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# Interagency Bison Management Plan

for

The State of Montana

and

Yellowstone National park

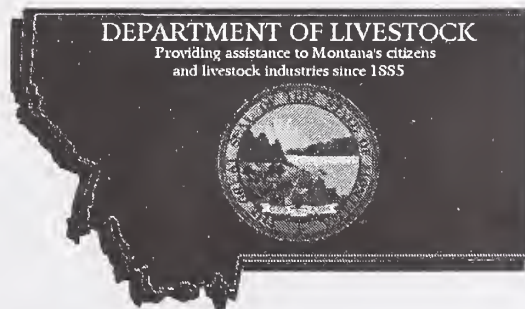
Record of Decision

December 22, 2000

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# DEPARTMENT OF LIVESTOCK



MARC RACICOT, GOVERNOR

PO BOX 202001

## STATE OF MONTANA

BRANDS ENFORCEMENT DIV. 406-444-2045  
ANIMAL HEALTH DIV. 406-444-2043  
BOARD OF LIVESTOCK - CENTRALIZED SERVICES 406-444-2023  
MEAT, MILK & EGG INSPECTION DIV. 406-444-5202

HELENA, MONTANA 59620-2001

December 22, 2000

Dear Interested Party:

The State of Montana hereby announces its intention to implement the Interagency Bison Management Plan. This Record of Decision is the culmination of a process that began with a Notice of Intent to prepare a cooperative bison management plan and environmental impact statement which was published in the July 1990 Federal Register. The process continued with a public review of a draft EIS that began on June 12, 1998 and ended on November 3, 1998. The draft EIS was jointly prepared by U.S.D.I. National Park Service (Yellowstone National Park), U.S.D.A. Forest Service (Gallatin National Forest), and Animal Plant Health Inspection Service and the State of Montana. The federal agencies subsequently released a final EIS in August 2000. The Montana Department of Livestock (DoL) and the Montana Department of Fish, Wildlife and Parks (FWP) developed a modified preferred alternative for analysis in their final EIS, which was released on November 15, 2000. The Record of Decision is based on the analyses contained in the draft EIS, the FEIS that was prepared by the federal agencies and released in August 2000, the federal responses to comments on the Federal FEIS, the analysis contained in Montana's FEIS, and the court ordered mediation. This document satisfies DoL's and FWP's responsibility to prepare a concise public record of decision concerning a proposed action for which an EIS is required, pursuant to the requirements of the Montana Environmental Policy Act (MEPA).

Thank you for your interest in bison management.

Sincerely,

A handwritten signature in black ink that reads "Marc Bridges".

Marc Bridges  
Executive Officer, Montana Department of Livestock

A handwritten signature in black ink that reads "Patrick J. Graham".

Patrick J. Graham  
Director, Montana Department of Fish, Wildlife and Parks



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STATE OF MONTANA  
RECORD OF DECISION  
INTERAGENCY BISON MANAGEMENT PLAN

The Montana Department of Livestock (DoL) and the Montana Department of Fish, Wildlife and Parks (FWP) have decided to implement the Interagency Bison Management Plan, as described in the attachment to this Record of Decision and approved by the Governor of the State of Montana, as the appropriate strategy for the management of bison that move from Yellowstone National Park into Montana. The Interagency Bison Management Plan is similar to the preferred alternative that was described and evaluated in the Final Environmental Impact Statement (FEIS), dated November 15, 2000, and is within the scope of that analysis. DoL and FWP will proceed to implement bison management according to the Interagency Bison Management Plan and in cooperation with the U.S.D.I. National Park Service (Yellowstone National Park), U.S.D.A. Forest Service (Gallatin National Forest), and U.S.D.A. Animal Plant Health Inspection Service. Implementation of the Interagency Bison Management Plan by DoL and FWP is contingent upon a decision by the federal agencies to implement a plan which contains the management actions described in the attached state approved plan. The effective date of the Interagency Bison Management Plan will be immediate upon issuance of the federal agencies' decision described herein.

Insofar as the Interagency Bison Management Plan and FEIS states or elaborates upon the reasons for or the methodologies used to reach this decision, those documents are incorporated into this Record of Decision by this reference.

#### RATIONALE FOR THE DECISION

Bison are essential to Yellowstone National Park 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 operators 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 also could adversely affect Montana's livestock industry. Several state and federal agencies 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. Therefore, cooperation of the agencies and their shared commitment to a single management plan is essential to effectively manage bison and the risk of transmission of brucellosis from bison to domestic livestock.

Bison management has been a major public controversy and a difficult issue for the State of Montana for the past 15 years. During that time DoL and FWP have participated in the



development and implementation of several interim management plans. They also have evaluated a variety of options to protect the ecological integrity of bison in Yellowstone National Park and to prevent brucellosis transmission from bison to cattle.

The Interagency Bison Management Plan emphasizes measures to maintain temporal and spatial separation between bison and cattle. This plan also establishes population targets for the bison herd and identifies management actions if and when bison move beyond the YNP boundary. Given the current risk, the temporal and spatial separation provisions of the plan when completed with other management actions described in the plan, should prevent transmission of brucellosis from bison to cattle. Moreover, the provisions for vaccination of both bison and cattle should further reduce the level of risk over time. Of the various alternatives considered, the Interagency Bison Management Plan is the only alternative that the state agencies are able to implement in cooperation with the federal agencies. Implementation of the Interagency Bison Management Plan is a joint state/federal action which will require interagency cooperation and coordination. As set forth in the Plan, the agencies will enter into the appropriate Memorandum of Understanding to describe specific commitments of personnel to all management actions and delineate operation details for implementation of the Plan.

## CONTEXT FOR THE DECISION

DoL and FWP have been working with U.S.D.I. National Park Service (NPS), U.S.D.A. Forest Service (USFS) and U.S.D.A. Animal and Plant Health Inspection Service (APHIS) for more than a decade to address the management of bison through development of a long-term management plan and Environmental Impact Statement (EIS). The Notice of Intent to prepare this EIS was published in the Federal Register on 11/1/89. While that plan and EIS were being prepared, the agencies agreed to cooperate in the implementation of an Interim Bison Management Operating Plan. The Interim Plan was approved in October 1990 and was revised several times thereafter. Environmental Assessments (EA) for the interim plans were prepared, in cooperation with the federal agencies, in 1990, 1992 and 1996. The Draft Environment Impact Statement (DEIS) for the Interagency Bison Management Plan for the State of Montana and Yellowstone National Park was finally released for public comment in June 1998.

While preparing responses to public comment and the Final EIS, the state and federal agencies were unable to agree on a preferred alternative. In December 1999, the federal government advised the Governor of the State of Montana of its intentions to withdraw from the Memorandum of Understanding under which the parties were preparing the EIS for the long-term bison management plan, to file a motion with the court for the dismissal of Montana's 1995 lawsuit against the federal agencies and to proceed to complete the final EIS without Montana as a co-lead. The federal agencies released a final environmental impact statement (FEIS) for Bison Management for the State of Montana and Yellowstone National Park in August 2000. DoL and FWP reviewed that document and determined that the Interagency Bison Management Plan was similar to federal preferred alternative and within the scope of the alternatives that were analyzed in the federal FEIS. DoL and FWP released their FEIS for the Interagency Bison Management Plan on November 15, 2000. In addition, DoL and FWP

reviewed the federal responses to the Federal FEIS and are in concurrence with those responses.

