

BISON VACCINATION ENVIRONMENTAL ASSESSMENT



DECEMBER 3, 2004



MONTANA DEPARTMENT OF LIVESTOCK

INTRODUCTION

Bison are essential to Yellowstone National Park (YNP) because they contribute to the biological, ecological, cultural, and aesthetic purposes of the Park. However, Yellowstone National Park is not a self-contained ecosystem for bison and periodic movements of bison into Montana regularly occur. Some bison are infected with brucellosis and may transmit this disease to cattle if bison movements from the Park into Montana are not controlled. Transmission of brucellosis from bison to cattle would have significant adverse effects on Montana livestock producers in the Yellowstone area and on the Montana cattle industry statewide. If the risks associated with brucellosis were not managed, the responses of officials who are responsible for regulation of livestock diseases in other states and countries could also adversely affect Montana's livestock industry.

The U.S. Department of the Interior, National Park Service (NPS); U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (APHIS); U.S. Department of Agriculture, U.S. Forest Service (USFS); the Montana Department of Livestock (Department); and the Montana Department of Fish, Wildlife and Parks (FWP) each have limited authority for the management of bison, the management of brucellosis in bison and/or the management of lands used by bison. None of the agencies, acting alone, has sufficient authority to manage bison across all jurisdictional boundaries. In recognition of the shared responsibility and the need for cooperation in bison management, the agencies approved respective federal and state Records of Decision to implement the Interagency Bison Management Plan (IBMP) in December 2000. Management under the IBMP includes actions to protect private property; actions to reduce the risk of transmission of brucellosis from bison to cattle; actions to maintain a viable, free-ranging population of Yellowstone bison; and maintain Montana's brucellosis Class Free status. The Records of Decision were supported with a draft Environmental Impact Statement (EIS) that was jointly prepared by all agencies, a federal final EIS (Federal FEIS) and a state final EIS (State FEIS).

The IBMP provides a framework to manage both bison and the risk of transmission of brucellosis from bison to domestic livestock. The IBMP emphasizes measures to maintain temporal and spatial separation between bison and cattle. This plan establishes population targets for the bison herd and identifies management actions if and when bison move beyond the YNP boundary. The plan also establishes a framework for adaptive management. In the context of the IBMP, adaptive management means testing and validating with generally accepted scientific and management principles the proposed spatial and temporal separation, risk management and other management actions. Under the adaptive management approach, future management actions could be adjusted, based on feedback from implementation of the proposed risk management actions.

PURPOSE AND NEED FOR THE PROPOSED ACTION

Effective vaccination of free-ranging bison in the Greater Yellowstone Area (GYA) would serve to reduce the risk of brucellosis transmission from bison to cattle, while conserving free-ranging bison. Vaccines may be effective in reducing the spread of

brucellosis in several ways. Vaccines can enhance the immune response capability to ward off an infection when the animal is exposed and thereby increase the level of bacteria required for an infective dose. Because abortion is the major mechanism for transmitting brucellosis, the use of vaccines can also decrease the frequency of abortion and thereby reduce the potential for transmission.

The IBMP anticipated that vaccination of bison would be incorporated as a strategy to reduce the prevalence of brucellosis within the bison herd and to reduce the risk of transmission from bison to cattle. Within the adaptive management framework, the plan specified that vaccination would be implemented incrementally. Initially, vaccination with a safe vaccine would involve injection of seronegative calves and yearlings that had been captured in the Western Boundary Area of YNP and injection of all vaccination-eligible bison captured in the Northern Boundary Area of YNP. Subsequent vaccination would involve injection of vaccination-eligible bison (initially defined as calves and yearlings) outside the Park using a safe and effective remote delivery system and vaccination of vaccination-eligible bison inside the park with a safe and effective remote delivery system. The Records of Decision defined the in-park vaccination program as: “A program for delivery of a safe and effective vaccine to vaccinate eligible bison inside Yellowstone National Park so as to decrease the risk of transmission of brucellosis and diminish the overall seroprevalence of brucellosis in Yellowstone bison. Vaccination eligible bison are expected to initially include calves and yearlings, and will include adult bison if and when the agencies deem a vaccine is safe and effective. The agencies will deem a vaccine safe and effective according to criteria established by the Greater Yellowstone Interagency Brucellosis Committee (GYIBC).”

Although the management plan referenced the eventual vaccination of bison, and the Federal FEIS projected consequences to the bison population based on assumptions regarding efficacy, a safe and effective vaccine, appropriate for use in bison, was not available at the time the Records of Decision were approved. The Records of Decision referenced the GYIBC Vaccination Protocol (Appendix A) and the protocol provides a standard for the analysis of a decision to implement bison vaccination, as described in the IBMP. But, neither FEIS analyzed any vaccines according to that protocol nor could they validate the assumptions regarding efficacy that were included in the population model. In the State FEIS, the state agencies committed that future decisions regarding bison management that may require additional Montana Environmental Policy Act (MEPA) analysis would include corresponding opportunities for public notice and comment.

Purpose

With approval of the Records of Decision, the agencies agreed to review ongoing vaccine research results and assess the consequences of using vaccines as they are developed. The Records of Decision also indicated that when the NPS and the State of Montana agree that a vaccine is safe for bison and non-target species, and the vaccine is at least somewhat effective in protecting vaccinated bison from infection, the agencies would determine when and where, within the approved management plan, that vaccine might be used.

Research on the *Brucella abortus* strain RB51 vaccine (RB51), including vaccination of bison, has been on-going since its discovery in the early 1980s. RB51 is a modified live vaccine that may impart long-term protective immunity to infection by *Brucella abortus* in cattle and bison. The properties of RB51 were described by Schurig et al. (1991). A technical summary of the characteristics and studies conducted by USDA, Agricultural Research Service (ARS) on the RB51 vaccine is available from ARS in a separate document entitled “Brief Summary of *Brucella abortus* Strain RB51 Research Conducted with Bison at the National Animal Disease Center” (Olsen, 2001). Unlike *Brucella abortus* Strain 19 vaccine (Strain 19), RB51 does not cause an animal to produce antibodies that would be detected by standard serologic tests for brucellosis (Cheville et al. 1993; Stevens et al. 1995; Van Metre et al. 1999).

The agencies have determined that RB51 is safe for use in free ranging bison and that it is safe for non-target species. The purpose of this analysis is to document that conclusion and to evaluate alternative options for adding a bison vaccination component to the IBMP.

Authorities

The draft EIS and Federal FEIS disclosed the statutes and regulations that define the mandates of all of the agencies with authority to manage bison (Federal FEIS p. 46 – 51). The Montana Legislature has designated bison that originate from YNP as a species requiring disease control. The Department is authorized to remove or destroy publicly owned bison that enter Montana from a herd that is infected with a dangerous disease or whenever those bison jeopardize Montana’s compliance with state or federally administered livestock disease control programs (81-2-120 (1) M.C.A.). The Montana Legislature also has found that bison pose a significant potential for the transmission of infectious disease to persons or livestock and for damage to persons and property (87-1-216(1)(c) M.C.A.). FWP is required to cooperate with the Department in the management of these bison. The preparation of this Environmental Assessment conforms to the requirements of the Montana Environmental Policy Act (Title 75, M.C.A.) and the regulations promulgated pursuant to that authority (32.2.201 – 32.2.246 A.R.M.).

APHIS has prepared a separate Environmental Assessment and issued a Finding of No Significant Impact (FONSI) and Decision Notice regarding bison vaccination, in conformance with the requirements of the National Environmental Policy Act (NEPA) and the regulations promulgated pursuant to that authority (7 Code of Federal Regulations (CFR) 372).

