

Harvard Risk Assessment of Bovine Spongiform Encephalopathy Update
Phase IA
Supplemental Simulation Results

Joshua T. Cohen, Ph.D.

Harvard Center for Risk Analysis

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1 Introduction

In response to the discovery of a BSE-infected cow in Washington State in December 2003, the U.S. Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) commissioned the Harvard Center for Risk Analysis (HCRA) to use the Harvard Bovine Spongiform Encephelopathy (BSE) simulation model to investigate the impact of alternative measures to mitigate exposure of the human population to the BSE agent. FSIS released the HCRA analysis in October 2005 and presented the findings of that analysis at a technical meeting open to the public in July 2006. FSIS subsequently received public comments on the HCRA analysis. As part of its response to those public comments, FSIS contracted for further analysis using the Harvard BSE simulation model. This report describes those analyses.

2 Methodology

2.1 Changes to the Base Case

The base case was revised as follows:

- *Antemortem* inspection – FSIS decreased the assumed probability that animals with clinical signs of BSE would be detected at *antemortem* inspection (Section 2.1.1)
- Poultry litter pathway for feed contamination – The simulation has been revised so that it now explicitly models contamination of cattle feed as a result of the recycling of poultry litter (Section 2.1.2).

2.1.1 Antemortem Inspection

Table 1 summarizes changes made to assumptions related to *antemortem* inspection.

| Assumption | Old value | New value |
|--|------------------|------------------|
| Probability of detecting BSE signs in animals that have reached the clinical stage of the disease – Ambulatory | 95% | 50% |
| Probability of detecting BSE signs in animals that have reached the clinical stage of the disease – Non-ambulatory | 85% | 25% |

2.1.2 Recycling of Poultry Litter¹

The simulation model assumes that a user-specified proportion of the meat and bone meal (MBM) produced is used in poultry feed, and a user-specified proportion of poultry litter is administered to cattle. The model assumes that 100% of infectivity in poultry feed ends up in poultry litter. As a result, the proportion of MBM infectivity that ends up in cattle feed via this pathway is the product of the proportion of MBM sent to poultry feed producers, and the proportion of poultry litter that is used in cattle feed.

Table 2 details the assumed disposition of MBM, based on the type of MBM producer and the type of material.

Table 2
Disposition of MBM

| | Type of Renderer and Type of MBM | | | | | |
|--|----------------------------------|-------------------|------------------------------------|-----|--------------------------------|-----|
| | Prohibited Ingredient Renderer | | Non-Prohibited Ingredient Renderer | | Mixed Type Ingredient Renderer | |
| | P | NP ^(b) | P | NP | P | NP |
| P Feed Producer (excluding poultry feed) | 50% | 50% | NA ^(a) | 50% | 50% | 50% |
| NP Feed Producer | 0% | 10% | NA ^(a) | 10% | 0% | 10% |
| Mixed Feed Producer | 5% | 10% | NA ^(a) | 10% | 5% | 10% |
| Poultry Feed Producer | 40% | 0% | NA ^(a) | 0% | 40% | 0% |
| Out (Unavailable to U.S. Cattle) | 5% | 30% | NA ^(a) | 30% | 5% | 30% |

Abbreviations: P – prohibited, NP – non-prohibited

Notes: (a) This analysis assumes no product from a non-prohibited renderer is labeled as prohibited

(b) Prohibited ingredient renderers may produce feed that is mislabeled as non-prohibited.

Of the infectivity that ends up in poultry feed and ultimately in poultry litter, this analysis assumes that 1% is used in cattle feed.

¹ This section draws on material prepared by Joshua Cohen (Tufts-New England Medical Center) for the USDA Animal and Plant Health Inspection Service (APHIS).

2.2 Alternative Scenarios

Because assumptions embedded in the base case influence the alternative scenarios, USDA FSIS re-ran the simulation for several of the scenarios central to its original evaluation. The October 2005 Harvard BSE Update includes the following three scenarios, all of which have been re-run.

- *USDA A* – Ban on slaughter for human consumption of all non-ambulatory disabled cattle (Federal Register: January 12, 2004 (Volume 69, Number 7 Pages 1861-1874)).
- *USDA B* – Prohibition for human consumption of brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column, and dorsal root ganglia of cattle 30 months of age or older, as well as small intestine and tonsils of all cattle (Federal Register: January 12, 2004 (Volume 69, Number 7 Page 1861-1874)).
- *USDA A and USDA B.*

In addition to these scenarios, the following additional alternative scenarios have been evaluated using the Harvard BSE simulation model:

- *USDA B12 and USDA B24*– Identical to *USDA B*, except that the prohibition applies to animals 12 months of age and older, or 24 months of age and older, respectively.
- *USDA B, 90% compliance, 95% compliance, and 99% compliance* – Identical to *USDA B*, except that compliance is assumed to 90%, 95%, or 99%, respectively. Table 3 details the proportion of key tissue groups assumed to be allowed into the human food supply.

