

FEDERAL COURT - TRIAL DIVISION

BETWEEN:

ANTHEA ARCHER and DARREL ARCHER
doing business as FAIRBURN FARM

APPLICANTS

AND

DR. GEORGE LUTERBACH,
THE CANADIAN FOOD INSPECTION AGENCY
and THE ATTORNEY GENERAL OF CANADA

RESPONDENTS

AFFIDAVIT OF JOAN ORR

I, JOAN ORR, of the Municipality of Campbellville in the Province of Ontario, MAKE OATH AND SAY AS FOLLOWS:

1. I am a toxicology consultant with 15 years of experience in the fields of hazard assessment and risk assessment. I have reviewed the following materials for the purposes of preparing this affidavit:
 - (a) The Affidavit of Anthea Archer sworn October 26, 2000;
 - (b) The Affidavit of Dr. George Luterbach sworn November 3, 2000;
 - (c) The Affidavit of Dr. John A. Kellar sworn November 9, 2000; and
 - (d) Selected documents produced by the Respondents pursuant to Rule 317.
2. I have also made independent enquiries of knowledgeable individuals and reviewed publicly available research sources. I have personal knowledge of the

matters hereinafter deposed to, except where stated to be based on information and belief, and where so stated I verily believe them to be true.

3. For 10 years I was employed by CanTox Inc. During my employment there I received mentoring from and worked closely with two of the world's leading experts in toxicology and risk assessment. These were Dr. C. Chappel, the founding president of the Society of Toxicology, and Dr I. Munro, former chairman of the Canadian Centre for Toxicology and former Director General of the Health Protection Branch. For the past four years I have been consulting successfully as an independent contractor. Attached hereto and marked as **Exhibit "A"** is a copy of my *curriculum vitae*.
4. I was awarded a Joint Honours BSc in Biology and Chemistry from the University of Waterloo in 1983 and a Master's Degree in Biochemistry from MacMaster University in 1985.
5. I have significant experience in preparing expert witnesses to give testimony on diverse issues, including silicone breast implants, 2,4-D, alachlor, benzoyl peroxide, phthalate esters, formaldehyde, EMF from cell phones, incinerator emissions, landfills and aspartame.
6. I have expertise in the area of Bovine Spongiform Encephalopathy (BSE) and other Transmissible Spongiform Encephalopathies (TSEs). While working under contract for the Health Canada Science Team on TSEs I reviewed over 1200 scientific papers and reviews on the subject, as well as many hundreds of newspaper, science news and internet articles. In 1999 I attended an international conference on TSEs where I heard presentations by and spoke with experts on TSE from all over the world. I have actively followed the science relevant to TSEs from November 1998 to the present.
7. This affidavit is organized into the following four sections:

Section I: Review of Affidavit of Anthea Archer

Section II: Review of Affidavit of Dr. J. Kellar

Section III: Review of Draft CFIA Risk Assessment dated September 8, 2000

Section IV: Relative Risk Assessments

Section I: Review of Affidavit of Anthea Archer

8. The Affidavit of Anthea Archer describes a number of facts that have a direct bearing on the BSE risk associated with the imported water buffalo. The most significant facts, in the order in which they are presented, are described below.
9. In the UK, water buffalo are heralded as the BSE-free animal of the future (A.A. Affidavit, paragraph 11). Water buffalo yogurt certified as BSE-free is sold in the UK (A.A. Affidavit, paragraph 12).
10. According to the Buffalo Research Institute in Shumen, Bulgaria, water buffalo are not fed feed of animal origin (A.A. Affidavit, paragraph 15).
11. The nineteen water buffalo imported into Canada were approved for export to Australia prior to their export from Denmark (A.A. Affidavit, paragraph 18).
12. The water buffalo were kept in quarantine in Denmark, had no contact with other cattle, and their feed was monitored. Receipts are available for hay and beet pulp purchased (A.A. Affidavit, paragraph 20).
13. Milk products from Denmark continue to be imported into Canada despite the BSE status of Denmark (A.A. Affidavit, paragraph 28).
14. Some of the animals originated in Bulgaria, but they had passed quarantine as required by the Danish authorities and had been accepted into the Danish herd in preparation for export to Australia (A.A. Affidavit, paragraph 32).
15. According to the CFIA risk assessment, the animals were not fed animal-based feed while in Denmark (A.A. Affidavit, paragraph 33). This has been confirmed by various persons having knowledge of the herd (A.A. Affidavit, paragraph 34).
16. A letter received from Dr. Villy Jensen, the veterinarian who attended the animals in Denmark, concluded that "...there should be no possible way, that the water buffaloes could have been contaminated by BSE in Denmark" (A.A. Affidavit, paragraph 35). This opinion is shared by Dr. Sorensen, also of Denmark (A.A. Affidavit, paragraph 44).
17. Canada reported a case of BSE in 1996 in an imported animal (A.A. Affidavit, paragraph 42).
18. Dr. Sorensen from Denmark has advised the Archers that he has no concerns about the possibility of the water buffalo having been contaminated with BSE in Bulgaria since the agricultural practices in that country are undeveloped, the