Decisions to be Made

The principle decision that will be made pursuant to this Environmental Assessment is the determination whether a safe vaccine, appropriate for use in bison, is available and, therefore, whether it is appropriate to initiate bison vaccination in the Western Boundary Area, as per the provisions of the IBMP, (c.f. IBMP, III.4). Other decisions include determination of the most appropriate way to coordinate bison vaccination with other bison management and research activities. Within the adaptive management framework,

the only criterion required to begin vaccination is the availability of a vaccine that is safe for use in bison and safe to non-target species. However, this Environmental Assessment (EA) also discloses current information regarding the efficacy of RB51, the proposed vaccine, for reducing brucellosis infection in bison.

Other Relevant Environmental Documents

This EA incorporates by reference the August 2000 Federal FEIS for Bison Management for the State of Montana and Yellowstone National Park and the corresponding Record of Decision dated December 20, 2000 and the November 2000 State of Montana FEIS for the Interagency Bison Management Plan and the corresponding Record of Decision, dated December 22, 2000.

APHIS completed an EA in November 2003 (Gertonson 2003) and issued a Finding of No Significant Impact in February 2004 concerning the subcutaneous vaccination of bison in the GYA.

FWP (2004) recently tentatively approved a limited public hunt for bison from the Yellowstone herd that enters Montana. That decision was supported with an EA.

NPS has indicated its intention to prepare an EIS to evaluate a comprehensive program of remote vaccination of bison in YNP. The Notice of Intent was published in the Federal Register on August 3, 2004.

The State of Montana and APHIS are considering a research project to evaluate the feasibility of bison quarantine as a non-lethal alternative to the removal of disease-free bison that are captured within the framework of the IBMP and are excess to the population objectives defined by the Plan. FWP recently released an EA for this proposed project.

Public Scoping

Public comments regarding bison management, in general, and the use of vaccines in bison management were summarized in the Federal FEIS and the State FEIS. Commenters who opposed vaccination of bison expressed concern for one or more of the following reasons: the cost for the research to develop the vaccine would be better spent on other bison research or management activities; vaccination would be costly, impractical, unrealistic and unworkable; or, vaccination would be treating bison like livestock. Some commenters opposed vaccination because they do not believe that brucellosis is a problem in this bison herd. Some commenters who advocated for vaccination of bison indicated that vaccination would be more humane than killing bison. Others expressed the belief that vaccination would be an effective element within an overall program designed to reduce the seroprevalance in this herd.

APHIS received similar public comments in response to the release of its EA for the subcutaneous vaccination of bison in the GYA. In addition, some commenters questioned the safety and efficacy of RB51 for use in bison. Some commenters expressed concern for the effect of capture, vaccination and tagging on the wild

characteristics of bison. Further, APHIS received comments that emphasized several points, including the cultural and biological uniqueness of a bison herd that has continuously occupied its native range in the wild; concern that vaccination is a tool for the management of livestock, not wildlife, and that treating wildlife like livestock is inappropriate because it would erode the wildness of the Yellowstone bison herd; concern that RB51 is not effective in bison and its use will not eliminate brucellosis from the herd; the belief that brucellosis has little effect on buffalo and that wild buffalo have never transmitted brucellosis to livestock; and the belief that management should be focused on cattle.

Persons who responded in support of APHIS' EA generally referenced the economic significance of brucellosis. They noted the investment that the livestock industry and the animal health regulatory agencies have made in efforts to eradicate brucellosis from the nation's livestock herds. They noted that brucellosis has been eradicated from every public bison herd with a history of brucellosis infection, except the herds in Yellowstone and Grand Teton National Parks. Now that the effort to eradicate brucellosis is nearly complete, they are concerned about the potential for livestock herds to become re-infected.

Issues Identified by the Public that are Within the Scope of the EA

The Department invited public comment specific to this EA for the purpose of clarifying the issues that it had determined were relevant to the decision and requested the public to identify additional pertinent issues. The public scoping period began with the project announcement on June 14, 2004 and continued through July 23, 2004. To facilitate public comment, the Department scheduled a scoping meeting in Helena on July 12, 2004. The Department also provided the opportunity for people to submit comments electronically, via the Department's website.

The Department received comments from 53 individuals. In addition, the Department received comments from the following organizations: Buffalo Field Campaign; Gallatin Wildlife Association; Greater Yellowstone Coalition; Intertribal Bison Cooperative; Montana Farm Bureau Federation; Montana Stockgrowers Association; National Parks and Conservation Association; and, National Wildlife Federation. Generally, comments were consistent with those submitted in response to previous environmental reviews related to bison management.

The Department determined that the following issues, identified by commenters during the public scoping period for this EA, are relevant to the scope of the pending decision:

- Healthy bison would pose no risk to livestock or other wildlife.
- The agencies have a responsibility to address the issue of brucellosis in bison because of the importance of agriculture to Montana's economy.
- The bison management plan has prevented the spread of brucellosis in Montana and vaccination of bison is the logical next step.
- Vaccination would provide additional options for keeping bison alive.
- Vaccination will, over time, help to ensure a disease free herd and reduce conflicts at the park boundary and reduce the cost for management.

- Research should be focused on developing a more effective vaccine for cattle.
- Vaccination will erode the wildness of bison.
- RB51 is not safe in bison.
- RB51 is not effective in bison.
- Vaccination will not be effective because only a portion of the herd will be vaccinated.
- Vaccination will not be effective because it will not prevent re-infection from elk.
- The EA should include appropriate epidemiological models to evaluate the long-term impact of vaccination.
- The EA should evaluate the effects of capturing and vaccinating newborn bison calves.
- Vaccination could result in increased efforts to capture emigrating bison.
- Vaccination to reduce seroprevalence would only be appropriate when a scientifically-proven safe and effective vaccine for bison is developed and also found to be safe on non-target species and can be administered in a non-intrusive manner.
- The EA should evaluate whether an agricultural approach to disease management is appropriate for wildlife.
- The EA should evaluate vaccination in the larger context of disease management and whether vaccinating bison will achieve the purpose of brucellosis eradication.
- The EA should evaluate the appropriate identification of vaccinated bison, with consideration for the fact that these animals will be observed by park visitors.
- If bison are vaccinated, there should be follow-up studies to determine the effectiveness of the vaccine.
- To be effective, any vaccination program should include all animals and all species that have the potential for transmitting brucellosis.
- All of the agencies were involved in the development of the IBMP. Therefore, all of the agencies should be involved in evaluating vaccination.
- The EA should outline the integration of various agency vaccination plans.
- Bison vaccination should be implemented in a manner that is consistent with the steps outlined in the IBMP.

Issues Identified by the Public that are Outside the Scope of the EA

Commenters also identified the following issues that are pertinent to bison management but outside the scope of the pending decision whether to include vaccination in the current management strategy. Most of these issues also have been evaluated in the FEIS for the IBMP or in environmental documents prepared by other agencies on other matters related to bison and elk management in the GYA.

- Bison management should be evaluated in the context of history. Bison were transplanted back into the park early in the 20th Century. Also, Yellowstone is the only national park with bison that has not addressed the issue of brucellosis.
- The overpopulation of bison and the associated over-grazing will exacerbate the problem.
- Montana achieved its brucellosis Class Free status at great expense. The current situation in Wyoming demonstrates the economic impact that would result from the loss of that status.

