanced surveillance conducted in both the U.S. and Canada appears to indicate that a European scale epidemic was averted by basic feed controls enacted in 1997. However, BSE surveillance programs are not intended to detect all BSE infected cattle. Even 100% testing schemes using advanced rapid test methods are not capable of detecting all infected cattle. Thus, a limited number of past events where BSE infectivity entered the animal feeding system, including into ruminant feeds, would not result in BSE cases that fall onto a predictable epidemic curve. Attempts to extrapolate the North American situation using surveillance data and assuming average incubation periods observed in Europe are not credible. It is inappropriate to use past surveillance results to predict with certainty the number of BSE infections, clinical cases and potential detections of BSE in the future. The FDA should consider the existence of clusters of cattle, grouped in time and geography, which are currently infected with BSE as they move forward with this rule.

PROLONGED ERADICATION PHASE WITH CURRENT FEED RULE

The 1997 feed regulation was intended to prevent the continued amplification of BSE should it have been introduced into the U.S. The regulation was never intended to prevent all leakage of prohibited animal proteins into cattle diets. We agree with FDA that even with "leakage" the current feed regulations will lead to the eventual eradication of BSE from North America. However, regardless of current feed rule compliance levels and lacking significant enhancement of feed regulations, eradication of BSE will be drawn out over several decades due to additional cattle being infected. Recent simulations using the Harvard model indicate the reproductive rate (R^0) of BSE transmission is currently upwards of 0.52 (Appendix C, Status Quo, 95th percentile).

To explain a R^0 statistic of 0.5, let's contemplate a hypothetical situation where 10 infected animals exist today. As these 10 cattle leave production they would directly infect 5 animals, which will in-turn infect 2 to 3 animals that end up infecting about 1 animal three turns of the rendering cycle later. Thus, these 10 initial cases would lead to the establishment of 9 additional, arguably preventable, cases despite BSE being eventually eradicated at some point in the distant future. During a January 2005 bilateral U.S./Canadian industry meeting in Washington DC, Canadian government scientists demonstrated this point. Their independent modeling research estimated that many additional cases of BSE would occur until eventual eradication of BSE was accomplished in 20 to 30 years, providing no additional measures were taken.

ENHANCED FEED CONTROLS ARE JUSTIFIED

Enhancing existing feed control measures would ensure that any remaining BSE does not contribute to the establishment of new, albeit declining, infections. Additionally,

enhancement would lead to the eradication of BSE from North America in the shortest timeframe possible. The economic disruption from the announcement of even one case of BSE in an animal born after “effective implementation” of the existing feed rule could devastate the entire U.S. cattle and beef sector. Numerous other industries ranging from retail food service to pharmaceuticals would also be severely impacted. The \$3.5 billion cost to date of the recent and still ongoing BSE related trade disruptions would be multiplied many times over if domestic consumers lost confidence in the beef supply and their trust in government agencies tasked to protect them. Potential economic impact estimated in the tens of billions of dollars is plausible. Failure to act stands to risk great harm with the U.S. cattle and beef sector.

A HARMONIZED NORTH AMERICAN APPROACH IS CRITICAL

The cattle, beef and animal feed industries in both the U.S and Canada operate most effectively when integrated as North American business sectors. While the BSE situation has impacted this cross-border integration, it is important to note that to date harmonized measures with regards to public and animal health policy has been taken. Harmonized regulatory measures facilitate the resumption of trade in animals and animal products allowing for reintegration of the affected industries. We urge FDA to collaborate with their Canadian regulatory counterparts to ensure harmonized North American animal feed control measures are adopted and implemented.

EVALUATION OF FEED CONTROL POLICY OPTIONS

In comments submitted in response to the FDA’s 2004 ANPRM, Cargill detailed a systematic approach that included the removal of the entire carcass of mature dead stock and the brains and spinal cords from mature cattle at slaughter from all animal feed. Using the Harvard Model we demonstrated that this “systems approach” significantly reduced the risk of additional BSE cases while being equally protective to animal and public health as a complete SRM ban from animal feed. The benefit of the systems approach was that it posed a much smaller disposal challenge. This smaller disposal challenge would allow for more rapid implementation of this measure as compared to a complete SRM ban.

Following the methodology of our comments to the ANPRM, Cargill utilized the Harvard BSE risk assessment model to evaluate the effectiveness of several policy options including that contained in the FDA proposed rule. With the assistance of Harvard researchers, we simulated the following 5 animal feed policy options.

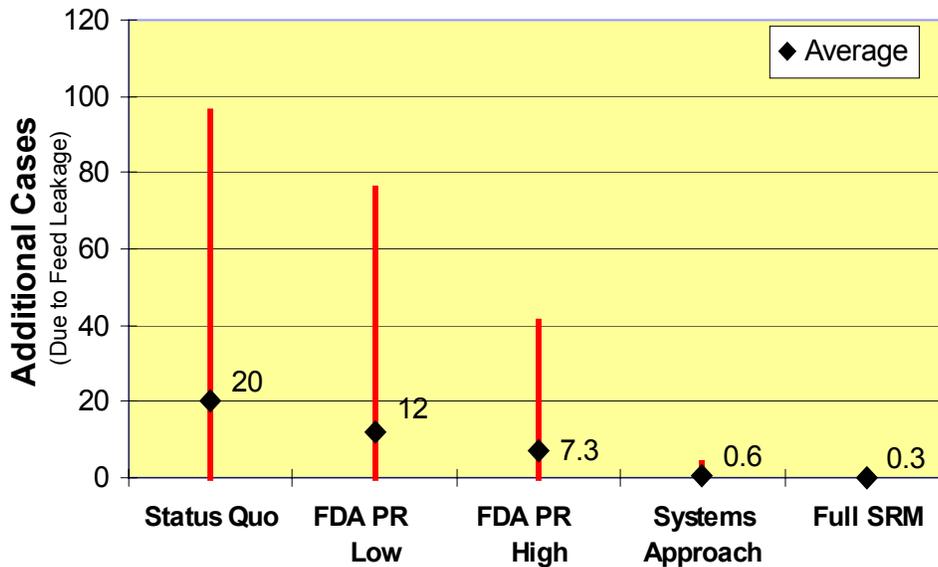
- Status Quo – no changes to current regulations
- FDA Proposed Rule with low compliance
- FDA Proposed Rule with high compliance
- Systems Approach proposed by Cargill
- Full SRM removal from animal feed

