Evaluation of GonaCon™, an Immunocontraceptive Vaccine, as a Means of Decreasing Transmission of *Brucella abortus* in Bison in the Greater Yellowstone Area

Environmental Assessment, May 2012

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I. Introduction

A. Background

In Yellowstone National Park (YNP), wild and free-ranging bison (*Bison bison*) are critical parts of a fully-functioning ecosystem as well as being important to the identity of the park. The bison are a part of the esthetic, cultural, and natural environment of the YNP. YNP bison are chronically infected with brucellosis, a contagious disease that the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (USDA/APHIS/VS) is striving to eliminate.

Brucellosis is a serious disease of livestock and wildlife that has significant animal and public health and international trade consequences. The disease is caused by bacteria of the genus *Brucella*. Brucellosis occurs primarily in cattle, bison, and swine; however, cervids, goats, sheep, and horses are also susceptible. In cattle and bison, the specific disease organism of concern is *Brucella abortus (B. abortus)*.

In its principal animal hosts, brucellosis causes loss of young through spontaneous abortion or birth of weak offspring, reduced milk production, and infertility. In cattle and bison, the disease localizes in certain lymph nodes, reproductive organs and/or the udder, causing spontaneous abortions in females and systemic effects in both male and female animals. Weight loss and lameness may also be associated with brucellosis infection.

The shedding[1] of *B. abortus* through the reproductive tract during an abortion or calving event may contribute to the transmission of infection to other animals that come in contact with the expelled bacteria now in the environment. Studies have shown that *Brucella* can persist on fetal tissues, vegetation and soil in YNP for as long as 81 days depending on environmental conditions (Aune et al., 2011). Spread of the disease occurs when the cattle and bison, which are social animals, sniff and lick a newborn calf, the afterbirth, and even an aborted fetus. This behavior provides an avenue for the disease to spread if *B. abortus* organisms are present. Additionally, *B. abortus* is present in the milk from infected females and can be transmitted to calves through suckling. There is no effective means of treating brucellosis in livestock or wildlife.

Studies investigating the prevalence of brucellosis in YNP bison have estimated that between 40% and 60% of YNP bison have been exposed to

[1] For purposes of the proposed study, "shedding" is to expel *B. abortus* from the body through the reproductive tract.

the disease. Further testing of animals that are seropositive[2] demonstrates that more than 40% of the seropositive animals are culture-positive, confirming actual infection with *B. abortus* (Meyer and Meagher, 1995; Cheville et al., 1998). In the areas outside the borders of YNP where livestock such as cattle are often raised, there is a concern that infected bison may transmit the disease to livestock if infected bison abort or calve.

Multiple Federal and state agencies[3] have participated in efforts to control the potential spread of brucellosis and conserve bison through the 2000 Interagency Bison Management Plan (IBMP) (MDoL and MFWP, 2000). In 1934, a federal brucellosis program was established as part of an effort to safeguard domestic livestock (See http://www.aphis.usda.gov/animal_health/animal_diseases/brucellosis/ for additional information regarding USDA APHIS' brucellosis program).

Safeguarding measures, such as preventing, detecting, and eliminating animal diseases, help to maintain the U.S. cattle industry's national and international trade interests, ensure food safety, and protect public health. The efforts of the national brucellosis program have nearly eradicated brucellosis from domestic cattle and bison populations. As of July 2009, all 50 States had attained Class-Free (disease-free) status for brucellosis in domestic cattle and bison (USDA APHIS, 2010a). Currently, the last known reservoir of bovine brucellosis is in the wild bison and elk population in the Greater Yellowstone Area (GYA). Prevention of the spread of brucellosis between infected wildlife and livestock continues to be an issue of concern. The proposed study discussed in this environmental assessment (EA) is designed to investigate the feasibility of using an immunocontraceptive vaccine, GonaCon™, as a non-lethal management option to decrease the potential risk of disease transmission by brucellosis-infected bison.

In humans, brucellosis is often referred to as undulant fever because it persists for several weeks or months and may get progressively worse if untreated. Humans are most commonly infected by consumption of unpasteurized dairy products produced from milk of infected animals, or they may become infected through direct contact with infected animal tissues such as aborted fetuses or reproductive materials. In humans, brucellosis initially causes flu-like symptoms that are treated with a rigorous course of antibiotics. In some isolated cases, the disease may develop into a variety of chronic conditions, including arthritis. Potential

[2] Bison that test positive on blood tests for brucellosis are referred to as being seropositive, and bison that do not test positive are referred to as being seronegative.

[3] U.S. Department of Interior National Park Service (NPS); U.S. Department of Agriculture Animal and Plant Health Inspection Service (APHIS); U.S. Department of Agriculture Forest Service (FS); Montana Department of Livestock (MDoL); and Montana Fish, Wildlife and Parks (MFWP).

effects of the proposed study on humans will be discussed in the potential environmental impacts section.

GonaCon™ Immunocontraceptive Vaccine

GonaCon™ is a contraceptive vaccine that stimulates an immune response in a vaccinated animal by producing antibodies that bind to a gonadotropin-releasing hormone (GnRH). GnRH is a naturally occurring hormone that signals production of sex hormones such as estrogen, progesterone, and testosterone. The anti-GnRH antibodies interfere with the ability of GnRH to signal production of sex hormones, resulting in temporary infertility. As long as adequate levels of anti-GnRH antibodies are present in the vaccinated animal, sexual activity, breeding, and reproduction are extremely unlikely.

GonaCon™ is currently approved under the United States Environmental Protection Agency's (EPA's) Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for use in female white-tailed deer as one tool to aid in reducing deer overpopulation (EPA Registration Number 56228-40). The immune response that causes temporary infertility in deer is accomplished with a single-shot vaccine. The length of time that a vaccinated female deer remains infertile depends on the individual animal, but some pen studies have shown that 4 out of 5 female deer remain infertile for 5 years (Miller et al., 2008a). Field studies have demonstrated lower rates of infertility ranging from 88% and 47% the first and second year after vaccination, respectively (Gionfriddo et al., 2009) to 67% and 43% the first and second year after vaccination, respectively (Gionfriddo et al., 2011).

GonaCon™ is not currently registered for use in bison. However, USDA conducted a small pilot study of penned bison and found that none of the 6 females vaccinated with GonaCon™ became pregnant the first year after treatment (Miller et al., 2004). In 2011, APHIS received approval from EPA to use GonaCon™ in female bison in the confined experimental use scenario discussed in this EA. Should the proposed study discussed in this EA proceed, the data obtained from it could potentially be used to add to the required data set needed for EPA to register the GonaCon™ vaccine for use in bison. However, the purpose for registering GonaCon™ in bison would not be for reducing overpopulation. The intended purpose of using GonaCon™ in female bison would be to manage reproduction in bison known to be infected with brucellosis by inducing temporary infertility, thereby decreasing the potential for transmission of brucellosis through abortion and calving events.