- Wild buffalo have never transmitted brucellosis to cattle.
- APHIS and the Montana Department of Livestock have no place meddling with the fate of the Yellowstone bison herd or participating in the management of bison.
- Current management is not based on sound scientific evidence, is not rational, is far from humane, and has not been adaptive in response to changing circumstances and/or new information.
- Hunting bison is not sport.
- Bison do not contract brucellosis.
- Vaccination is an attempt to contaminate the whole bison herd.
- Cancel the cattle leases.
- Stop the slaughter of bison in the national park.
- Protecting cattle from brucellosis transmission from bison does not solve the problem of protecting cattle from exposure to elk.
- Buffalo have a greater historical right to the land than cattle and cattle use of the area should be secondary to the needs of native wildlife.
- The genetic diversity of bison should be protected.
- Intrusive management affects the sacredness of buffalo and thus affects Native Americans.
- Capturing and handling wild bison is akin to treating wildlife like livestock. The handling and manipulation of animals will have significant negative effects on the population and should be evaluated in an EIS.
- Vaccination should be evaluated against the use of other management strategies such as creating and maintaining temporal and spatial separation between livestock and cattle, mandatory vaccination of livestock and landscape-level management.
- Ranchers should vaccinate their cattle. The EA should include a cost/benefit analysis of a mandatory cattle vaccination program.
- The EA should evaluate the effects of perpetuating a capture, test and slaughter program for wild bison.
- The EA should evaluate the distribution of bison on publicly-owned and other appropriate lands outside YNP.
- The EA should evaluate all wild animals that may carry and transmit brucellosis.
- Brucellosis may affect a few individual bison, but it does not threaten the viability of the herd. Vaccination is not necessary to protect the health and future of the bison.
- The vaccination program represents yet another intrusion into the free-ranging character and spirit of Yellowstone's bison and is inconsistent with natural regulation.
- Vaccination might be effective if administered in combination with other treatments and better testing methods and procedures. However, these other methods are still in development.
- Vaccination should be considered in conjunction with quarantine.
- Vaccination will likely lead to a park-wide capture, test and slaughter effort.

Relevant Issues

The Department has determined that the following issues are pertinent to the pending decision whether to incorporate vaccination of bison into bison management in the Western Boundary Area. These issues will be used to frame the analysis in this EA. The

relevant issues identified by the public, generally, are congruent with this list and those issues likewise will be addressed in this analysis.

1. Which vaccines are safe for use in bison?
2. Which vaccines are safe for non-target species?
3. How effective are available vaccines and vaccine delivery mechanisms in reducing the potential for brucellosis infection in bison?
4. How effective are available vaccines and vaccine delivery mechanisms in protecting bison from abortion?
5. What is the appropriate dosage of the preferred vaccine for bison?
6. How effective are remote delivery systems for vaccinating bison?
7. What vaccine delivery mechanisms will be used to vaccinate bison?
8. How will vaccination of bison facilitate achievement of the purposes of the IBMP?
9. How will vaccination of bison affect the dynamics of the bison population in YNP?
10. How will vaccination affect the risk of brucellosis transmission from bison to cattle; from bison to elk; and, from bison to bison?
11. How will vaccination affect Montana's ability to comply with the National Brucellosis Eradication Program?
12. What cultural issues are associated with vaccination of bison and how will those be affected?
13. How will vaccination of bison affect the public controversy associated with bison management?
14. How much will it cost to incorporate vaccination into bison management in the Northern and Western Boundary Areas?
15. How will the vaccination of bison affect bison hunting in the Northern and Western Boundary Areas?
16. What are the cumulative effects associated with vaccination of bison?

DESCRIPTION OF THE PROPOSED ACTION

Proposed Action

The Montana Department of Livestock proposes to vaccinate bison calves and yearlings, consistent with the adaptive management steps for the Western Boundary Area, as described in the IBMP. Vaccine eligible bison include bison that meet all of the following criteria: 1) calves (4 to 12 months of age) and yearlings (12 to 24 months of age); 2) captured as a result of other management actions to manage bison numbers and distribution in the Western Boundary Area; 3) tested to determine that the bison are seronegative for brucellosis; and, 4) otherwise eligible for live release because bison numbers do not exceed the population objective for the respective management area or the population does not exceed the population target of 3,000 for the whole bison herd. When the population exceeds the defined objective for the Western Boundary Area for the target for the whole bison herd, the Department may exercise discretion in determining whether to vaccinate and release otherwise eligible bison.

Vaccination will occur opportunistically, as an incidental activity to normal bison management activities. Capture operations will continue at the level required to maintain bison numbers and distribution in the Western Boundary Area, as defined by the IBMP. The Department does not propose additional capture operations specifically for the purpose of increasing the number of bison available for vaccination.

Once captured, bison will be separated into groups by sex and age to minimize injuries from bulls or cows. Unless otherwise removed because bison numbers exceed the population objective for the respective management area or the population does not exceed the population target of 3,000 for the whole bison herd, a blood sample will be drawn from each captured bison to test for brucellosis. Testing and diagnosis will be conducted under the direction of the State Veterinarian. Personnel involved in vaccination will be licensed veterinarians employed by, or contracting with, a State agency and/or APHIS. Testing will consist of the use of one or more brucellosis serologic field test(s). Serostatus will be determined using approved procedures published in the UM&R and/or CFR. While captured, each bison will be officially identified with an ear tag and/or other permanent means of identification, testing will be performed, and test records will be completed for each animal. Bison that test positive for brucellosis will be sent to slaughter or to an approved research facility. Seronegative bison will be released except that seronegative bison calves and yearlings will be held for vaccination and subsequently released. Some seronegative calves may be included in the proposed Bison Quarantine Feasibility Study. A veterinarian will inject the standard 2 mL dose of RB51 containing at least 10 billion and not more than 34 billion colony-forming units of the vaccine under the skin in the neck or shoulder area of vaccine-eligible bison. Bison will be closely observed for a 15-minute minimum for anaphylactic reaction, a rare allergic hypersensitivity, to the inoculation. Any bison exhibiting reaction to the vaccine will be treated with epinephrine. Following the vaccination procedure, the bison will be released or may be included in the proposed Bison Quarantine Feasibility Study. Identification will allow for the determination of vaccine effectiveness in individual bison that are subsequently recaptured.

ALTERNATIVES TO THE PROPOSED ACTION

No Action

Under this alternative, bison management in the Western Boundary Area would continue under the provisions of the IBMP. The Department would defer the decision to incorporate bison vaccination into the plan for the Western Boundary Area, pending the results of additional research regarding vaccines suitable for use in bison.

Other Actions that were Considered but not Analyzed

Vaccinate bison calves and yearlings according to a research protocol

Under this alternative, the Department would vaccinate of a limited number of bison calves and yearlings according to a protocol designed to expand on current research efforts to develop the most appropriate vaccine for use in wild bison. An experiment

sufficient to document whether vaccination had a significant efficacious effect would require matched cohorts of vaccinated and non-vaccinated eligible bison. All of the experimental animals would be fitted with radio collars, monitored and sampled at regular intervals, over time. Vaccine efficacy in a field situation then would be estimated with statistical comparisons of the sero-conversion rates between bison in the two cohorts. A study of this type should use a large number of bison. If the difference between sero-conversion rates is large, statistical significance could be determined with a relatively small sample. However, a small difference could not be detected unless the study included a large number of animals (T. Roffe, personal communication).

The Department did not consider this alternative because, at this point in the implementation of the IBMP, other research questions, relative to the adaptive management strategy, are of higher priority.

Vaccinate female calves and yearlings

This alternative is similar to the proposed action except that vaccine eligible bison would include only female bison calves and yearlings. Effects would be similar to those described for the proposed action. The Department did not consider this alternative because the IBMP defined vaccine eligible bison as all calves and yearlings. Moreover, vaccination of male calves and yearlings may protect some bulls from infection and thereby reduce the numbers of bulls that are subject to management removal.