A detailed description of the above-simulated options can be found in appendix A. The latest version of the Harvard model was used during the evaluation. This version reflected FDA compliance data from 2005 and beef processing industry practices as stipulated to Harvard by the USDA. One notable change to this version is that, at the request of USDA, the model now incorporates the feeding of poultry litter to cattle.

The purpose of our modeling exercise was to evaluate the relative effectiveness of the above feed control scenarios. To accomplish this, we simulated the introduction of 100 BSE infected cattle into the national cattle herd at the beginning of a 20-year period. Only relevant parameters were adjusted between scenarios. The following chart presents the average number of new BSE cases originating from prohibited ruminant proteins predicted to occur for each policy option¹. The vertical line for each scenario represents the range of probable outcomes from the 5th to the 95th percentiles.

Simulation of Policy Options

5th to 95th Percentile Ranges



As illustrated in the above graph, if no additional feed regulations are enacted (status quo) an average of 20 additional cases are predicted to develop with a 5% chance (95th percentile) of 96 or more cases. Depending upon compliance levels obtained with the

¹ Data tables from each scenario (policy option) can be found in appendix B. Note that in our comments to the ANPRM we graphed additional BSE cases from all modes of infection. In our current comments we have chosen only to review cases that the Harvard model indicates as arising from the “protein” mode of infection. “Protein” refers to prohibited ruminant protein. Other modes of infection such as maternal transmission are not relevant to feed rule changes, thus they have been dropped for the purposes of these comments. However, the data tables contain all output data from each scenario simulated.

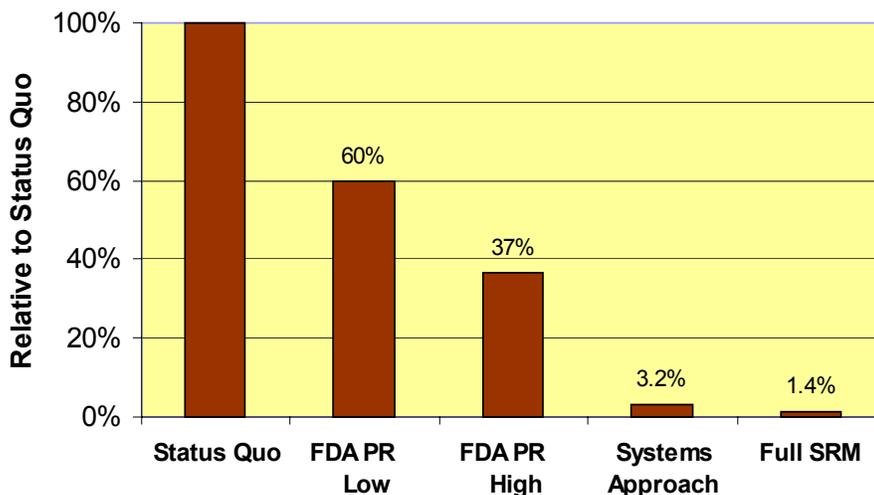
measures outlined in the FDA proposed rule, the average number of additional BSE cases would be between 7 and 12. While lower, the measures outlined in the proposed rule still provide for a wide range of probable outcomes as the 95th percentiles are at 76 and 41 additional cases for the low and high compliance levels respectively. The differences between the high and low compliance scenarios for the FDA proposed rule are solely related to the probability and extent of brain and spinal cord removal from cattle not passing ante mortem inspection (i.e.: dead and non-ambulatory). Parameter descriptions used to simulate these compliance levels can be found in appendix A.

As observed in the earlier modeling work reported in our ANPRM comments, the systems approach has again demonstrated the ability to provide nearly equal animal health protection as the full removal of all SRM. Additionally, the very tight 5th to 95th percentile range of probable outcomes demonstrates the robustness of both these options. Note that when evaluating the full SRM option, we modeled SRM removal as being completely perfect. In reality nothing is 100% perfect. Thus, the very close numerical outcome of the systems approach (modeled using realistic removal efficiency) to the full SRM scenario indicates that these feed control strategies are basically “equivalent”.

The extent of BSE infectivity remaining in the U.S. cattle herd cannot be accurately quantified as the dates, levels and pathways of exposure are unknown. We introduced 100 infected cattle in our simulations – the reality of the U.S. situation could be higher or lower than this simulated introduction. As discussed, our modeling efforts should be seen as an attempt to evaluate policy options based on their relative performance. The following graph evaluates policy options on a relative basis by comparing outcomes to a status quo policy option.