B. Purpose of and Need for the Proposed Action

The purpose of the proposed action is to conduct a study to evaluate whether GonaCon™, an immunocontraceptive vaccine, would be effective as a non-lethal method of decreasing the prevalence of brucellosis in the YNP bison population by preventing pregnancy, calving, and abortion, thereby preventing transmission of *B. abortus*. The major objectives of the proposed study are:

- To evaluate the efficacy of GonaCon™ as an immunocontraceptive vaccine in *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 the infertility produced by GonaCon™ has on the long-term survivability of *B. abortus* in infected female bison.

Use of an effective immunocontraceptive such as GonaCon™ to prevent pregnancy and eliminate the potential for abortions by infected bison would break the cycle of transmission of brucellosis. If female bison known to be infected with *B. abortus* do not become pregnant, they would not abort. Exposure of non-infected animals to the infected tissues and fluids from aborted fetuses would therefore be reduced.

The need for the proposed study is to provide information that would be used to evaluate the use of GonaCon™ as a nonlethal method of decreasing or controlling the risk of transmission of *B. abortus* in the YNP bison population. Brucellosis is spread within the animal population primarily through contact with infected birthing tissues or aborted fetuses and through the milk of infected cows. If GonaCon™ can effectively render brucellosis-infected female bison temporarily infertile, the primary routes of disease transmission would be blocked. In combination with other appropriate disease mitigation activities, the use of GonaCon™ may be an effective tool to assist in eliminating brucellosis from the YNP bison herd over time.

USDA APHIS has determined that under the provisions of the National Environmental Policy Act (NEPA) (see 42 U.S.C. 4321 et seq.) and APHIS' National Environmental Policy Act (NEPA) implementing procedures (see 7 CFR Part 372), an EA should be prepared for these proposed actions. The availability of this EA and a 30-day comment period will be announced by publishing a notice on the APHIS brucellosis program website, the IBMP website and/or local newspapers. APHIS' decision maker for the actions described in this EA will take appropriate action after reviewing the EA, its associated analyses, public comments received, and other relevant responses and recommendations.

II. Proposed Action and Alternatives

A. No Action (the Current Situation)

The no action alternative would result in not conducting the proposed study. If the proposed study is not conducted, the utility of GonaCon™ as a non-lethal reproductive control option in bison cannot be determined. Additionally, if the use of GonaCon™ in bison is not investigated, information would not be known on whether temporary infertility induced by GonaCon™ is effective in decreasing the shedding of *B. abortus* and ultimately the transmission of brucellosis. Without the proposed study, use of the immunocontraception approach as a viable disease management tool for bison would not be evaluated, and could not be considered as a potential management tool.

B. Proposed Action

The proposed action is to conduct a multi-year study to evaluate the potential for use of GonaCon™, an immunocontraceptive vaccine, as a non-lethal method of decreasing the prevalence of brucellosis in bison by preventing pregnancy, thereby preventing abortions and risk of transmission of brucellosis to uninfected animals from contact with infected tissues and fluids from aborted fetuses.

The proposed study would include the following activities that are discussed in further detail below:

- Capturing bison in the late winter/spring of 2011, 2012, 2013, and possibly 2014;
- Transporting the captured bison by stock trailer to APHIS' bison facilities in Gardiner, Montana;
- Collecting and evaluating blood samples to determine brucellosis infection status at the beginning of the study and monitoring infection status at regular intervals throughout the study;
- Housing, caring for, and tagging (for identification purposes) animals in Gardiner, Montana facilities;
- Injecting one group of seropositive female bison with GonaCon™ beginning in the spring of 2012;
- Commingling uninfected bulls with females during breeding season, documenting breeding behavior, and testing for pregnancy for five calving seasons;
- Monitoring pregnant bison with transmitters and daily observing them for abortions, labor, and births;

- Collecting and testing blood, milk, and vaginal swabs from female bison that give birth to test for brucellosis infection status;
- Monitoring exposure to aborted fetuses by other bison and evaluating fetuses collected during the study; and
- Evaluating data collected from the study to determine whether GonaCon™ decreases the shedding of *B. abortus* in bison.

Bison for the proposed study would be acquired during the winter when they naturally exit YNP. The capture of bison would be conducted using methods currently in use for capturing bison according to the details of the IBMP operating procedures (IBMPOP, 2009). These procedures include hazing and/or using weed-free hay to move them to a capture facility. Approximately 104 adult bison would be used in the proposed study: 24 female bison that are seronegative for brucellosis; 72 female bison that test seropositive for brucellosis; and 8 male bison (bulls) that test seronegative for brucellosis. Female bison would be yearlings, two-, and three-years of age. If temporary chemical immobilization of any animal is needed, opioid narcotics and alpha-2-adrenergics would be used by study personnel qualified in the administration of such drugs. All bison used in the study would be identified with uniquely numbered ear tags and microchip identification.

The proposed study would take place on several double-fenced pastures at facilities in the Gardiner, Montana area: the Brogan Bison Facility in Corwin Springs (60 acres), the Slip 'n Slide pasture (25 acres), and the Rigler pasture (32 acres), all of which are located north of Gardiner, Montana. All sites are within the GYA and along Highway 89. The Brogan Bison Facility, Rigler pasture, and Slip 'n Slide pastures are currently leased by APHIS VS and Montana Fish, Wildlife and Parks and are used by APHIS VS for the bison quarantine feasibility study (MFWP, 2005). These facilities were specifically designed and erected to hold bison in a quarantine environment with hay and water as needed for an extended period of time.

The study design is as follows: In spring 2012, animals would be randomly selected to go into groups of 16 to18 seropositive cows, four to six seronegative cows, and two bulls. Two replicate test pastures would be established in 2013 and possibly 2014 if not enough animals are captured in 2013. After three to four weeks of acclimation in the test pastures, *B. abortus*-infected female bison in one of the pastures would receive GonaCon™ vaccine (containing 3,000 micrograms in 3 milliliters of an adjuvant) delivered into the muscle on each side of the neck or hip. The sites of injection would be tattooed or otherwise marked and observed for any injection reaction. Bison in the remaining pasture would not be vaccinated.

Bulls would be separated from the cows outside of the breeding season from October to July. Prior to exposure to bulls, cows would have breeding tags[4] attached to them to document if bulls have mounted them to breed. Following first exposure of cows to bulls in 2012, five calving seasons would be observed (2013-2017). In February of each year, cows would be pregnancy-tested and fitted with vaginal transmitters to alert investigators to abortion or calving events.

During the abortion/calving seasons (from February until August of each year), daily observation for abortions, labor, and calving events would be conducted by study investigators. Within five days of abortion or calving, the cow would be immobilized and blood, milk, and vaginal swabs would be collected for testing. If possible, the calf would also be captured and eye swabs and blood would be collected for testing.