- animals graze naturally and water buffalo do not require protein supplementation to thrive (A.A. Affidavit, paragraph 44).
19. Bulgarian feta cheese is available in Canadian stores (A.A. Affidavit, paragraph 45).
 20. According to the OIE there have been no cases of BSE in water buffalo anywhere in the world (A.A. Affidavit, paragraphs 46 and 47).
 21. According to the Water Buffalo Institute in Shumen, Bulgaria there has never been a case of BSE in cattle or water buffalo in Bulgaria (A.A. Affidavit, paragraph 48).
 22. Animals that make up the other half of the Danish herd (originally from Bulgaria) from which the Archers' animals are derived are being milked for cheese in Denmark and a herd of similar origin is being milked for cheese in Australia without any concern being expressed by government authorities (A.A. Affidavit, paragraph 49).

Section II: Review of Affidavit of Dr. J. Kellar

23. I have reviewed the affidavit of Dr. Kellar and am of the opinion that it contains a technically accurate summary of many key scientific aspects of BSE. In some instances additional information would be helpful to evaluate the BSE risk presented by the water buffalo, particularly in comparison with other BSE or TSE-related risks that are tolerated in Canada. Where I have determined that additional information would be helpful I have noted this with reference to the paragraph number of Dr. Kellar's affidavit.
24. In paragraph 26 of Dr. Kellar's affidavit the following sentence appears: "The new disease was given the name Bovine Spongiform Encephalopathy because it was disease of cattle which, together with water buffalo, are classified as bovines ...". This should not be interpreted to mean that BSE has occurred in water buffalo or that water buffalo were considered in any way when the disease was named. In fact, as acknowledged by the CFIA, there have been no reported cases of BSE in water buffalo.
25. Dr. Kellar states in paragraph 15 that "[a] frequent finding among underdeveloped countries is the expression of negative disease status in the absence of documentation". I agree that the absence of reported disease in an underdeveloped country does not definitively indicate that disease has not occurred. Nevertheless, there are an estimated 155,000,000 water buffalo worldwide with an average

working life of 20 years or more (except for beef producing animals, which are killed at age 2 years). Attached hereto and marked as **Exhibit "B"** is a copy of correspondence from R. Palmer, an English expert on water buffalo. In view of the large number of water buffalo in the world, and the much longer lifespan of water buffalo than cattle and the greater opportunity for disease incubation, the absence of any reported case of BSE in water buffalo is noteworthy.

26. With respect to surveillance programs, it should be noted that in the United States 11,553 cattle brains (from 1986-2000) have been examined within a total national herd size of 43,000,000 (1997 cattle census data) (*i.e.* just 0.03% have been examined). Source data for these US figures are attached hereto and marked as **Exhibit "C"**. In Canada there have been 4512 cattle brains examined (data for 1992-1999) within a total national herd size of 14,370,000 (1998 data) (*i.e.* just 0.03% have been examined). Attached hereto and marked as **Exhibit "D"** is a copy of the GBR report for Canada, which includes source data for these Canadian figures on page 35. Even in Canada and the US, surveillance programs are not sufficiently rigorous to detect disease incidence if it occurs at low levels.

27. In paragraph 26(h) Dr. Kellar mentions a WHO report that lists countries to which animal feed potentially contaminated with the BSE agent was exported during a period of high risk. Dr. Kellar does not list the specific countries, although he does refer to Eastern Europe. Since Bulgaria is in Eastern Europe, it might be inferred that there is a possibility that MBM was exported from the UK to Bulgaria. Attached hereto and marked as **Exhibit "E"** is an excerpt from the Philips BSE Inquiry in England which provides the following list of countries to which the UK exported ruminant-based meat and bone meal, based on UK records:

Norway, Sweden, Switzerland, Czechoslovakia, Hungary, Nigeria, Thailand, South Africa, Malaysia, Taiwan, Hong Kong, South Korea, Japan, Canada, USA, Turkey, Kenya, Malta, Liberia, Lebanon, Saudi Arabia, Sri Lanka, Puerto Rico, Curaçao and Finland.

