

Comments by the Archers on the CFIA response dated December 20th, 2001 to questions posed by Dr. Bill Anderson, October 30th, 2001

**CFIA RESPONSE TO QUESTIONS ON THE RISK
ASSESSMENT ON WATER BUFFALOES IMPORTED FROM DENMARK
- JUNE 2001 -**

The following questions were submitted to the Animal, Plant and Food Risk Analysis Network (APFRAN) by Dr. Bill Anderson to obtain additional information for the new decision on the fate of the water buffalo imported in January 2000 by Darrel and Anthea Archer. The questions were provided to the Archers for their information and comment. In these questions, the June 2001 Risk Assessment is referred to as "Risk Assessment" and where "tab" is indicated it refers to the book of documents submitted in support of the Risk Assessment.

1. Provide clarification of the following statements as found in the Risk Assessment, the Risk Assessment supporting documents and the responses to the Archer's submissions to the process:

- i) In different places the prediction for the number of cases of BSE in Denmark for 2001 is reported as 10 and 100. Although 100 cases seems to be the predominant figure, what is the explanation for the discrepancy between the two estimates and the actual number of cases identified (4 according to the most recent report included)?

Dr. Preben Willeberg, CVO for Denmark, predicted there may be as many as 100 cases. The actual number reported to date is 6. However, it should be noted that one of the two laboratories approved for the conduct of BSE rapid tests in Denmark had its approval revoked because Danish inspectors found that the test kits in use at that particular laboratory were not able to detect positive BSE samples. This was reported to the Standing Veterinary Committee on May 30, 2001

(http://europa.eu.int/comm/food/fs/rc/svc/rap66_en.pdf).

As a result, some cases may have been missed.

- ii) In the paper (tab 43 from Risk Assessment) "The possible vertical transmission of BSE" concludes that even if natural transmission does occur, it would be insufficient to maintain the epidemic of BSE in the UK. What conclusion can be drawn regarding the maintenance of an endemic BSE situation?

Recent science indicates that the maternal route, as the sole mechanism of transmission is insufficient to maintain BSE as an endemic disease. The "conclusion that can be drawn" depends upon assumptions regarding the absence of all other risk factors in a country; assumptions which

cannot be proved or disproved based on current scientific information.

iii) Page 6 of the Risk Assessment carries statement "once BSE exposure has occurred, nothing can be done to prevent or control the progression of the disease". Is this statement limited to the progression of the disease in individual animals or does it extend to progression in groups of animals, in animal populations or in man?

The statement was meant to apply to individuals - once a person or an animal is infected, the disease is invariably fatal. The progression of disease in populations, once introduced, is dependent upon the controls that are in place, the most important of which is preventing infective material from reaching the food and feed supply. However, despite rigorously enforced feed bans and extensive testing programs, countries which have diagnosed BSE in native cattle can only lay claim to declining incidence rates. None has yet managed to eliminate the disease.

iv) The page 6 footnote of the Risk Assessment "a risk estimate of LOW was considered NOT ACCEPTABLE ..." is written in the past tense. Has the acceptability of LOW changed?

Low risk continues to be unacceptable for BSE.

B. Provide update of any new information which may be available since the completion of the June 2001 Risk Assessment :

i) Has a case of BSE or TSE-like disease been reported in water buffalo?

The OIE considers that water buffalo are susceptible to BSE. Although no case has been reported to date in water buffalo, the fact that there is minimal surveillance in this species means that this is of little practical significance.