Following an abortion, the fetus would be left at the abortion site for 24 hours to monitor exposure to other bison. The fetus would then be collected, tested, and incinerated at the Montana Veterinary Diagnostic Laboratory (MVDL) in Bozeman, Montana.

Blood testing of cows, bulls, and calves would be conducted three times a year: in February, calving time, and in the fall. Blood would be analyzed at the MVDL and/ or the National Veterinary Service Laboratories in Ames, Iowa throughout the study to determine *B. abortus* infection status of each animal.

Handling and physical restraint of bison for tagging or blood collection would take place in alleyways leading to standard bison manual squeeze chutes. Injection of the study animals with GonaCon™ would be done by study personnel experienced in administering intramuscular vaccines. Blood samples from study animals would be collected using established techniques for collection of blood from bison and would be performed by study personnel experienced with these techniques. An attending veterinarian would be available to address concerns about animal care and use for the study.

When the study is completed, all seropositive animals would be humanely euthanized following American Veterinary Medical Association-approved guidelines, and specimens would be collected from each animal for laboratory analysis. In addition, eggs and semen would be collected from these animals, including vaccinated animals, and frozen for genetic conservation. Per the conditions of the approval from EPA to use GonaCon™ in bison in this confined experimental use study, animals treated with GonaCon™ cannot be consumed by humans. These animals

[4] Breeding tags are devices that are temporarily adhered to the base of the cow's tail that indicate by a color change that the cow has been mounted.

would be disposed of by incineration or landfill burial. Seropositive animals from the study that have not received GonaCon™ injections would be distributed to Montana food banks as is routinely done with other YNP seropositive bison. Further discussion on the safety of consuming bison infected with *B. abortus* is discussed in the human health and safety section of this document. All animals that test negative for brucellosis for the duration of the study and satisfy existing bison quarantine release requirements outlined in the APHIS Uniform Methods and Rules (USDA APHIS, 2003) would be used for bison conservation purposes.

C. Other Alternatives Considered but Dismissed from Further Consideration

Because the most common route of transmission of *B. abortus* is contact with infected birthing fluids, aborted fetuses, and placental tissues, different methods of impacting the fertility of bison through the use of immunocontraceptive vaccines were considered as alternatives to the proposed action. If pregnancy could be prevented in *B. abortus*-infected female bison, transmission of *B. abortus* by this route could be eliminated or decreased.

APHIS considered the use of porcine zona pellucida (PZP), another type of immunocontraceptive vaccine that has been used in animal species such as dogs, coyotes, burros, wild horses, and deer (USDA APHIS, 2010b). PZP has also been demonstrated to effectively induce temporary infertility in captive bison (Frank et al., 2005). However, research has shown that the use of PZP can increase the period of time in which the treated animals exhibit breeding season behavior.

The PZP vaccine results in temporary infertility while still allowing female animals to have multiple estrous cycles in which they engage in prebreeding behavior and breed. This behavior can cause animals to use energy at times of the year, such as late fall and early winter, when they would otherwise be conserving energy. Miller et al. (2004) concluded that "…Prolonging the breeding season of bison in the GYA may be deleterious to the winter survival of dominant bulls and PZP vaccinated cows because of increased sexual activity during fall and early winter." Therefore, this alternative was dismissed from further consideration because investigating the use of a PZP vaccine would not be useful in brucellosis management strategies in bison since it is associated with increased mating and reproductive activity (Killian et al., 2007).

APHIS also considered the alternative of physical sterilization as a means of decreasing the transmission of *B. abortus* within bison populations and between bison and cattle in the GYA. Physical sterilization such as

spaying[5] or castration[6] has been recognized as a disease management strategy that could be used to reduce the potential transmission of brucellosis in infected wildlife populations. However, this type of sterilization is permanent. APHIS would not subject the bison in the study to physical sterilization. For this reason, this alternative was dismissed from further consideration.

III. Potential Environmental Impacts

The NEPA implementing regulations provide criteria that Federal agencies should evaluate, if applicable, in environmental documents for proposed actions. This section of the EA addresses the applicable criteria related to potential impacts from the no action alternative and from the proposed action. NEPA criteria that are applicable for consideration in this section of the document include animal impacts, human health and safety, and the physical environment.

A. No Action

Without the proposed action, efforts to gather scientific information to better understand the potential application of immunocontraceptive vaccines such as GonaCon™ as a nonlethal strategy for reducing the transmission of *B. abortus* and decreasing the prevalence of brucellosis in the wild bison population in YNP would be lost. Without the proposed action to assist in developing nonlethal strategies to effectively control and eliminate brucellosis, the disease may continue to spread within the wild, free-ranging bison population in the GYA.

B. Proposed Action

1. Impact of Proposed Action on Animals

a. Bison

The proposed study would not increase the risk of brucellosis being transmitted within the bison population. Therefore, this section focuses on the potential effects of the admistration of GonaCon™ in bison.

In this proposed study, the desired effect of administering GonaCon™ is the temporary suspension of reproductive activity in the vaccinated female bison. Miller et al. (2004) report that "The gonadotropin-releasing hormone (GnRH) vaccine is generally considered to provide temporary

[5]Surgical removal of the ovaries from female bison.

[6] Surgical removal of the testes of male bison.

sterilization, because the reproductive activity of the target animal returns as the GnRH antibody titer drops below a protective level." If the effect of this immunocontraceptive vaccine successfully places the vaccinated bison cows in a temporary nonreproductive state, the transmission of brucellosis by the female bison via shedding of *B. abortus* during calving or abortion may be eliminated.

A small study conducted at the Idaho Fish and Game Wildlife Health Laboratory in Caldwell, Idaho in 2002-2003 demonstrated "that a single injection of GnRH vaccine is effective in preventing conception in female bison for at least 1 yr" (Miller et al., 2004). In that study, three of the six GnRH-treated bison cows and five of the untreated bison cows were in the last month of pregnancy at the time of vaccination. They delivered normal calves in the first year, suggesting that the GnRH vaccine did not interfere with the pregnancy and could be administered safely during the last third of the pregnancy. Additionally, none of the six treated bison became pregnant during the first breeding season (Miller et al., 2004).

Undesired health effects have been minimal in the species of wildlife in which GonaCon™ has been used. Injection site reactions caused by the "water-in-oil (W/O) emulsion needed in the GonaCon™ formulation for development of a long-term immune response" have been observed (Miller et al., 2008b). These reactions were most commonly manifested as inflammation or swelling at the injection site, or the presence of granulomas (thickened tissue filled with fluid). This observation is not uncommon in other livestock vaccines (USDA APHIS, 2010b).