Table 3
Assumed Proportion of Tissue Allowed In Human Food

| Tissue | Base Case | USDA Scenario B | | | |
|------------------------|-----------|-----------------|---------|----------|------|
| | | 90% | 95% | 99% | 100% |
| All Ages | | | | | |
| Gut (all ages) | 0.01 | 0.001 | 0.0005 | 0.0001 | 0 |
| Tonsils (all ages) | 0.0046 | 0.00046 | 0.00023 | 0.000046 | 0 |
| Age ≥ 30 Months | | | | | |
| Brain | 0.01 | 0.001 | 0.0005 | 0.0001 | 0 |
| Spinal Cord | 0.01 | 0.001 | 0.0005 | 0.0001 | 0 |
| Eyes | 0.001 | 0.0001 | 0.00005 | 0.00001 | 0 |
| AMR Meat | 0.98 | 0.098 | 0.049 | 0.0098 | 0 |
| Beef on bone | 0.25 | 0.025 | 0.0125 | 0.0025 | 0 |

2.3 Sensitivity Analyses

Because assumptions embedded in the base case influence the sensitivity analyses, USDA FSIS re-ran the simulation for several of the key analyses. The October 2005 Harvard BSE Update includes the following three sensitivity analyses, all of which have been re-run.

- *Sensitivity 1* – Mislabeling and contamination – We have revised the base case values for these parameters to take into account new data on compliance rates. The sensitivity analyses evaluate the impact of replacing these assumptions with the more pessimistic base case assumptions from Harvard’s October, 2003 report. In particular, we increase the mislabeling rates to 5% for both MBM and feed production. We increase contamination rates increased to 14% (MBM production) and 16% (feed production).
- *Sensitivity 2* – Misfeeding – Misfeeding rate increased to 15%. This worst case value is the same as the worst case value used in Harvard’s October, 2003 report.
- *Sensitivity 6* – Incubation period – we expand the incubation period distribution (detailed in Section 3.1.1.6 in Cohen *et al.* (2003a)) by doubling the value of each percentile. For example, the 5th percentile is doubled from a base case value of 2.5 years to 5 years, the median is increased from a value of approximately 4 years to 8 years, and the 95th percentile is increased from a value of 7 years to approximately 14 years.

FSIS has also included the following sensitivity analyses:

- *Sensitivity 5* – *Antemortem* inspection – We make the *antemortem* inspector less effective at identifying cattle with clinical BSE signs. The *antemortem* inspector detects none of animals, regardless of ambulatory status.

- *Sensitivity 9* – Poultry Litter Recycling – We assume that 5% of poultry litter is used as cattle feed, rather than 1%, as in the base case.

3 Results

Results appear in Appendix 2 and 3 to this report. In order to facilitate reference to the contents of the October 2005 Harvard BSE Update report, these appendices retain the numbering scheme from that report to the extent possible. Table 4 summarizes the correspondence between this numbering scheme and the scenarios run.

Table 4
Numbering of Scenarios in Appendices to this Report

| Section Number | Scenario |
|----------------|---|
| 1 | Base Case |
| 2.1.1 | USDA A: Ban on Non-Ambulatory Animals to Human Food |
| 2.1.2a | USDA B: 12 Month Comprehensive SRM (Food Only) – 100% Compliance |
| 2.1.2b | USDA B: 24 Month Comprehensive SRM (Food Only) – 100% Compliance |
| 2.1.2c | USDA B: 30 Month Comprehensive SRM (Food Only) – 100% Compliance |
| 2.1.2d | USDA B: 30 Month Comprehensive SRM (Food Only) – 90% Compliance |
| 2.1.2e | USDA B: 30 Month Comprehensive SRM (Food Only) – 95% Compliance |
| 2.1.2f | USDA B: 30 Month Comprehensive SRM (Food Only) – 99% Compliance |
| 2.1.4 | Combined USDA Scenarios: A: Ban on Non-Ambulatory Animals to Human Food B: 30 Month Comprehensive SRM (Food Only) – 100% Compliance |
| 3.1 | Sensitivity 1: Pessimistic - Mislabeling and Contamination |
| 3.2 | Sensitivity 2: Pessimistic – Misfeeding |
| 3.5 | Sensitivity 5: Less Effective AM Inspection |
| 3.6 | Sensitivity 6: Longer Incubation Period |
| 3.9 | Sensitivity 9: High Poultry Recycling Rate (5%) |