In response to the federal agencies' notice to withdraw from the 1992 MOU and to proceed without Montana in the preparation of the FEIS for the Interagency Bison Management Plan, Montana sought relief in U.S. District Court. Under order of the court (*Montana v. US*, Cause No. CV95-6-H-CCL) the 1992 MOU was terminated and the dispute between Montana and the federal agencies was referred to mediation. In addition, the court ordered that the federal government could proceed with preparation and completion of the FEIS. By court order, Montana and the federal agencies participated in mediation sessions, under the supervision of Judge Robert M. Holter, U.S. Magistrate, between April and November, 2000. Through that process, Montana and the federal agencies were successful in resolving the dispute and provisions in the Interagency Bison Management Plan have been agreed to by all of the state and federal agencies.

## ALTERNATIVES CONSIDERED

The DEIS evaluated seven alternatives that the agencies agreed were potentially sufficient to accomplish the purpose and need for bison management. In addition, the DEIS disclosed several bison management strategies that had been suggested by the public during the scoping process; indicated that these suggestions would be precluded from further analysis; and, briefly explained the rationale for that decision. Both the federal and state FEIS disclosed and evaluated additional alternatives that were suggested during public comment to the DEIS.

## EFFECTS OF THE DECISION

The most noteworthy effects of the Interagency Bison Management Plan include:

- The plan will limit bison distribution to Yellowstone National Park and, during limited periods of the year, in certain areas that are immediately adjacent to the park.
- The plan may occasionally result in the removal of substantial numbers of bison. These removals will not jeopardize the integrity of this herd. However, bison management has been a controversial issue since the mid-1980s, when removals in response to emigrations of large numbers of bison began, and public controversy likely will continue.
- The plan will manage the risk of brucellosis transmission from bison to cattle through area-specific strategies to maintain temporal and spatial separation between bison and cattle and with vaccination protocols appropriate for both bison and cattle. Implementation of the plan will not eliminate the risk of transmission because it is not a brucellosis eradication plan. However, the plan will significantly reduce the risk of brucellosis transmission from bison to domestic livestock, due to the management actions prescribed.

## POLICY CONSIDERATIONS

The Interagency Bison Management Plan implements DoL's and FWP's statutory responsibilities to manage bison (81-2-120 M.C.A. and 87-1-216 M.C.A., to enter into an

agreement with Yellowstone National Park and other federal agencies for the long-term management of bison, and all other statutory obligations of the agencies.

## PRACTICAL MEASURES TO MINIMIZE HARM

The Interagency Bison Management Plan includes the following practical features to minimize the potential for environmental impacts that are inconsistent with the purpose and need for bison management:

- Bison removals will only occur near or beyond the boundary of Yellowstone National Park. The removal of nomadic bison pursuant to the plan will not jeopardize the ecological integrity of the bison herd within the park.
- Capture is the preferred method for removing bison that exceed either distribution or tolerance limits. While capture is the preferred method for removal, lethal strategies are also identified.
- The protocols for bison vaccination will be consistent with the standards for vaccine safety and efficacy, as defined by the Greater Yellowstone Interagency Brucellosis Committee.
- The plan incorporates contingency strategies to be implemented in the unlikely event that transmission of brucellosis from bison to cattle occurs.
- The plan incorporates contingency strategies to reduce lethal removals of bison when large numbers of bison have been removed.

The plan incorporates the concept of adaptive management. Adaptive management is a systematic process for continually improving management policies and practices by learning from the outcomes of operational programs.

## ENDANGERED SPECIES CONSIDERATIONS

On March 17, 2000, the National Park Service provided a biological assessment to the U.S. Fish and Wildlife Service pursuant to the requirements of Section 7 of the Endangered Species Act. The biological assessment concluded that the modified preferred alternative in the federal FEIS was not likely to adversely affect the following species listed under the ESA: bald eagle (*Haliaeetus leucocephalus*), grizzly bear (*Ursa horribilis*), Canada lynx (*Lynx Canadensis*), and gray wolf (*Canis lupus*). The National Park Service provided supplemental information on pending RB51 vaccine studies to FWS on July 6, 2000.

On July 20, 2000, the Acting Field Supervisor for the Montana Field Office concurred in the NPS determination of “not likely to adversely affect.” The Acting Field Supervisor noted that the Interagency Grizzly Bear Study Team is evaluating whether a possible reduction in other grizzly bear food sources may make bison a more important food source for grizzly bears. The study may result in needing to reinitiate Section 7 consultation. Additionally, if the final results of the ongoing biosafety studies on RB51 vaccine show that any of the listed species may be adversely affected by indirect exposure to the vaccine, NPS and Montana will need to provide a revised biological assessment.



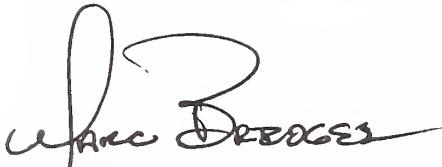
## QUARANTINE FACILITY DECISION

The Interagency Bison Management Plan includes provisions to evaluate whether a quarantine facility would be an appropriate component of the plan. If so, additional NEPA/MEPA analysis would be required to determine the design, location and operation parameters for a bison quarantine facility. Therefore, this Record of Decision does not include a provision to establish a quarantine facility.

## MONITORING

By its nature, a plan using adaptive management requires monitoring and adjustments as new information is obtained. The provisions of the Interagency Bison Management Plan identify the factors that the agencies will monitor to determine if the agencies are separating bison and cattle successfully, and, thus, lowering the risk of transmission of brucellosis. The agencies will meet at least twice annually to evaluate the operations of the prior winter and determine if modifications are necessary. This is also the appropriate time for the agencies to determine if the management efforts were successful and, thus, allowing the agencies to either move forward to the next step or, if at Step 3, continue at that step. DoL and FWP agree that the agencies will undertake in good faith to resolve all disputes reasonable at the local management level, elevating them only if there is an impasse. The agencies will use the best available scientific information to assist them in resolving such disputes.

## INTERAGENCY BISON MANAGEMENT PLAN

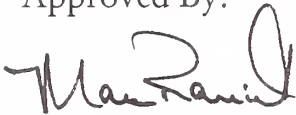
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Marc Bridges  
Executive Officer, Montana Department of Livestock

A handwritten signature in black ink, appearing to read "Patrick J. Graham".

Patrick J. Graham  
Director, Montana Department of Fish, Wildlife and Parks

Approved By:

A handwritten signature in black ink, appearing to read "Marc Racicot".

Marc Racicot  
Governor, State of Montana

Dated:  
December 20, 2000

## Interagency Bison Management Plan

### I. Preamble

Bison are an essential component of Yellowstone National Park 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 migrations into Montana are natural events. Some bison have brucellosis and may transmit it to cattle outside the Park boundaries in Montana if bison migrating from the Park are allowed outside the Park without appropriate management measures. Transmission of brucellosis from Yellowstone bison to cattle in Montana could have not only direct effects on local livestock operators, but also on the cattle industry statewide. Because bison which leave YNP are under the management jurisdiction of the state of Montana, the cooperation of several agencies is required to fully manage the herd and the risk of transmission of brucellosis from bison to Montana domestic cattle.

The parties recognize that the cooperation to address the existence of brucellosis in the bison herd involves the management of wild bison on both private and public lands, which requires different approaches to risk and disease management than standard situations involving brucellosis in domestic cattle or bison. The parties also recognize that cattle vaccination and management of cattle on public lands is an important element of managing the risk of transmission of brucellosis from bison to cattle. The management of bison under this plan will include actions to protect private property; actions to reduce the risk of transmission of brucellosis from bison to cattle; and, actions to maintain a viable, free-ranging population of Yellowstone bison.

