

SECOND DECLARATION OF PHILIP B. STARK, PH.D.

11 July 2005

1. I have read Dr. Cox's declaration of 27 June 2005. Nothing in those 47 pages leads me to change the opinions I expressed in my declaration of 8 June 2005, because his arguments don't hold water. I will give some examples below. The Secretary's decision was reasonable: opening the border under the new regulations poses little if any risk to people or cattle in the US.
2. Dr. Cox says that I don't understand risk analysis and implies that I can't evaluate his work.<sup>1</sup> Berkeley is widely acknowledged to be one of the best universities in the world.<sup>2</sup> I have been a professor of statistics there since 1988 (see attachment 3 to my 8 June 2005 declaration). Dr. Cox is using—or abusing—elementary statistical techniques. There is no doubt that I can evaluate his claims.
3. According to Dr. Cox, the probability of importing BSE-positive cattle from Canada under the new regulations is very close to 100%.<sup>3</sup> I say it is very close to 0%. My 8 June 2005 declaration points out some of the errors that led him astray. His 27 June 2005 declaration corrects only one of those errors,<sup>4</sup> a relatively unimportant one.
4. The primary, if not the only, means of transmission of BSE is through contaminated feed.<sup>5</sup> A feed ban like the 1997 Canadian ban prohibits feeding most mammalian protein to ruminants. This curtails the recycling of infectious material.<sup>6</sup> Feed bans are very effective at reducing exposure and slowing—if not halting—the spread of BSE. This is demonstrated by experience in the UK.<sup>7</sup> Canadian cattle under 30 months of age are very unlikely to be BSE-positive.<sup>8</sup> And younger animals, even if infected, have much lower

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1 Cox decl, 27 June 2005, at 9, 12–15, 18–23, 26.

2 For example, in 2004, UC Berkeley was ranked second in the world by Times Higher, the higher education supplement of the London Times, and fourth in the world by the Institute of Higher Education, Shanghai Jiao Tong University. See [http://www.thes.co.uk/statistics/international\\_comparisons/2004/top\\_unis.aspx?window\\_type=popup](http://www.thes.co.uk/statistics/international_comparisons/2004/top_unis.aspx?window_type=popup) and <http://ed.sjtu.edu.cn/rank/2004/top500list.htm>

3 Cox decl, 27 June 2005, at 5, 13, 14, 27.

4 Dr. Cox corrects an error I pointed out on pages 9 and 10 of my 8 June 2005 declaration (he got the number of targeted tested cattle in Belgium wrong by a factor of 10). He also acknowledges that his figure for the number of BSE tests in Canada was out-of-date. Cox decl, 27 June 2005, at 26.

5 Stark decl, 8 June 2005, at 3.

6 US Department of Agriculture's Assessment of the Canadian Feed Ban, February 2005, at 2, 9. (Exhibit 1 to Plaintiff's Motion for Summary Judgment, 9 May 2005.)

7 Stark decl, 8 June 2005, at 8.

8 Stark decl, 8 June 2005, at 7, 11. Dr. Cox questions the basis for my conclusion that the prevalence of BSE-positives among younger Canadian cattle is now essentially zero. Cox decl, 27 June 2005, at 28. Data from the UK and EU show that the prevalence of

infectivity than older infected animals.<sup>9</sup>

5. Dr. Cox says, “Overall, the main point I have been trying to get USDA to understand is that, in sufficiently many trials (e.g., millions per year), for the type of imperfect probabilistic system now in place to manage BSE risks, *anything that can go wrong eventually will go wrong, with probability close to 1.*”<sup>10</sup> I understand and agree—except for the crucial detail he puts in parentheses. Will importing a million head of cattle per year from Canada under the new regulations have the result that “the probability of importing multiple BSE-positive cattle from Canada in the next few years is close to 100%?”<sup>11</sup> His 7 May 2005 declaration suggests that it would take about five weeks to import the first BSE-positive cow.<sup>12</sup> The estimates in his 27 June 2005 declaration imply that it would take about four months.<sup>13</sup> I still say that—according to his models with the worst errors corrected—it will take 7 to 110 centuries.<sup>14</sup> His model implies that we need to import billions of cattle, not millions, before the first mad cow crosses the border.