28. The Philips Inquiry also notes that exports to these countries could have continued until 1996, when all such exports were banned:

Philips BSE Inquiry: Volume 16, Chronology of Events

<http://www.bseinquiry.gov.uk/report/volume16/chron2.htm>

27 March 1996

Commission Decision 96/293/EC prohibits the export from the UK of live bovine animals, their semen and embryos; meat of bovine animals slaughtered in the UK which are liable to enter the animal feed or human food chain, and materials destined for use in medicinal products, cosmetics or pharmaceutical products; and mammalian-derived MBM.

29. It can therefore be concluded that Bulgaria did not receive imports of MBM from the UK. This is consistent with the information received from Bulgarian authorities that Bulgarian water buffalo were not fed animal-based feed (see A.A. Affidavit, paragraph 15), as well as a letter received from Dr. Alexiev of Bulgaria dated November 7, 2000, a copy of which is attached hereto and marked as **Exhibit “F”**.
30. In paragraph 27 Dr. Kellar notes that there is considerable concern over the possibility that the UK sheep flock has been infected with BSE. The basis for these concerns has been published in the scientific literature (Aguzzi, 1998; Aguzzi and Brandner, 1999; Collinge, 1999). Recently it has been reported in the press that the UK is considering massive culls of sheep and restrictions to consumption of sheep products by humans. A copy of the news article is attached hereto and marked as **Exhibit “G”**.
31. It has been proven that sheep can acquire BSE through consumption of contaminated material (Foster et al., 1996; Foster et al., 1993). As indicated by Dr. Kellar, it is not possible to differentiate easily between scrapie and BSE in sheep. A biochemical method of differentiating between the two diseases has been described (Hill et al., 1998), but has not been developed sufficiently to be useful as a general screening tool (Collinge, 1999). The source of contamination in sheep is thought to be the same meat and bone meal that was fed to cows and exported to many countries. Meat and bone meal (MBM) has not been imported to Canada since 1978 due to restrictions unrelated to BSE, but it has been imported from other BSE affected countries (see Exhibit “D”, GBR Report for Canada, page 39).
32. Canada imported live cattle from the UK during the period 1982-1990. Of those imported in 1988 and 1989, 53 were slaughtered and 11 were rendered (see GBR Report for Canada, page 39).
33. Since potentially contaminated animals and feed were imported to Canada, and recycling feeding practices continued in Canada until 1997 (see Dr. Kellar’s affidavit, paragraph 43) the possibility that BSE exists in Canadian sheep, or in sheep from the US or any other country that imported UK feed and employed cannibalistic animal feeding practices, cannot be ruled out.

34. There is a concern that BSE in sheep may be even more dangerous than BSE in cows if the sheep form of the disease, like scrapie, can be spread among animals while having the host range of BSE (which includes humans) (Nature editorial , 1998). Scrapie was diagnosed in 14 sheep flocks in Canada in 1999 (see CAHNet Bulletin, Spring 2000, edition 4, page 23, a copy of which is attached hereto and marked as **Exhibit “H”**).
35. In paragraph 30 Dr. Kellar discusses BSE incidence in the UK and some other countries. The most recent statistics on BSE incidence worldwide are attached hereto and marked as **Exhibit “I”**. Geographical BSE Risk (GBR) ratings reflect the likelihood of a country to experience a case of BSE based on a rigorous assessment conducted by the Scientific Steering Committee of the European Commission. The methodology is summarized on pages 7 and 19 of the Canada GBR Report (Exhibit “D”). The ratings may be summarized as follows as listed in the Final GBR Risk Assessment, an excerpt from which is attached hereto and marked as **Exhibit “J”**:

Level I (highly unlikely that cattle harbouring BSE are present in the country):

Argentina, Australia, Chile, Norway, New Zealand and Paraguay

Level II (unlikely but not excluded that cattle harbouring BSE are present in the country):

Austria, Finland, Sweden, Canada and the USA

Level III (likely, but not confirmed, or confirmed at a lower level that cattle harbouring BSE are present in the country):

Belgium, Germany, Denmark, France, Ireland, Italy, Luxembourg, the Netherlands, Spain and Switzerland

Level IV (confirmed at a higher level that cattle harbouring BSE are present in the country):

UK and Portugal

36. In paragraph 44 of his affidavit Dr. Kellar mentions the implementation of the ruminant to ruminant feed ban, which made it illegal to feed ruminant derived materials to ruminants. Exclusions to the feed ban include bovine-derived tallow, gelatin and blood (see CFIA Feeding Regulations, a copy of which is attached hereto and marked as **Exhibit “K”**), which permits the continuation of a cannibalistic feeding pathway. In addition, the feed ban does not prohibit the