Objectives This plan is not intended to be a brucellosis eradication plan, but rather is a plan for the management of bison, intended to prevent the transmission of brucellosis from bison to cattle. Nevertheless, it sets forth actions to address brucellosis within the bison herd. To this end, Montana and the United States will work cooperatively towards the implementation of a Interagency Bison Management Plan. This Interagency Bison Management Plan reaffirms the principle purpose for action described in the Draft and Final Environmental Impact Statements “to maintain a wild, free-ranging population of bison and address the risk of brucellosis transmission to protect the economic interest and viability of the livestock industry in Montana.” A series of three adaptive management steps are prescribed in this Interagency Bison Management Plan that will minimize the risk of transmission of brucellosis to cattle grazing on public and private lands adjacent to Yellowstone National Park and will, when all criteria are met, provide for the tolerance of a limited number of untested bison on public lands and private lands where permitted adjacent to Yellowstone National Park during winter. Implementation of the Interagency

Bison Management Plan will not cause APHIS to downgrade Montana's brucellosis class-free status.

The management actions set forth in this plan which reflect occurrence of certain actions by an expected date are the agencies anticipated time periods in which certain management steps may commence. The actual change in management from one step to another are dependent upon all criteria being met or obtained prior to the particular step being implemented.

## II. Definitions

**Adaptive Management:** In the context of the bison management plan and the modified preferred alternative, 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.

**Temporal Separation:** Separation of cattle and bison in time. Maintaining a specified period between the time bison depart or are hazed from certain lands outside the Park and the time cattle move onto those lands.

**Spatial Separation:** Prevention of cattle and bison from commingling or from utilizing the same area or adjacent areas at the same time.

**Agencies:** as used herein means the Department of the Interior - National Park Service (NPS), United States Department of Agriculture - Forest Service (USFS) and/or Animal and Plant Health Inspection Service (APHIS); and the State of Montana Departments of Livestock (MDOL), and Montana Fish Wildlife & Parks (MFWP), unless a state or Federal agency is specifically named herein.

**In-Park Vaccination Program:** 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"). (GYIBC Protocol attached hereto).

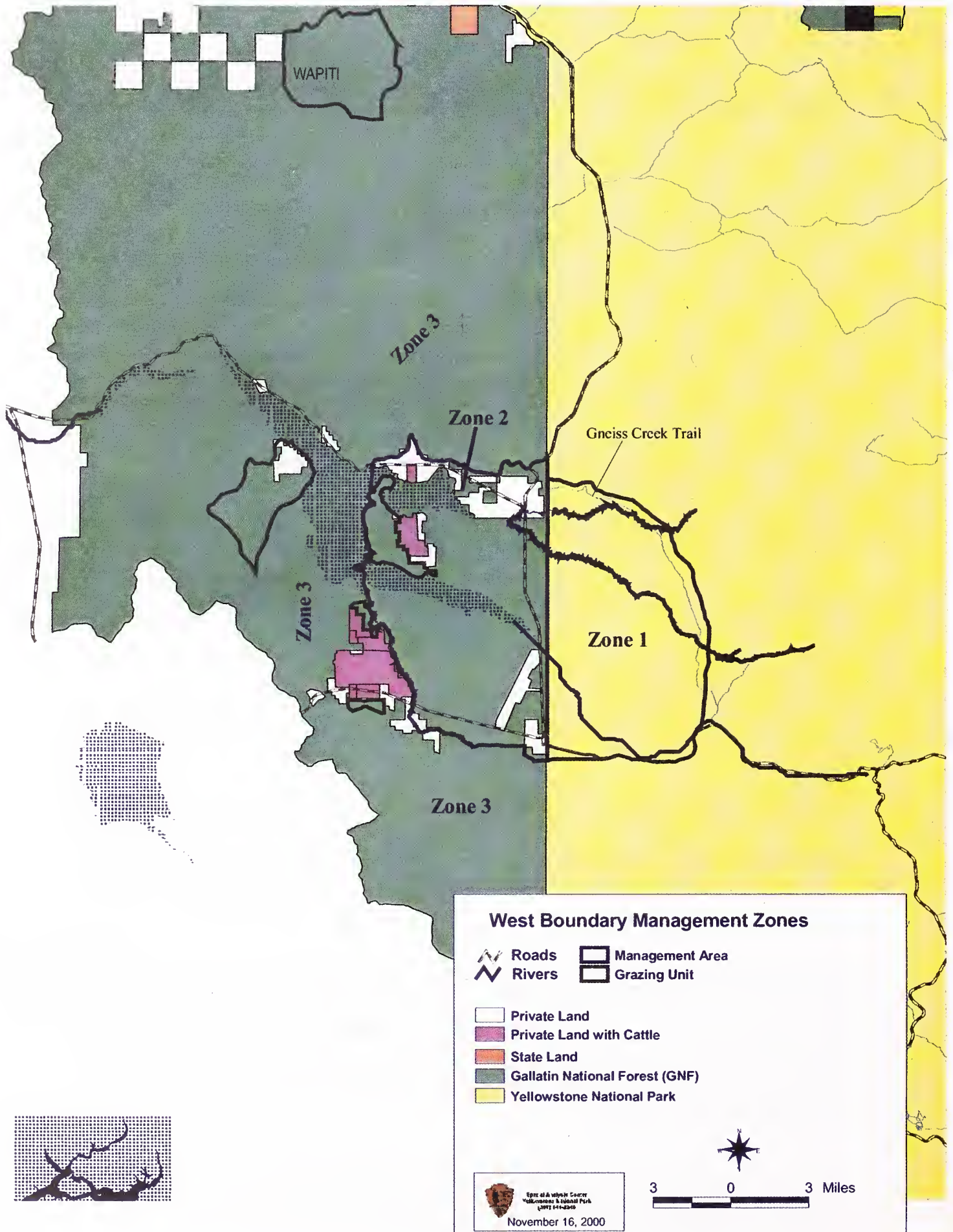


### III. Adaptive Management Steps in the Western Boundary Area

The agencies agree to manage bison in the western boundary area as follows:

1. The West Yellowstone region of the western boundary area is shown on the attached map. See Map, West Boundary Management Zones (Figure 1 to this Plan).
2. In step 1 (expected winter 2000/2001 through winter 2002/2003), after cattle are removed from Zone 2 in the fall, the agencies will haze bison exiting the Park into the West Yellowstone area back into the Park. When hazing becomes ineffective, the agencies will capture bison. The agencies will test all captured bison and send seropositives to slaughter or for use in jointly approved research. All seronegatives up to a specified tolerance level (up to 100 bison) will be released. Seronegative pregnant bison will be allowed to enter Montana under the following conditions:
  - a. Seronegative pregnant bison may not enter Montana until cattle are removed in Zone 2 in the fall. If cattle remain on private lands in the West Yellowstone area within Zone 2 during the fall or winter, a buffer as described in paragraph 2.e below will be maintained until the cattle are removed from those lands;
  - b. Each seronegative pregnant bison moving out of the park after cattle are removed in the fall and before April 1, will receive a radiotelemetry collar or similar device and vaginal radio telemetry implant during handling at capture facilities and released to allow agencies to monitor bison locations and recapture if needed;
  - c. If a telemetered seronegative bison either aborts or gives birth outside the Park, the site of the abortion or birth will be located. If the abortion / birth site contains the *B. abortus* bacteria, the site will be monitored for research purposes and/or actions will be taken to ensure all *B. abortus* bacteria are gone by the time cattle return to the area in late spring/early summer;
  - d. Telemetered female bison that aborted or calved and had shed the *B. abortus* bacteria will be captured to permit further testing or otherwise removed. If it is unclear whether a telemetered female bison that aborted or calved had shed the *B. abortus* bacteria, then the bison may be captured to permit further testing or otherwise be removed as determined by the Montana State Veterinarian in consultation with APHIS;
  - e. In the first year of the Interagency Plan's implementation, all seronegative pregnant bison outside of the park will be removed by the agencies by April 1 and will not be allowed outside the Park again until cattle are removed in the fall.