6. He says, “for the specific case of BSE-positive cattle imported from Canada, *it appears that* a failure rate of several BSE-positive cattle per year *may be* quite realistic.”<sup>15</sup> (emphasis added). The italicized words are escape hatches. If we take them literally, he is merely speculating, not offering an opinion. If we ignore them, he is free to disavow the assertion later. He often leaves such escape hatches,<sup>16</sup> and takes advantage of them in

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BSE-positives among low-risk cattle born after a feed ban is thousands of times lower than the rate among high-risk cattle born before the feed ban. The prevalence of BSE-positives among high-risk Canadian cattle born before the feed ban is low to begin with. (High-risk cattle include those found dead or dying, those exhibiting obvious symptoms of distress, and so forth. 70 FR 469; Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathy (TSE) in the EU in 2003, at 2–3, 6.

[http://europa.eu.int/comm/food/food/biosafety/bse/annual\\_reps\\_en.htm](http://europa.eu.int/comm/food/food/biosafety/bse/annual_reps_en.htm))

9 Stark decl, 8 June 2005, at 4, 7–8.

10 Cox decl, 27 June 2005, at 34.

11 Cox decl, 27 June 2005, at 14.

12 Cox decl, 7 May 2005, at 24.

13 Dr. Cox has revised his estimate that there are 6.25 BSE-positive cattle per million head of imports down to 2 BSE-positives per million. Cox decl, 27 June 2005, at 4, 42. If we leave all of his other numbers alone, this revision changes the expected time to the first BSE-positive import to 3.5 months. See Stark decl, 8 June 2005, at 13.

14 Stark decl, 8 June 2005, at 12.

15 Cox decl, 27 June 2005, at 34.

16 “[T]he quantitative risk of importing BSE cases into the US *may well be* very high.” Cox decl, 25 February 2005, at 2, emphasis added. “[W]ith the BSE prevalence rates that have been observed in the past year, *if* these translate into a few cases of BSE per million cattle being imported into the United States, then it is a statistical near-certainty that some BSE cases will be imported into the US if Canadian imports resume.” Cox decl, 25 February 2005, at 7, emphasis added. (This sentence is also a tautology: Dr. Cox assumes that a few BSE cases per million would be imported, and concludes that some cases would be

subsequent declarations. For example, his 7 May 2005 declaration appears to offer a data-based estimate that there would be 6.25 BSE-positives per million cattle imported from Canada under the new regulations.<sup>17</sup> This now turns out to be a hypothetical illustration.<sup>18</sup> Conversely, the “hot-spot model” was introduced “as a simple hypothetical numerical example.”<sup>19</sup> Indeed, there are no data to support any of the numbers in the example, and some are not to be taken seriously. The model assumes that 0.1% of imported cattle are unusually risky in terms of spreading BSE.<sup>20</sup> That’s one in a thousand. His own latest estimate of the rate of BSE-positives among imports is two in a million.<sup>21</sup> I say it’s closer to one in a billion.<sup>22</sup> With imports of about a million head of cattle per year, 0.1% means that about a thousand infective cattle would be imported from Canada—per year. So far, a grand total of four infected Canadian cows have been found. Yet the hot-spot model is crucial to his latest argument that opening the border will lead to a public health disaster.<sup>23</sup>

7. Referring to the importation of BSE from Canada, Dr. Cox says, “USDA and its experts have offered no demonstration (excluding repeated statements of unsupported personal belief) that this will not happen (with probability close to 1) or that it will not have severe consequences when it does happen.”<sup>24</sup> He claims further that I operate according to the rule, “What you don’t see or don’t know (sic) can’t hurt you.”<sup>25</sup> But in my 8 June 2005 declaration, I used his model. I corrected the worst of his errors using surveillance data from Canada, the UK and the EU. See paragraph 5 for the results. My opinion—that opening the border creates negligible risk—is grounded in the data, the scientific literature, and the administrative record.

8. According to Dr. Cox, quantitative risk analysis uses “bounds and uncertainty and sensitivity analyses to avoid relying on unreasonable assumptions. Thus, risk analysts typically do *not* ‘assign a numerical value’ to such uncertain risks when doing so would require unreasonable assumptions. Instead, we use ranges, bounds, distributions, and uncertainty and sensitivity analyses to discover what conclusions can about (sic) drawn

imported.) “[T]he rate is such that *it appears that there may be* a greater than 99% probability of importing BSE...” Cox decl, 25 February 2005, at 7. “[*I*]t appears that resuming imports would create quantitative risks of importing BSE into the United States that are not low in any usual sense ...” Cox decl, 7 May 2005, at 26, emphasis added.