- feeding of bovine material to pigs or chickens nor the feeding of pigs and chickens to cows or sheep.
37. Import restrictions prevent the importation of bovine-derived material for animal feed into Canada from BSE countries, but do not prevent the importation of pig- or chicken-derived materials. In BSE countries, or countries with unknown BSE status, these non-bovine animals could be fed contaminated feed and then be imported into Canada and fed to Canadian cows or other livestock. In addition, bovine material from countries of unknown BSE status can be imported into Canada for use in feed for non-bovine animals, subject to an import permit. There are no import restrictions on bovine semen or embryos as long as certain conditions for their harvesting and preparation are met.
 38. Paragraph 55 of Dr. Kellar's affidavit states that ruminant products from Denmark are banned from importation into Canada. Cheese products are not affected by this ban and Danish and other European Cheeses are available in Canadian and US stores, restaurants and via the internet (examples are attached hereto and marked as **Exhibit "L"**).
 39. According to a letter sent from the CFIA to Animal Health and Production Division Area Import Officers (Applicants' Documents, Tab 9), although all live ruminants and ruminant meat products from Denmark are refused entry, semen and embryos are allowed entry as long as they comply with conditions set out for the importation of embryos from other BSE countries. Protein-free tallow and milk and milk products are specifically exempt from import restrictions and can be imported from BSE countries.
 40. In paragraph 77(b) Dr. Kellar expresses the opinion that Ms. Archer's statement regarding the feeding history of the water buffalo "must be questioned relative to its veracity". Ms. Archer has stated that the animals have never been fed animal-based feed. I have reviewed the basis for Ms. Archer's belief and the results of this research are attached hereto and marked as **Exhibit "M"**.
 41. The most significant concern regarding feeding practices expressed by the CFIA relates to the Bulgarian born animals. The CFIA assumes that statements regarding feeding practices made by Bulgarian officials are not trustworthy. Professor Alexiev has stated that the animals were never fed animal-based feed in Bulgaria. Professor Alexiev is a recognized world authority on water buffalo and their management. He has written a book on the subject, he has written a chapter for a World Animal Science publication (a copy of which is attached hereto and marked as **Exhibit "N"**), he is President of the Bulgarian Buffalo Association, a member of the Standing Committee of the International Buffalo Federation, and

- he is presently organizing the International Buffalo Congress to be held in Venezuela.
42. Professor Alexiev's views on the feeding practices of water buffalo in Bulgaria are confirmed by a survey of feeding practices for buffalo world-wide, which confirms that water buffalo are not fed animal-based feed with the exception of some herds in Brazil which may receive bone meal and some animals raised on feedlots in Italy.
 43. The animals imported by the Archers were originally destined for Australia (indeed animals of similar origin have been successfully imported into Australia), and the importer from Australia as well as Australian authorities were satisfied with assurances they received that the animals were not fed animal-based feed. The decision of the Australian authorities to take no action against the water buffalo imported from Bulgaria and Denmark also confirms the Bulgarian claim that the animals were not fed animal-based feed. Australia is one of only six countries given the lowest GBR rating by the Scientific Steering Committee. Australia has also demonstrated its intolerance for TSEs by being one of only two countries to have eradicated scrapie. As a country with a significant economic interest in livestock trade and animal products Australia is unlikely to tolerate any significant risk of losing its BSE-free status.
 44. An international conference on BSE in which feeding practices were discussed was held in Sofia, Bulgaria in 1990 (see Exhibit "E"). From this it may be concluded that authorities and scientists in Bulgaria were aware of precautions required to be taken with respect to ruminant feeding.
 45. All available evidence supports the conclusion that the animals imported by the Archers were not fed animal-based feed in either Denmark or Bulgaria. In my review of documents and scientific literature I have discovered no evidence to the contrary.
 46. In paragraph 77(b) Dr. Kellar suggests that feed products may contain minor ingredients such as minerals and vitamins that may in turn contain ruminant-based materials. He also suggests that some products may be improperly labelled and may contain animal materials they would not ordinarily be expected to contain. CFIA import policies do not preclude the importation of products containing highly processed animal products such as vitamins and minerals, and there are no restrictions on these with respect to either animals or countries of origin.
 47. It is therefore possible, within the framework of Canadian regulation, for animal feeds and supplements to be imported into Canada from any country, including