Map, West Boundary Management Zones (Figure 1)

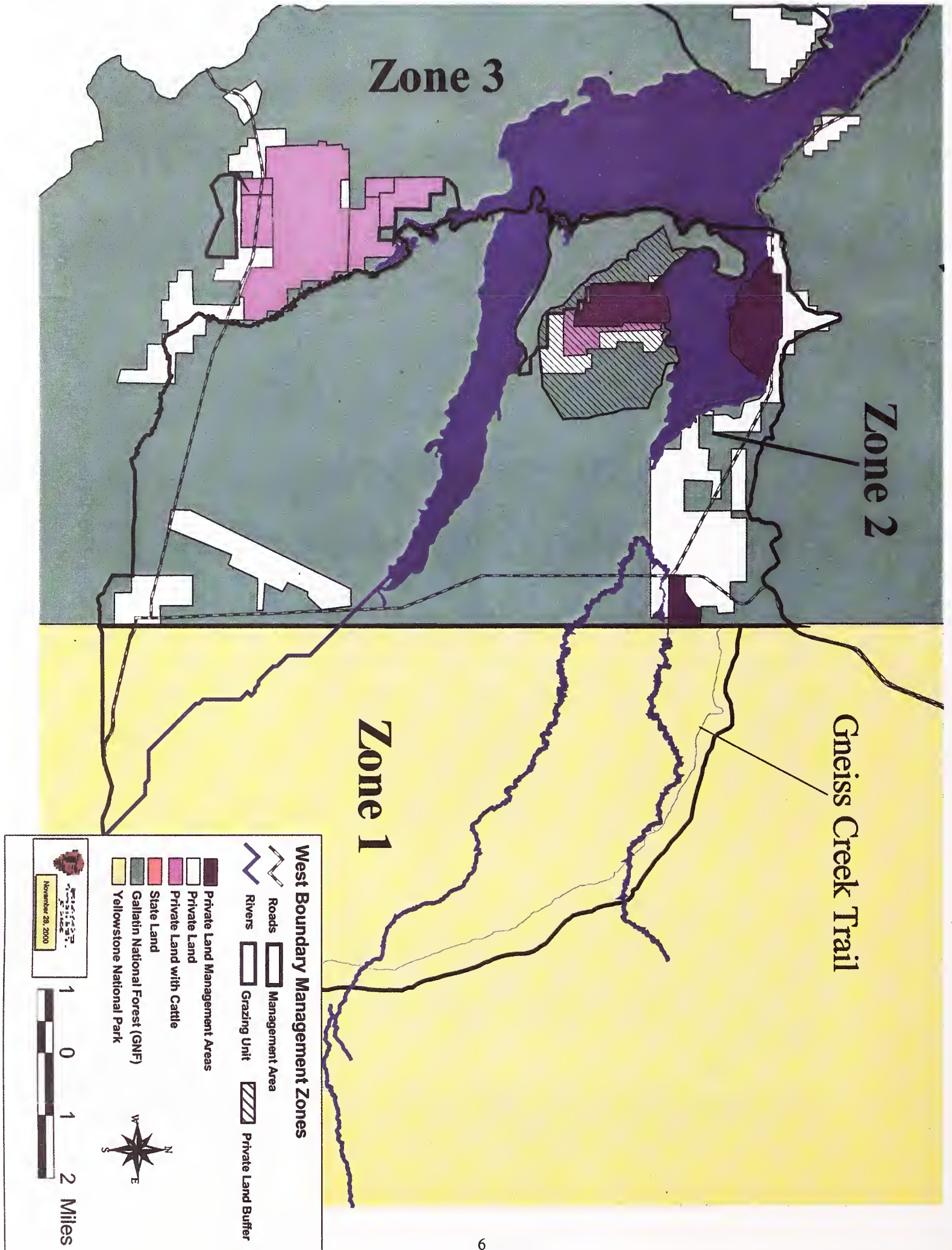




After April 1, all bison outside the Park will be kept away from private lands which will be grazed by cattle a sufficient distance to manage the risk of disease transmission. For each area of private property with cattle, the distance will be set by the State Veterinarian in consultation with APHIS. See Map, Private Land Buffer Zones Within Zone 2, Figure 2.

- f. In the second year of the Interagency Plan's implementation, all seronegative pregnant bison outside the Park will be removed by the agencies by April 15. After April 1, all bison outside the Park will be kept away from private lands a sufficient distance (as described in paragraph 2.e) to manage the risk of disease transmission;
  - g. In the third year of the Interagency Plan's implementation, all seronegative pregnant bison outside the Park will be removed by the agencies by May 1. After April 1, all bison outside the Park will be kept away from private lands a sufficient distance (as described in paragraph 2.e) to manage the risk of disease transmission;
  - h. Both of the time periods outlined in paragraphs f and g may be modified by the joint agreement of the agencies if the persistence and viability research indicates that the dates should be adjusted.
- 3. During step 1, the agencies will conduct further research regarding the viability of *B. abortus* bacteria in the environment and will conduct research regarding the rate of fetal disappearance in the area, under the principles of adaptive management. The research will allow the agencies to further refine their ability to adjust the temporal separation between cattle and bison, given prevailing climatic conditions outside the park during the spring. The agencies anticipate that this research will last one to two years. The agencies will jointly determine when there is enough data to apply the findings of such research to management.
  - 4. During Step 1, every attempt will be made to capture and test bison that leave the Park. Seronegative calves and yearlings that are captured will be vaccinated with a safe vaccine (the safety of the vaccine is determined by the agencies according to criteria established by GYIBC, as attached hereto). Bison that could not be captured but are tolerated will be permitted outside the park until May 15. After May 15, those bison that could not be captured and cannot be hazed will be subject to lethal removal. (See paragraph 13).
  - 5. These management practices will continue in step 2 (expected winter 2002/2003). In step 2, which begins when a safe and effective remote delivery mechanism is available,

Map, Private Land Buffer Zones Within Zone 2, (Figure 2)





any untested vaccination-eligible bison allowed in the West Yellowstone area will be remotely vaccinated.

6. Step 3 (expected in the winter of 2003/2004), allowing untested bison outside the Park in the western boundary area, will begin when all the following criteria are met:
  - a. bacterial viability and fetal disappearance research described in paragraph 3 is sufficient to allow agencies to determine an adequate temporal separation period. Based upon the research, the Agencies will recommend the period of temporal separation. The final decision on the duration of temporal separation will be made by the Montana State Veterinarian;
  - b. initiation of a vaccination program of vaccination-eligible bison inside the park with an effective remote delivery system (see definition);
  - c. demonstrated ability to enforce the spatial separation during the time that it takes to satisfy criteria a and b above;
  - d. controlling the number of bison in zone 2, which shall not exceed 100 bison within Zone 2.

#### **IV. Management of Western Boundary Area**

Management actions in the western boundary area will be implemented as follows:

7. In all three steps, bison in the western boundary area will be managed in zones, using topography and progressively more intense management to ensure temporal and spatial separation between bison and cattle. Bison will be hazed back into the park in the spring by May 15, and captured or shot after May 15 to ensure none remain outside the Park in the western boundary area during the applicable temporal separation period.
8. In the western boundary area, although topography is not as restrictive to movement as it is north of the Park, bison moving toward and beyond the proposed Zone Management Areas are highly visible. However, steep terrain and heavy snow depth to the west will help keep bison from crossing onto private lands west of Hebgen Dam.
9. Three zones will be established in the western boundary area. There is an extra buffer area beyond zone 3 where no cattle are grazed in winter, yet bison are not allowed (see attached map, Figure 1.).

