WYOMING
GAME AND FISH DEPARTMENT

"Conserving Wildlife - Serving People"

July 8, 2002

Steve Williams, Director
U.S. Fish and Wildlife Service
1849 C Street, Room 3012
Washington D.C. 20240

Sent via FedEx Overnight Delivery, and
Fax via 202-273-3501

Dear Steve:

Attached please find a proposal by the State of Wyoming to vaccinate elk on the National Elk Refuge. This proposal is submitted to your office for a compatibility review pursuant to the Settlement Agreement entered June 21, 2002 in the case Wyoming vs. United States.

The Settlement Agreement provides that this proposal identify all information the Fish and Wildlife Service should consider when conducting the compatibility determination. Please note that such information to be considered includes the proposal and supporting documentation of articles and studies referenced as well as all citations cited, and studies and data contained within those references.

We look forward to working with your office in the future. We hope to begin vaccinating elk on the Refuge this winter and, therefore, time is of the essence; if we can help facilitate the compatibility review, let me know. If you have questions, please do not hesitate to call me at 307-777-4501.

Sincerely,

E. Tom Thorne, DVM

E. Tom Thorne, D.V.M.
Acting Director

ETT/cmc

Enclosure

cc: Governor Geringer
File

NATIONAL ELK REFUGE VACCINATION PROTOCOL
Wyoming Game and Fish Department
(June 2002)

Introduction

Bovine brucellosis is a disease caused by the bacteria *Brucella abortus* that can affect cattle, wild ruminants, and humans. It typically causes abortion in ruminants, and undulant fever in humans (Hunter and Kreeger, 1998). Some elk (*Cervus elaphus*) in the Greater Yellowstone Area (GYA) are infected with brucellosis (Thorne et al., 1978a). Brucellosis in the GYA, associated problems, potential solutions, and agency perspectives and commitments to its resolution have been reviewed (Thorne et al., 1997).

Herein is a proposal by the Wyoming Game and Fish Department, representing the State of Wyoming, to vaccinate elk on the National Elk Refuge (NER) with strain 19 (S19), a modified live strain of *B. abortus*, via biobullet as a means to reduce brucellosis-induced abortions.

In the GYA, brucellosis in elk is most prevalent in elk that spend at least some time on winter feedgrounds (Herriges et al., 1989). While artificial concentration of elk on feedgrounds contributes to the relatively high prevalence of the disease, feedgrounds also offer the opportunity to vaccinate elk efficiently (see below). There is a great deal of evidence both from clinical trials and from field experiments that indicates vaccination of elk with S19 is effective in reducing the prevalence of brucellosis in elk.

Brucellosis in elk mimics the disease in cattle (Morton et al., 1982; Thorne et al., 1978b; 1981). Strain 19 was used in cattle for over 60 years, and was considered instrumental in eradicating the disease (Nicoletti, 1990). Because the disease is similar in elk and cattle, S19 should provide protection in elk. Controlled clinical trials testing S19 in elk have been conducted since 1977. These studies indicate that S19 is safe and efficacious.

Strain 19 Vaccination of Elk

From 1977-1981, Thorne et al. (1981) conducted five different experiments in which elk were vaccinated with approximately 1×10^{10} Colony Forming Units (CFU) of S19 (standard dose). The vaccinated elk along with nonvaccinated controls were challenged with 7.5×10^{6} CFU of *B. abortus* strain 2308 at 6, 52, and 104 weeks after vaccination. Although each of the individual experiments was fairly small, the combined results indicated that calving success of 30 vaccinated elk was 60%, while calving success of 26 nonvaccinated elk was 31%. A few pregnant elk aborted because of S19 vaccine, which was consistent with results in cattle.

Trials were then conducted using a reduced dose because of the S19-induced abortions caused by the standard dose (the reduced dose had become the recommended dose for cattle). A series of very similar experiments to those described above were conducted using 3.6×10^{7} to 7.6×10^{9} CFU of S19. Results with the reduced dose were similar to those with the full dose: 62% of 37 vaccinated elk and 33% of 9 nonvaccinated elk delivered healthy calves (Herriges et al., 1989).

More recently, experiments using S19 have been repeated using larger numbers (T. Roffe, personal communication). Roffe used a dose of 4.42×10^9 to 8.58×10^9 CFU of S19 and challenged elk 1-2 years later with 1×10^7 CFU strain 2308 *Brucella abortus*. Abortion rates were higher in all groups than those in earlier experiments (possibly because of higher challenge dose), but S19 provided significant protection ($P = 0.02$). Results are preliminary, but at this time, 2 of 44 controls (5%) and 11 of 45 vaccinates (24%) have delivered healthy calves.

Taken together, results of all clinical trials indicate that S19 will protect 20-30% of vaccinated elk from aborting due to brucellosis. This level of protection is similar to that observed in cattle, and vaccination in the field is believed to be even more valuable than that observed in clinical trials due to greater herd immunity and reduced shedding of bacteria (Enright and Nicoletti, 1997). Modeling of brucellosis in elk indicates that this rate of protection from abortion could eventually result in a decrease in prevalence of brucellosis within an elk herd (Gross et al., unpubl. data).