- Bulgaria, regardless of the BSE status of that country. Data on actual imports are accumulated by Statscan. Import data for the for animal-based and feed products for use in animals serves as a surrogate for Canadian import data in proving examples of the types of products that could be imported and the countries from which they could be imported. US import data for 1999 are attached hereto and marked as **Exhibit “O”**. The very feed products Dr. Kellar believes may have been mislabelled or may have inadvertently contained animal materials not reflected in the labelling, and which he believes may have contaminated the water buffalo in Bulgaria, can be legally imported into Canada and fed to cattle in this country.
48. According to Dr. Kellar products such as fertilizer, fish meal and vitamin/mineral lick consumed by the water buffalo in Bulgaria could conceivably have contained contaminated meat and bone meal. There are no import restrictions on these types of products (except for fertilizer known to contain bovine bone meal) from BSE countries to Canada, since they are not expected to contain infectious material.
49. In paragraph 77(c) Dr. Kellar raises the possibility that the animals could have been contaminated through the administration of vaccines or veterinary pharmaceuticals. According to Dr. Hans Sorensen of the Danish Veterinary Authority, the animals were not vaccinated in Denmark nor in Bulgaria. This is confirmed on page 5 of the CFIA risk assessment dated September 8, 2000, a copy of which is attached hereto and marked as **Exhibit “P”**. This is also consistent with information provided by Ms. Archer in a facsimile dated November 16, 2000, a copy of which is attached hereto and marked as **“Exhibit “Q”**. The animals also did not receive natural hormone products (cows could have received a synthetic reproductive hormone, Estrumate, to prepare them for breeding, but this poses no BSE risk).
50. In paragraph 78 Dr. Kellar suggests that the water buffalo could develop BSE and could spread it to the national cattle herd. Even if the water buffalo did develop BSE, the ruminant-ruminant feed ban would prevent the spread through feed. In addition, contact between buffalo and cattle could be prohibited to prevent possible animal-animal spread.
51. Consistent with the lack of opportunity for contamination of the national cattle herd with BSE from the Archers’ water buffalo, the CFIA risk assessment concludes that the risk of this mode of spread is low. Furthermore, the national cattle herd has already been exposed to BSE by virtue of the existence in Canada for seven years of an animal imported from the UK that did develop clinical BSE (see J.K. Affidavit, paragraph 38). In addition, the UK animals that were rendered and slaughtered would have gone into the food chain. On page 40 of the GBR assessment for Canada the following statement appears:

However, since the external challenges did occur during a period of very low stability, it cannot be excluded that some domestic animals were infected with BSE in the late 80s early 90s, resulting in a certain domestic prevalence. If these animals were rendered while approaching the end of the incubation period, e.g. 93-98, a second wave of domestic infections would have resulted. These animals could show symptoms in the late 90s or beyond.

52. Imported MBM from BSE countries before the implementation of feed and import bans could also have contaminated the food chain. Recycling and amplification of the infectious agent could have occurred until 1997 through cannibalistic feeding practices. Recycling and amplification as well as additional challenges with the agent could still be occurring through the import of pigs and chickens fed contaminated ruminant-based feeds and fed through recycling feeding practices in their home countries. There are no BSE-related restrictions on non-ruminant feed imports.
53. It is therefore possible that the BSE agent is currently present in the national cattle herd. By contrast, it is highly unlikely that, even if infected, the Archers' water buffalo could contaminate the national cattle herd.
54. In paragraph 78 Dr. Kellar expresses concern over the possible revocation of Canada's BSE-free status if a second case of BSE was to develop. This concern is likely unfounded since Canada has received a GBR rating of II despite a previous reported case of BSE in an imported animal. The concern of the SSC is that the disease may be incubating in the general cattle population. If a case occurred in imported water buffalo it could be easily demonstrated, providing proper records are kept, that these animals were not fed animal-based feed in Canada and were not exposed to the national cattle herd. The SSC has consistently taken a scientific and reasonable approach to their many assessments and there is no reason to expect this would change.
55. In paragraphs 82 to 84 Dr. Kellar describes the dire consequences if a case of BSE developed in a native cow or in a water buffalo. He considers the two situations to be equal in degree of severity. In fact, the occurrence of a case of BSE in the water buffalo would almost certainly be attributed to exposure occurring before the animals came to Canada. There are no domestic exposure sources due to the animals being fed vegetable-based feed, not being vaccinated, not requiring dietary supplementation, not being administered bovine-derived hormones and not being in contact with other cattle. The occurrence of a case of BSE in a native cow would be a much more serious matter since the origin of exposure could only be the result of import, husbandry, or past and present Canadian veterinary and feeding practices. It is the existence of BSE in native cattle, as opposed to