Vaccination with Strain 19

This alternative would be similar to the proposed action except that a 2 milliliter dose containing at least 2.7 billion and not more than 10 billion colony-forming units of Strain 19 vaccine would be used. Strain 19 has been used extensively to vaccinate domestic bison calves and no widespread negative effects have been reported related to its use (Roffe and Olsen 2002). However, there have been few studies on the biosafety of Strain 19 for bison and for non-target species. Limited studies suggest that Strain 19 is safe for use in bison calves (Davis et al. 1993; Olsen et al. 1997). However, Strain 19 may cause a high rate of abortion when used to vaccinate pregnant, adult female bison (Davis et al. 1991). Limited research suggests that vaccination of bison calves with Strain 19 at the recommended dose is not effective in preventing infection if the vaccinates are subsequently challenged as adults (Davis 1993).

Calfhood vaccination with Strain 19 has been effectively used as part of an overall management program to eradicate brucellosis from other chronically infected public bison herds (Cheville et al. 1998). However, the Department has concluded that Strain 19 vaccine is not appropriate for use in wild bison because the vaccine can cause infection and can cause the development of antibodies that would be detected by standard serologic tests for brucellosis; and, is pathogenic to humans. Although not of concern if vaccine eligibility is limited to calves and yearlings, Strain 19 also can cause spontaneous abortion when injected into pregnant females. The GYIBC Protocol specifies that a major advantage of any vaccine would be the ability to differentiate vaccinates from animals infected with *Brucella* field strain either by a serologic test or by alternative

methods. As noted in the APHIS EA (Gertonson 2003), the antibodies produced by a vaccinated animal can interfere with the serologic tests that are designed for detection of brucellosis. That EA also indicated Strain 19 is currently approved as one tool in the National Brucellosis Eradication Program to combat *Brucella abortus*; but in recent years, it is no longer used because of the availability of a RB51; some states no longer allow vaccination with Strain 19 as part of state eradication plans; and, the efficacy of Strain 19 in bison is in doubt.

Remote Vaccination

This alternative would implement vaccination of vaccine eligible bison, including calves, yearlings and adults, with a remote vaccine delivery system. The agencies agree that remote vaccination of vaccine eligible bison within the management areas and inside Yellowstone National Park should eventually be incorporated into the IBMP. However, as described in the adaptive management framework, implementation of this step is contingent upon the availability of a safe and effective remote delivery mechanism. Research projects are in progress to evaluate remote delivery mechanisms and vaccines that might be appropriate for remote delivery.

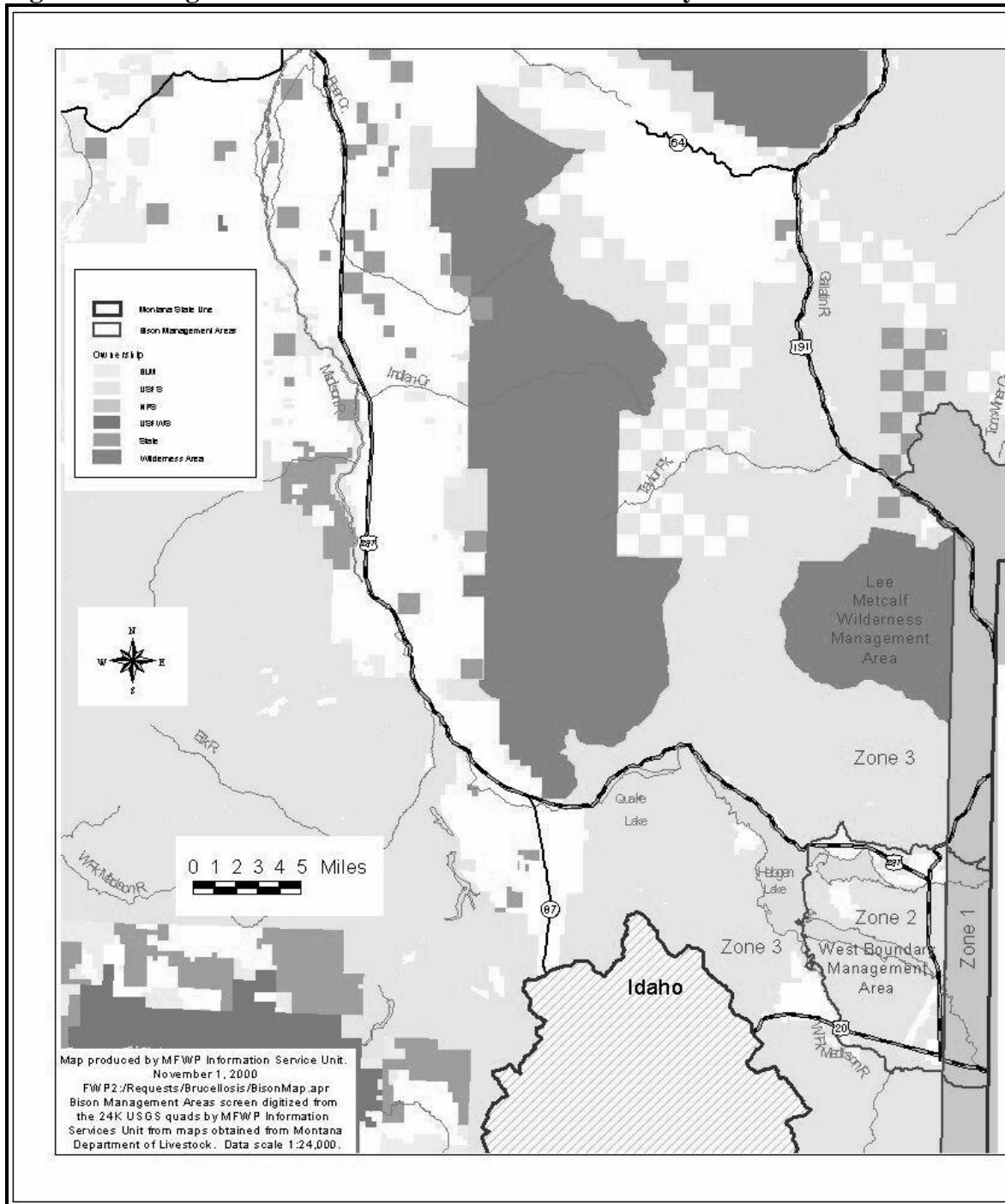
Aune et al. (2002) indicated that a large-scale vaccination program for the GYA would require an array of remote delivery systems. They also noted that, while the use of vaccines to control brucellosis in bison and elk has been discussed at length, limited progress has been made in overcoming the most significant limitation, i.e. the development of a reliable remote delivery system. Remote delivery with currently available technology is ineffective in bison beyond 20 yards (Roffe et al. 2001). Olsen et al. (2002) suggested that ballistic delivery might require a greater dose of RB51 than the standard dosage used for hand injection in bison.

The Department did not consider this alternative within this EA because, in approving the IBMP, the agencies indicated that the decision to amend the Plan to include remote vaccination would be supported with an EIS. The Department is not prepared to initiate an EIS at this time because there is uncertainty whether a remote delivery system, sufficient to achieve the purposes of the IBMP, is available for field application at this time.

DESCRIPTION OF THE AFFECTED ENVIRONMENT

Bison vaccination would occur within the Western Boundary Area, as described in the FEIS for Bison Management for the State of Montana and Yellowstone National Park (Figure 1-following page).

Figure 1. Management zones within the Western Boundary Area.