“[T]he probability of importing multiple BSE-positive cattle from Canada in the next few years *may be* close to 1 ... my main point is that the risk *appears to be* close to 1 ...” Cox decl, 27 June 2005, at 12–13, emphasis added.

17 Cox decl, 7 May 2005, at 23–24.

18 Cox decl, 27 June 2005, at 15. Indeed, he currently does not “claim to know what fraction of young Canadian cattle are BSE-positive.” Cox decl, 27 June 2005, at 15.

19 Cox decl, 7 May 2005, at 16.

20 Cox decl, 7 May 2005, at 16.

21 Cox decl, 27 June 2005, at 4, 42. See also paragraph 9.

22 See footnote 37 below.

23 Cox decl, 27 June 2005, at 13, 17, 20, 23.

24 Cox decl, 27 June 2005, at 34. See also pp. 32–33.

25 Cox decl, 27 June 2005, at 28.

that are robust to uncertainties in the assumptions.”<sup>26</sup> (“Robust to uncertainties” means unaffected by the uncertainties.<sup>27</sup>)

Dr. Cox claims that “the risk of importing BSE-positive cattle is close to 1 under a broad range of alternative models and assumptions.”<sup>28</sup> He presents data-based calculations only for one specific model—a model that ignores the effect of the feed ban and the strong dependence of infectivity on age. Dividing the rate of BSE-positives among imported Canadian cattle by 2 or 3 does not affect his conclusions. Dividing by 2,800—the observed ratio in the EU of the rate of BSE-positives among older cattle to the rate among younger cattle—reverses his conclusions. Dividing by 2,800 was necessary to correct his estimate for the number of BSE-positives among imported cattle, because only younger cattle are imported.<sup>29</sup>

Quantitative risk analysis, as practiced by Dr. Cox, is neither objective nor transparent. Conclusions depend on assumptions that are considered reasonable—by him. Assumptions and parameters are varied only in ways that are considered reasonable—by him.<sup>30</sup> These choices are profoundly subjective, and remain hidden behind a veil of rhetoric and the illusion of mathematical rigor. The choices he has made contradict the science and the data.

9. Dr. Cox objects that dividing by 2,800 “depends on substituting *detected* cases for *actual* ones, and is therefore not valid.”<sup>31</sup> He forgets that his own calculations are based on the four detected cases of BSE in Canadian cows, and on the relationship between detected cases among high-risk animals and low-risk animals in the EU. Furthermore, his calculation allows for undetected cases among low-risk animals in Canada, and I followed suit. His estimates of the rate of BSE-positivity among imported Canadian cattle are—in

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26 Cox decl, 27 June 2005, at 12.

27 Cox decl, 27 June 2005, at 12–13.

28 Cox Decl., 27 June 2005, at 14–15; see also p. 23

29 Stark decl, 8 June 2005, at 11–12. Dr. Cox concedes that if his estimates are off by a factor of a few thousand, that “could” change his conclusions. Cox decl, 7 May 2005, at 26.

30 Dr. Cox claims that “Even if it were true that assigning a numerical value [to the risk] required unreasonable assumptions, this would not necessarily make it reasonable to state that the risk is low, in any given situation,” and claims that his conclusions are saved through the use of ranges, bounds, distributions, etc. Cox decl, 27 June 2005, at 12. His ranges, bounds, and so on are discussed in text. I say the risk is low because (i) the infectious load of BSE in Canada was low even before the feed ban, (ii) feed bans work, (iii) young cattle, even if infected, have low infectivity, and (iv) many protective measures ensure that if an infected cow reaches the US, it is unlikely to spread BSE into the US herd or food supply. For example, the animal would be slaughtered before reaching 30 months of age—when infectivity is still quite likely to be extremely low. See paragraph 4 above, AR 8341–45, and 70 FR 460–61, 466–67, 482–83. (AR 8044–45, 8050–51, 8066–67.)

