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Room 102 Cotton Annex  
Washington, DC 20250.

Comments from Food Animal Concerns Trust (FACT) in response to the Harvard Risk Assessment of Bovine Spongiform Encephalopathy (BSE) Update; Notice of Availability and Technical Meeting

Comments submitted by  
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Food Animal Concerns Trust (FACT) is a non-profit organization that advocates better farming practices to improve the safety of meat, milk, and eggs. Since Bovine Spongiform Encephalopathy (BSE) was first recognized in the mid 1980s, FACT has worked diligently with Federal regulatory agencies to develop an appropriate response to the threat to human and animal health presented by this fatal degenerative disease. FACT regrets not being able to send a representative to the July 25, 2006 public meeting and appreciates this opportunity to submit written comments on the updated risk assessment model. FACT has reviewed the updated risk assessment model and materials available on the FSIS website and would like to express our appreciation for the work done by the Harvard Center for Risk Analysis and others in the creation of the model and in this current update.

At the same time, FACT believes that the updated model has not incorporated the latest information on infectivity to BSE at very low doses. The United Kingdom Department for Environment Food and Rural Affairs (DEFRA) infectious dose experiment has shown that cattle can be orally infected with doses as low as 0.001 grams. As reported in the Hill Report 2005, one of fifteen calves (7%) fed a 0.001 gram dose was later shown to be infected. The Harvard Risk Assessment Model never explicitly states how large in grams is one ID50. From the sources listed in the review, it appears that 0.1 gram of infected brain includes one ID50. Based on this assumption about the size of an ID50, using the Harvard Risk Assessment Model's linear dose-response function predicts only 0.5% risk of infection at the 0.001 gram dose (.01ID50). Thus the model underestimates the likelihood of infection at the .001 gram level by 13%. The .001 gram infectious dose is the lowest level tested so it is unclear at what dose level no infectivity will be detectable. FACT recommends that the model be modified to include a dose-response function in four parts. For exposure to doses below 0.0001 gram (.001ID50), there is no risk of infection. This is one order of magnitude smaller than the lowest known level of infectivity. For exposure from 0.0001 gram (.001ID50) to 0.01 gram (.1ID50) the chance of infection is 7%. For exposure greater than .01 gram, the chance of infection equals that of the current model increasing linearly to 100% at 2 ID50s. For doses higher than 2 ID50s, the risk would remain the same. This modified dose-response function would more accurately model the existing information on infectivity at very low doses.

The model's underestimation of the likelihood of infection by very low doses may explain why the model's results are inconsistent with the evidence from Europe indicating

that “commingling” between prohibited and non-prohibited meat and bone meal can be a significant cause of new BSE cases after a ruminant feeding ban is in place (SSC 2000). Peer reviewer #1 pointed this out in his comments to the updated model (Appendix 4, page 7) stating “I consider this element to continue to be underestimated.” In their response, the reports authors stated that even with pessimistic assumptions about commingling examined in the October 2003 risk assessment, the effects on additional BSE cases were minimal. FACT believes that this points to a flaw in the model not that the risk from commingling is low. The current model does not accurately reflect expert scientific opinion on how BSE can continue to spread after a ruminant feed ban is in place. This model flaw may be resolved by correcting the dose-response function at very low doses. The models unrealistic assumptions about the risk of infection from low doses is also likely to lead to an underestimation of the impact of requirements for dedicated production lines as examined in the 2005 update.

FACT appreciates that FSIS has placed the actual model on the website as a DOS executable file. While this is commendable there is no associated documentation explaining how the model could be used. FACT recommends that some minimal instructions on running the model and interpreting results be included.

Thank you.

References:

Hill Report 2005. Review of the Evidence for the Occurrence of 'BARB' BSE Cases in Cattle. Report by William G. Hill for UK DEFRA. Available at: <http://www.defra.gov.uk/animalh/bse/pdf/hillreport.pdf>

SSC 2000. Final Opinion of the Scientific Steering Committee on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR). Adopted on July 6, 2000. Available at: [http://ec.europa.eu/food/fs/sc/ssc/out113\\_en.pdf](http://ec.europa.eu/food/fs/sc/ssc/out113_en.pdf)