Cattle Distribution and Vaccination in the Western Boundary Areas

Two cattle herds graze seasonally on private lands in Zone 2 in the Western Boundary Area. The operator of one herd resides in Idaho and grazes cattle on his own property. A Certificate of Veterinary Inspection (CVI) and a Montana importation permit are required for this operator to import cattle for grazing purposes on his property in Montana.

Montana law requires all vaccination-eligible female cattle imported into Montana are official calfhood vaccinates (OCV) against brucellosis. This owner also operates in compliance with a plan administered by the Idaho State Veterinarian, which requires testing of the test-eligible cattle upon return to Idaho. The other livestock producer is a Montana resident who leases private land. The Department, APHIS, and the operator have developed a herd plan. Although the plan has not yet been finalized, the producer operates in compliance with it. The herd plan requires calfhood vaccination of all eligible cattle and annual testing of all test-eligible cattle grazing in the West Yellowstone Area. In addition, the first year the private land was leased by this producer, all test-eligible cattle were tested negative prior to turn out. APHIS pays the direct costs for testing and vaccination. The herd plan also specifies grazing dates, locations and cattle numbers.

During summer 2003, six livestock producers grazed cattle on private land leases within 2 miles of Zone 2 in the Western Boundary Area. These operations included 135 cow-calf pairs, 23 cows, 450 heifers and 12 bulls. The majority of the cattle were imported from Idaho and, consistent with the Montana importation requirements, all of the eligible cattle were official calfhood vaccinates. One Montana producer grazes approximately 70 cow-calf pairs in this area, of which, all vaccination-eligible female cattle are official calfhood vaccinates.

Cattle Distribution and Vaccination in the Northern Boundary Areas

The grazing lease on the Royal Teton Ranch (RTR) is no longer in effect. However, RTR now grazes its own cattle on portions of its land in Zone 2. APHIS and the Department are in the process of developing a herd management plan for this herd. The Eagle Creek area was cattle-free at the time the IBMP was implemented. However, one livestock producer now utilizes private property in the Eagle Creek area seasonally for his cattle. APHIS and the Department have initiated the process to develop a separate herd management plan for these cattle.

ANALYSIS OF IMPACTS

Analysis Common to All Alternatives

The effects of implementing the IBMP were evaluated in previous State and Federal Environmental Impact Statements. Those effects will continue under all alternatives. Additional effects, specific to a decision to revise current management to include vaccination are evaluated in this EA.

Any decision to begin bison vaccination within the framework of the IBMP is contingent upon an analysis of safety and efficacy, according to the GYIBC Vaccination Protocol (Appendix A). This protocol defines the standard for the analysis of safety and efficacy for all alternatives. Within the adaptive management framework, the decision to initiate vaccination of bison in the Western Boundary Area capture facilities would begin when it is determined that a vaccine that is safe for use in bison and safe for non-target species is

available. Subsequent decisions to initiate remote vaccination are contingent upon the development of a safe and effective system for vaccine delivery.

The Department understands that there are differing opinions about the appropriateness or necessity of an emphasis on brucellosis in the management of bison that move from YNP into Montana. While there is public controversy about brucellosis and wildlife, there is some level of agreement about the science of brucellosis among professionals, who are knowledgeable concerning brucellosis and wildlife. The GYIBC (1997) documented the information about brucellosis, as it might relate to management of bison and elk in the GYA, for which there is general agreement among the technical experts employed by the responsible state and federal agencies. That information was presented by the GYIBC in a “white paper.” The analysis in this environmental assessment is based on the information that was summarized in that “white paper” and more recent information derived from controlled scientific studies.

Roffe et al. (1999) reported findings that indicated a relation between *Brucella* serology and culture in bison similar to those reported from studies of chronically infected cattle herds. Rhyan et al. (2001) also suggested that, in many aspects, the disease in bison is similar to that in cattle. Although it was not the primary focus of their research, Olsen and Holland (2003) reaffirmed the potential for *Brucella abortus* to persist in bison until attainment of reproductive age, despite extensive use of vaccination and serological testing.

PROPOSED ACTION

The IBMP included provisions to incorporate bison vaccination because the agencies determined that vaccination was consistent with the objectives of taking steps to reduce the prevalence of brucellosis in bison; reducing the potential for brucellosis transmission from infected bison to susceptible bison; reducing the risk of transmission of brucellosis from bison to domestic livestock; and, assure regulatory veterinarians in other states and countries that management of Yellowstone bison is sufficient to prevent the transmission of brucellosis from bison to domestic livestock.

Vaccine Safety to Bison

Brucella abortus strain RB51 is a modified live vaccine. Because the vaccine is a solution of live bacteria, it is appropriate for use only if it is known that the vaccine does not cause disease in vaccinated bison and that the vaccinated bison do not shed the organism, posing a risk of transmission to other bison or non-target species.

Biosafety studies focus on four vaccine characteristics. These include shedding, transmission, persistence, and pathology (Roffe and Olsen 2002). Initial studies of RB51 in bison have demonstrated that this vaccine induces an acquired immune response similar to that observed in cattle; does not induce antibodies that could be confused with surveillance tests; does not cause observable ill effects; and does not interfere with subsequent pregnancies and the delivery of normal calves (Olsen et al. 1997, 1998). Other studies have demonstrated that vaccinates do not shed RB51 and, consequently, do

not transmit the vaccine organism to other animals (Roffe et al. 1999). Although the vaccine persists for a longer period in vaccinated bison calves, as compared with cattle, it does not cause significant pathology. The conclusion from these studies is that RB51 is safe for use as an injectable vaccine in bison calves. Olsen and Holland (2003) suggested that RB51 also may be safely used to booster vaccinate pregnant bison.

Studies on the use of RB51 in adult bison (Palmer 1997; Elzer et al. 1998; and, Roffe and Hunter, unpub.), although not conclusive, suggest that RB51 may induce abortions in adult pregnant females. A similar potential also has been reported for cattle (Van Metre et al. 1999). Studies by Elzer et al. (1998) and Olsen et al. (1998, 1999) suggest that RB51 does not cause significant pathology in bulls but may persist for an extended period in the testicles and some vaccine may be shed in semen. However, the vaccine apparently does not affect sperm production.

Several commenters expressed concern whether it was safe to vaccinate young calves. During typical capture operations, field personnel attempt to avoid capturing cows with red calves at their side. If captured, the Department will not vaccinate young calves. In cattle, animals less than 4-months-old are not vaccine eligible because their immune system is not mature enough to mount an effective antibody response. Vaccination typically will occur during late December through early April. At that time of year, eligible calves will be 8 to 12 months of age.

Vaccine Safety to Non-target Species

Vaccination of free-ranging wildlife may unintentionally expose other, non-target species to RB51. This could occur if the vaccinated animal developed a vaccine induced infection and subsequently shed RB51. Exposure of non-target species also might occur if the vaccinated animal died before clearing the vaccine. Non-target species also would be susceptible to exposure to field strain *Brucella* via similar routes of exposure. The lack of problems with brucellosis, except in bison and elk, suggest that the field strain of *Brucella* does not have adverse effects on non-target species. Therefore, it might be concluded that vaccine strains of the same organism likely would not adversely affect non-target species.