As part of the GonaCon™ EPA registration process for use in deer, the health effects to the vaccinated deer were evaluated. Vaccinated animals showed no external evidence of inflammation at known injection sites; however, when muscle tissue at the injections site was sectioned, the injection sites appeared to be comprised of whiteish scar tissue, some containing vesicles of sterile fluid. All blood chemistry analyses were similar between treated and untreated deer. (Killian et al., 2006). Other types of injected products that alter animal hormones are currently used in livestock in the United States (USDA APHIS, 2010b).

Ensuring humane handling and treatment of all bison during the proposed study activities would be a priority. Application of animal identification tags, administration of GonaCon™ vaccine, and evaluation of pregnancy status, calving, or abortion `activities would be conducted at appropriate times during the proposed study. These activities would be overseen by the study's attending veterinarian and would not be expected to cause more than momentary or slight pain or discomfort. All temporary restraining and handling or temporary immobilization and handling activities would be conducted as quickly and efficiently as possible and in

a manner that would prevent undue stress, trauma, injury, or any unnecessary discomfort to the animal. If temporary immobilization is necessary, bison cows would be immobilized in locations within the facilities that are safe for the animals and the proposed study personnel. Veterinary oversight for animal care and handling, restraint, and sample collection would be provided during the proposed study activities. Wildlife biologists trained and experienced in the handling of bison would also be participating in the proposed study activities.

If necessary, study personnel would use the Federal Drug Administration (FDA)-approved anaesthetic and pain-killing (analgesic) drug combinations to immobilize the animals in order to prevent any potential negative impacts to the bison during the collection of study samples. The immobilization drugs would be used according to standard animal administration techniques, and it is expected that the bison would be immobilized for no more than 20 minutes. Vital signs of the immobilized bison would be monitored by qualified study staff throughout the sampling procedures and the initial recovery phase. To further ensure humane handling of the bison, every precaution would be taken by study staff to prevent immobilization- or handling-related trauma, injury, or death to the bison. The standard chemical immobilization protocol that would be used in this proposed study is widely used in bison and other wild ungulates without long-term effects (Kreeger and Arnemo, 2007).

In the GonaCon™ EPA registration process for use in deer, concerns were initially raised by some States that GonaCon™ would eliminate the need to use hunting as a tool to control deer overpopulation. Contraception alone would not reduce overabundant deer populations to healthy levels (USDA APHIS, 2010b). In deer, GonaCon™ is meant to be used in combination with other wildlife management tools to control populations. Assuming the use of GonaCon™ is eventually registered by EPA for bison, it is equally implausible to conclude that use of the contraceptive vaccine in bison would result in any significant population decreases in bison in the absence of other management tools (USDA APHIS, 2010b).

b. Non-Target Species

The proposed study would not increase the risk of brucellosis being transmitted to non-target species. Therefore, this section focuses on the risk of non-target species being exposed to GonaCon™.

In the proposed study, it is unlikely that non-target species would be exposed to GonaCon™. The proposed study protocol includes both risk mitigation measures that prevent direct exposure of non-target species to GonaCon™ and measures that limit the potential for secondary exposure of non-target species to GonaCon™.

To prevent direct exposure to non-target species, GonaCon™ would be administered directly to the study bison by hand-injection with a syringe. By using this direct-injection method, there would be no potential for accidental injection of non-target species with GonaCon™.

To prevent the risk of secondary exposure, the study plan includes measures to restrict access to treated animals by predators or other non-target species. To prevent access by larger wild animals, the bison in the proposed study would be maintained in double-fenced pastures, not on open range, thereby physically limiting potential contact between treated bison and wild animals such as elk, bears, and coyotes.

Abortions or calving events by GonaCon™-treated bison should be very minimal since the expected effect of treatment with GonaCon™ is to prevent pregnancy. The proposed study protocol includes actions to detect abortion or calving events, and the fencing would also physically limit some wild animals from accessing infected bison tissues from the GonaCon™-treated bison. The study protocol also includes standard operating procedures for proper removal and disposal of *B. abortus*-infected animal tissues from GonaCon™-treated bison from the study area to further limit potential exposure.

As discussed above, some larger animal species can be physically prevented from accessing the study area. However, some species such as birds of prey, smaller rodents, or insects cannot be prevented from accessing the study area. In the event that a non-target species were to consume GonaCon™-treated infected bison carcasses or GonaCon™-treated *B. abortus*-infected animal tissues, there would be no anticipated adverse effects from the GonaCon™ vaccine. Because GonaCon™ is made of proteins, it is broken down into smaller amino acids through digestion when it is consumed and has no contraceptive effect on non-target species (Fagerstone et al., 2008; Fagestone et al., 2010).

As part of the registration process for the use of GonaCon™ in deer, EPA concluded that there is no known danger associated with eating deer that have been vaccinated with GonaCon™ (USEPA, 2007). Similar injectable hormone-altering products are used routinely in livestock applications (USDA APHIS, 2010b).

2. Human Health and Safety

a. General Public

The proposed study discussed in this EA would be conducted on double-fenced, private facilities where access by the general public to bison and potentially infected animal tissues such as aborted fetuses or reproductive materials would be prohibited. The protocol for the study contains

standard operating procedures for handling and safely disposing of any potentially brucellosis-infected materials generated from the animals in the study. The general public would have no risk of being exposed to either GonaCon™ -treated or untreated animals from the study or any potentially infected materials generated from the study.

There is no danger of transmission of the infection to humans from consuming cooked meat from *B. abortus*-infected bison. The *B. abortus* bacteria that causes brucellosis is typically not found in muscle tissue, and normal cooking temperatures kill any existing bacteria (USDA APHIS, 2011). Additionally, EPA and FDA concluded that there are no known human food safety concerns associated with eating deer that have been vaccinated with GonaCon™ (USEPA, 2007 and FDA, 2005).

b. Worker Safety

Personnel who would be involved in the proposed study are qualified and have the expertise and experience needed to carry out the study activities. These activities include wildlife chemical immobilization, proficiency in administration of animal vaccines, veterinary care, animal restraint, tagging and marking animals, sample collection, and field evaluation of reproductive behaviors and activities.

Standard operating procedures would be in place to protect personnel involved in carrying out the proposed study activities. The standard operating procedures would include measures for safe and humane handling of bison to prevent injury to study personnel and to bison; safe handling and administration of GonaCon™; safe and humane collection of study samples for analysis; and safe handling procedures for study samples, including the safe handling and proper disposition of potentially infected animal tissues. In addition to the standard operating procedures and safety measures, at least one cell phone would be available at all times to facilitate contact in emergencies, and first aid kits would be available at all times in the event of injury to study personnel.