Effectiveness of Policy Options

Average Cases Remaining Relative to No Additional Action



Our research using the Harvard BSE risk assessment model indicates that the proposed rule would reduce average future BSE cases due to prohibited ruminant protein by 40 to 63% depending upon level of SRM removal achieved in non-inspected cattle. The systems approach and full SRM removal options would reduce these cases by a projected 97 to 99% respectively and would do so with a much higher level of confidence.

RESEARCH INDICATES RULE MODIFICATIONS ARE NEEDED

Based primarily on our modeling work, Cargill believes the measures outlined in the FDA proposed rule should be strengthened further. On a technical basis our modeling demonstrates that best case, the proposed rule as it stands will only be about 60% effective in reducing future cases of feed-borne BSE. The FDA should take actions to increase both the effectiveness and robustness of the proposed rule. Cargill recommends that the FDA adopt the following modifications into a final rule.

- 1) Do not prohibit from animal feed any materials derived from dead and non-ambulatory disabled cattle that can be age verified as being 30 months or less in age.
- 2) Prohibit from use in animal feed materials from dead and non-ambulatory disabled cattle over 30 months in age.²
- 3) Prohibit the use of hypobaric (vacuum) rendering for the processing of inedible ruminant materials.

The use of young dead and non-ambulatory cattle for animal feed purposes that can be verified to be 30 months of age or less does not pose a significant BSE risk. The use of dentition, records and animal identification systems are appropriate methods for establishing age. A significant quantity of material from dead feedlot cattle that is currently rendered should continue to be utilized in animal feed with no appreciable impact on BSE risk.

Cargill does not believe that brain and spinal cord removal from mature non-inspected cattle (dead and non-ambulatory) over 30 months in age is acceptable for use in animal feed for several reasons. First, our modeling indicates that due to the high-risk nature of this sub-population of cattle, all SRM would need to be removed in order to alleviate the elevated risk posed. Secondly, the vast majority of these mature dead cattle carcasses are not in a physical condition and/or handled under conditions where all SRM could be removed in a practical cost effective manner. Thirdly, the removal of all SRM from dead stock carcasses can't be effectively enforced or verified. Document trails would be useless – the only effective means to verify SRM removal is on-site inspection. The highest risk carcasses should not be dealt with in the least verifiable manner.

² FDA should allow for the harvesting of striated muscle meat from non-inspected animals for use in animal feed for non-food producing non-ruminant animals. Both muscle tissue and the intended use of this material are considered very low risk.

The prohibition of hypobaric rendering of inedible ruminant materials was simulated as part of the systems approach. We believe this measure is an integral part of the solution. Hypobaric rendering systems provide no meaningful reduction of TSE infectivity. While most rendering systems in the U.S. would reduce TSE infectivity by 90 to 99%, hypobaric systems generally allow nearly all infectivity to pass to into products intended for animal feed. The cluster of BSE cases in Alberta associated with hypobaric processing should provide FDA an indication as to the risk posed by this method of processing. Additionally, we are concerned that TSE affected non-bovine species could pose a risk when processed under hypobaric conditions. Hence, establishment of minimal processing conditions for inedible ruminant materials would be a prudent step.

DISPOSAL ISSUES HAVE SOLUTIONS

In our comments to the ANPRM, Cargill estimated the systems approach would require the alternative disposal of slightly under 500 million pounds of materials that are currently rendered into animal feed. The vast majority of this volume would come from mature cattle dead stock, primarily dairy cows. We have reviewed this estimate using multiple approaches and still conclude this quantity is a reasonable approximation. See appendix D for a detailed discussion of disposal issues.

We believe that producers and meat processors should have access to all appropriate disposal solutions. The USDA and state governments should take the lead in approving appropriate disposal methods on a state or regional basis. Prescriptive solutions that create single disposal channels should be avoided, as this would stifle innovation.

Disposal costs will vary based on the geographic region and method selected. The USDA commissioned a comprehensive study to review and evaluate carcass disposal technologies.³ Eight general methods, from basic to advanced technologies, were reviewed in the report. This independent study contains cost ranges for a variety of disposal methods. We strongly encourage FDA to review the cost data provided by the comprehensive USDA report for use in any economic analysis of disposal needs. Economic data from potentially biased sources should be critically reviewed.

SUMMARY

Cargill appreciates the recognition by FDA that additional measures to enhance BSE feed regulations are warranted by the probable low-level status of BSE in North America. The need to minimize the potential for additional BSE cases due to feed leakage is critical to protect the economic health of multiple sectors. The need to ensure eradication of BSE from North America in the most direct manner with robust controls is paramount. A harmonized regulatory approach with Canada is necessary to achieve this goal.

³ Carcass Disposal: A Comprehensive Review, National Agricultural Biosecurity Center Consortium USDA APHIS Cooperative Agreement Project, Carcass Disposal Working Group, March 2004

Cargill recognizes that FDA has attempted to balance BSE risk reduction with potential disposal challenges. The measures currently outlined in the proposed rule do not adequately protect against the development of additional BSE cases and are unlikely to significantly shorten the timeframe to BSE eradication. The FDA should modify the proposed measures to reflect the science-based “Systems Approach” that Cargill has outlined.

Cargill recognizes this approach will initially create disposal challenges, especially for the dairy sector. We believe that cost-effective carcass disposal solutions can be implemented. We encourage USDA and states to work with all affected industries to ensure appropriate disposal methods are available to cattle and dairy producers and to all affected meat processors.

We greatly appreciate the opportunity to comment on this very important matter.