Archer Correspondence with Dr. Steve Dealler in the UK and representatives of the OIE indicate that as water buffalo are ruminants there is no reason to believe that they could not be susceptible to a spongiform encephalopathy. It should be noted that in sheep genetic factors have been identified that confer an animal's resistance or susceptibility to scrapie, with the resistant genotype more prevalent in certain breeds (Cotswold). Therefore it cannot be definitively stated that water buffalo would be susceptible to a TSE. Water buffalo have been productive in dairies for over twenty years and live naturally longer than cows; however, there has been no recorded case of BSE in water buffalo. Italy has 120,000 water buffaloes producing milk for cheese and no case of BSE has been found in their water buffalo herds even though 48 cases were identified in cattle in 2001. Thus

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 significant.

ii) Have the Australians determined their course of action with respect to the water buffalo imported from Denmark? Does their decision include the Australian-borne offspring of the imported animals? Has Chile included the Chilean-borne offspring in their actions to remove/destroy Danish imported animals following the declaration of BSE in that European country?

The information we have received from Australia is that the imported animals will be kept in lifelong quarantine with no restrictions placed on milk products. We have not been provided with an official position on restrictions which may or may not be placed on progeny. Of the 65 cattle imported by Chile, 16 have been slaughtered and incinerated while another 48 along with their progeny are being held in quarantine pending the outcome of litigation. Samples for testing have been taken from the slaughtered animals and results are pending. The progeny of these cattle are currently being held in quarantine. Presumably the decision on whether or not they should also be slaughtered will depend upon the outcome of the tests on the dams.

Archer As previously stated by the Archers, communications with the importer in Australia indicate that the Australian government has monitored but not extended quarantine of the imported animals since they arrived and no further restrictions have been placed upon them. In response to an enquiry to Geoff Ryan of AFFA on January 1st, 2002 the following was received from Narelle Clegg, Manager Live Animal Imports, AQIS, Australia on January 3rd. (A copy of this e-mail to the Archers was copied by Dr. Clegg to Dr. S. Kahn of the CFIA):

"Milking buffalo were last imported into Australia in 1996. These animals originated in Bulgaria but underwent a period of quarantine in Denmark before export. There are no quarantine restrictions imposed on these animals, their progeny or their products. The outbreak of BSE in Europe resulted in the suspension of the import protocol for cattle and buffalo from Europe in 1997."

Note: If these water buffalo had been imported into Canada within the past ten years they would be under the same destruction notice as our animals imported January 2000 as referenced by the CFIA in No. 11 of this document. Australia has a Category I GBR rating, whereas Canada has a Category II GBR rating.

iii) Has there been any further scientific reports relating to the role of environmental contamination as a mechanism for the transmission of BSE or other TSE?

BSE is not known to be transmitted horizontally in cattle

other than in feed. The scrapie agent is excreted into the environment in certain tissues and other animals exposed to those tissues are at risk of developing the disease. The pathogenesis of BSE in sheep may be similar to that of scrapie but there is no direct evidence for this hypothesis. The CWD agent is transmitted horizontally between susceptible cervids. It appears that the environment can become contaminated and can serve as a source of exposure to the agent.

Archer *It should be noted that BSE has not been identified as contaminating the environment. Results of research continue to maintain that BSE is transmitted through feed from the central nervous system of infected animals.*

iv) Have there been any field or experimental studies regarding the potential role of rodents and felines as a mechanism for cross contamination of meat meals and animal feeds at the rendering plant, feed mill or farm (as a possible pathway for the extension of the UK BSE epidemic)?

The CFIA is unaware of any such study.

v) Have there been any additional scientific reports regarding the potential of milk for the transmission of BSE? Have experimental studies used bovines or animal models with an equivalent sensitivity to BSE? In the reply to the Archer's document "Consideration of evidence...imported into Canada in January, 2000" page 16 carries the statement "There is no likelihood of transmission of BSE associated with milk and milk products, regardless of their origin". Please comment on the absolute value of "no likelihood" in this statement considering the limited research on milk and milk products including in animal models with reduced susceptibility to BSE.

Experimental studies to date have shown no infectivity in milk from BSE affected cows. In accordance with international standards (OIE and WHO), CFIA BSE import policies exempt milk and milk products. Milk and milk products that qualify for importation into Canada may be imported regardless of the BSE status of the country of origin.

vi) Has an official GBR rating been reported for Bulgaria?