31 Cox decl, 27 June 2005, at 33; see also pp. 18–19, 29.

chronological order—over 5.5 per million,<sup>32</sup> 3 per million,<sup>33</sup> over 2 per million,<sup>34</sup> 6.25 per million,<sup>35</sup> and 2 per million.<sup>36</sup> My calculations, based on his model but correcting the biggest flaws in his input data, show that the rate is one in a billion, or less.<sup>37</sup>

10. Dr. Cox now defines BSE-positive cattle to include those with pre-clinical infections, undetectable by current testing methods.<sup>38</sup> He points out that “all older animals with BSE were first younger animals with BSE ... BSE infection is generally thought to occur during an animal’s youth, usually during its first year.”<sup>39</sup> If he wants to change his definition of BSE-positivity, that’s fine—but then he needs to take into account the fact that younger infected cattle have much lower infectious loads than older infected cattle.<sup>40</sup> And cattle born after the feed ban are much less likely to be infected than cattle born before the feed ban.<sup>41</sup>

11. I say that Dr. Cox ignores the 1997 Canadian ban on feeding most mammalian protein to ruminants in his calculations.<sup>42</sup> The response: his “analysis is predicated on *using*

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32 Cox decl, 28 January 2005, at 6.

33 Cox decl, 25 February 2005, at 2.

34 Cox decl, 25 February 2005, at 4–5.

35 Cox decl, 7 May 2005, at 24.

36 Cox decl, 27 June 2005, at 4, 42.

37 The rate is derived as follows: there have been four BSE-positives in about 68,000 tests of high-risk animals in Canada. In the EU, the ratio of the BSE-positive rate in high-risk animals to that in low-risk animals is 20, and the ratio of the number of BSE-positives among cattle over 30 months old to the number of BSE-positives among animals under 30 months old is about 2,800. Combining these factors gives the estimate  $(4/68,000) \times (1/20) \times (1/2,800) = 1$  per billion. A reasonable lower bound is 1 per 10 billion, which is derived using Dr. Cox’s figure of 60 for the ratio of the BSE-positive rate in high-risk animals to that in low-risk animals, and the USDA figure of 10,000 for the ratio of the number of BSE-positives in older cattle to the number of BSE-positives in younger cattle:  $(4/68,000) \times (1/60) \times (1/10,000) = 1$  per 10 billion. See Stark decl, 8 June 2005, at 11–12. According to Dr. Cox, “...the example numbers that I used are intended to provide ‘a rough order-of-magnitude estimate (sufficient for quantitative risk estimation, as discussed below),’ not an exactly ‘correct’ number.” Cox decl, 27 June 2005, at 13. But his estimate is off by a factor of thousands.

38 Cox decl, 27 June 2005, at 4.

39 Cox decl, 27 June 2005, at 4.

40 See paragraph 4. He seems to concede this. Cox decl, 27 June 2005, at 1, 19. Imported cattle, even if infected, would be slaughtered well before they pose much risk. Stark decl, 8 June 2005, at 4–5, 7–8.

41 See paragraph 4. He concedes that “... excluding cattle over 30 months old presumably greatly reduces the prevalence of detectable BSE cases ...” Cox decl, 7 May 2005, at 24. Also, the prevalence of BSE-positives “might be lower to the extent that only younger animals are imported, with prevalence rates of BSE prion contamination less than in the general herd.” Cox decl, 27 June 2005, at 4.

42 Stark decl, 8 June 2005, at 2, 12.

*actual empirical rates of observed BSE cases after the feed ban*, rather than hopes about possible future rates, to drive calculations.”<sup>43</sup> That feed bans work is a matter of experience, not hope.<sup>44</sup> However, cattle are usually infected in the first year of life,<sup>45</sup> so a feed ban protects cattle born after the ban, not cattle born earlier.<sup>46</sup> The four Canadian cows discovered to have BSE were most likely exposed to contaminated feed produced before the ban.<sup>47</sup> If the new regulations were in force tomorrow, imports would be limited to cattle born in 2003 or later. Very few of those cattle are likely to have been exposed to contaminated feed. Among cattle born in 2003 and later, no case of BSE has been detected. In fact, no case of BSE has been detected in Canadian cattle born since April 1998. Dr. Cox’s claim to empirical virtue is hollow.<sup>48</sup>

12. “[T]he first mad cow has already crossed the border,” he points out repeatedly,<sup>49</sup> concluding that the probability of importing BSE from Canada is 100%. However, the issue is what will happen in the future if the border is re-opened under the new rules. The cow in question could not have been imported, because it was too old.<sup>50</sup>