Sincerely,

David W. Harlan
Director of Global Animal Health & Food Safety

Appendices

- A** ASSUMPTIONS AND PARAMETERS USED IN MODEL SIMULATIONS
- B** RESULTS OF MODEL SIMULATIONS
- C** REPRODUCTIVE RATE (R^0) TABLE
- D** DEAD STOCK DISPOSAL
- E** CLARIFICATIONS ON ERG STUDY

Appendix A

ASSUMPTIONS AND PARAMETERS USED IN MODEL SIMULATIONS

For purposes of our modeling, we introduced one hundred (100) twelve month old animals (50 beef and 50 dairy replacements) that were incubating BSE into the U.S. cattle herd at the beginning of the simulations. All simulation trials were run out for 20 years. Output from each simulation reflects 5000 model trials. A level of 1% of poultry litter produced being fed to cattle was used across all scenarios.⁴ Output sheets from each simulation run can be found in Appendix B.

Feed compliance levels and industry practices reflect 2005 data provided to Harvard by FDA and USDA. All scenarios except the systems approach were simulated with the following rendering inactivation probabilities:

- 50% probability of 2 log inactivation
- 45% probability of 1 log inactivation
- 5% probability of no inactivation

Only parameters discussed below were changed between the scenarios evaluated.

Status Quo

This scenario reflects current conditions in the U.S. No changes to model parameters were made.

FDA Proposed Rule, low compliance

Removal of brain and spinal cord from slaughter cattle over 30 month in age was identical to that simulated for in the systems approach.

Removal of brain and spinal cord from all cattle not passing inspection (dead and non-ambulatory) was simulated at the following levels:

- 20 % probability of 100% removal
- 40% probability of 90% removal
- 20% probability of 60% removal
- 20% probability of no removal occurring

⁴ The Harvard model assumes that any BSE infectivity contained in poultry feed ends up being incorporated into poultry litter. The model assumes that live poultry do not accumulate BSE infectivity into their tissues. In addition it is assumed that conditions found in the poultry digestive tract do not inactivate BSE infectivity. Thus, the model will transfer any BSE infectivity occurring in poultry feed into poultry litter regardless of the intermediate source; spilled feed or fecal droppings. We are concerned that FDA indicated in the proposed rule that there is no reason to believe that BSE infectivity survives in the feces of birds that consumed infected feed. The absence of evidence does not indicate evidence of absence. The pH, time and temperature conditions of the poultry digestive tract are nowhere near as extreme as those conditions known to inactivate BSE infectivity, even in a partial manner. While poultry litter does not appear to be a significant route for BSE transmission, its pathway should not be discarded as being completely irrelevant.

FDA Proposed Rule, high compliance

Removal of brain and spinal cord from all cattle not passing inspection (dead and non-ambulatory) and from inspected slaughter cattle over 30 months in age was simulated to occur at levels identical to that simulated for slaughter cattle in the systems approach.

Systems Approach

All materials from non-inspected cattle over 30 months in age were completely removed from all animal feed 100% of the time. Removal of brain and spinal cord from slaughter cattle over 30 months in age was simulated to occur at the following levels:

- 50% probability of 100% removal
- 30% probability of 99% removal
- 20% probability of 98% removal

To simulate discontinuance of hypobaric rendering conditions, the rendering parameter indicating a 5% probability of processing with no inactivation was eliminated and the probability of a 1 log inactivation was increased from 45% to 50%.

Full SRM Removal

Absolute removal of all SRM from slaughter cattle, based on USDA age appropriate definitions of SRM, was simulated to occur 100% of the time. Additionally, all materials from non-inspected cattle were completely removed from all animal feed 100% of the time.

Appendix B

RESULTS OF MODEL SIMULATIONS

The following data are presented in the tabular format used in the Harvard BSE Risk Assessment Study. If unfamiliar with this format, please consult the Harvard Study for interpretation of the labels used.

Output data sheets from simulation runs are presented in the following order. Tables are labelled in the upper left corner.

- Status Quo
- FDA Proposed Rule, low compliance
- FDA Proposed Rule, high compliance
- Systems Approach
- Full SRM Removal