10. The zones and actions in each are described below:

- a. Zone 1- YNP habitat where bison will be subject to hazing in the spring when bison are being moved from Zone 2 back into the Park before May 15. Between May 15 and when cattle are removed from the area in the fall, limited hazing of bison will occur in Zone 1 if needed to maintain spatial separation.
  - b. Zone 2- USFS winter habitat with some private property where bison will be managed for: i) spatial and temporal separation; ii) lethal removal for private property concerns; iii) bison tolerance limits (up to 100); and, iv) bison park population size (3,000). Each of these triggers for management actions is independent (e.g., removing bison to maintain the 100 bison tolerance limit does not depend on the overall bison population size). Management actions within Zone 2 could include tolerating, hazing, capturing and testing, vaccinating and lethally removing bison, or removing for use in jointly approved research as set forth in this plan.
  - c. Zone 3 is the area where bison that leave Zone 2 will be subject to lethal removal.
11. In step 3, vaccination eligible untested bison that exit the Park will be remotely vaccinated with a safe vaccine unless otherwise determined by the agencies. Vaccination eligible bison that are captured will be vaccinated with a safe vaccine.
12. Consistent with the various risk management actions regarding the tolerance and management of bison on the lands outside the Park, the agencies will maintain temporal and spatial separation of bison and cattle on public and private lands. From April 1 of each year, bison outside the Park will be kept away from private lands a sufficient distance (as defined in paragraph 2 above) to manage the risk of disease transmission.
13. In addition to the spatial separation that the zone management approach provides, the agencies will ensure temporal separation in the West Yellowstone area in all phases where it is needed as follows:
- a. Bison will be hazed back to the park by the agencies by May 15 (see paragraph 2 and 6 regarding steps leading to application of this provision to seronegative pregnant and untested bison).
  - b. The beginning date for hazing bison back into the Park will be determined by the agencies which will consider environmental factors such as weather.

- c. The temporal separation period will commence on May 15 unless the agencies agree that the temporal separation period will commence at an earlier date.
  - d. The ultimate decision on the duration of an appropriate temporal separation period is left with the discretion of the Montana State Veterinarian.
  - e. The temporal separation period will dictate the turn-on date for cattle onto public grazing allotments.
14. To ensure temporal separation after May 15, bison in the West Yellowstone boundary area that cannot be hazed back into the park will be captured and tested. Seropositives will be sent to slaughter, and seronegatives sent to quarantine, if available, and, if not available may be sent to slaughter or be removed for jointly approved research. Bison that cannot be captured will be subject to lethal removal.

#### **V. Maintaining the Northern Boundary - Reese Creek to Yankee Jim Canyon**

15. In step 1 (expected winter 2000/2001 through winter 2001/2002), while cattle graze Royal Teton Ranch (RTR) lands under a private grazing lease, NPS would continue to monitor bison from approximately November 1 to April 30 within YNP and use hazing within YNP to prevent bison movement north onto private and public lands in the Reese Creek area. If hazing is unsuccessful, the NPS will operate the Stephens Creek capture facility and capture all bison attempting to exit the Park in the area. The agencies will test all captured bison, send seropositives to slaughter, and temporarily hold up to 125 seronegatives bison at the Stephens Creek capture facility. Vaccination eligible bison that are captured would be vaccinated with a safe vaccine. Once the capacity of the capture facility is reached, all additional bison attempting to exit YNP would be removed at the Stephens Creek facility (seropositive bison would be sent to slaughter and seronegative bison may be sent to a quarantine facility, if available, and, if not available, may be sent to slaughter or be removed for jointly approved research). The seronegative bison held at the facility will not be retested and will be released to the Park in the spring. Bison outside the Park that cannot be hazed back into the Park and evade capture would be subject to lethal removal. Every effort will be made to avoid conducting necessary lethal management actions on RTR ranch lands. The agencies, with the Forest Service as the lead agency, will initiate an evaluation of potential sites for a capture facility in Zone 2. (See Paragraph 19).
16. During Step 1, the agencies will conduct further research regarding the viability of *Brucella abortus* bacteria in the environment and will conduct research regarding the rate of fetal disappearance in the area, under the principles of adaptive management. The research will allow the agencies to further refine their ability to adjust the

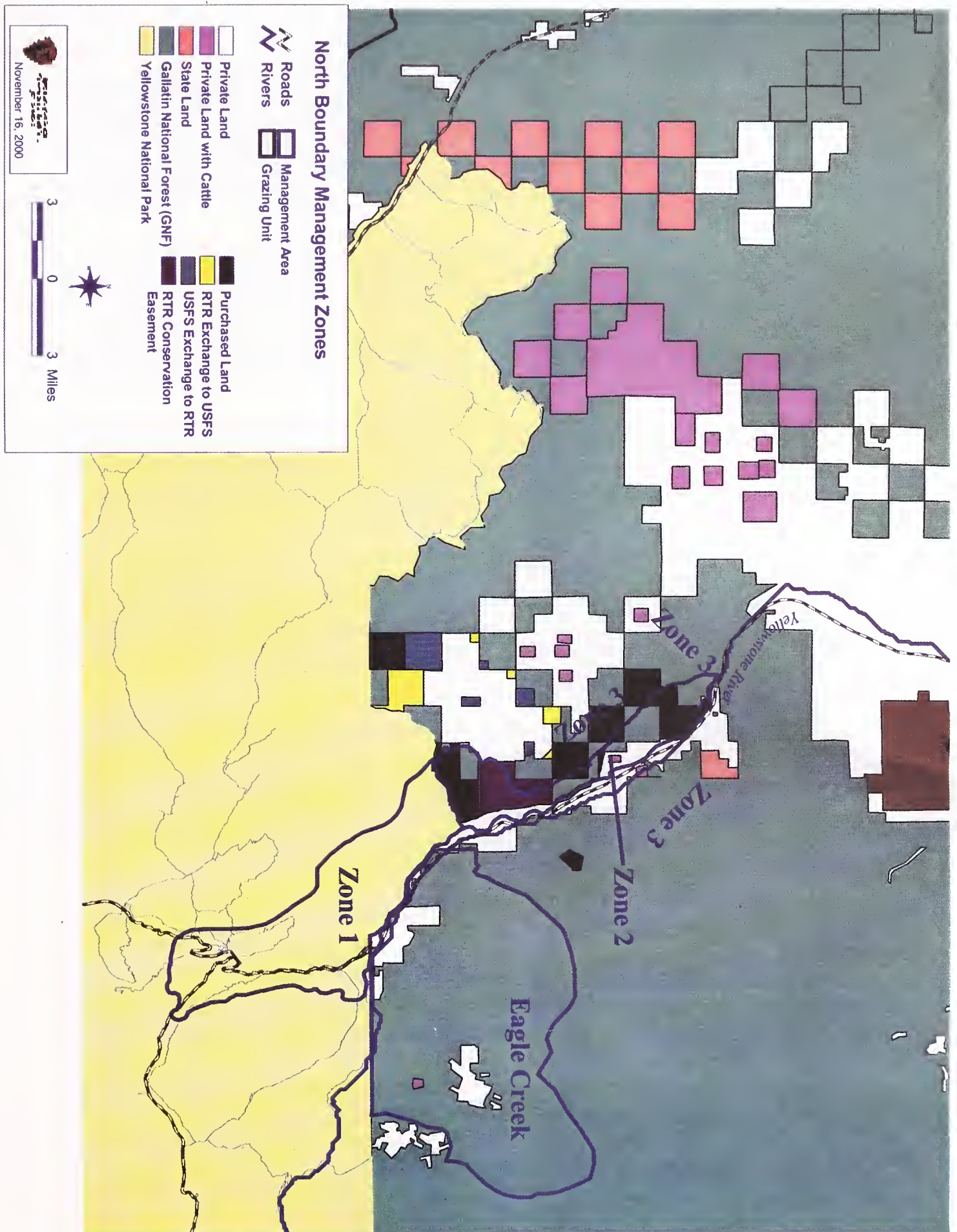


temporal separation between cattle and bison, given prevailing climatic conditions outside the park during the spring. The agencies anticipate that this research will last one to two years. The agencies will jointly determine when there is enough data to apply the findings of such research to management.