13. Dr. Cox asks for a comparison of vCJD to other health risks.<sup>51</sup> The first death from

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43 Cox decl, 27 June 2005, at 23; see also p. 8. He criticizes my use of cumulative rates (Cox decl, 27 June 2005, at 29) but uses them himself, for exactly the same purpose, in previous declarations. Stark decl 8 June 2005, at 15. His estimates for the rate of BSE-positives among Canadian cattle were based on cumulative rates. The numerator was the cumulative number of Canadian cows found to have BSE, and the denominator was the cumulative numbers of tests. Cox decl, 28 January 2005, at 6; Cox decl, 25 February 2005, at 4, 5; Cox decl, 7 May 2005, at 23. In his latest declaration, he appears to use both cumulative rates and annual incidence rates. Cox decl, 27 June 2005, at 4, 42.

“Cumulative” rates include data for previous years. Annual “incidence” rates use data only for the current year.

44 See paragraph 4.

45 Stark decl, 8 June 2005, at 6; Cox decl, 27 June 2005, at 4. Dr. Cox had claimed, contrary to epidemiological findings, that the four BSE-positive Canadian cows were infected when they were over three years old. He no longer seems to defend that assertion: see paragraph 10. Also see USDA, Summary of the Epidemiological Findings of North American Bovine Spongiform Encephalopathy Positive Cattle, April 2005. (Exhibit 11 to Plaintiff’s Motion for Summary Judgment, 9 May 2005.) Cox decl, 28 January 2005, at 7.

46 Stark decl, 8 June 2005, at 8.

47 Stark decl, 8 June 2005, at 5.

48 Similarly, Dr. Cox claims to be “answering ‘what is happening now?’” (Cox decl, 25 February 2005, at 7) when in fact he is using data that bear on the rate of BSE infection in Canadian cattle 7 or 8 years ago—before the 1997 Canadian feed ban was effective.

49 Cox decl, 27 June 2005, at 8, 13, 19, 37.

50 USDA, Summary of the Epidemiological Findings of North American Bovine Spongiform Encephalopathy Positive Cattle, April 2005, at 11–12. (Exhibit 11 to Plaintiff’s Motion for Summary Judgment, 9 May 2005.)

51 Cox decl, 27 June 2005, at 5. He also says that the argument on p. 15 of my 8 June 2005 declaration that vCJD is not a problem in Canada “is specious, as it does not account for

vCJD in the UK was in 1995. From 1995 to the time of writing, there was an average of about 15 vCJD deaths per year in the UK.<sup>52</sup> In England and Wales alone, there are about 500 deaths per year from food poisoning.<sup>53</sup> The risk of vCJD—even in the UK epidemic—was small by comparison.<sup>54 55</sup>

Dr. Cox makes much of the distinction between voluntary and involuntary risks,<sup>56</sup> although this distinction is not as sharp as he claims. An earthquake might be an act of god—but for many people, living in an earthquake zone is a voluntary assumption of risk. Another example: perhaps not a tea-drinker himself, he scorns the idea that tea is risky. You can eliminate the risk by avoiding the beverage.<sup>57</sup> However, every sip of liquid we

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the well-known long incubation time of vCJD, nor the known difficulties in accurately diagnosing vCJD.” Cox decl, 27 June 2005, at 29. Experience in the UK suggests that the incubation time for vCJD is perhaps 10 years. See Plaintiff’s Reply Memorandum in Support of Its Application for Preliminary Injunction, 28 February 2005, at 6, and figure 1 of Cox decl, 7 May 2005, at 5. BSE-positive cattle were found in Canada 12 years ago. USDA, Summary of the Epidemiological Findings of North American Bovine Spongiform Encephalopathy Positive Cattle, April 2005, at 17. (Exhibit 11 to Plaintiff’s Motion for Summary Judgment, 9 May 2005.) There is no further discussion of diagnostic issues in the declaration; there are no citations on this issue. Is Dr. Cox suggesting that diagnostic procedures are less accurate in Canada than in the UK? On what basis?