Status Quo	Mean	5th	25th	50th	75th	95th
Epidemic Statistics						
Total Infected	130	100	110	110	120	210
Total Infected w/o Imports	29	4	7	10	24	110
Total Clinical	68	56	61	65	71	94
Probability N Infected > 0	0.012	0	0	0	0	0
R ₀ Parameter	0.17	0.038	0.065	0.091	0.19	0.52
Mode of Infection						
Maternal	8.5	4	6	8	11	14
Spontaneous	0	0	0	0	0	0
Protein	20	0	0	0	15	96
Blood	0.093	0	0	0	0	1
Exogenous	0	0	0	0	0	0
Mode of Death						
Slaughter	53	32	37	42	52	110
Die on Farm - Render	28	19	23	27	31	42
Die on Farm – No Render	48	37	42	46	51	70
ID50 Sources						
From Slaughter	66,000	28,000	47,000	62,000	81,000	110,000
From Death on Farm	240,000	160,000	200,000	230,000	270,000	350,000
Disposition of ID₅₀s						
1 To Prohibited MBM	53,000	22,000	37,000	50,000	65,000	91,000
2 Eliminated by SRM ban	0	0	0	0	0	0
3 Eliminated by Rendering	220,000	140,000	180,000	210,000	240,000	310,000
4 To NP MBM - Contamination	0.056	0	0	0	0	0.0008
5 To NP MBM - Mislabeling	1,200	0	0.034	100	1,000	10,000
6 Out After Rendering	5,500	110	1,100	2,200	11,000	20,000
7 To Prohibited Feed	7,100	480	1,700	3,600	12,000	22,000
8 To NP Feed - Misdirected	41,000	15,000	28,000	38,000	51,000	75,000
9 To NP Feed - Contamination	0	0	0	0	0	0
10 To NP Feed - Mislabeling	280	0	0	0.015	26	1,000
11 To Blood	5.8	0.22	1.5	3.9	8.1	18
12 Out After Feed Production	48,000	19,000	33,000	45,000	59,000	83,000
13 Misfed to Cattle	120	0	0	0	0.0015	240
14 Total to Cattle	690	0	0.029	2.6	100	2,700
15 Total Potential to Humans	29	0.063	0.41	1.6	4.4	260
16 Eliminated by AM Inspector	37,000	10,000	20,000	30,000	50,000	70,000
Human Exposure						
Brain	0.99	0	0	0	0	0
Spinal Cord	0.036	0	0	0	0	0
Blood	0.27	0	0	0	0.0073	1.3
Distal Ileum	23	0	0	0	0	260
Contaminated Organ Meat	0	0	0	0	0	0
Eyes	0.00038	0	0	0	0	0
Contaminated Muscle Meat	1.4	0.035	0.14	0.73	2.1	4.5
AMR	1.5	0	0	0.0036	0.033	2.3
Beef on Bone	1.9	0	0	0.0026	0.028	2.3
Trigeminal Ganglia	0	0	0	0	0	0
Tonsils	0.031	0	0	0	0	0.51

FDA PR, Low Compliance	Mean	5th	25th	50th	75th	95th
Epidemic Statistics						
Total Infected	120	100	110	110	120	190
Total Infected w/o Imports	20	4	7	10	15	87
Total Clinical	66	56	61	65	69	81
Probability N Infected > 0	0.0082	0	0	0	0	0
R ₀ Parameter	0.14	0.038	0.065	0.09	0.13	0.47
Mode of Infection						
Maternal	8.2	4	6	8	10	14
Spontaneous	0	0	0	0	0	0
Protein	12	0	0	0	5	76
Blood	0.098	0	0	0	0	1
Exogenous	0	0	0	0	0	0
Mode of Death						
Slaughter	47	32	37	41	47	91
Die on Farm - Render	27	19	23	26	30	37
Die on Farm – No Render	46	37	42	45	50	60
ID50 Sources						
From Slaughter	62,000	27,000	45,000	60,000	77,000	110,000
From Death on Farm	240,000	160,000	200,000	230,000	260,000	320,000
Disposition of ID₅₀s						
1 To Prohibited MBM	19,000	6,600	12,000	18,000	24,000	35,000
2 Eliminated by SRM ban	160,000	110,000	140,000	160,000	180,000	220,000
3 Eliminated by Rendering	80,000	47,000	64,000	75,000	90,000	120,000
4 To NP MBM - Contamination	0.022	0	0	0	0	0.000028
5 To NP MBM - Mislabeling	450	0	0.0015	22	230	2,700
6 Out After Rendering	2,100	33	290	810	2,200	8,600
7 To Prohibited Feed	2,400	140	570	1,200	2,900	8,900
8 To NP Feed - Misdirected	15,000	4,100	8,700	13,000	19,000	30,000
9 To NP Feed - Contamination	0	0	0	0	0	0
10 To NP Feed - Mislabeling	95	0	0	0.00076	10	270
11 To Blood	5.6	0.17	1.4	3.6	7.8	18
12 Out After Feed Production	17,000	5,600	11,000	16,000	22,000	32,000
13 Misfed to Cattle	25	0	0	0	0	42
14 Total to Cattle	220	0	0.025	2.2	38	870
15 Total Potential to Humans	7.3	0.061	0.34	1.4	3.3	13
16 Eliminated by AM Inspector	35,000	10,000	20,000	30,000	50,000	70,000
Human Exposure						
Brain	1.1	0	0	0	0	0
Spinal Cord	0.028	0	0	0	0	0
Blood	0.27	0	0	0	0.0057	1.4
Distal Ileum	1.6	0	0	0	0	0
Contaminated Organ Meat	0	0	0	0	0	0
Eyes	1.3E-7	0	0	0	0	0
Contaminated Muscle Meat	1.3	0.033	0.14	0.72	2.1	4.5
AMR	1	0	0	0.0034	0.037	1.8
Beef on Bone	2	0	0.00036	0.0062	0.063	2.9
Trigeminal Ganglia	0	0	0	0	0	0
Tonsils	0.0046	0	0	0	0	0