Bulgaria does not currently have an official GBR rating. Many of the countries in the immediate geographic vicinity have reported indigenous cases of BSE over the past year and have received GBR 3 rating. Bulgaria submitted information to the SSC which initiated the European GBR assessment process. As the results are long passed due, it would appear that Bulgaria withdrew from the process and the final report of the SSC GBR of Bulgaria is therefore not available.

Archer An e-mail was sent by the Archers on January 1st, 2002 to the Secretary of the Scientific Steering Committee of the European Commission requesting a date when the GBR decision on Bulgaria will be available. The response received from Joachim Kreysa, January 3rd: "Bulgaria has not withdrawn from the GBR-assessment process but this was delayed for other reasons. It is now expected that a GBR for Bulgaria will be known in February or early April".

vii) Is there any evidence to suggest that water buffalo could not become asymptomatic carriers of BSE infectivity any thereby pose a threat to their offspring? To the environment? To human health?

The CFIA is unaware of any such evidence.

Archer There is no evidence to suggest that BSE is transferred horizontally from one symptomatic animal to another, nor is there is any evidence of horizontal or vertical transmission in asymptomatic animals.

viii) Has the detailed review of imports of MBM from the UK been completed as mentioned on page 3 of "Consideration of evidence...imported ... in January, 2000"?

A detailed review of available individual import transactions from the EU for the years 1990 to 2000 did not reveal any imports of ruminant meat and bone meal for the purpose of livestock feeding.

Archer a) The report, in draft form, prepared for Health Canada entitled "Risk Assessment of Transmissible Spongiform Encephalopathies in Canada" (June 2000) prepared by Joan Orr M.Sc. and Mary Ellen Starodub M.Sc., contains information regarding the importation of animal feed containing pig or poultry material from countries with BSE where these animals could have been fed contaminated ruminant-derived feed. In Canada ruminants are fed material derived from poultry or hogs generating a possible recycling route for BSE contaminated prions to pass into cattle. Calves are particularly susceptible through ruminant derived blood, tallow, gelatin and hydrolysed proteins. All of these products are listed as imported from countries with BSE, a high risk of developing BSE or unknown BSE status.

b) The Sunday Times of Great Britain, February 2001, published an export table for meat and bonemeal from the UK around the world. This table identified 125 tons of imported meat and bonemeal into Canada between 1993 and 1996. The CFIA has stated that any questionable material would have been processed for pet food, however, there is no label on pet food stating that it is unsuitable for ruminants. There are many examples of pathways for cross-contamination where ruminants may ingest pet food. For example:
- Livestock guardian dogs who live with sheep may be fed processed pet food to which the sheep may have access, thus offering an avenue for cross-contamination through feed.
- A recent television news item showed a pet reindeer in Canada eating dog

food.

There is also a risk with humans ingesting pet food. For example some children eat dog biscuits and some financially disadvantaged seniors eat canned cat and dog food.

ix) Has the CFIA conducted the risk assessment to determine whether or not the risks posed by current feeding practices are acceptable? See 8.2c) of "Consideration of evidence...imported into Canada in January, 2000".

Please see response to above viii). Domestic feeding practices are being reviewed to determine if they continue to be appropriate in light of the current risk factors for BSE in Canada.

Archer When reviewing domestic feeding practices the precautionary principle should not overlook the various documentation, readily accessible, suggesting that although it is highly unlikely that BSE from Europe will become endemic in North America, there is concern that a North American strain may be present. Examples from outbreaks of mink encephalopathy in farmed mink in Wisconsin (four since 1947) and in Blackfoot, Idaho (1963), were all attributed to prepared feed consisting of meat from local dairy cows that were staggering ("downer cows"). The first outbreak in 1947 preceded the arrival of scrapie in North America and the first recognized case of BSE in cattle in the UK in 1986. Diseased mink fed back to cattle resulted in a "downer cow" syndrome in those cattle. Richard Marsh of the University of Wisconsin concluded in 1996 that "If spontaneous cases of prion diseases can occur in humans, they likely also occur in animals. Normally not naturally transmitted, those spontaneous incidents can still pose a danger by the unnatural act of cannibalism as seen in kuru in humans, or by the intervention of man and the feeding of animal protein to ruminants."

