Using Decision Science to Empower Informed Choices about Health, Safety, and Environmental Risks

Risk in Perspective

EVALUATING THE RISK OF BOVINE SPONGIFORM ENCEPHALOPATHY IN THE UNITED STATES

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"…under all foreseeable introduction scenarios, the prevalence of BSE decreases over time and it is virtually eliminated from the country within 20 years."

In 1998, as Great Britain dealt with the crisis of Bovine Spongiform Encephalopathy (BSE) in cattle and variant Creutzfeldt Jakob Disease (vCJD), the related disease in humans, the U.S. Department of Agriculture engaged the Harvard Center for Risk Analysis (HCRA) to analyze the potential of such outbreaks in the United States. In November 2001, we reported to the USDA that if BSE were introduced into the United States, measures now in place should prevent any substantial spread of the disease to animals or the human food supply.

The project demonstrated the value of HCRA's decision science expertise to regulators facing a "real world" risk management challenge. Based in part on our work, the USDA has proposed several modifications to existing safety regulations that could reduce the already low risk even further.

The Research

Our work took two forms. First we engaged in an in-depth investigation of both BSE and vCJD. We studied the experience of Great Britain, where around 100 people had been killed by vCJD and where hundreds of thousands of animals had fallen ill or were culled from the herd to stem the spread of BSE. We learned about the practices of animal agriculture in the U.K. and in other European countries, and about the efforts of the British government to bring the cattle epidemic under control.

We then investigated the American animal agriculture industry and its interface with relevant government regulations, including the ban on importation of certain animals and restrictions on certain animal feed practices. We learned about the similarities and differences between the industry in the United States and in the U.K. A critical part of this first phase of research was the hiring of Silvia Kreindel, who has both a Masters Degree in Epidemiology and a Doctorate in Veterinary Medicine.

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Based on this extensive research, we then constructed a probabilistic simulation model to help characterize the possible outcomes that might arise should BSE be introduced into the U.S. or arise spontaneously. We identified baseline values and plausible ranges for key parameters that influence the predicted spread of the disease. These included, among others:

- The degree of compliance with restrictions on animal feed practices.

- The quantity of the transmissible disease agent being carried in various animal tissues, depending on the time since they became infected.

- Use of certain slaughtering and processing techniques.

We then used the model to investigate the impact of various alternatives on the possible spread of BSE among U.S. cattle and the potential for human exposure to the BSE agent. In all, we investigated 29 sets of alternative assumptions about the biological characteristics of BSE, and about typical practices in the U.S. rendering industry, in animal feed production, and in animal farming, among others. This "sensitivity analysis" helped us identify the assumptions whose uncertainty would have the greatest impact on the model's results.

We simulated what might happen if BSE were introduced into the U.S. cattle population through the importation of between 1 and 500 infected cattle. We also simulated what might happen if the disease arose spontaneously in cattle already in the United States. Though we challenged the modeled U.S. system with imported live animals, our findings would apply to other types of challenge like contaminated animal protein or cattle feed. We also considered what could occur if cattle received feed that contained rendered protein from animals infected with scrapie, a disease similar to BSE found in sheep.

In addition, we used the model to investigate several historical scenarios, including the possibility that potentially infected cattle were imported from the U.K. before 1989, when the United States banned such imports. We also ran scenarios to see what might have occurred had BSE arisen spontaneously in the U.S. prior to 1997, when the FDA banned the practice of using rendered protein from ruminant species to fortify cattle feed. Finally, we simulated the effects of various risk management options, including a ban on the rendering and recycling of animals that die on the farm, and a ban on the recycling of specified risk materials (SRM – tissues such as brain and spinal cord thought to contain most of the infectious BSE agent in an animal.)

Our model is not amenable to formal validation because there has never been a controlled experiment in which the introduction of BSE into a country and the resulting consequences have been monitored and measured. However, we were able to evaluate the plausibility of our model using the small BSE outbreak in Switzerland. Working with experts there, we developed assumptions to reflect the practices, procedures, and conditions in that country. We then ran our simulation using those assumptions and found that it reproduced the magnitude and time course of the Swiss outbreak reasonably well. This gives some assurance about the plausibility of our findings for the United States, and demonstrated that with adjustments for local practices, procedures, and regulations, our model can be adapted for use in other countries.