FDA PR, High Compliance	Mean	5th	25th	50th	75th	95th
Epidemic Statistics						
Total Infected	120	100	110	110	110	150
Total Infected w/o Imports	16	4	7	9	14	50
Total Clinical	65	55	61	64	68	76
Probability N Infected > 0	0.0042	0	0	0	0	0
R ₀ Parameter	0.12	0.038	0.065	0.083	0.12	0.33
Mode of Infection						
Maternal	8.1	3	6	8	10	13
Spontaneous	0	0	0	0	0	0
Protein	7.3	0	0	0	3	41
Blood	0.097	0	0	0	0	1
Exogenous	0	0	0	0	0	0
Mode of Death						
Slaughter	44	31	37	40	45	73
Die on Farm - Render	26	19	23	26	29	35
Die on Farm – No Render	46	37	41	45	49	56
ID50 Sources						
From Slaughter	61,000	27,000	45,000	59,000	76,000	100,000
From Death on Farm	230,000	160,000	200,000	230,000	260,000	310,000
Disposition of ID₅₀s						
1 To Prohibited MBM	6,200	2,800	4,400	5,700	7,300	10,000
2 Eliminated by SRM ban	220,000	160,000	190,000	220,000	250,000	290,000
3 Eliminated by Rendering	27,000	17,000	21,000	24,000	27,000	33,000
4 To NP MBM - Contamination	0.0055	0	0	0	0	3.5E-6
5 To NP MBM - Mislabeling	150	0	0.00029	11	110	1,100
6 Out After Rendering	640	17	130	310	1,200	2,100
7 To Prohibited Feed	980	110	330	680	1,400	2,500
8 To NP Feed - Misdirected	4,700	1,700	3,100	4,300	5,600	8,000
9 To NP Feed - Contamination	0	0	0	0	0	0
10 To NP Feed - Mislabeling	40	0	0	0.00028	8.8	190
11 To Blood	5.4	0.2	1.4	3.6	7.7	17
12 Out After Feed Production	5,600	2,500	3,900	5,200	6,600	9,100
13 Misfed to Cattle	15	0	0	0	0	27
14 Total to Cattle	79	0	0.027	2.1	26	290
15 Total Potential to Humans	6	0.061	0.28	1.2	3.2	11
16 Eliminated by AM Inspector	35,000	10,000	20,000	30,000	50,000	70,000
Human Exposure						
Brain	0.054	0	0	0	0	0
Spinal Cord	0.038	0	0	0	0	0
Blood	0.28	0	0	0	0.0036	1.3
Distal Ileum	1.9	0	0	0	0	0
Contaminated Organ Meat	0	0	0	0	0	0
Eyes	8.1E-8	0	0	0	0	0
Contaminated Muscle Meat	1.3	0.034	0.12	0.69	1.9	4.5
AMR	0.97	0	0	0.003	0.028	1.1
Beef on Bone	1.5	0	0.00036	0.0055	0.056	2.3
Trigeminal Ganglia	0	0	0	0	0	0
Tonsils	0.0047	0	0	0	0	0

Systems Approach	Mean	5th	25th	50th	75th	95th
Epidemic Statistics						
Total Infected	110	100	110	110	110	120
Total Infected w/o Imports	8.7	4	6	8	11	15
Total Clinical	64	55	60	63	67	72
Probability N Infected > 0	0.002	0	0	0	0	0
R ₀ Parameter	0.079	0.038	0.057	0.074	0.098	0.13
Mode of Infection						
Maternal	8	3	6	8	10	13
Spontaneous	0	0	0	0	0	0
Protein	0.64	0	0	0	0	4
Blood	0.092	0	0	0	0	1
Exogenous	0	0	0	0	0	0
Mode of Death						
Slaughter	39	31	36	39	42	48
Die on Farm - Render	26	19	23	26	29	33
Die on Farm – No Render	44	36	41	44	48	53
ID50 Sources						
From Slaughter	59,000	27,000	44,000	58,000	73,000	97,000
From Death on Farm	220,000	160,000	200,000	220,000	250,000	300,000
Disposition of ID₅₀s						
1 To Prohibited MBM	300	130	210	280	370	530
2 Eliminated by SRM ban	240,000	170,000	210,000	240,000	270,000	320,000
3 Eliminated by Rendering	5,200	2,900	4,100	5,100	6,200	8,200
4 To NP MBM - Contamination	0.00031	0	0	0	0	0
5 To NP MBM - Mislabeling	7.1	0	0	0.0016	2.6	28
6 Out After Rendering	33	0.0056	2.7	26	46	120
7 To Prohibited Feed	110	26	59	95	150	260
8 To NP Feed - Misdirected	160	41	90	140	200	320
9 To NP Feed - Contamination	0	0	0	0	0	0
10 To NP Feed - Mislabeling	4.9	0	0	0	1.1	26
11 To Blood	5.5	0.19	1.4	3.6	7.8	17
12 Out After Feed Production	270	110	190	260	340	490
13 Misfed to Cattle	2	0	0	0	0	13
14 Total to Cattle	5.6	0	0.0029	0.22	2.7	27
15 Total Potential to Humans	6.8	0.058	0.3	1.2	3.2	13
16 Eliminated by AM Inspector	34,000	10,000	20,000	30,000	40,000	70,000
Human Exposure						
Brain	1.1	0	0	0	0	0
Spinal Cord	0.19	0	0	0	0	0
Blood	0.28	0	0	0	0.0046	1.4
Distal Ileum	1.1	0	0	0	0	0
Contaminated Organ Meat	0	0	0	0	0	0
Eyes	2.4E-6	0	0	0	0	0
Contaminated Muscle Meat	1.3	0.034	0.12	0.66	1.8	4.3
AMR	1.3	0	0	0.003	0.03	2.3
Beef on Bone	1.6	0	0.00036	0.0055	0.057	2.9
Trigeminal Ganglia	0	0	0	0	0	0
Tonsils	0.0043	0	0	0	0	0