Based upon the fact that the origin of the BSE outbreak in the UK remains a mystery (ref: correspondence with MAFF UK January 2001 and on-line research) and based upon the fact that agricultural practices in North America are similar to those in Europe, it would appear that an error in a feed mill (13% currently do not follow guidelines in the United States; in Canada there are no regulations controlling the treatment of spinal cords during slaughter) or another combination of unfortunate events, could provide an ideal medium for cases of BSE to be found in North America.

In Canada the classification 'Specified Risk Materials' is not used to classify brains, spinal cord, eyes, spleens, tonsils, etc. They are classified as 'by-product' if used as an ingredient in foods. In addition the classification 'Meat' comprises cuts of meat plus blood residue, bone, nerves with no assurance that these products were not contaminated with brain or spinal material ('A Qualitative Review of the fresh and processed meat industries in Canada as they relate to Transmissible Spongiform Encephalopathies', conducted by Mallot Creek

Strategies Ltd).

3. The FAO press release (tab 19), the Risk Assessment and the response to the Archer's submission refer to the "precautionary approach". What is the FAO's definition of the precautionary approach and how does the Risk Assessment intend that the CFIA risk managers apply this concept? What is the Canadian federal government position on the precautionary principle and how it should be applied?

The precautionary approach was conceived of in the environmental sector and was stated as follows: "in order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation". (Rio Declaration, 1992)

This was then extrapolated to the public health arena in the following manner: "Action to reduce risk should not await scientific certainty. When there is reasonable evidence that serious infectious diseases could be transmitted by blood (responsible parties should not refrain) from taking essential precautionary measures until causation has been proven with scientific certainty" (Krever commission report, 1997).

Archer The FAO Press Release of 01/03 (tab 19) advises "that there is an urgent need to ... implement effective surveillance for BSE in cattle and controls on the animal feed and meat industries... this means: laboratory testing of samples from slaughtered cattle, and correct disposal of fallen stock and improved processing of offals and by-products". The FAO also recommends applying HACCP, identifying potential problems and taking corrective measures addressing "the production of animal feed, the raw materials used, cross-contamination in the feed mill, labelling of manufactured feeds, the feed transport system, as well as monitoring imported live animals, slaughtering methods, the rendering industry and the disposal of waste materials."

Respectfully, the FAO Press Release does not suggest slaughtering imported live animals.

In its simplest terms, the precautionary approach can be defined as:
Scientific uncertainty + Suspected harm = Precautionary action.

Archer In following the mitigating measures proposed by the Archers there would be no "suspected harm" associated with the imported water buffalo herd at Fairburn Farm. According to Dr. Gray, author of the report from the Harvard Center for Risk Analysis, (<http://www.aphis.usda.gov/oa/bse>) speaking on National Public

Radio December 7th, 2001, "As far as we know in BSE, the disease is only contained in a few parts of a sick animal. It's in its brain, in its spinal cord and some other tissues of its central nervous system. If you can prevent those parts of an animal from getting to other animals, you can prevent the spread of the disease."

Furthermore, Dr. Linda Detwiler, listed in the Risk Assessment as an Assessment Reviewer, stated on the same programme "Well, the way the disease is spread, the primary if not sole route, is when you have an animal that's sick with the disease, that animal is slaughtered, rendered and then fed back to cattle. There's no scientific evidence at all that the disease spreads from cow to cow. And I think that's important for the whole world."

Water Buffalo are a different species than cows and to date have no recorded case of BSE or other transmissible encephalopathy anywhere in the world. Mitigating measures proposed by the Archers will monitor the animals during life and after death they will not enter the food chain.