- imported water buffalo, that would represent the “tip of the iceberg” explained by Dr. Kellar in paragraph 37 of his affidavit. It is not reasonable to regard the occurrence of BSE in water buffalo who are part of an imported, isolated herd to be of the same significance to Canadian trading partners and beef consumers as the occurrence of a case of BSE in the national cattle herd. This is consistent with the view held by Geoff Ryan of the Australian Quarantine and Inspection Service who stated that if there is a ban on ruminant to ruminant feeding, then “a single case of BSE, or even numerous cases, in imported animals has no epidemiological significance” (Applicants Documents, tab 8).
56. In paragraph 84 Dr. Kellar suggests that the water buffalo could be the source of the first native case of BSE in Canadian cattle and could be the source of the first case of vCJD in Canada. This is an outrageous statement that is unsupported by any of the facts Dr. Kellar has presented in his affidavit. It is much more likely that the first native case of BSE in Canada will result from past practices including the importation of potentially contaminated cattle and cattle-based feeds, supplements, vaccines and veterinary pharmaceuticals coupled with recycling feeding practices that continued until 1997. Other sources of exposure more likely to cause BSE in a native cow than the Archers’ water buffalo include the practice of feeding domestic and imported pig and chicken remains to cows when these animals themselves are fed through recycling feeding pathways and could be harbouring the BSE agent. A list of animal based products imported into the US is shown in Exhibit “O”, and it is likely that similar types of product are imported into Canada.
57. Cannibalistic feeding pathways, which continue to be tolerated in Canada, have been recognized as carrying a potential risk of BSE transmission and several countries have banned or are considering a ban on the use of any animal ingredients in any animal feed. Copies of news articles on this topic are attached hereto and marked as **Exhibit “R”**.
58. With respect to vCJD, the most likely source of the first case will be immigrants from or frequent travellers to the UK who have consumed contaminated beef products. This is consistent with the ban imposed by Health Canada on these individuals donating blood.
59. Another more likely source of human TSE in Canada than BSE in imported water buffalo is chronic wasting disease in domestic elk. This disease is known to be incubating in Canadian herds, as confirmed by three cases that have been reported in official sources (see Exhibit “H”) and a further three or more cases reported in the press. This number probably represents an underestimate of the true incidence, since CWD is not a reportable disease and compensation is available for only 50% of the value of culled animals, thus reducing the incentive to report voluntarily.

60. The possibility exists that contaminated products from elk are reaching Canadian consumers. CFIA notes on its website that it is not known whether these products carry a risk for humans. A copy of the material posted on the CFIA website is attached hereto and marked as **Exhibit "S"**. They claim there is no scientific evidence for transmission of CWD to humans. Since the TSEs are all so similar in pathology and in transmissibility and all that have been tested have a wide host range, it is scientifically defensible to presume that CWD could cross to humans. Recently evidence was presented at a conference indicating that in an in vitro system, protein molecules from infected elk were found to have the ability to effect a change in human protein molecules considered to be associated with the transmission of TSE (a copy of news article relating to this is attached hereto and marked as **Exhibit "T"**).
61. Dairy products have never been subject to import bans and imported cheese products have been available to the Canadian public, thus exposure to dairy products from BSE countries occurred for many years prior to the importation of the water buffalo. The buffalo mozzarella cheese made in Canada could reasonably be expected to be of lower risk than imported products, since all aspects of animal husbandry and cheese production can be strictly controlled and monitored. In Italy, animal-based rennet (from the stomach of calves) is used, while in Canada vegetable rennet will be used. In addition it is possible that animals were fed animal-based feed on feed lots in Italy, thus increasing the BSE risk. The displacement in the market of imported product by locally produced product would be expected to result in a reduced risk (assuming that dairy products do pose a risk – this possibility cannot be excluded, but has not been proven).