Vaccination of Elk on Feedgrounds

The Wyoming Game and Fish Department (WGFD) first started brucellosis surveillance in elk in 1971 by collecting blood samples from elk trapped on winter feedgrounds. Sera from the blood samples were analyzed using four standard tests to determine seroprevalence of brucellosis. If two of the four standard tests were positive, the serum sample was considered positive (Morton et al., 1981). Prior to the use of S19 vaccine on free ranging elk, seroprevalence was 35% (744/2137) for all feedgrounds. This average includes data from all feedgrounds, including those with very small sample sizes. Seroprevalence at individual feedgrounds ranged from 2% (1/44) to 61% (14/23) prior to vaccination. Location, feedground establishment date, feedground management, sample sizes, and elk behavior contributed to this large range of seroprevalence.

There are 22 WGFD feedgrounds as well as the NER located in western Wyoming. During the past 18 years, elk on 22 of 23 feedgrounds have received Strain 19 (S19) vaccine by remote delivery using an air rifle and biodegradable bullets. From 1985 through 1995, 23,640 elk were vaccinated (Thorne et al., 1997). No disease or other problem attributable to the vaccine was seen in elk or other species. Both cow and calf elk are vaccinated during the first two years a vaccine program is initiated. Following this 2-year initiation period, calves become the primary targets for vaccination.

Elk have been vaccinated at the Greys River (aka Alpine) feedground for the longest period (18 years). Dell Creek is the only feedground where the S19 vaccination program was not conducted. The period in which S19 vaccination was conducted varies on the remaining 21 feedgrounds. The vaccination program was initiated on most of the WGFD-operated feedgrounds from 1985-1997. Elk vaccination was conducted on the NER in 1989-91 and has not been conducted there since that time.

One problem associated with S19 was that the four standard tests did not differentiate between S19-vaccinated elk and elk exposed to field strain *B. abortus*. A competitive

enzyme-linked immunosorbent assay (cELISA) test was validated in cattle in 1991 and then in elk in 2001 to differentiate between S19 vaccinates and field strain.

Since elk vaccination was initiated, cELISA seroprevalence has been 19% (158/854) for 8 feedgrounds (Table 1). Seroprevalence on individual feedgrounds varied from 9% (23/258) to 36% (58/161). Several factors such as location, pre-vaccination seroprevalence, duration of vaccination program (if at all), and feedground management may have contributed to this range of seroprevalence. This 19% seroprevalence rate included data from Dell Creek where vaccination was not conducted and the NER where vaccination was only conducted during 1989-91. Excluding the data from these two feedgrounds, the seroprevalence rate was 14% (69/491).

Greys River Feedground

Elk vaccination was initiated in 1985 on the Greys River Feedground (GRFG). These 18 years of S19 inoculation in elk are the longest duration of any vaccinated feedground. Pre-vaccination (1971-84) seroprevalence at GRFG was 43% (125/294) and 46% (94/203) for the years 1971-74, and 1976 when adequate sample sizes were collected. Since the S19 program was initiated, cELISA seroprevalence has been 9% (23/258) for the period of 1993-1999. Thus, vaccination significantly ($P = 0.002$) reduced seroprevalence on this feedground compared to pre-vaccination rates (Kreeger and Olsen, 2002).

These serologic results did not include 2000-02 data at GRFG. A vaccine failure during 1998 was thought to have increased seroprevalence during the past few years. After the vaccination program was complete for the 1998 season, vaccine potency testing showed a drop from 5.3×10^9 to 3.5×10^7 CFU. A vaccine dose below 10^9 CFU was considered insufficient to stimulate an immune response. Essentially, two lots of vaccine produced in 1995 had lost potency and were used through the 1998 vaccination season.

Some unprotected calves from the 1998 vaccine failure probably were exposed to field strain *Brucella*, and 2–4 years later (2000-02) aborted during pregnancy on the feedground. These abortions exposed other elk that were vaccinated in the past to field strain *Brucella*. These recently-exposed animals should have had some immunity from being vaccinated, but developed positive (false-positive) serology results due to exposure to field strain *Brucella*. If infection had actually increased during the past three years, reproductive rates should have dropped in the past two years due to abortions. Calf to cow ratios did not significantly change in the past two years (2001-02) when compared to the five year average from 1996-2000. Calf:cow ratios were 27:100 during 2001-02 and 29:100 during the five-year average from 1996-2000.

National Elk Refuge

Elk vaccination was conducted during 1989-91 on the NER. A total of 2,272 (1660 calves and 612 cows) elk were vaccinated during those three years. Seroprevalence was 38% (429/1123) prior to initiation of vaccination on the NER or surrounding feedgrounds. After 1990, seroprevalence was 28% (111/402) using the four standard tests. The use of the cELISA test on NER samples was not conducted for numerous

years in the 1990's, although vaccinated animals were detected during 2002 using cELISA. This indicated that there was some interchange with wintering elk from surrounding feedgrounds, probably the Gros Ventre feedgrounds. The NER currently has a seroprevalence of 28% post-vaccination compared to 38% prior to vaccination.