With respect to the CFIA position, there is no explicit reference to the precautionary approach in our legislation but precaution and prevention are part of the way we do business (Presentation to the Public Health Science Forum, December 2000; on CFIA website). In terms of practical application, precaution is used when there is scientific uncertainty and the potential for serious harm to the Canadian agricultural industry or human health.

Archer A letter directly from the Canadian Ministry of Agriculture June 23, 1999 to the Archers set out clearly "CFIA veterinarians may need to visit the country of origin to evaluate its animal health status and veterinary infrastructure, and the herd of origin.... The Canadian policy on importation of live animals takes into consideration the risk of introducing bovine spongiform encephalopathy (BSE) into Canada." Therefore, if the aforementioned "Canadian policy" was implemented and the precautionary approach was "part of the way we do business" why were they not adequately addressed when the risk assessment on importing animals from Denmark was prepared (paid for by the Archers) prior to issuing the Import Permit? Why was the CFIA unaware that the USDA had imposed a ban on all imports of live animals from all European countries, including Denmark, on December 12, 1997 (USDA/APHIS) published in the Bovine Spongiform Encephalopathy (BSE) Response Plan Summary, October 1998.

CFIA's current policy to dispose of animals in Canada identified as a risk for BSE is based on a scientific assessment that even a low risk of introduction of BSE into Canada is not acceptable.

For further information, please see the CFIA website under "What's new". On November 27th, 2001, a document was

posted entitled "A Canadian Perspective on the Precautionary Approach/Principle".

Archer The Archers endorse the principle set out in "A Canadian Perspective on the Precautionary Approach/Principle" however, it is essential that decisions are made on scientific principles and available research. The Canadian Food Inspection Agency Corporate Business Plan Update 2000 - 2002 declares that "We are Canada's largest science-based regulator". The mitigating measures proposed by the Archers are consistent with the precautionary principle, i.e. they take precautions to keep the imported animals out of the food chain even though there is no reasonable risk that the animals are or could have been infected with BSE or an equivalent.

4. In the Risk Assessment (Page 29) the risk estimate is "VERY LOW" for the older group of calves. Given the period of time since the assessment would this time place the other group of calves at a risk estimate of "VERY LOW"? In other words, is time a mitigating measure where the Risk Assessment suggested that testing of the dams (post-mortem test) would be required to lower the likelihood (or probability) of infection? Is it CFIA policy to release animals into the national herd without further mitigation when the risk estimate is "VERY LOW"?

Yes, time is a mitigating measure in the case of the younger calves and they would now be expected to have a risk of "very low" also.

Depending on the disease, the CFIA has considered an assessed risk of "very low" or "negligible" as acceptable. However, regardless of the probability of disease entry and the capacity to contain and eradicate the risk, even a single case of BSE in an imported animal could have a significant negative impact on consumer confidence, productivity and export market access. Accordingly, current policy is that the importation of BSE-susceptible species from countries not considered free of BSE is prohibited. Any animals imported from such countries must be destroyed or re-exported.

Archer Geoff Ryan of AQIS in an e-mail to Brian Jamieson of Ag.Canada in March 2000 stated: "I consider that the buffalo imported from Denmark are a negligible BSE risk and certainly hope there is no local hysterical reaction. After all if there is a ban on the feeding of ruminant tissue to ruminants a single case of BSE, or even numerous cases, in imported animals has no epidemiological significance"

As defined by the OIE Animal Health Code "a country or zone may be considered provisionally free from BSE if all cases of BSE have been clearly demonstrated to originate directly from the importation of live cattle...and the affected cattle...have been slaughtered and completely destroyed". Canada's current

"provisionally free from BSE status" has been obtained despite the fact that BSE was recorded in an imported animal in 1993. It is Canada's lack of an effective feed ban for seven (7) years that has a significant negative impact for obtaining "BSE free status"

Water buffalo are fed grass and vegetable foods such as roots (carrots, parsnips, beet pulp), feed that is not recognized as carrying BSE. No grass fed cow has been diagnosed with BSE hence the susceptibility of water buffalo to BSE through feed cross-contamination is negligible

From Villy Jensen, Regional Veterinary Officer, Vejle, Denmark, where the water buffalo were domiciled in Denmark, letter dated October 20, 2000 to the Archers, confirming the feed consumed by the water buffalo, concluded sic "Therefor there should be no possible way, that the water buaffaloes could have been contaminated by BSE in Denmark". (This was included as an Exhibit to the affidavit of Anthea Archer, October 2000).