Cook and Rhyan (2002) reviewed the various studies related to the effects of RB51 on non-target species. They concluded that oral exposure to RB51 had minimal adverse impacts to deer mice, ground squirrels, prairie voles and ravens (Janusewski et al. 2001). There was no evidence of shedding of the RB51 and, except for the ground squirrels, the test animals had cleared the bacteria within 8 – 12 weeks. Moose, pronghorn, mule deer and bighorn sheep that were exposed to RB51 developed RB51 infections, but there was no morbidity or mortality attributable to the vaccine (Kreeger et al. 2002). Coyotes also developed RB51 infections and, with one exception, the infections cleared within 6 weeks. RB51 had minimal adverse effects on deer mice and the probability of deer mice transmitting the vaccine strain to other animals is low (Cook et al. 2001.) Preliminary studies suggest that RB51 does not negatively affect production in black bear. Other studies (Elzer et al. 2000) suggest that RB51 is safe for pronghorn. RB51 has not been tested in wolves. However, because RB51 is safe for coyotes (Davis et al. 2000) and safe

for domestic dogs, it might be extrapolated that RB51 also is safe for other canids. Roffe (Unpublished) did not observe any effect on grizzly bear reproduction resulting from oral delivery of RB51 or on coyotes, as a surrogate for wolves.

Vaccine Efficacy in Bison

Studies have demonstrated that RB51 is an effective vaccine in cattle (Olsen et al. 1999). Efficacy studies in bison have been less conclusive. It also is difficult to make definitive conclusions when comparing the results from different efficacy studies because sample size, experimental design, methodology and the calculation of efficacy, all of which may differ between studies, can affect the result (Roffe and Olsen 2002). In early studies with RB51 (Olsen et al. unpubl. and Olsen et al. 1997), adult cows that had been vaccinated as calves were subsequently challenged with field strain *Brucella* during their first pregnancy and most successfully calved. However, sample sizes were small and some of these studies did not include control animals. In more recent studies that employed the standard cattle challenge with Strain 2308, the virulent form of *Brucella abortus*, (Olsen et al. 2003), 9 of 13 unvaccinated cows and 11 of 44 cows that had been vaccinated as calves aborted in response to challenge during the 5-6 month of gestation. Infection rates in the vaccinated and control groups were similar, but the amount of bacteria that was recovered from the uteri and mammary glands of the vaccinates was less. Therefore, it is likely that vaccination reduces the potential transmission of *Brucella* from infected vaccinates to other susceptible bison. In another recent study (Elzer et al. 2002), abortion rates were similar between a control group and two vaccinate groups, one that received a single calthood vaccination that the other vaccinated three times at 7, 12 and 15 months of age. Dosages used in these studies were 10^{10} CFU.

When they prepared the EIS, the agencies used a stochastic model to evaluate the consequences of management actions on bison. The model included an analysis of the change in seroprevalence as a result of vaccination. One result of this analysis was the suggestion that a herd immunity of 20% would be effective in reducing seroprevalence in the herd, while a 10% herd immunity would have no detectable effect. Herd immunity is the product of vaccine efficacy and delivery rate. For example, a herd immunity of 21% could be achieved by vaccinating 30% of the calves with a vaccine that has a 70% efficacy. Using the same model, Gross et al. (2002) estimated that a herd immunity of 50% could be achieved by vaccinating 75% of the calves with a vaccine that has a 70% efficacy. It is unlikely that vaccination of captured animals at the Stephens Creek facility and the capture facilities in the Western Boundary Area will result in the vaccination of 75% of the calves. Moreover, given the uncertainty regarding the efficacy of RB51, it is not possible to validate assumptions used in the model or to predict the level of herd immunity that might result from the proposed vaccination protocol.

The elk herd in the GYA also is chronically infected with *Brucella abortus*. It is unlikely that a vaccination program for bison would succeed in the elimination of brucellosis from bison without a concomitant program for elimination of brucellosis in elk (Cheville et al. 1998).

Bison Population Dynamics

The estimated size of the YNP bison population was estimated at 2,616 when the IBMP was implemented in 2000. Since then, the herd has increased to about 4,240 bison (Table 1).

Table 1. Bison population estimates in Yellowstone National Park.

Winter	Previous summer population estimate	Late winter population estimate
2000/2001	2616	2870
2001/2002	3283	3300
2002/2003	3900	3160 (range 3050 to 3690)
2003/2004	4250	3604 (range 3430 to 4352)
2004/2005	4240	

Since 1997, 326 bison have been captured and removed from the Western Boundary Area and an additional 6 bison have been removed by other lethal means (Table 2). A total of 144 bison were captured, tested and released from the capture facilities in the Western Boundary Area. Numbers of bison that will be vaccinated in the Western Boundary Area is dependent upon the number of bison that move into that area. Vaccination will be incidental to other management activities in that area and the Department does not propose to significantly change the intensity of management. It is unlikely that the total number of calves and yearlings vaccinated in the Western Boundary Area would ever exceed 100 bison in any one year.

Table 2. Summary of bison management actions in the Western Boundary Area.

Year	Captured	Slaughtered	Released	Hazed
1997-1998	15	11	4	>300*
1998-1999	142	90	52	615
1999-2000	0	0	0	415
2000-2001	14	5**	9	1,591
2001-2002	262	202**	63	1,026
2002-2003	20	13**	8	1,603
2003-2004	18	11**	8	52

*Totals of hazed animals include animals that may have been hazed multiple times

**Totals include lethal removal of animals that were not first captured

Since 2000, 495 bison have been captured and removed at the Stephens Creek facility. In addition, 198 bison were captured, tested and returned to the Park from the Stephens Creek facility. In 2003-04, NPS, with cooperation from all agencies, initiated vaccination of seronegative bison at the Stephens Creek facility (Table 3-following page). Following vaccination, the bison were held at the facility and subsequently released back into the Park in the spring. There were no apparent adverse effects to those vaccinated bison.

Table 3. Summary of bison vaccinations at the Stephens Creek Facility, 2003-04.

Age	Male	Female
Calf	32	46
Yearling	18	17

Using the stochastic model that was developed for the EIS, Gross et al. (2002) noted that capturing, testing and removing seropositive animals from a small proportion (10% to 25%) of the population would be ineffective in reducing the prevalence of brucellosis in the herd. However, they noted the potential for this approach to result in the removal of larger numbers of bison because transmission efficiency would increase. Results of the model suggested that a larger percentage of the seropositive bison would have experienced a recent infection and thus would be more likely to be highly infectious and a larger percentage of bison that came in contact with those bison would be susceptible to developing infection upon exposure. Gross et al. (2002) also noted that the model predicted that a synergistic effect would occur if vaccination were used in combination with capture, testing and the removal of seropositive bison.

Monitoring and Evaluation

Vaccinated animals will be individually marked with a metal ear tag. Identification will facilitate subsequent evaluation of vaccine efficacy in those animals that are subsequently captured and tested.

Risk of Brucellosis Transmission from Bison to Cattle

Olsen and Elzer (2002) noted that it is unlikely that vaccination, alone, would be sufficient to eradicate a disease from wildlife, even under the most favorable circumstances. Also, it would take a period of time following implementation of a vaccine-based control program before a reduction in disease prevalence would become noticeable. Vaccination of bison calves and yearlings, in combination with the capture, testing and removal of seropositive bison in the Western Boundary Area likely will result in the reduced prevalence of brucellosis in the overall herd. However, insufficient numbers of seropositive animals will be removed and insufficient numbers of bison will be vaccinated to eradicate brucellosis from this bison population. Therefore, even with vaccination, temporal and spatial separation will be required to manage the risk of brucellosis transmission from bison to cattle.