The GonaCon™ immunocontraceptive vaccine would be provided for the study in pre-mixed syringes and stored in locked containers except when actively being used to inject study animals. Personnel handling the vaccine would take appropriate precautions to prevent accidental self-injection. Pregnant women would not be involved in the handling or injecting of GonaCon™ at any time during the proposed study to avoid any potential risks associated with accidental exposure to the immunocontraceptive vaccine. Immobilization drugs and associated reversal drugs would be available for use if needed in the study. These drugs would be properly stored in locked containers to prevent improper access.

3. Physical Environment

As previously mentioned, proposed study activities would occur in several pastures at the Brogan Bison Facility, just north of Corwin Springs (60 acres), and the Slip ‘n Slide pasture (25 acres) and/or Rigler pasture (32 acres), located north of Gardiner, Montana.

The Brogan Bison Facility is used by APHIS VS for bison research. Forage at the pastures includes a mix of cultivated and native grasses. The upper pasture is on a steep slope along the west side of the property with several grass benchlands[7] and steep, rocky drainages. The vegetation is composed of thinly forested slopes, interspersed with native bunchgrass rangelands (MFWP, 2005). Bassett Creek runs through the property and flows into the Yellowstone River.

The Slip ‘n Slide and Rigler pastures are located in close proximity to each other, just south of Yankee Jim Canyon. The pastures are double-fenced. The landscape is gently sloping and consists mostly of native grassland, except for the mixed alfalfa- and grass-cultivated hay meadows. Slip ‘n Slide Creek runs through the Slip ‘n Slide property and flows into the Yellowstone River. There are no brooks or creeks running through the Rigler pastures. The pastures are primarily surrounded by Gallatin National Forest and State of Montana land. Montana Fish, Wildlife and Parks historically leases the pastures on the ranch for bison to graze on (MFWP, 2011).

The potential environmental impacts of the proposed study on the physical environment would primarily be due to bison grazing in confined areas. The main issues of concern regarding confined grazing are effects on soil, vegetation, and water quality. These aspects are discussed below.

a. Soil and Vegetation

Livestock grazing in confined pastures can negatively affect soil quality by compacting the soil or causing soil erosion due to loss of vegetation cover. With a loss of vegetation, invasive species also threaten pastures. Most studies and discussions on the impacts of grazing focus on cattle because 70% of the western United States is grazed by livestock, which is primarily composed of cattle (Fleischner, 1994). Cattle are similar to bison in that they are large generalists and ungulate herbivores that can disturb terrestrial communities; however, differences in the two animals, such as forage selection and social organization (Hartnett et al., 1997; Steuter and Hidinger, 1999), may influence their impacts on soil and vegetation.

[7] Steps or shelves in the mountainside that are the remains of former riverbanks or lakeshores.

Bison have a stronger preference for perennial grasses than cattle. Cattle consume a higher percentage of forbs[8] in their diet than bison, and they use wooded areas and riparian zones more intensively than bison (Steuter and Hidinger, 1999). Due to the lower diversity of plants consumed by bison and the bison's preference for herbaceous vegetation, there may be a reduction in the abundance of dominant grasses, an increase in the survival of subordinate species, and an increase in species diversity, when compared to land grazed by cattle (Hartnett et al., 1997). Additionally, physical disturbances that bison exhibit during non-grazing activities, such as wallowing[9] may assist in ecodiversity (Hartnett et al., 1997).

The proposed action would not alter historic land use (for information regarding historic or cultural sites, see section below in the section on other environmental review requirements) at the pastures; therefore, overall effects to soil and vegetation would not be increased. Approximately 100 bison would be placed on 120 irrigated acres of land, averaging about one acre of land per bison. This density is expected to have only minimal impacts on the land. In addition, landowners at each ranch or facility implement management practices to minimize effects to soil and vegetation. Pasture rotation is practiced at or between facilities as necessary, so that each pasture is periodically rested and the land is not overused. Lastly, the bison at all facilities would be supplemented with hay, further limiting pasture grazing.

b. Water

GonaCon™ is a protein that is broken down within the treated bison; its metabolites would not be anticipated to be any greater than what would naturally occur. Therefore, this section focuses on other potential environmental impacts of bison grazing near water.

Potential environmental impacts from bison grazing in pastures could include a degradation of nearby water quality by manure, urine, and sediment being deposited into local waters. While bison that have access to a water body may directly deposit manure and urine into the water, wastes excreted onto land may also be transported to water bodies via leaching and surface runoff.

Grazing management practices can lessen the environmental impacts of streamside pastures. While many studies describe the impact of cattle

[8] Herbaceous flowering plants other than grass.

[9] When bison roll in shallow depressions in the soil, covering themselves with dirt or mud.

grazing on water bodies, few studies have concentrated on the effects of native ungulates on stream health. Russell et al. (2009) states that the proximity of cattle to the stream, the amount of time they spend by or in the stream, and the intensity and length of cattle grazing can all influence the water quality of nearby streams. One can assume the same behaviors in bison would also impact water quality.
Bison spend less time in streams or riparian habitats than cattle (Fleischner, 1994). Fleischner describes a study conducted in Utah regarding the feeding ecology of cattle and bison. The study noted that "cattle distribution was limited to gentle slopes near water, regardless of forage, while bison roamed widely, seemingly unaffected by slope or proximity to water." As previously mentioned, cattle forage on a higher percentage of forbs and woody vegetation and maintain a larger breadth of diet niche than bison. Fritz et al. (1999) take this one step further and state that a higher percentage of forbs and woody vegetation occurs in the riparian zone, so cattle are more likely to impact stream riparian zones than bison.

Fritz et al. (1999) studied the distribution and diversity of macroinvertebrates (e.g., insects, worms, snails and crayfish) in relation to bison crossings in prairie streams. The study suggests that impacts of bison on communities at the bottom of the streams was spatially limited, and that the bison may have less impact on stream communities than other studies of the impact of cattle. While comparison to cattle provides a noteworthy point of reference, it is important to point out that it is difficult to compare environmental responses with cattle versus bison due to confounding effects of site, weather, and management.

The pastures that would be utilized in the proposed study have historically been used for bison research or as livestock pastures, so deposits of manure, urine, and sediment due to the proposed study are not expected to increase the historic amount of contaminants entering the Yellowstone River. While the Brogan Bison Facility does have a creek running through it, bison do not have access to the creek. Only bison at the Slip 'n Slide ranch would have direct, but limited, access to a creek. The access site to this creek was historically used for livestock and is at a point on the creek where the bank is shallow and covered with rocks. A shallow crossing means that bison would not have to climb up and down the bank, which would eventually cause the banks to erode. In addition, water would be provided to the bison, limiting the time that bison would visit the creek. Lastly, because only a portion of the total number of bison tested would be present on this pasture and those bison would spend limited time in streamside environments, the impact to water bodies is expected to be minimal.

IV. Other Environmental Review Requirements

A. Endangered or Threatened Species

Section 7 of the Endangered Species Act (ESA) and its implementing regulations require Federal agencies to ensure that their actions are not likely to jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of critical habitat. Proposed study activities would occur in pastures in southern Park County in Montana.