52 National Creutzfeldt-Jakob Disease Surveillance Unit, University of Edinburgh.  
<http://www.cjd.ed.ac.uk/figures.htm>

53 Salmonella alone is responsible for about 100 deaths per year in the UK. G.K. Adak, S.M. Long and S.J. O’Brien, Trends in indigenous foodborne disease and deaths, England and Wales: 1992 to 2000, 51 *Gut* 832 (2002) at 833, 836, 838.  
<http://gut.bmjournals.com/cgi/reprint/51/6/832>. A comparable figure for the US is about 1,400 deaths per year, with 500 from Salmonella. This is derived from Table 3 of P.S. Mead, L. Slutsker, V. Dietz, L.F. McCaig, J.S. Bresee, C. Shapiro, P.M. Griffin, and R.V. Tauxe, Food-related illness and death in the United States, 5 *Emerging Infectious Diseases* 607 (1999). <http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm>

54 Other risks are higher still: in the US in 2000 and 2001, there were over 12,000 deaths per year from alcohol-related liver disease and over 43,000 deaths per year in motor vehicle accidents. *Statistical Abstracts* (2003), table 116. In the 1990s, there were over 400,000 smoking-related deaths per year in the US. American Cancer Association, *Cancer Facts & Figures* (2000) at 28; J.L. Fellows, A. Trosclair, E.K. Adams, and C.C. Rivera, Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Economic Costs — United States, 1995–1999, 51 *Morbidity and Mortality Weekly Report* 300 (2002), Centers for Disease Control. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5114a2.htm>

55 Dr. Cox objects to my comparison of BSE rates in the UK and Canada, because the UK has active surveillance of healthy cattle. Stark decl, 8 June 2005, at 15; Cox decl, 27 June 2005, at 29–30. However, active surveillance has been responsible for less than 1% of BSE detections in the UK. DEFRA, BSE: Statistics - BSE - GB weekly cumulative statistics, 1 July 2005. <http://www.defra.gov.uk/animalh/bse/statistics/weeklystats.html>

56 Cox decl, 27 June 2005, at 9–10.

57 Cox decl, 27 June 2005, at 37.

take, like every bite of food we eat represents a voluntary assumption of risk, created by food-borne pathogens and carcinogens (both natural and synthetic). There is also a large risk of cardiovascular disease associated with excess calories. In the aggregate, such risks far exceed the risks from vCJD, even in the UK during the epidemic.

14. There is a repeated claim that heterogeneity—different rates of BSE-positivity in different groups of cattle—can only increase the risk of importing BSE-positives from Canada.<sup>58</sup> An example is given,<sup>59</sup> which amounts to this. There are two cows, one in Alberta and one in Quebec. The cows are statistically independent. Each cow has a 50% chance of being BSE-positive. (The chances are the same for both cows: this is homogeneity.) If we import both cows, the chance of importing a BSE-positive is 75%.<sup>60</sup> On the other hand, suppose that the Alberta cow is BSE-positive for sure, while the other cow is BSE-negative. (This is extreme heterogeneity: one chance is 100%, the other is 0%.) If we import both cows, the chance of importing a BSE-positive cow is now 100%. In this example, heterogeneity increased the chance of importing a BSE-positive cow.

Generally, the risk of importing BSE-positive cattle is determined by the rate of BSE-positives among imports, not the rate in the herd. The rate among imports is the key parameter in Dr. Cox's calculations. But heterogeneity in the herd can lower the rate of BSE-positives among imports,<sup>61</sup> as the next example shows.

Suppose there are two BSE-positive cows in northern Alberta, and two BSE-negative cows in southern Alberta.<sup>62</sup> We import only the two cows from southern Alberta: the chance of importing a BSE-positive is 0%. In this example, heterogeneity in the herd reduces the risk. Heterogeneity in the herd can increase the risk, or decrease the risk.

To get a more realistic example, replace northern Alberta with cattle born before 1999, and southern Alberta with cattle born after January 2003. (Heterogeneity is due to time, not geography.) Suppose BSE-positives are concentrated among animals born before 1999.<sup>63</sup> If we import only animals born after January 2003, the risk is reduced—almost to

58 Cox decl, 25 February 2005, at 3, 4; Cox decl, 27 June 2005, at 30–32.

59 Cox decl, 27 June 2005, at 32.

60 The chance that at least one of the cows is BSE-positive is  $1 - 0.5^2 = 0.75$ , or 75%.

61 Page 13 of my 8 June 2005 declaration notes that the rate of BSE-positives among imports is low, because of heterogeneity in the herd. He says my reasoning is “fallacious,” because it contradicts the assumption he wants to make—namely, the rate of BSE-positives among imported cattle is high. Cox decl, 27 June 2005, at 32. He focuses on heterogeneity among imports. He ignores heterogeneity in the herd—due to age—when estimating the rate of BSE-positives in the herd, let alone the rate among imports. That is why his estimate of the rate of BSE-positives among imports is far too high, as I showed. Stark decl, 8 June 2005, at 11–12.