Based on simulations of brucellosis in elk and bison, Gross et al. (1998) suggested that, even in the absence of movement between herds, eradication of brucellosis in wild ungulates would be exceedingly difficult. Eradication via vaccination would likely require a multi-decade effort to vaccinate a sufficient number of calves to ensure complete immunization of at least 40% of all elk calves and 50 to 60% of bison calves. Although eradication is not feasible, they suggested that the level of risk of brucellosis transmission from wildlife to domestic livestock could be substantially reduced through an effective vaccination program. Peterson et al. (1991) concluded that when 80% of all females were vaccinated, it would not be possible to reduce seroprevalence to 10% in the Grand Teton herd over a 20-year period. This, in part was due, to the assumption of a

constant rate of infection by elk. Those authors noted that it would not be possible to achieve the objective of 10% seroprevalence without limiting contact between susceptible bison and infected bison and elk.

Dobson and Meagher (1991) also modeled the dynamics of brucellosis and the Yellowstone bison herd. They concluded that brucellosis would be present in this herd whenever it exceeded a threshold population of 200 bison. Thus, the level of removals necessary to eradicate brucellosis also might eradicate the bison. They suggested that this circumstance might be different were it possible to remove only infected animals. It also might be possible to eradicate the disease through extensive vaccination with an effective vaccine. But, they noted that this would not be achievable with the currently available vaccines. As an alternative to eradication, they recommended establishment of a buffer zone between bison and domestic livestock. Within that zone, the only permissible cattle would be vaccinated or neutered animals.

Surveillance of Cattle

Market Cattle Identification (MCI) is the national program for surveillance of brucellosis in cattle and privately owned bison. The program requires that a minimum of 95% of all cattle, 2-years and older, processed at state or federally inspected slaughter facilities be tested for brucellosis. Since implementation of the IBMP, there have been no cattle from the bison management areas identified and traced through the MCI. Statewide, from October 1, 2000 to June 4, 2004, there have been 42 MCI tracebacks of Montana-origin cattle. Subsequent investigations were completed on these tracebacks and in all cases, there was no evidence to suspect a brucellosis infection in the herds of origin.

Brucellosis Milk Surveillance Test (BMST) is a national program for surveillance of brucellosis in all dairy herds producing commercial milk. The program requires that a minimum of 2 BMST are conducted annually on all dairy herds producing commercial milk. Since October 1, 2000, BMST have been conducted every 4-6 weeks on all Montana dairy herds producing commercial milk, with no evidence to suspect a brucellosis infection in the herds. Although there are no dairy herds within the Western or Northern Boundary Areas of YNP, this surveillance is an important component of the statewide brucellosis surveillance, and provides a means for early identification of brucellosis affected dairy herds.

Two cattle herds graze seasonally on private lands in Zone 2 in the Western Boundary Area. The operator of one herd resides in Idaho and grazes cattle on his own property. A Certificate of Veterinary Inspection (CVI) and a Montana importation permit are required for this operator to graze cattle on his property in Montana. Montana law requires all vaccination eligible female cattle imported into Montana are official calfhood vaccinates (OCV) against brucellosis. This owner also operates in compliance with a plan administered by the Idaho State Veterinarian, which requires testing of the test-eligible cattle upon return to Idaho. The other livestock producer is a Montana resident who leases private land. The Department, APHIS, and the producer have developed a herd plan. Although the plan has not yet been finalized, the producer operates in compliance with it. The herd plan requires calfhood vaccination of all eligible cattle and annual

testing of all test-eligible cattle grazing in the West Yellowstone Area. In addition, the first year the private land was leased by this producer, all test-eligible cattle were tested negative prior to turn out. APHIS pays the direct costs for testing and vaccination. The herd plan also specifies grazing dates, locations and cattle numbers.

Montana's Compliance with the National Brucellosis Eradication Program

The potential economic consequences of Montana's failure to comply with the National Brucellosis Eradication Program were detailed in the FEIS. Hendry (2002) described the various ways that in which brucellosis affects cattle operations and, in general, the rural communities whose economies are dependent on agriculture. The Department does not believe that a decision to postpone vaccination of bison calves and yearlings would be interpreted by animal health authorities as a failure to comply with the National Brucellosis Eradication Program and does not anticipate any associated economic effects.

Vaccination is used within the context of a herd brucellosis management plan, as defined by the Brucellosis Eradication Uniform Methods and Rules (UMR; USDA 2003), and typically involves vaccinating female calves aged 4 to 12 months (official calthood vaccinates). Historically, *Brucella* vaccines have been administered to female calves to provide some protection, while minimizing adverse effects such as retained antibody titers and the occasional disease-causing effect of the vaccine on pregnant adult females (Roffe and Olsen 2002). On occasion, adult female cattle and bison can also be vaccinated (official adult vaccinates), if part of a herd approved for whole-herd vaccination. Roffe and Olsen noted that privately owned bison were included in the National Brucellosis Eradication Program in the 1980's because of widespread infection in domestic bison herds. Methods for management of brucellosis affected bison herds generally follow those established for cattle, as outlined in the UMR. Vaccination is one component of a herd brucellosis management and eradication plan. RB51 has been approved for use in brucellosis eradication in cattle and bison. Vaccines may only be administered by Federal, State and/or accredited veterinarians.

The Department understands that current bison management actions in the Western Boundary Area are intended to maintain temporal and spatial separation of bison and cattle and will not achieve eradication of brucellosis from this bison herd. The Department also understands that the addition of vaccination of calves and yearlings to the management plan in the Western Boundary Area is not intended to achieve eradication. However, the Department anticipates that vaccination of calves and yearlings will, over time, result in a lower incidence of brucellosis in this herd because the frequency of transmission will be reduced and the percentage of susceptible animals also will be reduced. Thus, the Department has determined that a decision to begin vaccination of bison calves and yearlings in the Western Boundary Area would be consistent with its commitments pursuant to the National Brucellosis Eradication Program.

Cheville et al. (1998) noted that, given the lack of sufficient information and the lack of capability, brucellosis eradication as a goal is more a statement of principle than a workable program. They suggested that, in the near future, the best possible approach is

a management emphasis on the reduction of risk of brucellosis transmission from wildlife to cattle. The Department understands that risk reduction is the focus of current management. Revision of current management to include subcutaneous vaccination of bison calves and yearlings with RB51 is consistent with a focus on risk reduction, even though the efficacy of the vaccine is uncertain and only a portion of the eligible bison will be vaccinated.

Public Controversy

From public comments that were submitted in response to the EIS and again in response to the APHIS vaccination EA and during public scoping for this EA, it is apparent that some people question whether the transmission of brucellosis from YNP bison to domestic livestock is possible. These people refer to the lack of documented cases and the lack of controlled field studies that are specific to YNP bison. It is correct that transmission from YNP bison to cattle has not been documented. It also is correct that YNP bison have been actively managed to prevent free association with cattle. This bison herd is infected with brucellosis. The mechanisms of brucellosis transmission in infected Yellowstone bison herds are similar to that observed in infected cattle herds (Roffe et al. 1999; Rhyan et al. 2001). Consistently, from 35% to 50% of those bison that have been sampled, test positive for the presence of antibodies to *Brucella*. Therefore, the Department has concluded that brucellosis is being maintained in this herd through frequent transmission from bison to bison; that transmission of brucellosis from bison to cattle is possible; and, that compliance with the National Brucellosis Eradication Program and corresponding state statutes and regulations requires management that maintains temporal and spatial separation between bison and cattle. The Department also has concluded that the potential for transmission of brucellosis within the bison herd and from bison to cattle would be reduced with the addition of vaccination to the plan for management of bison in the Western Boundary Area.

Some people express concern that bison are wildlife, the Department is not a wildlife management agency and the Department personnel are not trained in wildlife management. They believe, therefore, that the Department should have no authority for the management of this bison herd. However, the Department's authority for bison management is clearly defined in Montana statute. This authority was assigned to the Department in recognition of the fact that the regular movement of bison from YNP into Montana is a recent phenomenon; the fact that brucellosis is endemic in this herd; and, the fact that brucellosis poses a significant risk to Montana's economy. Authority for the management of bison is shared among several agencies and the Department participates in the IBMP with the understanding that the plan honors the authorities of all of the cooperating agencies.