There are two federally listed mammals in Park County: the Canada lynx (*Lynx canadensis*) and the grizzly bear (*Ursos arctos horribilis*). Critical habitat has been designated for the Canada lynx in Park County.

Canada lynx: Areas designated as critical habitat for the Canada lynx include boreal forest landscapes that provide one or more of the following primary constituent elements for the lynx: snowshoe hares for prey; abundant, large, woody debris piles that are used as dens; and winter snow conditions that are generally deep and fluffy for extended periods of time (USDOI FWS, 2009).

Grizzly bear: In Montana, grizzly bears primarily use meadows, seeps, riparian zones, mixed shrub fields, closed timber, open timber, sidehill parks, snow chutes, and alpine slabrock habitats. Habitat use is highly variable between areas, seasons, local populations, and individuals. Grizzly recovery zones (areas identified where grizzly bear distribution is primarily within), including the Yellowstone area in northwest Wyoming, eastern Idaho, and southwest Montana (9,200 square miles), are estimated at more than 580 bears (FWS, 2011).

At all three locations, the pastures are double-fenced with an 8-foot woven wire fence and an electric high tensile fence to contain the study bison. These fences would also prevent Canada lynx and grizzly bears from entering the pastures. If Canada lynx or grizzly bears were to enter the pastures and consume GonaCon™-treated bison, there would be no effect on these species. The vaccine is made of proteins, and when consumed, is broken down into amino acids in the gastrointestinal tract, thereby having no contraceptive effect (Fagerstone et al., 2008; Fagerstone et al., 2010).

Federally-listed species and other non-target wildlife would not be directly exposed to GonaCon™ because the vaccine would be injected directly into the test bison and not administered orally in bait form. No wildlife habitat would be altered or disrupted by proposed study activities. No

helicopters would be used as part of this proposed study; therefore, no disturbance to wildlife in the surrounding area is expected. Although the study pastures occur within the designated critical habitat of the Canada lynx, the proposed study would have no effect on the primary constituent elements of that habitat and would not adversely modify it. Therefore, APHIS has determined that the proposed action would have no effect on the grizzly bear or Canada lynx.

B. Bald and Golden Eagle Protection Act

The Bald and Golden Eagle Protection Act (16 U.S.C. 668-668c) prohibits anyone, without a permit issued by the Secretary of the Interior, from "taking" bald eagles, including their parts, nests, or eggs. The Act provides criminal penalties for persons who "take, possess, sell, purchase, barter, offer to sell, purchase or barter, transport, export or import, at any time or any manner, any bald eagle ... [or any golden eagle], alive or dead, or any part, nest, or egg thereof." The Act defines "take" as "pursue, shoot, shoot at, poison, wound, kill, capture, trap, collect, molest or disturb."

There are no known bald eagle nests around the facilities; nesting areas are further down river (Jeremy Zimmer, USDA, Forest Service, Gardiner, MT, pers. comm.). However, golden eagle nests could be in the vicinity of the facilities, although specific nests are not known. Therefore, the proposed study is not expected to have any impact on nesting bald or golden eagles. In addition, activities occurring during the proposed study would not differ significantly from activities normally occurring at these pastures. “Eagles are unlikely to be disturbed by routine use of roads, homes, and other facilities where such use pre-dates the eagles’ successful nesting activity in a given area. Therefore, in most cases ongoing existing uses may proceed with the same intensity with little risk of disturbing bald eagles” (FWS, 2007). If study personnel discover the presence of any bald or golden eagle nests in the area, this information would be reported to the Wildlife Program Manager at Gallatin National Forest.

Golden eagles have been observed flying over the Brogan Bison Facility (Jeremy Zimmer, USDA, Forest Service, Gardiner, MT, pers. comm.) and bald eagles could be flying in the area as well. The activities that would occur during the proposed study would not differ significantly from activities that normally occur in these pastures. Therefore, no disturbance of eagles would occur as a result of the proposed study; eagles in the area would be accustomed to these activities.

Although program personnel would remove daily any aborted calves or treated or non-treated bison that could die during the study, bald and golden eagles in the area could potentially consume these items. However, “[i]mmunocontraception vaccines provide few risks for

consumptive use of dosed wildlife; the antibodies that prevent reproduction are only one of millions of other antibodies present in animals, all of which are harmless to the organism that digests them, like any other proteinaceous food consisting of amino acids" (Fagerstone et al., 2010). Therefore, no eagles would be harmed if consumption of these items occurred.

C. Historic and Cultural Resources

In accordance with Section 106 of the National Historic Preservation Act of 1966 and its implementing regulations[10], APHIS prepared a summary of the proposed project and submitted it to the Montana State Historic Preservation Office (SHPO) for consideration of potential impacts to historic resources. On November 28, 2011, APHIS received a letter of concurrence from the Montana SHPO agreeing that there were no findings of potential impacts to historic resources for the proposed study.

D. Tribal Consultation and Coordination

In accordance with Executive Order 13175: Consultation and Coordination with Indian Tribal Governments[11], APHIS has prepared a summary of the proposed project and provided it to 26 tribes who may have interests in YNP. In addition to the 26 identified tribes, APHIS also provided a summary of the project to all tribes located near YNP and in States adjacent to Montana who might potentially have interest in the project.

On December 19, 2011, APHIS held a conference by telephone with tribes to provide an opportunity to discuss the proposed project in more detail and discuss potential concerns that the tribes may have. Tribes that participated in the call showed an interest in the details of the project, and several requested additional information on the history of the GonaCon™ immunocontraceptive vaccine. APHIS agreed to provide background information to tribes. No tribes voiced any major concerns about the project.

APHIS will continue to conduct outreach to interested tribes and keep them updated on the activities associated with the project.

[10] National Historic Preservation Act of 1966 (16 U.S.C. 470f) and implementing regulations (36 CFR §800).

[11] Executive Order 13175: Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 9, 2000).

V. Cumulative Impacts

This EA examines the activities associated with a proposed study to evaluate whether GonaCon™, an immunocontraceptive vaccine, would be effective as a non-lethal method of decreasing the prevalence of brucellosis in the YNP bison population by effecting temporary infertility in bison cows and thereby preventing transmission of *B. abortus*. Activities associated with the proposed study are not expected to result in adverse cumulative effects.

In order to conduct the proposed study, approximately 96 female and 8 male bison that naturally exit YNP over the period of as many as three years would be housed at pasture locations in the Gardiner, Montana area. Some of the female animals in the study would be injected with GonaCon™, which would reduce the likelihood of pregnancy and delivery of offspring in the treated animals. Untreated females may give birth to offspring, which would increase the total number of animals associated with the study.