Furthermore the e-mail, Reference 1 in the Supporting Documents to the Risk Assessment from Professor Alexo Alexiev, President of the National Association of Buffalo Breeders in Bulgaria and Member of the Standing Committee of the International Buffalo Federation, states sic "Bulgaria is absolutely free from the ?mad cow?disease (BSE)...The Bulgarian Veterinary Service is very strict and conducts very strong control in this direction."

5. The documents supporting the Risk Assessment contain several papers which discuss the maternal cohort studies. These papers include complex statistical analysis with a number of significant confounding variables. In simplified terms, what conclusions can be drawn from these documents regarding maternal transmission of BSE?

Recent science indicates vertical transmission (from dam to offspring in utero) does not occur. Experimental studies to date have shown no infectivity in milk from BSE affected cows to offspring.

6. What is the margin of error of the risk estimates in the semi-quantitative approach used in the Risk Assessment ?

The risk assessment is a qualitative risk assessment. A semi-quantitative risk assessment is one in which some of the inputs and some of the outputs are quantitative while the others are expressed in qualitative terms. The outputs of the risk assessment, that is, the risk estimates, are all expressed in qualitative terms.

The uncertainty in the risk estimates cannot be quantified because of their qualitative nature. In order to give a level of confidence in the risk estimates, peer review by risk analysts and TSE specialists was employed. This represents the best means for validating qualitative risk estimates and ensuring that the analysis is based on the

most up-to-date and credible information available.

7. Scrapie has been endemic in the UK for over two hundred years. In the mid twentieth century, Canada, the United States, Australia and New Zealand imported UK breeding stock to build their respective sheep industries. Scrapie has since become endemic in Canada and the United States. What theories are advanced to explain how Australia and New Zealand remained free of this disease while Canada and the United States did not? What import policies, domestic disease control measures, husbandry practices or stroke of luck contributed to this significant difference in disease status?

Both Australia and New Zealand have long had extremely stringent and conservative import policies. This has been a key factor in their success. When both countries had cases of scrapie in imported animals, they took immediate action to eliminate the scrapie infected animals and all possible sources of contamination. This included, in the case of New Zealand, permanent closure of a quarantine area for livestock use. Import policies for Australia and New Zealand do not permit importation from countries not considered free from scrapie.

8. The degree to which economic factors are to be included in the risk (consequence) assessment and risk management processes is the subject of comment in the Risk Assessment, the Archers submission and the response to the Archer's submission. For the purpose of clarity on this debated issue, provide a clear description of the aspects of economic factors which may or may not be included in the risk analysis which would also respect the Federal Court rulings involving application of the Health of Animals Act and Regulations.

Article 5.3 of the Sanitary Phytosanitary Agreement of the World Trade Organization clearly defines the economic factors that can be considered in an import risk analysis, as follows:

“In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.”

Furthermore, Article 1.3.2.4 of the International Animal Health Code of the Office international des épizooties (OIE) provides the guidelines for conducting a consequence assessment as presented below:

“Consequence assessment consists of describing the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring. This estimate may be either qualitative (in words) or quantitative (a numerical estimate). Examples of consequences include:

- a) Direct consequences - animal infection, disease and production losses, public health consequences
- b) Indirect consequences - surveillance and control costs, compensation costs, potential trade losses, adverse consequences to the environment.”

Archer Canada's current "provisionally free from BSE status" has been obtained despite the fact that BSE was recorded in an imported animal in 1993. This did not seem to have economic implications. Furthermore, the mitigating measures proposed by the Archers would ensure that there is no harm to human health, the economy or the Canadian agricultural industry.
An environmental risk assessment was completed by the CFIA prior to issuing the Import Permit.