Torbit et al. (2002) expressed the concern that the controversy surrounding Yellowstone bison is further evidence of continuing erosion of public trust responsibility, with a potential collapse characterized by wildlife populations tolerated at the whims of special interests that may dictate wildlife occurrence according to personal enrichment or inconvenience. The Department does not agree that this perspective correctly characterizes the purpose of bison management. Regardless, the effects of vaccination,

relative to this concern, are within the overall scope of the bison management plan, as evaluated in the Federal FEIS and in the State FEIS.

Costs

Costs for bison management operations in the Western Boundary Area are approximately \$590,000 per year. The additional costs to implement the proposed action range are approximately \$2.57 - \$7.27/animal vaccinated. These costs include miscellaneous supplies, vaccine (\$0.47 - \$3.02/dose) and veterinarian costs (\$2.00 - \$4.00/vaccination).

Public Hunting

A 21-day withdrawal period is required before vaccinated animals are suitable for human consumption. The proposed public hunting season would be scheduled from November 15 through February 15. In most years, it is anticipated that vaccination would begin during mid-January. Therefore, it is possible that hunters could harvest recent vaccinates. This effect could be minimized by advising hunters of the possibility of harvesting vaccinated calves and yearlings and encouraging them to only harvest an adult bison. As noted in the EA for the hunting season, the effect also could be mitigated by limiting harvest to adult bulls during the period when vaccination overlaps with the hunting season.

Secondary and Cumulative Impacts

Secondary impacts are those impacts to the human environment that are indirectly related to agency action, i.e. they are indicated by a direct impact and occur at a later time or distance from the triggering action. The Department did not identify any secondary impacts associated with the proposed action.

Cumulative impacts are those impacts to the human environment that, individually, may be minor for a specific project but, when considered in relation to other actions, may result in significant impacts. The Department determined that cumulative impacts, if any, are within the scope of this analysis.

Based on numbers of bison handled at the Stephens Creek and Western Boundary Area since implementation of the IBMP, it is unlikely that the total number of calves and yearlings vaccinated in both areas would ever exceed 200 bison in any one year. Circumstances that might result in vaccination of larger numbers of bison likely would be associated with other revisions to the IBMP and decisions to implement those revisions would be supported with additional NEPA and/or MEPA review.

The decision to vaccinate calves and yearlings at the capture facilities in the Western Boundary Area is independent of any subsequent decision to implement a program of remote vaccination. That decision will be supported with a separate MEPA analysis, based on criteria outlined in the Records of Decision for the IBMP.

NO ACTION ALTERNATIVE

Under this alternative, bison management would continue under the provisions of the IBMP. The Department would defer the decision to incorporate bison vaccination into the management of bison in the Western Boundary Area. This alternative responds to the uncertainty regarding the efficacy of RB51 in reducing the prevalence of brucellosis in the bison population. However, it does not respond to the provision of the IBMP to begin vaccination when a safe vaccine became available.

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APPENDIX A.

GYIBC Protocol

Criteria and Evaluation Protocols for Vaccines

Because the current most likely brucellosis vaccine candidates for use in bison are forms of live *Brucella abortus* bacteria, criteria regarding the biosafety (i.e., the lack of pathology or other harmful effects) induced by the vaccine have been developed. For domestic livestock, these include (NAS 1998) ensuring lack of clinical signs of acute disease do not appear after vaccination ensuring bacteria are not present in nasal secretions, saliva, or urine ensuring bacteria do not persist in the bloodstream for more than 3 days ensuring bacteria do not persist in lymph nodes for more than 16 weeks ensuring evidence of humoral or cellular immunity is present 14 days after infection ensuring no inflammation or chronic tissue injury appears ensuring neither placentitis nor abortion occurs in pregnant animals ensuring immunosuppression after 16 weeks does not cause recrudescence ensuring bacteria recovered after 12 weeks growth in the host are genetically identical with the vaccine strain.

In addition to biosafety, there are other elements to be evaluated for administration of a live bacteria vaccine to free-ranging wildlife. To address this subject, the Technical Subcommittee, at the request of the Greater Yellowstone Interagency Brucellosis Committee's (GYIBC) Executive Committee, developed a protocol for evaluating safety and efficacy of a wildlife vaccine against brucellosis in the Greater Yellowstone Area. The following indented text is that protocol:

“The purpose of this protocol is to establish guidelines for the development and evaluation of new brucellosis vaccines to be used in free-ranging elk (*Cervus elaphus*) and bison (*Bison bison*) inhabiting the Greater Yellowstone Area. This protocol is not intended to evaluate current vaccination programs being applied to these species. The recommendations for the following criteria regarding efficacy and safety are based on the assumption that any brucellosis vaccine evaluated by these criteria would have defined dosage, route of administration, and age restrictions for any application of the vaccine. The vaccine strain would demonstrate stable characteristics following in vitro and in vivo passage. Efficacy evaluations within the principal species should include animals of minimal recommended age, at the minimally recommended dosage and administered in accordance with recommendations. For safety evaluations within the principal species, animals should be of minimal recommended age, at the maximal recommended dosage, and administered in accordance with recommendations. The assumption is also made that the criteria for approval of a vaccine as safe would be the same in both male and female animals in the targeted population. For the purposes of this paper, the definition of a calf would be a bison or elk of less than 12 months of age. Restrictions on use (e.g., sex and age) may be applied without rejection of the vaccine in total. For example, limit use to females because of adverse reactions in males.”

Calfhood Vaccination

Safety. To be defined as safe, a vaccine would not have any clinical effects that would increase predation or decrease survivability. However, adverse clinical effects, such as listlessness, anorexia, depression, and arthritis, which are transient and minimal with no long-term effects on survival may be acceptable. There should be no statistical difference between vaccinates and controls on these factors. A safe calfhood vaccine would not be shed from a vaccinate prior to parturition. The vaccine strain would not persist to the first calving in 95% or greater of the vaccinated individuals, or persistence of the vaccine strain would not be associated with a significant reduction in the survivability (i.e., no pathology) or the reproductive potential of the individual (i.e. repeated fetal loss, infected calves, or decreased fertility). There should be no statistical difference between vaccinates and controls on these factors.

Efficacy. To be defined as efficacious in females, a vaccine must induce statistically greater protection against fetal loss, infected calves, or infection in pregnant vaccinates after experimental challenge when compared with nonvaccinated animals in the same experiment. Infection is defined as either number of colony-forming units (CFU) per gram of tissue and/or number of infected tissues. Use of model predictions must indicate that the vaccine, when used alone without other management influence, would reduce the prevalence of brucellosis in the targeted wildlife population. Experiments would need to be conducted to evaluate the duration of immunity of the vaccine but these experiments would not be required for initiation of use of the vaccine if all other safety and efficacy criteria were met. A vaccine should provide long-term immunity and/or be able to be safely boosted during the life of the animal.

Other. A major advantage of any vaccine would be the ability to differentiate vaccinates from animals infected with *Brucella* field strain either by a serologic test or by alternative methods.

Nontarget Species A vaccine candidate cannot cause deleterious effects on the short-term survivability of representative ungulates, rodents, carnivores or avian species under experimental conditions. Candidate species that should be strongly considered for evaluation include: moose, bighorn sheep, antelope, mule deer, coyotes, wolves, ravens, *Microtus*, *Peromyscus*, and ground squirrels. Other species could be added if scientific data support their inclusion.