Section III: Review of Draft CFIA Risk Assessment dated September 8, 2000

62. In this section I discuss the draft risk assessment prepared by CFIA (see Exhibit "P"). Where appropriate, I also refer to additional pertinent information.
63. Feed as a risk factor is discussed on page 5 of the CFIA risk assessment. The assessment concludes that the animals born in Denmark were not fed feed of animal origin.
64. It is also stated on page 5 that no information is available about the feed of the buffalo originating in Bulgaria. In fact, information concerning the feeding practices of the water buffalo in Bulgaria is readily available by consulting the literature, the Archers and their contacts. From this information it can be concluded that it is unlikely the animals originating in Bulgaria were fed animal-based feed. This conclusion is supported by the following:

- (a) A survey of buffalo feeding practices indicates that it is very unusual to feed animal products to water buffalo (the only case of this is in Brazil, where some farms reportedly feed bone meal and Italy where some animals are raised on feedlots). See Exhibit “M”;
 - (b) Bulgaria is not listed among the countries to which MBM was exported from the UK (secondary imports cannot be ruled out; however, Bulgarian authorities state that neither cattle nor water buffalo are fed animal based feeds). See Exhibits “E” and “F”.
 - (c) Professor Alexiev, the source of the information regarding buffalo feeding practices, is a recognised expert in the field of water buffalo feeding and management. See Exhibits “F” and “N”;
 - (d) Danish and Australian authorities are also satisfied that the water buffalo were not fed contaminated feed. See A.A. Affidavit, Exhibits “Q” and “Y”;
 - (e) Australia has imported animals of similar origin, and was willing to import the very animals imported by the Archers. See paragraph 18 of A.A. Affidavit, Exhibit “Q”;
 - (f) An international conference on BSE in which control measures were discussed was held by the OIE in Bulgaria in 1990 (see Exhibit “E”), thus it can be assumed that authorities in Bulgaria were aware of precautions required to prevent the spread of BSE.
65. Vaccines are listed as other risk factors and it is noted on page 5 of the CFIA risk assessment that the animals were not vaccinated. See Exhibit “P”.
66. Dr. Kellar identifies other risk factors as including salt licks containing vitamins of animal origin or feedstuffs that were improperly labelled. As discussed above, these feeds or feed supplements from Bulgaria and similar countries can legally be imported into Canada and thus pose no greater risk to Bulgarian water buffalo than they would to Canadian cattle if imported. See Exhibit “K” and Applicants Documents tab 11.
67. The administration of reproductive hormones, or the use of invasive instruments as part of a breeding program, are risk factors that should have been considered in the CFIA risk assessment but were not. I am advised by Ms. Archer that the animals were serviced naturally by a bull and were therefore not exposed to any invasive instruments. Although some cows may have been treated with a synthetic

- hormone to prepare them for mating, this does not present a BSE risk (see Exhibit “Q”).
68. The CFIA has conducted literature and internet searches which revealed no reported cases of BSE in water buffalo. This is confirmed by letters from, among others, Professor Alexiev of Bulgaria (see Exhibit “F”) and R. Palmer of England (see Exhibit “B”).
 69. The CFIA risk assessment correctly points out that water buffalo are potentially susceptible to BSE. The absence of reported disease cannot be considered to be proof that the disease does not exist in water buffalo, particularly since most of the world’s water buffalo population resides in India, China and Pakistan where no disease surveillance programs exist. However, surveillance is not completely lacking. Mr. Palmer confirms the existence of surveillance programs in Italy, Bulgaria and Romania. Time constraints preclude investigation into these programs, however the existence of a surveillance program in Bulgaria adds additional weight to the statement by Professor Alexiev that there is no BSE in that country (See Exhibits “B” and “F”).
 70. Mr. Palmer also indicates that surveillance has been conducted in the UK on water buffalo residing in that country and as many as 250 water buffalo brains could have been studied. Some would have been sufficiently old (7-10 years) to show signs of BSE if infected. Although not determinative, these surveillance programs reinforce the absence of reported cases of BSE in water buffalo. Furthermore, surveillance programs in the United States and Canada are also incapable of providing definitive proof of the absence of disease due to the very small percentage of animals tested (0.03% in the US; 0.03% in Canada).
 71. The CFIA risk assessment concludes that the likelihood of infection of the 10 water buffalo originating in Denmark is LOW and the likelihood of infection of the 9 water buffalo originating in Bulgaria is MEDIUM. This assessment of the likelihood of infection of the Bulgarian animals is based upon ignorance of actual feeding practices in Bulgaria. Based upon available information concerning the feeding practices of water buffalo in Bulgaria the likelihood of infection of the Bulgarian animals may also be considered LOW.
 72. Based on the following considerations, the likelihood that the imported water buffalo are contaminated with BSE is probably lower than the likelihood that Canadian native cattle are contaminated with BSE:
 - (a) The national herd was exposed to BSE through the presence of an infected cow being resident for seven years and possibly through consumption of

rendered feed produced from other cattle imported from the UK and consumption of rendered feed from other BSE countries;