Full SRM	Mean	5th	25th	50th	75th	95th
Epidemic Statistics						
Total Infected	110	100	110	110	110	110
Total Infected w/o Imports	8.3	4	6	8	10	14
Total Clinical	63	55	60	63	67	72
Probability N Infected > 0	0.0022	0	0	0	0	0
R ₀ Parameter	0.075	0.038	0.057	0.074	0.091	0.12
Mode of Infection						
Maternal	7.9	3	6	8	10	13
Spontaneous	0	0	0	0	0	0
Protein	0.27	0	0	0	0	0
Blood	0.085	0	0	0	0	1
Exogenous	0	0	0	0	0	0
Mode of Death						
Slaughter	39	31	36	39	42	47
Die on Farm - Render	26	19	23	26	29	33
Die on Farm – No Render	44	36	41	44	47	53
ID50 Sources						
From Slaughter	60,000	26,000	44,000	58,000	73,000	99,000
From Death on Farm	230,000	160,000	190,000	220,000	250,000	300,000
Disposition of ID₅₀s						
1 To Prohibited MBM	140	6.2	24	59	140	530
2 Eliminated by SRM ban	250,000	180,000	220,000	250,000	280,000	320,000
3 Eliminated by Rendering	580	65	190	380	760	1,600
4 To NP MBM - Contamination	0.000041	0	0	0	0	0
5 To NP MBM - Mislabeling	3.4	0	0	0	0.012	5.2
6 Out After Rendering	14	0	0.012	0.32	3.5	54
7 To Prohibited Feed	57	0.29	3	12	42	220
8 To NP Feed - Misdirected	69	0.76	5.6	19	62	260
9 To NP Feed - Contamination	0	0	0	0	0	0
10 To NP Feed - Mislabeling	2.1	0	0	0	0.00077	2.7
11 To Blood	5.3	0.18	1.3	3.5	7.5	17
12 Out After Feed Production	130	6.4	23	55	130	510
13 Misfed to Cattle	1	0	0	0	0	0.066
14 Total to Cattle	3.2	0	0.00063	0.051	0.81	8.6
15 Total Potential to Humans	6	0.058	0.3	1.3	3.2	11
16 Eliminated by AM Inspector	34,000	10,000	20,000	30,000	50,000	70,000
Human Exposure						
Brain	0.32	0	0	0	0	0
Spinal Cord	0.14	0	0	0	0	0
Blood	0.29	0	0	0	0.0052	1.6
Distal Ileum	1.3	0	0	0	0	0
Contaminated Organ Meat	0	0	0	0	0	0
Eyes	5E-6	0	0	0	0	0
Contaminated Muscle Meat	1.3	0.031	0.12	0.7	1.9	4.5
AMR	1.2	0	0	0.003	0.031	1.2
Beef on Bone	1.5	0	0.00036	0.0054	0.057	2.9
Trigeminal Ganglia	0	0	0	0	0	0
Tonsils	0.0038	0	0	0	0	0

Appendix C

Reproductive Rate (R^0)

	Average	95 th Percentile
Status Quo	0.17	0.52
PR – Low	0.14	0.47
PR – High	0.12	0.33
Systems	0.08	0.13
Full SRM	0.08	0.12

Appendix D

DISPOSAL ISSUES

In our comments to the ANPRM, Cargill estimated the Systems Approach would require the alternative disposal of around 500 million pounds of materials that are currently rendered into animal feed. The bulk of this volume would be derived from mature cattle dead stock that are currently processed into animal feed ingredients. The following chart was submitted with our comments to the ANPRM. It provides an annual volume estimate for various categories of dead stock and non-ambulatory disabled cattle in the U.S. Assumptions on number of carcasses, average weight and percent currently going to rendering were based on an informal survey of several individuals in the U.S. rendering industry. Results were further reviewed with a prominent rendering industry consultant to assure that reasonable assumptions were made.⁵

Estimated Number and Weights of Dead & Non-Ambulatory Cattle by Type⁶

	# Carcasses	Average Weight (pounds)	Total Weight (pounds)	% Currently Rendered	Total Rendered (pounds)
Calves under 500 lbs	2,365,000	200	473,000,000	5%	23,650,000
Feedlots	300,000	750	225,000,000	90%	202,500,000
Beef Cows	1,400,000	1100	1,540,000,000	10%	154,000,000
Dairy Cows	400,000	1300	520,000,000	60%	312,000,000
Total	4,465,000		2,758,000,000		692,150,000

For purposes of our comments to the proposed rule we decided to re-calculate total annual volume of dead and non-ambulatory cattle. These re-calculated estimates (below) were based on data from USDA reports where available, when feasible replacing input obtained by the informal survey. The following 2 charts detail our revised estimates.

Estimated Annual Volume of Dead and Non-Ambulatory Cattle

	Population ⁷	% Death Loss ⁸	# Dead	Avg. Weight	Total Weight
US Calf Crop 2004	37,625,400	6.5%	2,445,651	150	366,847,650
Beef - replacements, Jan 2005	5,745,900	1.1%	63,205	800	50,563,920
Beef - mature breeding cattle	36,000,000	1.1%	396,000	1100	435,600,000
Beef - feedlot cattle	30,000,000	1.0%	300,000	750	225,000,000
Dairy – cows	9,000,000	4.8%	432,000	1300	561,600,000
Mature cattle sent to slaughter	7,000,000	1.2%	84,000	1200	100,800,000
Dairy - weaned heifers	3,000,000	1.8%	54,000	750	40,500,000

Total = 1,780,911,570

⁵ Personal communication, Dr. Fred Bisplinghoff

⁶ Submitted in Cargill comments to FDA ANPRM, August 2004

⁷ Population values derived from USDA-NASS January 1 inventory and industry estimates.