17. Step 2 begins (expected winter 2002/2003) when cattle no longer graze private lands outside YNP on portions of lands known as the RTR in Zone 2 during the winter.
  - a. In Step 2, as in step 1, NPS would continue to monitor bison within YNP. Bison attempting to exit the Park in the Reese Creek area would be captured and tested at the Stephen's Creek capture facility. Seropositive bison would be sent to slaughter and a limited number of seronegative bison, including seronegative pregnant bison (see paragraph 18), will be released. Vaccination eligible bison that are captured would be vaccinated with a safe vaccine. In Step 2, all released bison must remain in Zone 2 west of the Yellowstone River and South of Yankee Jim Canyon on lands controlled by the USFS and RTR.
  - b. In Step 2, during the first year that bison move to the Reese Creek area, the number of seronegatives that will be released and will be allowed in Zone 2 will not exceed 25 bison. After gaining sufficient experience in successfully managing approximately 25 bison outside the Park in Zone 2, the agencies will tolerate up to 50 bison. Successfully managing the bison outside the Park means that the agencies are able to enforce spatial and temporal separation including near the northern end of Zone 2 at Yankee Jim Canyon as set forth in the attached map. See Map, Northern Boundary Management Zones, Figure 3. After gaining sufficient experience successfully managing approximately 50 bison outside the Park in Zone 2, the agencies will tolerate up to 100 bison. The numbers of bison outside the Park, enumerated in this paragraph, will be the maximum in Montana at any given time on the Northern boundary area. The agencies may adjust these numbers based on the experience gained during step 2.
  - c. After the applicable tolerance limit of Zone 2 is reached during Step 2, NPS will attempt to prevent further movement of bison north of YNP. If hazing becomes ineffective, the NPS will operate the Stephens Creek capture facility and capture all additional bison attempting to exit the Park in the Reese Creek area. Bison attempting to exit the Park that cannot be hazed or captured would be subject to lethal removal. The agencies will test all captured bison, send seropositives to slaughter, and temporarily hold up to 125 seronegative bison at the Stephens Creek capture facility. Vaccination eligible bison that are captured would be vaccinated with a safe vaccine. Once the capacity of the capture facility is reached, all additional bison exiting YNP would be removed at the Stephens



Map, Northern Boundary Management Zones,, (Figure 3)



Creek facility (seropositive bison would be sent to slaughter and seronegative bison may be sent to a quarantine facility, if available, and, if not available, may be sent to slaughter or be removed for jointly approved research). The seronegative bison held at the facility will not be retested and will be released to the Park in the spring.

- d. All bison outside YNP in Zone 2 would be hazed back into YNP no later than April 15. Those bison that cannot be hazed will be subject to lethal removal.
18. During Step 2, the following procedures will be followed for seronegative pregnant bison outside the Park in the Reese Creek area:
- a. Each seronegative pregnant bison moving out of the park after cattle are removed in the fall, will receive a radiotelemetry collar or similar device and vaginal radio telemetry implant during handling at the Stephens Creek capture facility and released to allow agencies to monitor bison locations and recapture if needed;
  - b. If a telemetered seronegative bison either aborts or gives birth outside the Park, the site of the abortion or birth will be located. If the abortion / birth site contains the *B. abortus* bacteria, the site will be monitored for research purposes and/or actions will be taken to ensure all *B. abortus* bacteria are gone by the time cattle return to the area in late spring/early summer;
  - c. Telemetered female bison that aborted or calved and had shed the *B. abortus* bacteria will be captured to permit further testing or otherwise removed. If it is unclear whether a telemetered female bison that aborted or calved had shed the *B. abortus* bacteria, then the bison may be captured to permit further testing or otherwise be removed as determined by the Montana State Veterinarian in consultation with APHIS.
19. During Step 2, the agencies will evaluate the most effective means to enforce the northern boundary between Zone 2 and Zone 3 at Yankee Jim Canyon, including considering the need, design, and location of a capture facility within Zone 2, most likely on Forest Service lands. The agencies will consult with RTR on the location of the capture facility. The purpose of such a facility in Zone 2 would be to enforce spatial separation between Zone 2 and Zone 3 when hazing or other management practices become ineffective or to capture bison over the tolerance limit (initially 25 and eventually presumed to be 100). Captured bison could be moved to Stephens Creek for holding, sent to slaughter, or to a quarantine facility, if available, or removed for jointly approved research. The agencies, with the Forest Service as the lead agency, will complete any necessary NEPA analysis for the capture facility.



20. Step 3 (expected 2005/2006), allowing untested bison outside YNP in the northern boundary area in Zone 2 would begin when the agencies have collected enough information on bison movements and behavior in Zone 2, as well as the agencies ability to monitor and manage bison in the Reese Creek area of the northern boundary area. Step 3 will begin when the following criteria are met.
- a. bacterial viability and fetal disappearance research described in ¶ 17 is sufficient to allow agencies to determine an adequate temporal separation. Based upon the research, the Agencies will recommend the period of temporal separation. The final decision on the duration of temporal separation after April 15 will be made by the Montana State Veterinarian;
  - b. initiation of a vaccination program of vaccination-eligible bison outside the park and inside the park with an effective remote delivery system;
  - c. demonstrated ability to enforce spatial separation;
  - d. demonstrated ability to control the maximum number of bison in Zone 2, which maximum number will be determined pursuant to paragraph 17.b above.
21. In Step 3, NPS would continue to monitor bison within YNP. Limited hazing may be conducted to limit the total number of bison north of YNP. Up to 100 untested bison will be allowed to move into Zone 2 of the Reese Creek area. Vaccination eligible untested bison that exit the Park will be remotely vaccinated with a safe vaccine unless otherwise determined by the agencies. NPS will capture all bison that attempt to leave YNP at the Stephens Creek facility when the tolerance limit of area Zone 2 is reached. The agencies will test all captured bison, send seropositives to slaughter, and temporarily hold up to 125 seronegative bison at the Stephens Creek capture facility. Vaccination eligible bison that are captured will be vaccinated with a safe vaccine. Once the capacity of the capture facility is reached, all additional bison exiting YNP in excess of the Zone 2 tolerance limit would be removed at the Stephens Creek facility (seropositive bison would be sent to slaughter and seronegative bison may be sent to a quarantine facility, if available, and, if not available, may be sent to slaughter or be removed for jointly approved research). The seronegative bison held at the Stephens Creek facility will not be retested and will be released to the Park in the spring.
22. In step 3, all bison outside YNP would be returned to YNP by April 15. All bison in Step 3 must remain in Zone 2 west of the Yellowstone River and South of Yankee Jim Canyon. All bison which cross the river to the east, or reach the constriction point of Yankee Jim Canyon will be subject to hazing, capture or lethal removal.

