

**Finding of No Significant Impact
for the Proposed Study:
*Evaluation of GonaCon™, an Immunocontraceptive Vaccine, as a
Means of Decreasing Transmission of Brucella abortus in
Bison in the Greater Yellowstone Area***

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) prepared an environmental assessment (EA) in January 2012 for the proposed study: *Evaluation of GonaCon™, an Immunocontraceptive Vaccine, as a Means of Decreasing Transmission of Brucella abortus in Bison in the Greater Yellowstone Area*. The EA was in compliance with the National Environmental Policy Act of 1969 (NEPA), as amended (42 United States Code 4321 *et seq.*), the Council on Environmental Quality regulations for implementing the procedural provisions of NEPA (40 Code of Federal Regulations (CFR) 1500B1508), the USDA regulations implementing NEPA (7 CFR part 1), and APHIS' NEPA Implementing Procedures (7 CFR part 372).

Notification and Availability of the Environmental Assessment to the Public

At a public Interagency Bison Management Plan (IBMP) meeting in December 2011, APHIS made brief a statement about its plans to issue an environmental assessment (EA) for the proposed study in early 2012. In accordance with NEPA regulations, APHIS publicly announced the availability of the EA through a Legal Notice in two local Montana newspapers—the Billings Gazette and the Bozeman Daily Chronicle—on January 26, 2012. The Legal Notice provided two website addresses where the EA was available and also provided an APHIS, VS Area Office telephone number and address from which a paper copy of the environmental assessment could be obtained. Through publications of the Legal Notice, APHIS provided a 30-day public comment period and requested that written comments be sent by February 25, 2012, to the APHIS VS Area Office or to an e-mail address established for the comments. In response to requests to allow additional time for commenting, APHIS extended the comment period through March 13, 2012, and announced the extension of the comment period on the same two web addresses that the original announcements were made. By the end of the extended comment period, more than 1,500 comments were received. Comments received after the end of the extended comment period were recorded as late comments. No new issues were raised in the late comments.

A summary of and responses to the comments is included as an appendix to the EA. Most of the comments received raised the same or similar points on the EA and have been summarized accordingly in the comment response appendix.

Environmental Assessment

The EA for the proposed study is incorporated by reference into this document. The EA is available electronically at the following websites:

- http://www.aphis.usda.gov/animal_health/animal_diseases/brucellosis/
- <http://www.ibmp.info>.

Paper copies of the EA document are available upon request from the following office:

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Veterinary Services Area Office
208 North Montana Avenue, Suite 101
Helena, MT 59601
Telephone: (406) 449-2220

The EA for the proposed study analyzed two alternatives: (1) No Action; and (2) the Proposed Action. Two other alternatives—use of an alternate immunocontraceptive vaccine (Porcine zona pellucida) and use of physical sterilization—were considered but dismissed from further consideration. The proposed action is to conduct a study on private land in the Gardiner, Montana area to evaluate several issues relating to GonaCon™, an immunocontraceptive vaccine that results in temporary infertility in treated animals. The proposed study has three major objectives:

- To evaluate the efficacy of GonaCon™ as an immunocontraceptive vaccine in *Brucella abortus* (*B. abortus*)-infected female bison;
- To evaluate the effect on shedding by *B. abortus*-infected female bison that are rendered temporarily infertile by GonaCon™; and
- To evaluate the effect that infertility produced by GonaCon™ has on the long-term survivability of *B. abortus* in infected female bison.

In order to assess the potential for future use of GonaCon™ in brucellosis management strategies, this initial field research is critical. The data gathered from the proposed study will provide valuable initial information on the use of GonaCon™ as an additional potential tool for managing brucellosis in YNP bison under the adaptive management approach.

Based on my review of the EA and the comments received on it, I have determined that the proposed action (the proposed study) as described in the EA is the preferred alternative. The activities that would be conducted under the proposed action would achieve the objectives of the study without any significant impacts to the quality of the human environment. Conclusions regarding considerations of impacts are discussed in more detail below.

Bison

In the proposed study, male and female bison would be acquired during the winter when they naturally exit Yellowstone National Park. Approximately 104 bison would be used in the study: 24 female bison (cows) that test seronegative for brucellosis, 72 female bison that test seropositive for brucellosis, and 8 male bison (bulls) that test seronegative for brucellosis. The test animals would be separated into groups and housed on several double-fenced pastures on private land in the Gardiner, Montana area. Bulls would be separated from cows except during the breeding season from October to July.

In the spring, prior to the breeding season in the first year of the study, selected seropositive female bison would be treated with the GonaCon™ vaccine and identified as such. During the breeding season, cows and bulls would be pastured together and allowed to breed. Cows would be tested for pregnancy, and pregnant animals would be fitted with transmitters to alert study investigators to any calving or abortion events. Five years of calving seasons would be observed in the study. The bison in the study would be under the care of experienced bison

study investigators, including wildlife biologists and veterinarians who would be responsible for ensuring that appropriate animal care practices are followed.