In August 2011, the National Park Service conducted an annual bison population estimate (NPS, 2011). According to the 2011 survey, the total bison population in YNP was estimated to be approximately 3,700 bison. This total was approximately 200 lower than the survey from the previous summer, but the decrease was "within the natural range of expectation for wild bison."

Assuming the proposed study would result in approximately 104 bison being removed from the larger bison population of YNP, the effect of removing this number of bison over multiple years is well within the natural range of expectation for bison. This decrease in the numbers of bison in YNP is not anticipated to cause any cumulative negative effects to the overall bison population.

One of the goals of the IBMP is to manage temporal and spatial separation of bison and cattle to mitigate potential transmission of brucellosis. Currently, this is accomplished through hazing, capture, test and slaughter of seropositive animals, and vaccination of seronegative animals and a limited hunt in Montana. The proposed study may provide important information that would allow for re-evaluation and re-consideration of some of the current IBMP activities. This may result in impacts to future decision-making regarding protocols for bison habitat management, bison vaccination strategies, and bison hunt activities. IBMP activities that could be impacted include strategies to maintain appropriate bison population and distribution, should bison habitat be expanded.

VI. Agencies or Persons Contacted

U.S. Forest Service, Gallatin National Forest

Montana Fish, Wildlife and Parks

Montana State Historic Preservation Office, Montana Historical Society

USDA, Animal and Plant Health Inspection Service, Veterinary Services

USDA, Animal and Plant Health Inspection Service, Policy and Program Development, Environmental and Risk Analysis Services

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APPENDIX A

Summary of and Responses to Comments Received on the Environmental Assessment: Evaluation of GonaCon™, an Immunocontraceptive Vaccine, as a Means of Decreasing Transmission of Brucella abortus in Bison in the Greater Yellowstone Area

Background and Introduction

In January 2012, APHIS announced the availability of an Environmental Assessment (EA) describing and analyzing the impacts of a proposed study of the use of GonaCon™, an immunocontraceptive vaccine, as a disease management tool for brucellosis in bison. APHIS received more than 1,500 comments on the EA. APHIS carefully reviewed the comments received on the EA for the proposed study and then grouped comments under similar issues. Summaries of each issue that APHIS identified as relevant to the EA, as well as responses to each issue, are discussed in detail below. Some commenters raised issues that were outside of the scope of the EA. Although APHIS is not required to address issues that are not relevant to the EA, APHIS believes it is important to acknowledge and discuss the concerns of the public and has attempted to respond to some of these more prevalent issues in the introductory paragraphs of this document.

As described in the EA, the proposed study is a preliminary investigation of a potential disease management tool under field conditions. The proposed study would take place on private land outside of Yellowstone National Park (YNP). The locations where the study would be conducted are described in detail in the EA document. Some commenters questioned why APHIS did not analyze the impacts of the study on visitors to YNP, but because the study is not being conducted in YNP, these potential impacts are outside of the scope of the required analysis under National Environmental Policy Act (NEPA) requirements.

The proposed study is not a study testing the large-scale, population-wide use of the GonaCon™ immunocontraceptive vaccine. The results from the proposed study will need to be obtained and analyzed before any additional larger-scale work with GonaCon™ in bison is conducted. If, in the future, additional studies are proposed or plans are made to use GonaCon™ on a larger scale, appropriate analyses under NEPA would be required. These future NEPA analyses would consider issues such as impacts to hunters, impacts to population dynamics of bison, and any other relevant broader issues. However, because the study proposed in the current EA is initial field research that would be conducted on a very small scale on private land in a confined area, these broader issues were not considered to be within the scope of the required analysis.

The use of GonaCon™ as described in the proposed study is not a permanent sterilization option for bison. As the EA states, “The intended purpose of using GonaCon™ in female bison would be to manage reproduction in bison known to be infected with brucellosis by inducing temporary infertility, thereby decreasing the potential for transmission of brucellosis through abortion and calving events.” Contraception was a proposed option in past plans to manage bison, including the Record of Decision (ROD) for a final Environmental Impact Statement (EIS) for the Bison Management Plan (BMP) in Montana and YNP in December

2000 that was dismissed at that time. GonaCon™ was not an available contraception option during past analyses. At that time, the available contraception options were different from GonaCon™ because they caused repeated and prolonged breeding activity, difficulties with administering them to bison, and questions about potential impacts to the immune system that could make bison more susceptible to disease.

As discussed in the EA, GonaCon™ is currently registered with the U.S. Environmental Protection Agency (EPA) as an immunocontraceptive for use in deer. The use of GonaCon™ in deer under the existing, publicly-available, EPA-approved label is limited to wildlife management situations specific to deer. Conclusions regarding statements on the label that apply to deer cannot necessarily be directly applied to the use of GonaCon™ in bison.

General project-related issues, as well as some of the specific issues commenters raised regarding the use of GonaCon™ in bison are discussed in more detail in the Issues and Responses below.

Issues and Responses

Issue: The public was not adequately notified of the availability of the EA and the length of the public comment period was too short.

Response: As required under NEPA regulations, APHIS prepared and published a legal notice announcing the comment period on the EA for the proposed GonaCon™ study in bison. The legal notice was published in two Montana newspapers on January 26, 2012. At the same time, the legal notice and associated EA document were posted on the Interagency Bison Management Plan (IBMP) website located at www.ibmp.info in the News section. The EA document was also posted on APHIS' website at http://www.aphis.usda.gov/animal_health/animal_diseases/brucellosis/ . The initial 30-day comment period for the EA ended on February 25, 2012. In response to requests from several parties, the comment period was subsequently extended until March 13, 2012, and a legal notice announcing the extension of the comment period was posted on the IBMP website at the address above. Comments could be sent either in writing to APHIS at a Montana Veterinary Services office, or submitted electronically via a unique, EA-specific, e-mail address. As of the close of the extended comment period, APHIS received more than 1,500 comments on the EA. Some late comments were received and were noted as received after the close of the comment period, but no new issues were raised in the late comments.

In addition to the publication information discussed above, APHIS representatives made a brief statement during a public Interagency Bison Management Plan meeting in December 2011 about plans to issue an EA for the proposed study. APHIS told the meeting attendees that the EA would be issued in early 2012.

Issue: The EA for the proposed study should have been available before the bison were obtained for the study.

Response: APHIS, along with other partners in the Yellowstone area, signed a ROD for a final EIS for the BMP in Montana and YNP in December 2000. Under the BMP approach, as adopted by the associated ROD, it is permissible to capture bison for

research purposes. Because some time was needed to obtain enough bison for the proposed GonaCon™ study, the animals needed for the proposed research were obtained under the conditions of the existing BMP and ROD. Therefore, no additional NEPA for collection of bison was necessary and, as required by NEPA, APHIS prepared an EA for the proposed GonaCon™ study.