Dell Creek Feedground

The Dell Creek Feedground (DCFG) is the only feedground where elk were never vaccinated, thus it serves as a control feedground. Seroprevalence for 1989 and 1998-2002 was 47% (87/185). DCFG seroprevalence was very similar to pre-vaccination seroprevalence at GRFG. The DCFG seroprevalence of 47% was significantly higher than both the post-vaccination results from all feedgrounds as a whole (19%) and the GRFG (9%).

These data indicate that vaccination with S19 reduced the prevalence of brucellosis in feedground elk. In addition, there is an abundance of field and clinical trial data indicating that the vaccine is safe under feedground conditions. We strongly believe that long-term vaccination of elk on the National Elk Refuge will reduce the prevalence of brucellosis without harming elk or other species.

Table 1. Feedground seroprevalence pre- and post-vaccination.

	Seroprevalence to Field Strain *Brucella*	
Feedground Location	Pre-Vaccination	Post-Vaccination
All	35% (744/2137)	19% (158/854)
Greys River	43% (125/294)	9% (23/258)
NER	38% (429/1123)	28% (111/402)
Dell Creek (control)	47% (87/185)	

Protocol for Vaccination of Elk on the National Elk Refuge

The use of S19 vaccine to control brucellosis in free-ranging elk at the NER was attempted only from 1989-91. Over 2,000 doses were administered to adult female and juvenile elk over the 3-year period.

Elk are fed a pelleted alfalfa ration at four different sites on the NER: Shop, McBride, Nowlin, and Poverty Flats. Large feed trucks distribute the daily ration. Relatively long feedlines are established with approximately 8–10 pounds per elk fed daily.

The WGFD proposes to use a tracked, over-the-snow vehicle (LMC 1500 Bearcat or equivalent) to follow the feed trucks during feeding operations to acclimate and deliver the vaccine. Juvenile elk (and adult female elk if necessary) fed at the four sites will be vaccinated using an air-powered biobullet gun from the Bearcat vehicle(s). Vaccination will take place early in the feeding season to provide immunity to brucellosis before exposure to field strain *Brucella abortus* occurs.

Acclimation

Beginning with the onset of supplemental feeding, elk will be acclimated to the presence of the Beartrac vehicle(s) and sounds associated with vaccination. A pump air-pistol will be dry-fired at varying velocities to acclimate elk to the report of a gun as the Beartrac vehicle passes along the feedlines. After elk become accustomed to the sound of the pistol, vaccination guns will be dry-fired. At the beginning of the feeding season, the acclimation process will occur while feed trucks are dispensing pellets. Ideally, elk at a minimum of 2 feeding sites will be acclimated daily. As the animals become accustomed to the presence of the Beartrac vehicle(s) and vaccination guns, the vehicle(s) will spend progressively longer amounts of time afield and closer to the elk. Detailed notes on elk behavior will be kept during the acclimation process. Based on 15 years experience at state-operated feedgrounds, completion of the acclimation process may vary from a few hours to several days or weeks. Small amounts of hay may be used to help hold elk near the Beartrac vehicles.

Vaccination

Delivery of vaccine will begin when elk become acclimated to the vaccination process. This determination will be somewhat subjective, but will require elk to remain within 50–75 feet of the Beartrac vehicle as it passes along a feedline and occasionally comes to a stop. Vaccination will target juvenile animals (and adult female elk if necessary) at each of the four feeding sites.

From 1995-1999, juvenile elk numbers have averaged 1,169 (range: 949 to 1,458). Data collected at the state-operated feedgrounds have shown a large variation in the amount of time required to complete vaccination. For example in 2002, the average vaccination time was 20 calf elk/hour (range: 7–57 elk/hour). Presently, no estimate for acclimation or vaccination time can be given due to the unknown response of elk to this management action.

Ideally, two vaccination teams would be used. Use of a second vaccination team will depend on the NER allowing use of their snow vehicle (Thiokol) or rental of a second vehicle. An attempt to vaccinate 80-100% of the calves and > 50% of the cows would be coverage objectives for the NER. This would mean approximately 3,200 (1,200 calves and 2,000 cows) elk will be vaccinated per year, for the first few years. Depending on vaccination coverage during the first couple of years, vaccination of calves only would be the primary objective during the following years.

Success of the vaccination program will depend on close coordination and good cooperation with NER personnel and sleigh ride concessionaires.

Projected equipment, personnel needs, and costs

Four employees for 2 months each would be needed to vaccinate simultaneously at two different feed sites per day. Two individuals would make up each vaccination team, one person to vaccinate and one to drive. Two vaccination teams can be used if the NER provides use of their snow vehicle or one is rented; otherwise only one vaccine team could be supported.

Media

Vaccination on the NER is an event that will likely draw the attention of statewide, and, perhaps, national media. One person will be designated as the local WGFD spokesperson on this issue, and all media interview requests will be directed to that individual (Jackson/Pinedale Information Specialist). This person will be knowledgeable enough to handle all possible questions or direct questions to another knowledgeable WGFD representative and has the authority and discretion to publicly discuss sensitive information.

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