23. In the northern boundary area three zones are designated for bison management. See Map, Northern Boundary Management Zones, Figure 3. The zones and actions in each are described below:
- a. Zone 1 – YNP winter habitat in the Reese Creek vicinity that bison normally occupy. During Step 1, bison attempting to exit the Park may be subject to hazing, capture, testing and vaccination, or lethal removal. During Step 2, bison attempting to exit the Park may be subject to hazing, capture, testing and vaccination, or lethal removal after the number of seronegative bison released to occupy Zone 2 specified in paragraphs 17 above is reached. During Step 3, bison attempting to exit the Park may be subject to hazing, capture, testing and vaccination, or lethal removal after the number of untested bison in Zone 2 specified in paragraph 21 above is reached.
  - b. Zone 2 – Area north of park boundary in the Reese Creek area, West of Yellowstone River, and south of Yankee Jim Canyon where bison will be managed for: i) spatial and temporal separation; ii) lethal removal for private property concerns; iii) bison tolerance limits (up to 100); and, iv) bison park population size (3,000). Each of these triggers for management actions is independent (e.g., removing bison to maintain the 100 bison tolerance limit does not depend on the overall bison population size). Management actions within Zone 2 could include tolerating, hazing, capturing and testing, vaccinating, removing bison to quarantine, removing for use in jointly approved research and lethally removing bison as set forth in this plan. During steps 2 and 3 as bison approach Cinnabar Mountain/Corwin Springs bridge area their behavior and movements will be monitored by the agencies to assure all bison remain west of the Yellowstone River at all times. During Steps 2 and 3 as bison approach the Cutler Lake/Cutler Meadows area they will be increasingly monitored to assure all bison remain west of the Yellowstone River and south of Yankee Jim Canyon. As bison move towards Yankee Jim Canyon they may be hazed or captured to reduce the threat of movement beyond Yankee Jim Canyon. Hazing and capture may include moving bison away from the Yankee Jim Canyon area to reduce the potential for bison to leave Zone 2. See paragraph 24 for further discussion regarding RTR lands within Zone 2.
  - c. Zone 3 is the area where bison that leave Zone 2 would be subject to lethal removal.
24. RTR Lands: When bison will be allowed to be on RTR lands as set forth herein, it is agreed that active bison management including vaccination shall not routinely take



place thereon. When exigencies require management actions, the agencies shall notify RTR of the contemplated action, and seek RTR approval therefore, which shall not be unreasonably withheld. Exigencies include actions to:

- a. protect life or property;
- b. address migrations of bison inconsistent with paragraphs 15, 17-20, and 25 outside the Park in the northern boundary area.
- c. haze bison back into the Park in the spring of each year;
- d. enforce spatial and temporal separation where necessary.

Lethal removal will not be routinely accomplished on RTR lands and shall require the same permissive procedures as set forth above.

The agencies intend to have as little bison management on RTR lands as possible. Nevertheless, the agencies may be required to take management actions on RTR lands as authorized under Montana or Federal law and the provisions of this plan.

In step 1, the agencies will cooperate with RTR to develop a Bison Management Plan for the Royal Teton Ranch that is consistent with the provisions of this Interagency Bison Management Plan. Should the Interagency Bison Management Plan be altered, the agencies will cooperate with RTR to adjust the RTR Plan so that the RTR Plan will remain consistent with the Interagency Bison Management Plan. Before the RTR Plan can be implemented, the state and federal agencies must approve the RTR Plan.

## **VI. Management of the Northern Boundary Area - Eagle Creek / Bear Creek**

- 25. In all steps of this plan, agencies would allow untested bison into the Eagle Creek/Bear Creek region of the northern boundary area. Bison in the Eagle Creek/Bear Creek area would be monitored twice per week during the winter. If they approach the Little Trail Creek/Maiden Basin hydrographic divide, they would be monitored daily. The agencies will maintain a boundary at the Little Trail Creek/Maiden Basin hydrographic divide by hazing. Bison crossing the hydrographic divide will be subject to lethal removal.

## **VII. Livestock Management Provisions**

- 26. In addition to bison vaccination, the State of Montana will encourage voluntary vaccination of vaccination-eligible cattle that may graze in areas outside the Park that

bison may occupy in the winter. If by the fall of 2001, 100% voluntary vaccination of vaccination-eligible cattle in areas outside the Park that may be occupied by bison was not achieved, the State will make such vaccination mandatory. The federal government will reimburse the direct cost of the vaccination. The areas subject to the provisions of this paragraph are depicted as Zone 2 in both the north and western boundary areas as shown in Figures 1 and 3. Cattle on lands within two miles of Zone 2 in both the north and western boundary areas may be subject to mandatory vaccination if required by the State veterinarian in consultation with APHIS. APHIS will also provide funds for voluntary vaccination of cattle within two miles of Zone 2 in the north and western boundary areas.

27. Beyond these steps, APHIS and Montana will conduct additional monitoring of cattle herds that graze in areas that bison may occupy during the winter, which may include regular testing of test-eligible cattle and possible adult vaccination of these cattle herds. APHIS will also do the following: a. make funding available to certify individual cattle herds that graze in areas that bison may occupy in winter, as brucellosis-free; and b. pay the direct costs of any additional testing of any cattle that might be recommended by APHIS and the State Veterinarian pursuant to this Plan. Test eligible cattle within Zone 2 in both the north and western boundary areas, as shown in Figures 1 and 3, will be subject to testing. Test eligible cattle on lands within two miles of Zone 2 in both the northern and western boundary areas, or on lands in Zone 3 if bison have been present (despite the provisions of this Plan precluding bison from occupying such areas), may be subject to mandatory testing if required by the State veterinarian in consultation with APHIS. APHIS will also provide funds for voluntary testing of cattle within two miles of Zone 2 in the north and western boundary areas.

## **VIII. Other Management Provisions**

28. The population target for the whole herd is 3,000 bison. If the late- winter/early-spring bison population is above the 3,000 target, specific management actions may be undertaken at the Stephens Creek capture facility or outside the Park in the western boundary area to reduce its size. For example, instead of hazing bison remaining in boundary areas back into the park in the spring, they may be removed to quarantine or slaughter.
29. The agencies may agree to modify elements of this plan based on research and/or adaptive management findings. Implementation of management actions by the agencies will be conducted in accordance with this Plan and any memorandum of understanding and/or procedure agreements developed by the agencies, which may

provide agency personnel with flexibility to achieve the objectives of the actions set forth in this plan.

30. Absaroka Beartooth Wilderness: Untested bison would be allowed to roam freely into the Absaroka-Beartooth Wilderness north of the park, including the upper portions of Hellroaring and Slough Creek. This is a large area with no cattle, and bison would not be monitored or managed in any way. An exception may include human safety concerns, which would be dealt with on a case by case basis. Because of the high elevation and rugged topography, no more than a few (usually solitary male) bison are expected to occupy these areas.

Cabin Creek/Lee Metcalf/Upper Gallatin: Occasionally bison move north out of the West Yellowstone Basin into the Cabin Creek Recreation and Wildlife management area, the Monument Mountain Unit of the Lee Metcalf Wilderness or into the Upper Gallatin River above the mouth of Taylor Fork. Cattle are not present on these portions of the Gallatin National Forest. There is a cattle grazing allotment in the area of the upper Taylor Fork. Bison would not be allowed on this cattle allotment within the upper Taylor Fork area and would be prevented from crossing the Sage Creek-Wapiti Creek divide. Bison movements would be periodically monitored, and bison crossing outside these areas or entering private lands could be hazed or shot. Bison may attempt to winter in these areas but are expected to return to the park in the spring. Bison may use these areas during all seasons provided they are not approaching the Taylor Fork cattle allotment when cattle are present or causing property damage.