62 In his hypothetical, the average of the probabilities that a cow is BSE-positive is a mathematical idealization of the BSE-positive rate: in his hypothetical and mine, the herd average probability of being BSE-positive is 50%.

63 This hypothetical is a good approximation to reality in Canada. See paragraph 4 and Stark

the vanishing point. Dr. Cox seems to be showing with strict mathematical rigor that, in the presence of heterogeneity, the rate of BSE-positives among imports must exceed the rate for the herd.<sup>64</sup> But in fact, he simply assumes what needs to be proved.

15. Poisson models can be homogeneous (the rate is the same everywhere) or heterogeneous (the rates depend on space or time, for example).<sup>65</sup> “Poisson model,” without further qualification, is generally understood to mean homogeneous Poisson model. Dr. Cox’s data-based calculations use only homogeneous Poisson models for the occurrence of BSE.<sup>66</sup> He apparently concedes that homogeneous Poisson models do not fit the data, and now claims that his conclusions do not depend on homogeneity.<sup>67</sup> He says his “analysis and conclusions allow for a *heterogeneous* Poisson process.”<sup>68</sup> I’ve read four

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decl, 8 June 2005, at 7–8.

64 He cites Hoeffding’s inequality and alludes to other theorems. Cox decl, 27 June 2005, at 30–31. Neither Hoeffding’s inequality nor the other theorems answers the critical question—how does heterogeneity in the herd affect the rate of BSE-positives among imports? The mathematics answers a different question: for a given rate of BSE-positives among imports, how does heterogeneity affect the risk? The examples in text show that heterogeneity in the herd can reduce the rate of BSE-positives among imports. More generally, mathematical results have assumptions and conclusions. If Dr. Cox appeals to a theorem, he should say what the assumptions are, and why they hold for the application he has in mind. Then he should say how the conclusion of the theorem advances his cause. Even in his hypothetical, heterogeneity of imports increases some risks but decreases others. For example, heterogeneity decreases the chance of importing more than one BSE-positive cow.

65 Cox decl, 27 June 2005, at 21.

66 Apart from the hot-spot model (see paragraph 6), each of his calculations has only one rate, not different rates for different places or times. See, e.g., Cox decl, 25 February 2005, at 3; Cox decl, 7 May 2005, at 21, 22, 24, 25–26, 27; Cox decl, 27 June 2005, at 14–15, 21, 31; see also Stark decl, 8 June 2005, at 12–13. In all Poisson models, events occur independently. Dr. Cox acknowledges this. He says that BSE cases in Canada are independent or nearly so, because there is no horizontal transmission and no epidemic. Cox decl, 25 February 2005, at 3; Cox decl, 7 May 2005, at 21; Cox decl, 27 June 2005, at 30–31. That is not enough: there are other sources of dependence, for example, contaminated feed. Later, he contradicts himself, saying that Poisson models do not require statistical independence, and that independence “is not central to my reasoning or conclusions.” Cox decl, 27 June 2005, at 14.

67 Cox decl, 27 June 2005, at 4. “My estimate that the risk of importing BSE-positive cattle is close to 1 under a broad range of alternative models and assumptions is *illustrated* by the simple Poisson-based calculations, but is not *dependent* on them.” Cox decl, 27 June 2005, at 14–15. “[It is not true that] my main conclusions depend in any way on the assumption of a Poisson model...the homogeneous Poisson model does provide a useful way to illustrate more general points with specific, simple numerical results ... the homogeneous Poisson model is not essential to any of my main conclusions...” Cox decl, 27 June 2005, at 21–22.

68 Cox decl, 27 June 2005, at 21.

declarations by Dr. Cox in this matter, and his report to R-CALF.<sup>69</sup> I found no calculations or data to support this assertion.<sup>70</sup>

16. The declaration of Dr. Gail Charnley (24 June 2005) generally supports the positions taken by Dr. Cox, without providing additional arguments or data. My responses to Dr. Cox apply equal well to Dr. Charnley—on the number of cattle that must be imported to get a BSE-positive,<sup>71</sup> on the prevalence of BSE-positives among younger Canadian cattle,<sup>72</sup> and so forth. She cites authority to prove that risk assessment must be quantitative,<sup>73</sup> but there is authority in the other direction too.<sup>74</sup> I find the Secretary’s blend of quantitative and qualitative argument to be reasonable and persuasive.