The Findings

Animal Exposure

Our analysis found that current practices make the United States agricultural system resistant to any plausible challenge from BSE should it be introduced into this country. With the regulations currently in place, particularly the ban on incorporating rendered ruminant protein into feed that is fed back to healthy cattle, we found that even if a large number of BSE-infected cattle were introduced, the disease is highly unlikely to become established in the United States. We found that the feed ban is critical to controlling the risk because it appears from the U.K. experience that the disease spreads among animals when infected parts of slaughtered animals are rendered and fed back to healthy animals. The feed ban breaks this cycle. In the absence of the feed ban, our model predicts that the number of BSE-infected animals would grow rapidly, just as it did in the U.K. in the 1980s. Our model assumes less than complete compliance with the feed ban, and still indicates that under all foreseeable introduction scenarios, the prevalence of BSE decreases over time and it is virtually eliminated from the country within 20 years.

For example, if one infected animal is imported into the U.S. (despite the ban on importing ruminants from countries known to have BSE), the model predicts that there is around a 95 percent chance that it would fail to infect even a single additional animal. If five such animals were imported, the chance that additional animals would become infected is 25 percent. If 500 infected animals were imported, it is almost certain that additional animals would become infected. However, despite the potential for additional animals to become infected, the simulation predicts that the number of infected animals would begin to decline almost immediately. Ten years following the introduction of one infected animal, there is a greater than 99 percent chance that the disease would be eliminated from the U.S. Following the introduction of five infected animals there is more than a 95 percent likelihood that the disease would be gone. And following the introduction of 500 infected animals, the probability that the disease would be eliminated from the U.S. after 20 years is nearly 90 percent.

These findings presume no additional governmental action beyond current regulations, though the U.S. government has stated that major additional efforts would be made to control BSE if even one case is found.

Human Exposure

Because of the incomplete scientific understanding of the biology of BSE and vCJD, it is currently not possible to predict the chance that an individual will contract vCJD following exposure to BSE. Our study does suggest, however, that even if BSE were introduced into the U.S. cattle population, exposure to BSE in the human food supply would be substantially less than exposures that occurred in the U.K. We quantified this exposure in terms of the so-called "cattle oral ID50", an amount of the infectious agent that can cause an exposed bovine to become infected with 50 percent probability.

If ten infected animals were imported into the United States, around 50 cattle oral ID50s would become available for human consumption over 20 years. If 500 infected animals were imported, 3,400 cattle ID50s would reach the human food supply over 20 years. To put these numbers in perspective, it is estimated that over the course of

the BSE epidemic in the U.K., which has so far resulted in just over 100 cases of vCJD, there were approximately 1,000,000 infected animals that

likely would have meant several million cattle oral ID50s to which humans might have been exposed.

Prior Undetected Introduction

As noted earlier, it is illegal to import ruminants into the United States from any nation known to have BSE-infected animals. But because 334 animals were imported from England between 1980 and 1989 prior to the importation ban, we examined their potential to introduce BSE into the U.S. We considered this possibility even though the typical incubation period for the disease is four - five years, and despite the fact that BSE has not been detected in the United States despite 12 years of active surveillance.

Information about the cattle that were imported suggests that they did not pose a high risk of carrying BSE. Government tracking systems identified half of the 334 imported animals and recorded that they were destroyed before they could contaminate farms, animal feed, or the human food supply. Records that tracked all but a few of the other animals indicate that they lived for an extended period in the U.S. without developing disease, well beyond the typical incubation period for BSE. Other information suggests these animals were not likely to carry BSE infection. Because these animals were imported as breeding stock, not as beef or dairy production animals, they were less likely to be subjected in England to the high-risk feeding practices believed to be responsible for exposing

U.K. dairy and beef cattle to BSE. Finally, none of the animals came from farms where cases of BSE were found in other animals born during the same year, further evidence that they were probably not exposed to high-risk feed practices.