Non-target Species

The proposed study would not increase the risk of brucellosis being transmitted to non-target species. It is also unlikely that non-target species would be exposed to GonaCon™ because it is administered by direct hand-injection only into study animals by study personnel. The study protocol includes risk mitigation measures to restrict access to treated animals by predators or other non-target species. The pastures used in the study are double-fenced to prevent access by larger animals, providing physical separation between study animals and animals such as elk, bears, or coyotes. GonaCon™ causes temporary infertility in treated animals, so abortions or calving in treated animals are anticipated to be minimal. However, study personnel would monitor the study locations closely to detect and remove any potentially *B. abortus*-infected fetuses or animal tissues from GonaCon™-treated bison to further limit potential exposure to non-target species. Despite the protections built into the study to prevent non-target species from being exposed to GonaCon™, in the event that a non-target species were to consume carcasses or other tissues from GonaCon™-treated study animals, no adverse effects are anticipated. The GonaCon™ vaccine is made of proteins which are broken down during digestion when consumed, thereby having no contraceptive effect on non-target animals.

In addition to general consideration of potential non-target species risks from the proposed study, APHIS also considered the potential impacts specifically to bald and golden eagles from the proposed study activities. There are no known bald eagle nests in the areas around the proposed study locations. No specific golden eagle nests are known to be in the proposed study locations. Golden eagles have been observed flying over one of the proposed study locations, but the activities associated with the proposed study would not differ significantly from normal activities in the study locations, therefore no disturbance of eagles is expected to occur. As discussed above, even if eagles were to consume carcasses or animal tissues from GonaCon™-treated bison from the proposed study, no adverse effects to the eagles are anticipated.

Threatened and Endangered Species

The EA for the proposed study considers potential impacts to threatened and endangered species in the study locations in Gardiner, Montana, which is located in southern Park County. Two federally listed species occur in Park County: the Canada lynx and the grizzly bear. For the Canada lynx, critical habitat has been designated in the county. APHIS has determined that the proposed study would have no effect on the two listed species. Although both animals could be located in the general areas near the study locations, there is no risk that they would be treated with GonaCon™ because the administration of the vaccine is by direct hand-injection only. The proposed study protocol includes measures to physically restrict access to the GonaCon™-treated bison. Because the proposed study would be conducted on existing ranches on private land, no potential habitat areas would be disturbed by the activities in the proposed study. Helicopters would not be used in the proposed study, so no disturbance to wildlife in the areas surrounding the study locations is expected.

Human Health and Safety

The EA for the proposed study considers impacts to both the general public and to workers involved in the conduct of the study. No risk of exposure to GonaCon™ to the general public results from the activities associated with the proposed study, which would be conducted on private, double-fenced properties with no access by non-study personnel. There are no risks associated with consumption of bison from the study. Both bison that test seropositive for brucellosis and bison treated with GonaCon™ from the study would not be allowed to be consumed by humans and would be humanely euthanized when the study is completed.

Personnel who are involved in the conduct of the proposed study are trained and qualified for the work they would be performing and have experience in the activities associated with the proposed study. Standard operating procedures would be in place to protect study personnel from risks associated with the activities conducted in the study, including handling of live animals, handling of GonaCon™, and handling of animal tissues potentially infected with *B. abortus*.

Physical Environment

The proposed study would not adversely impact soil, vegetation, or water resources in the proposed study locations. The land that would be used for the proposed study consists of pastures that have been used for bison research or as livestock pastures, so the impacts from the proposed study to these locations would not be increased beyond existing levels. The low density of animals on the land would further ensure that no proposed study-related impacts occur. While one of the proposed study pastures does have a stream running through it, bison from the proposed study would not have access to the stream.

Historic and Cultural Resources

APHIS considered the potential impacts to historic and cultural resources from the proposed study. APHIS submitted a summary of the proposed study, and received concurrence from the Montana State Historic Preservation Office that there were no findings of potential impacts to historic resources from the proposed study.

Tribal Consultation and Coordination

In accordance with Executive Order 13175, APHIS coordinated with Tribal officials to ensure that they were informed about the proposed study and any considerations that may impact their interests. In December 2011, APHIS provided information to 26 Tribes about the proposed study and invited them to participate in a conference call to discuss the proposed study. During that conference call, APHIS shared its plans with Tribal representatives to prepare and issue the EA for comments and also offered to provide additional information regarding the study to Tribes upon request. APHIS is not aware of any issues that were raised by any of the representatives contacted regarding the proposed study.

Finding

Agencies prepare EAs to analyze issues relating to proposed actions and determine whether there are any significant environmental impacts that are likely to occur as a result of the proposed action. If an agency determines that significant impacts to the quality of the human environment would occur, an environmental impact statement must be prepared. Based on the information provided in the environmental assessment, I have determined that the proposed study will not significantly impact the quality of the human environment, and, therefore, that no environmental impact statement is needed.



Dr. Donald E. Herriott
Associate Regional Director – Western Region
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Date