31. Management actions outside the Park will be jointly supported operations conducted by personnel assigned by Montana DOL and MFWP, USFS, APHIS, and NPS. The in-Park vaccination program will be implemented by personnel from NPS. The agencies, and RTR ranch where appropriate, will enter into the appropriate memorandum of understanding to describe specific commitments of personnel to all management actions, delineate operation details for implementation of the plan, and describe reporting requirements for the elements described in the Plan, including those for the implementation of the vaccination program. In addition the agencies will prepare any necessary memorandum of agreement for the funding of all management actions.

## **IX. Contingency Measures**

32. Transmission: Upon disclosure of (1) a brucellosis-affected cattle herd in a management area or (2) a brucellosis-affected cattle herd outside the management areas but for which APHIS and the Montana State Veterinarian concur that the source is



traced back to a management area, the agencies will implement modified management measures pending the completion of an investigation expected to last 60 days or less, during which Montana and APHIS animal health authorities will conduct an epidemiologic investigation to determine the source of infection. Disclosure of a brucellosis-affected herd means that an APHIS-approved Designated Brucellosis Epidemiologist has determined that an animal that is part of the herd is infected with field-strain *B. abortus*. The Management Areas for purposes of this provision is defined as Zone 2 plus 5 miles within Montana depending on terrain.

- a. Modified Management Measures During Investigation: During the post-disclosure period only seronegative non-pregnant bison will be allowed in Zone 2 up to the prevailing tolerance limit. The agencies will employ non-lethal measures whenever possible to ensure that only seronegative, nonpregnant bison remain outside the Park during the post-disclosure investigation.

Upon the initiation of the post-disclosure investigation period, the agencies will determine whether to apply the modified management measures described above in both the western boundary and Reese Creek northern management areas, or only to the area associated with the brucellosis-affected herd. As warranted by information from the investigation, the agencies can adjust the area(s) outside the park to which the modified management measures are applied. The final decision on the areas outside the park to which the modified management measures will be applied will be made by the Montana State Veterinarian, in consultation with APHIS. The agencies may agree that more or less conservative measures are necessary based on the knowledge and experience gained to date through the adaptive management framework, including but not limited to *Brucella* viability, spatial and temporal separation, and seroconversion rate(s).

- b. Investigation results: Post-investigation bison management will depend on the results of the investigation.
  - i. If the investigation finds that either cattle or elk were the source of infection or that bison were not the source of infection, the agencies will continue with the Interagency Bison Management Plan.
  - ii. If the investigation finds that the (1) Yellowstone bison were the source of the *Brucella abortus* infection or (2) eliminates cattle as a likely source but the source cannot be definitively determined (e.g. source unknown), the agencies will allow only seronegative, nonpregnant bison outside the Park in both the west and north boundary areas. The agencies may agree that the modified

management measures are required only in the western boundary area or in the Reese Creek portion of the northern boundary area. They may also agree that more or less conservative measures are required based on the knowledge and experience gained to date through the adaptive management framework, including but not limited to Brucella viability, spatial and temporal separation, and seroconversion rate(s).

- c. Continuation of Interagency Bison Management: If the parties have not agreed to replace the interim modified management measures with a modified Interagency Bison Management Plan based on risk management within two years of the disclosure, the Interagency Bison Management Plan will terminate.
33. Animal Health Authority Sanctions: In the event other jurisdictions impose sanctions on livestock from Montana as a result of the implementation of this plan the following will occur:
- a. Montana in conjunction with APHIS will consult with animal health authorities of those jurisdictions and seek removal of any sanctions;
  - b. If those jurisdictions refuse to remove the sanctions imposed on the movement of livestock, Montana may, in Montana's sole discretion, implement bison management actions necessary to allow for the free marketability of livestock transported from the state;
  - c. The federal agencies retain the discretion to cease endorsing and participating in activities leading to lethal control measures or other joint actions outside the Park should Montana exercise its rights under paragraph 33.b.
34. If Montana is not tolerating untested bison outside the Park in Zone 2 of the west boundary area by the winter of 2003-04 or by the initiation of a vaccination program of vaccination-eligible bison inside the park, whichever is later, the federal agencies will cease endorsing and participating in activities leading to lethal control measures and may withdraw from other joint management actions outside the Park, until Montana is tolerating untested bison outside the Park.

If Montana is not tolerating untested bison outside the Park in Zone 2 of the northern boundary area when the conditions for moving to Step 3 in the northern boundary are met, the federal agencies will cease endorsing and participating in activities leading to lethal control measures and may withdraw from other joint management actions outside the Park, until Montana is tolerating untested bison outside the Park.

If, after the in-Park vaccination program has been initiated, it is terminated or if implementation is deemed inadequate by Montana, Montana will cease tolerating untested bison outside the Park and may withdraw from other joint management actions.

Should either the Federal agencies or Montana invoke the provisions of this paragraph bison outside of YNP will be managed by Montana.

35. Should the federal agencies invoke their discretion under paragraph 33.c or 34, the federal agencies will continue to recognize in their issuance of permits or continuation of permits or other agreements that bison management actions outside the Park are under Montana's jurisdiction.
- 36.a. The agencies may agree to temporarily modify elements of this plan to mitigate total removal of bison due to exigent circumstances arising from severe winter conditions. Based on data from 1996-97, winter kill during severe winters is assumed to be approximately 10% of the early winter bison population and would be in addition to management removals described below. If the bison population declines to 2300 within a single winter, the agencies will meet to evaluate modifications to the prevailing management prescriptions that could reduce the total management removal of bison from the population. If the bison population declines below 2300 within a single winter, the agencies may, on a temporary basis for that winter, increase implementation of non-lethal management measures to provide management flexibility and reduce the total management removal of bison from the population. If the bison population declines below 2100 within a single winter, the agencies will, on a temporary basis for that winter, increase implementation of non-lethal management measures. To determine if the thresholds of 2300 bison and 2100 bison are reached, the following equation will be used: estimated early winter bison population less 10% of early winter bison population less management removals.
- 36b. If modifications to prevailing management prescriptions are implemented within a single winter according to circumstances described in 36.a., the agencies will consider all credible information about the herd status and extent of population decline to determine whether management prescriptions and mitigation measures described above in 36.a. should be continued for the subsequent year(s).



# **Protocol for Evaluating Safety and Efficacy of a Wildlife Vaccine against Brucellosis in the GYA**

**Prepared for the Greater Yellowstone Interagency Brucellosis Committee**

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 will 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 will be the same in both male and female animals in the targeted population. For the purposes of this paper, the definition of a calf will be a bison or elk of less than 12 months of age. Restrictions on use (e.g., sex, 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, that 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 will not be shed from a vaccinate prior to parturition. The vaccine strain will not persist to the first calving in 95% or greater of the vaccinated individuals, or persistence of the vaccine strain will 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 to non-vaccinated 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, will reduce the prevalence of brucellosis in the targeted wildlife population.

Experiments will need to be conducted to evaluate the duration of immunity of the vaccine but these experiments will not be required for initiation of use of the vaccine if all other safety and efficacy criteria are met. A vaccine should provide long-term immunity and/or be able to be safely boosted during the life of the animal.

### **Adult Vaccination**

#### *Safety*

A safe vaccine will not induce significant reductions in survivability or reproductive efficiency as statistically demonstrated in clinical trials.

A safe vaccine will not cause a significant reduction in recruitment in the population of the target species.

#### *Efficacy*

A vaccine will be determined to be efficacious if it induces statistically greater protection in vaccinates against fetal loss, infected calves, or infection after experimental challenge when compared to non-vaccinated animals in the same experiment. In addition, modeling must indicate that the vaccine, when used alone without other management influence, will reduce the prevalence of brucellosis in the targeted wildlife population.

#### *Other*

A major advantage of any vaccine would be the ability to differentiate vaccinates from animals infected with *Brucella* field strains 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 supports their inclusion.









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