Given the information we have about these imported cattle, as well as what we know about U.S. agricultural practices in the 1980s, we estimated that there is around one chance in five that these animals might have introduced some BSE infectivity into cattle feed in the U.S. If such contamination did occur, it is possible that BSE propagated in the United States for as long as 17 years before the feed ban was established in 1997. However, the amount of infectivity introduced could not have been large because if it had been, so many animals would have gotten sick by now that they would have been detected by surveillance systems. The possibility remains either that the cattle imported before the ban introduced a small amount of infectivity into the U.S. and that no additional animals became infected, or that additional animals became infected but the disease has since died out, or that the disease is present in the U.S. today but at a prevalence below the level of reliable detection. Our results indicate that this last possibility is unlikely, less than five percent.

Critical Pathways

Our study also identified several factors and practices that most influence the likelihood that BSE could spread among animals. They include:

- Incomplete compliance with the feed ban.

- Misfeeding of cattle with feed intended for pigs or poultry (which can legally contain rendered cattle protein).

- Mislabeling of feed and feed products for consumption by cattle.

- The rendering of seemingly healthy cattle that might be carrying BSE when they die on the farm, and the subsequent use of this material in the production of cattle feed.

Factors that affect the risk to the human food supply include:

- Consumption of brain and spinal cord tissues from cattle (since these tissues carry almost all the infectious material in the animal),

- Consumption of meat from advanced meat recovery (AMR) systems, which can be contaminated with potentially infected nervous system tissues. (These systems extract the meat left on the bone after hand

butchering. Although the spinal cord, which is part of the central nervous system and could carry the BSE agent, is supposed to be removed before processing by AMR, it is sometimes not removed, or may not be removed completely. In these cases, the AMR product may become contaminated with spinal cord tissue and hence with the BSE agent, if it is present.

Further Research

To identify the factors and assumptions that contribute the most to the uncertainty in our results, we set each parameter in our model to its baseline value and then recorded the impact of changing each parameter's value to either its largest or smallest plausible value. We identified four areas where more information would be most valuable:

- Compliance with the feed ban

- The extent of misfeeding

- What happens to animals that die on the farm

- Compliance with meat processing rules governing removal of high risk tissues (brain and spinal cord) from slaughtered animals.

Impact

In conjunction with the release of the HCRA study, the USDA announced in November a series of actions to reduce the low risk posed by BSE even further. They will more than double the number of cattle to be tested for BSE in the current fiscal year to 12,500, up from 5,000 during 2001. The USDA also plans to publish a policy options paper outlining additional regulatory actions that may be taken to reduce the potential risk of exposure and to ensure that the U.S. feed supply remains free of potentially infectious materials. To ensure its decisions are science-based, options will be tested using HCRA's simulation model to determine their potential impact on animal and public health.

The USDA will consider:

- Prohibiting the use of brain and spinal cord from specified categories of animals in human food

- Prohibiting the use of central nervous system tissue in boneless beef products, including meat from advanced meat recovery (AMR) systems

- Prohibiting the use of the vertebral column from certain categories of cattle, including downed animals, in the production of meat from advanced meat recovery systems.

In addition to these impacts, the HCRA research approach and model may be used by other countries to evaluate the potential for BSE spread if it is introduced.

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Summary

Our study found that if BSE were introduced into the United States, its spread to other animals and the contamination of the human food supply would both be very limited. Indeed, even at present incomplete levels of compliance with government regulations, and based on current knowledge, we predict that the current measures would eventually eradicate the disease, whether an introduction has already occurred or occurs in the future.

Continued restrictions to keep infected animals or contaminated feed from entering the country, and ensuring compliance with the feed ban, will ensure that the risk remains low. Additional attention to the labeling of animal feed, to animal industry practices such as the processing of animals that die on the farm and the misfeeding of farm animals, and to the risk implications of advanced meat recovery, are warranted.

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