⁸ Death loss values derived from 2 USDA-APHIS-VS, NAHMS reports: Dairy 2002, Part I, page 57; Beef Cow/Calf Health & Productivity Audit (CHAPA), August 1994, page 10.

Estimated Volume of Dead and Non-Ambulatory Cattle Currently Rendered

	Total Weight	% Rendered ⁹	Pounds Rendered
US Calf Crop 2004	366,847,650	10.0%	36,684,765
Beef - replacements, Jan 2005	50,563,920	20.0%	10,112,784
Beef - mature breeding cattle	435,600,000	20.0%	87,120,000
Beef - feedlot cattle	225,000,000	90.0%	202,500,000
Dairy – cows	561,600,000	60.0%	336,960,000
Cows dead at packers	100,800,000	80.0%	80,640,000
Dairy - weaned heifers	40,500,000	60.0%	24,300,000
		Total all ages =	778,317,549
		Total over 30 months =	504,720,000

Overall these revised estimates come close to our original total estimate for volume (weight) of dead and non-ambulatory cattle aged over 30 months and currently rendered for use in animal feed. Claims of different volumes currently rendered should be evaluated in the above manner to ensure realistic assumptions are used.

EPA estimates that a total of 236 million tons of solid waste was disposed of in U.S. landfills in 2003.¹⁰ Addition of all 500 million pounds of materials (0.25 million tons) to solid waste landfills would increase the total amount handled in these facilities by 0.1%. While we do not anticipate the entire volume of this material would go to solid waste landfills, the entire volume could easily be accommodated if the need arose.

Disposal costs will vary based on geographic region and disposal method selected. The USDA recently completed a comprehensive study to review and evaluate carcass disposal technologies.¹¹ Eight technologies from basic to advanced were reviewed in the report. This independent study contains cost ranges for a variety of disposal methods. In addition to disposal methods discussed in this study, Cargill and others have collaborated with Dr. Bruce Miller of Penn State University on the evaluation of a disposal alternative that shows great promise. Research conducted by Dr. Miller earlier this year has demonstrated the technical feasibility of utilizing raw ground carcass material as a fuel source when co-fired with coal in fluid bed combustion boilers.¹² This concept, if commercialized, has the potential to utilize a tremendous volume of animal tissue material using an existing infrastructure. Leaders such as Dr. Miller will work to develop innovative solutions for animal materials that are no longer allowed into animal feed. We encourage government agencies to foster this type of research.

⁹ USDA-APHIS-VS, NAHMS Beef '97, Part III, January 1998, page 28. Assumption made that the rate of calf rendering was half that of beef cow collection.

¹⁰ EPA, Municipal Solid Waste Generation, Recycling, and Disposal in the United States: Facts and Figures for 2003, accessed on 12/18/05. <http://www.epa.gov/epaoswer/non-hw/muncpl/msw99.htm>

¹¹ Carcass Disposal: A Comprehensive Review, National Agricultural Biosecurity Center Consortium USDA APHIS Cooperative Agreement Project, Carcass Disposal Working Group, March 2004

¹² Funded in part by America's cattle producers using Beef Check-Off funds.

We question the conclusion by some that on-farm and alternative carcass disposal methods will degrade public and animal health. In support of this statement, we point out that the majority of cattle mortalities today appear to be safely disposed of through means other than rendering. We are not aware of ongoing disease outbreaks arising from such non-feed disposal. We do not dispute that improper disposal could potentially cause environmental and/or public health concerns. For this reason we support the proper use of disposal methods that have been reviewed by USDA and individual states. We believe these concerns may be hyped for the purposes of avoiding regulatory enhancement of BSE feed controls.

Appendix E

CLARIFICATIONS ON ERG STUDY

Comments provided to Eastern Research Group were not accurately reflected in the following paragraph excerpted from their report.

Under the definition of PCM, ambulatory cattle under 30 months of age do not generate any PCM and their slaughter and disposition would not be affected by the rule. At this time, however, large slaughterers do not have a practical means for determining age of slaughter animals at a point sufficiently early in processing to affect processing of the animals. Therefore, ERG forecasts that most large slaughterers will handle all cattle as if they are over 30 months of age, even though the vast majority of slaughtered animals are less than 30 months of age (Harlan, 2005). Small slaughterers generally handle a larger percentage of older animals. All so-called deads and downers (animals that died other than by slaughter and non-ambulatory cattle), regardless of age, will also generate banned materials. This analysis assumes that all cattle will have, at a minimum, brain and spinal cord removed prior to processing.

We communicated to ERG that under a short list SRM scenario, cow packers that handled a limited number of fed cattle (under 30 months) would probably remove the brain and spinal cord from all animals as this would be more economical than trying to sort the heads by age. ERG apparently assumed that this meant that all packers would remove brain and spinal cord from all cattle of all ages due to an inability to determine age. The following clarifications are offered:

1. The above italicized paragraph from the ERG report incorrectly summarizes the verbal communication between ERG and Cargill. Note that the statement is contrary to Cargill's comments submitted to the FDA ANPRM.
2. Beef processors currently utilize a variety of methods to determine age of cattle at slaughter. FSIS allows the use of these multiple aging methods to differentiate cattle into 2 age categories for the purpose of SRM exclusion from human food. These same aging methods would be used for limiting the removal of brain and spinal cord from animal feed to slaughter cattle over 30 months in age.
3. Based on economic considerations and volume, some processors may find it easier to remove brain and spinal cord from all cattle rather than approaching this task by sorting cattle by age. However, we believe this will only be the case for a very small proportion of fed-cattle sent to slaughter.