I agree that “The risk of importing BSE-infected cattle into the US from Canada is greater than zero.”<sup>75</sup> However, I disagree with the assertion that “if a quantitative estimate of the risk of importing BSE-infected cattle cannot be supported ... the risk should be

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69 Louis Anthony Cox, Jr., Evaluation of the Adequacy and Appropriateness of Risk Analysis Used by the U.S. Department of Agriculture Animal and Plant Health Inspection Service in Support of Proposal to List Canada as a Bovine Spongiform Encephalopathy Minimal Risk Region. AR 4916–34.

70 He has a theoretical argument, but it shows the wrong thing. See paragraph 14 and footnote 64. He complains that I present no goodness-of-fit test to support the claim that the Poisson model does not fit the data for Canada, the UK, or France, or Switzerland. “Despite the rhetoric, I do not find any solid technical content here. The basis for this claim appears to be Dr. Stark’s unsupported opinion.” Cox decl, 27 June 2005, at 22–23. On the contrary, the very papers he cites reject the Poisson model. Stark decl, 8 June 2005, at 13.

71 Charnley decl, 24 June 2005, at 4. My response is in paragraph 5.

72 Charnley decl, 24 June 2005, at 4, 5. My response is in footnote 8.

73 Charnley decl, 24 June 2005, at 2, 3, 6.

74 According to the Codex Alimentarius, “The weight of evidence integrating quantitative and qualitative data may permit only a qualitative estimate of risk.” Codex Alimentarius, Principles and Guidelines for the Conduct of Microbiological Risk Assessment (1999) at 6. [http://www.codexalimentarius.net/download/standards/357/CXG\\_030e.pdf](http://www.codexalimentarius.net/download/standards/357/CXG_030e.pdf) See also 70 FR 504–05 (AR 8088–89).

“[T]he field of risk analysis teaches that, to make rational decisions, a more quantitative approach is essential.” Cox decl, 27 June 2005, at 15. Leading scholars in a variety of fields disagree with this assertion. D.P. Green and I. Shapiro, *Pathologies of Rational Choice Theory: A Critique of Applications in Political Science*. Yale University Press (1994). D. Kahneman and A. Tversky, eds., *Choices, Values, and Frames*, Cambridge University Press (2000). A.K. Sen, *Rationality and Freedom*, Harvard University Press (2002). Professors Kahneman (a psychologist) and Sen (an economist) are Nobel laureates. Professors Green and Shapiro are leading political scientists.

75 Charnley decl, 24 June 2005, at 4.

maintained at zero.”<sup>76</sup> in other words, the border should remain closed until a quantitative risk estimate can be made. I gave several examples of severe risks that we accept<sup>77</sup>, including the risks of earthquakes—which cannot be quantified in any sensible way. I remain convinced that “reasonable precautionary measures”<sup>78</sup> are in place—in Canada and the US—to mitigate the already very low risks of importing BSE. See paragraph 4 and footnote 30.

17. Dr. Cox claims that his conclusions hold in many scenarios, but there are numerical details for two scenarios only. The first is the “hot-spot model,”<sup>79</sup> discussed in paragraph 6. The numbers in this model are silly. The second scenario is a homogeneous Poisson model,<sup>80</sup> discussed in my declaration of 8 June 2005. The inputs to this model are substantially in error. If the input data are corrected, the model gives the conclusion that opening the Canadian border under the new regulations creates negligible risk: it would take many centuries before the first mad cow crosses the border.

I declare under penalty of perjury that the foregoing is true and correct.

\_\_\_\_\_ Dated \_\_\_\_\_ July 2005.

Philip B. Stark

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76 Charnley decl, 24 June 2005, at 5.

77 Stark decl, 8 June 2005, at 1.

78 Charnley decl, 24 June 2005, at 4.

79 Cox decl, 7 May 2005, at 16.

80 Cox decl, 25 February 2005, at 3; Cox decl, 7 May 2005, at 21–22, 24, 25–26.