The risk assessment on the importation of water buffalo into Canada from Denmark was conducted within the bounds of these international agreements and guidelines. This was confirmed by the decision rendered by Justice Pelletier on January 17th, 2001. The Justice confirmed that the Minister is entitled to consider the public interest in a BSE-free Canada in making a decision on this case.

Archer The Honourable Mr. Justice Pelletier continued in the paragraph referred to above "But it is sincerely to be hoped that he (the Minister) will show the same level of concern for the fate of the applicants, whose only fault in all of this was to rely upon a risk assessment for which they were charged \$1,000".

Nowhere in the final risk assessment or CFIA Response is there any recognition of the research undertaken by the applicants, the continued expressed desire to cooperate with the CFIA and other agencies and ministries of the Canadian government, the mitigating measures proposed by the applicants, the loss of business as well as loss of projected businesses to the local economy; Nowhere is there any acknowledgement that income from the investment has been denied the applicants for two years since importing the water buffalo from Denmark.

Furthermore, the cramped quarantine conditions resulted in three deaths (two calves were injured and unable to nurse, and a yearling heifer).

Management restrictions due to quarantine have resulted in bull calves maturing and impregnating females including heifers on their first estrus - a situation that would not have arisen had the sexes and age groups been separated as requested on many occasions by the Archers. Dr. Francine Lord, of the CFIA, stated that the health and welfare of the animals was the CFIA's primary concern, however, this has not been the case.

The benefits of trade, whether to the producers associated with the importation or to Canadian society as a whole, cannot be considered in an import risk analysis. An example of such consideration would be the beneficial aspects of developing a buffalo cheese industry in Canada. This has no relevance to a risk assessment.

Archer Acknowledging the importance of preventing potential diseases entering Canada and with deference to the risk assessment team it should be pointed out that the Government of Canada, in the Federal Framework for Action in Rural Canada states the vision for rural Canada is:

- Vibrant communities and a sustainable resource base contributing to our national identity and prosperity
- Citizens making informed decisions about their own future
- Canadians sharing the benefits of the global knowledge-based economy and society, and taking full advantage of opportunities for personal and sustainable community development.

Community economic development must be a high priority in the Government of Canada and decisions taken by the CFIA should encompass the priorities identified by Canadian citizens through the Rural Dialogue without compromising human or animal health.

9. As a study group of animals would the Archer's imported water buffalo and their offspring serve any value as a animal disease research project? Specifically for TSEs?

Tremendous amounts of research on BSE are being undertaken in Europe. Due to the exotic status of BSE in Canada and limited resources allocated to research, CFIA's research projects currently focus on CWD and scrapie. There is no current or planned CFIA project that would benefit from the donation of the water buffalo.

Archer The imported water buffalo, documented and monitored during the normal course of farming and milk production, could be an important source of information at a future date. The Archers will undertake such documentation in a similar manner to the UK maintaining a link with experts in the field and preparing regular reports on file at Fairburn Farm, available to the CFIA at any time. This will be undertaken because the Archers believe in this project as a valuable addition to the local economy, to the Canadian Cheese Industry and as a tourism/educational component on Vancouver Island. The Archers will notify the CFIA of any changes or concerns regarding the health or domicile of the

water buffalo under guidelines developed between the Archers and the CFIA with input from experts in BSE research.

It has never been suggested that the water buffalo themselves would be donated.

10. What impact, if any will the European Union decision to prohibit, effective October 1, 2001, importation of live animals, embryos and certain animal products from countries not enforcing mammalian feed bans to ruminants? Would this impact on the proposal to restock Danish cattle herds with Canadian genetics? Does this decision impact on the consequence assessment? Are the Europeans applying some extension of the precautionary principle to extend the ban to embryos where there is opinion that embryo transfer represents the safest way to move genes around the world? (See tab 43) Will the decision impact on CFIA's attempt to have a re-evaluation of its GBR rating report?