- (b) Cattle in the national herd were fed through recycling feeding practices until 1997;
 - (c) Cattle can still be fed non-ruminant based feed and non-ruminants can be fed ruminant-based feed, both domestic and imported, providing an opportunity for indirect recycling of the BSE agent, if it is indeed present in the food chains of Canada or other countries;
 - (d) Cattle are vaccinated and treated with hormones, some of which could be derived from bovine material; and
 - (e) The risk factors listed above do not apply to the imported water buffalo.
73. The CFIA risk assessment concludes that even if a water buffalo was to be infected with BSE, the ruminant to ruminant feed ban would minimize the possibility of exposure to other ruminants and thus “the release probability can be considered to be LOW”.
74. The consequence assessment included as part of the CFIA risk assessment is based strictly on economic and political factors and not on animal or human health.
75. No attempt is made in the CFIA risk assessment to evaluate the positive economic factors that may be associated with the presence of water buffalo in Canada.
76. In the final section entitled Risk Estimation, the assessment states: “given a low to medium release probability...”. In the previous section entitled Exposure Assessment, the assessment states “...the release probability can be considered LOW”. This is an inconsistency between the assessment and the conclusion.

Section IV: Relative Risk Assessments

77. An approach to risk assessment that is often used, particularly in cases where it is not possible to predict absolute levels of risk (as is the case with BSE), is relative risk assessment. In a relative risk assessment the risks from a new product being introduced are weighed against existing risks, or against the background risks. This gives some perspective on the level of concern that might reasonably be attributed to the new risk under assessment. A relative risk assessment comparing

the animal and human health risk factors associated with the imported water buffalo and other TSE-related risks that exist in Canada is presented below.

78. No attempt is made in the CFIA risk assessment to consider the possible impact on human health associated with the presence of the imported water buffalo in Canada. The only human health considerations relate to the consumption of cheese products made from buffalo milk. Dairy products are exempt from import restrictions and can be sourced from countries with BSE, including the UK. This policy is presumably based on the belief that dairy products do not pose a risk of BSE. There have been no studies suggesting that dairy products carry a BSE risk. However, dairy products do contain white blood cells, which have been associated with the transfer of BSE infection through the body of experimental animals (Brown et al., 1999; Cervenakova, 2000).
79. There is also a recognition in the scientific literature that BSE infection may be transferred from cow to calf, and a role for milk in this process has not been ruled out (Donnelly et al., 1997; Wilesmith et al., 1997). The possibility that dairy products can carry some risk of BSE if they are derived from infected animals cannot be excluded on the basis of currently available data. Thus the human health risk from cheese imported from BSE countries is higher than the risk from dairy products from the imported water buffalo, which are likely to be free from infection and will reside under controlled conditions in Canada. (See paragraph 37 of Dr. Kellar's affidavit for a discussion of the likelihood that there are many more infected animals in a BSE country than actually develop the full-blown clinical disease).
80. Similarly, it can be predicted that the risks associated with buffalo mozzarella would be lower with product produced in Canada than from the same product produced from related animals residing in Denmark or product produced in Italy. Italy has a GBR rating of III, possibly feeds animal-based feed to buffalo on feed lots and also uses animal rennet, whereas in Canada vegetable rennet is used. Accordingly, the production of buffalo mozzarella in Canada would result in an overall risk reduction since local product could be expected to displace some of the imported product in the market place.
81. A comparison of risk factors for BSE in cows, BSE in buffalo and CWD in elk is presented in the table below in order to give some perspective on the relative risks of disease emergence in these three cases.

Relative Risk Comparison – Animal Health

Risk Factor	BSE (buffalo)	BSE (cow)	CWD (elk)
TSE reported in native animals or source herd	No	No	Yes
Ingested ruminant-based feed in the past	Unlikely	Likely (unless born post 1997)	?
Ingested non-ruminant based feed made from animal fed by recycling pathway that was fed ruminant based feed (e.g. pig, chicken) in the past	Unlikely	Likely	?
Ingesting ruminant-based food in the present	No	No	No
Ingested non-ruminant based feed made from animal fed by recycling pathway that was fed ruminant based feed (e.g. pig, chicken) in the present	No	Likely	?
Exposed to ruminant based vaccines or hormones	No	Yes	?
Exposed to animal feed (of any type) from BSE countries in the past	Unlikely	Yes	?
Exposed to animal feed (of any type) from BSE countries in the present	No	Possibly	

SWORN BEFORE ME at the Municipality of Milton, in the Province of Ontario, this _____ day of November, 2000.

A Commissioner for Oaths or Notary Public in and for Ontario.

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List of Scientific Papers referred to in this Affidavit

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