This decision highlights the need to avoid even the perception of risk with respect to BSE. Even though Canada has never had a case of BSE and many European countries have, this ruling will prohibit the export of Canadian animals, embryos and certain animal products to Europe due to the Category 2 GBR rating of Canada by the EC. However, Canada meets the OIE requirements for a country free of BSE. In the case of embryos, the Europeans appear to have ignored some scientific evidence, i.e. research (in process of publication) that demonstrates that embryos do not pose a risk. The CFIA has continued to protest the Category 2 rating.

Archer Countries with Category I rating, such as Australia, have imported live animals from countries with subsequent confirmed cases of BSE. The charts available through the OIE identify that Australia can account for all imported ruminants from the UK and continental Europe, whereas Canada cannot trace all imported cattle from the UK and Europe. (<http://europe.eu.int>).

Furthermore Australia has set no restrictions on the water buffalo imported in 1996, their progeny or milk production (please see Archer's comment to above B,ii (2,ii))

11. On October 24, 2001 the Archer's have provided Fairburn scenarios - mitigating measures. Provide comments on this submission.

Taking into account the conclusions of the risk assessment (that the imported water buffalo present a BSE risk), established CFIA policy precludes release of the animals from quarantine. Consistent with scientific opinion and with Canadian Government policy in relation to serious foreign animal diseases, CFIA's current policy has the objective of preventing the entry of BSE into Canada. This goal is best served by removing from Canada all animals identified as presenting a BSE risk that is higher

than that associated with animals in the national herd. The risk associated with such animals may be addressed by destruction of the animals or their physical removal from Canada. Over the past decade this policy has been applied to cattle imported from the UK, cattle imported from other European countries, cattle imported from Denmark, sheep imported from Denmark and is being considered for application for cattle born in Japan imported in Canada via the US. CFIA has systematically traced and ordered the disposal of all ruminants imported into Canada from non BSE free countries over the past decade.

Archer There are several reasons to suspect that there is a greater risk in the national herd than in the water buffalo. It has not been possible to trace all animals imported from Denmark and other non BSE free countries as many imported cattle and sheep were not registered. When records are inadequately maintained animals cannot be traced if they are removed from the original farm of import whether through sale as live or butcher animals, or due to the death or relocation of the importer, etc. Tests performed on ruminants taken from farms under this policy in 2000 did not produce any positive results according to verbal information from the CFIA.

Animals not removed from the farms are currently used for breeding purposes and progeny are sold for breeding stock and meat.

Furthermore, there is no import ban on pig based products for animal feed. Pigs possibly fed contaminated ruminant material in the country of origin can legally be imported here and fed to cows. Rendered animals products, or waste designated for rendering and feeding to animals came from several BSE countries in 1999. Possibility of infection to cows is ongoing and the possibility of incubation of BSE in the national herd cannot be ruled out.

The CFIA has previously stated that the risk assessment is not quantitative therefore the following qualitative review of the comparison of risk factors in the national herd gives some perspective on the relative risks of disease emergence:

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	

(prepared by Joan Orr, M.Sc. and included in her sworn affidavit of November 23rd, 2000)

The role of risk assessment is to evaluate risk, based on a scientific assessment, having regard to established policies and practices, relevant precedents and the practical framework of the animal health program. Under this framework, options for disease control and exclusion include measures such as quarantine, testing, treatment, destruction and disposal.

Any finding of unacceptable risk is further considered as to the scope, feasibility and desirability of implementing measures to manage risk. Importations from BSE infected countries have been applied in accordance with Canada's highly risk averse approach to BSE. Imports from such countries have been and continue to be dealt with by measures relating to live animal quarantine, destruction or re-export of imported animals. There is no finding in the risk assessment to warrant a different approach in the case of the water buffalo.

Archers *The proposed mitigating measures are sufficient to completely eliminate any risk to animal or human health that may be associated with the presence of the imported water buffalo in Canada.*