Issue: Several commenters indicated that the purpose and need for the study is too narrow and that all methods to reduce seroprevalence or infection rates should be considered in this EA. Also, there was a failure to provide information as to why the study is needed.

Response: As described in the EA, the need for the proposed study is to provide information that would be used to evaluate the use of GonaCon™ as a nonlethal method of decreasing or controlling the risk of transmission of *Brucella abortus (B. abortus)* in the YNP bison population. Brucellosis is spread within the animal population primarily through contact with infected birthing tissues or aborted fetuses and through the milk of infected cows. If GonaCon™ can effectively render brucellosis-infected female bison temporarily infertile, the primary routes of disease transmission would be blocked. In combination with other appropriate disease mitigation activities, the use of GonaCon™ may be an effective tool to assist in eliminating brucellosis from the YNP bison herd over time. Evaluating all of the methods to reduce seroprevalence or infection rates in YNP bison is beyond the scope of the proposed study and EA. However, if the use of GonaCon™ were to be considered for use as a tool to reduce seroprevalence in YNP bison, then the appropriate NEPA document would be prepared that would likely include discussion of other alternatives or methods to reduce the prevalence of brucellosis in YNP bison.

The proposed study is an opportunity to acquire needed information to determine if GonaCon™ might be an effective tool to assist in eliminating brucellosis from the YNP bison herd over time. In addition, the data collected in this study is part of the data set that would be required by EPA to register the GonaCon™ vaccine for use in bison if a decision to pursue such a registration is made.

Issue: Many commenters indicated that the use of GonaCon™ would be harmful to the genetics of YNP bison and that APHIS needs to disclose how its program would impact bison genetics, including the recently-described, genetically-distinct subpopulations of YNP bison. Some commenters were concerned that the use of GonaCon™ would eliminate natural resistance to brucellosis by preventing bison that have recovered from brucellosis from producing young.

Response: These comments are beyond the scope of this EA. This EA analyzed the potential environmental effects of the proposed study, which would test approximately 104 bison. If this study does not take place, those bison would not be part of the YNP bison population, as per the Interagency Bison Management Plan (IBMP). The IBMP states that a limited number of untested bison may be allowed in certain areas outside of YNP. However, if bison numbers exceed the tolerated limits, they are to be hazed back into the park. If they cannot be hazed back into the park, they are to be captured and tested for evidence of brucellosis. Seropositive bison are to be slaughtered or used for

research. Seronegative bison are to be held at the capture facility, used in research, sent to slaughter, or sent to a quarantine facility if one is available.

If GonaCon™ is found to be a viable tool for decreasing the transmission of *Brucella abortus* in bison, and if agencies at any point consider using GonaCon™ in YNP bison, the potential impacts that the use of GonaCon™ could have on bison genetics, including potential effects to any natural resistance that bison may have to brucellosis, would be evaluated.

Issue: APHIS has exaggerated the human health risk and human health impacts of brucellosis in the EA.

Response: APHIS has no incentive to exaggerate human health risks or impacts of brucellosis in the EA. APHIS provided information regarding the human health risks and impacts of brucellosis in the EA as part of an overall description of the disease. Brucellosis infections can occur in both animals and humans, with different symptoms and outcomes. The proposed GonaCon™ study would investigate the feasibility of a potential method for decreasing transmission of brucellosis among bison. The focus of the study is not on decreasing transmission risk from bison to humans.

Issue: APHIS inflated numbers as to the prevalence of brucellosis in wild bison. The EA cites a study by Meyer and Meagher to support statements that 40% of bison test positive for brucellosis, but actually it says rate is 28% for males and 20% for females, and the rate is possibly as low as 10% herd wide.

Response: APHIS appreciates and recognizes that many studies reporting varying prevalence rates have been conducted over the years. APHIS also appreciates and recognizes that various study protocols are used for conducting prevalence studies. APHIS' intent in citing the Meyer and Meagher study was only to indicate that there is evidence supporting the presence of brucellosis in the YNP bison population. It was not APHIS' intent to indicate a true prevalence in the YNP bison population.

Issue: APHIS should provide documentation from EPA that GonaCon™ is approved for use in bison and discuss the human health impacts of consuming GonaCon™-treated bison.

Response: The results from the proposed study could be used as part of the data set that would be required for EPA registration of GonaCon™ in bison at a future date. However, the data required for EPA registration would consist of more studies than just the one proposed in the EA. As detailed in the EA, APHIS shared the proposed study details with EPA for the GonaCon™ bison study and obtained agreement from EPA that the proposed study could be conducted under existing guidelines for small-scale research to develop data that would be necessary for future registration. APHIS agreed that any bison treated with GonaCon™ in the proposed study will not be consumed by humans and disposition of the treated animals from the study is discussed in the EA. If, in the future, the use of GonaCon™ in a larger-scale application is proposed, the issues associated with potential human consumption of bison treated with GonaCon™ would be examined in required NEPA analyses.

Issue: APHIS did not provide enough background information to Tribes about the project prior to the December 2011 conference call.

Response: In December 2011, prior to issuance of the EA for public comment, APHIS invited 26 Tribes to participate in a conference call to discuss the proposed study. In the letter inviting Tribes to participate in the conference call on December 19, 2011, information on the study was provided. The information provided to the Tribes was current at the time of the conference call, and remains consistent with the study design today as described in the EA. 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.

Issue: The EA is not in compliance with Section 106 of the National Historic Preservation Act because there was no involvement by Tribal Historic Preservation programs from tribes that may have historical resources impacted by the proposed action.

Response: The EA includes information on the actions APHIS took to comply with Section 106 requirements. In addition to the Montana Historic Preservation Office, APHIS provided information on the study to Tribal Nations with a vested interest in YNP and bison issues, Tribal Bison Managers, and Tribal Historic Preservation Offices. APHIS is not aware of any issues that were raised by any of the representatives contacted regarding the proposed study.

Issue: The EA uses the words exposure and infection interchangeably and this is incorrect. Also, the EA interchangeably uses infected and seropositive as terms.

Response: APHIS has been careful and specific in the use of the terms employed to describe brucellosis status and believes the wording in the EA is correct as written.

Issue: The permit to acquire bison expired 12/31/2011. Is there a new permit?

Response: APHIS has an existing Research Permit (Permit #5892) to acquire bison for the proposed study. The current permit expires December 31, 2012.

Issue: IBMP partners have not reviewed and approved this study. Which IBMP partners are involved in the research?

Response: There is no statement in the ROD binding the IBMP partners to obtain consensus on research conducted on bison or brucellosis. IBMP partners do not have to approve research by individual agencies, even if the results may inform bison management. Individual agencies can continue to do the work that their respective missions require; APHIS is an animal health agency working towards answers to an animal health problem in the case of the proposed study. It will also inform the IBMP for future management decisions, at which time they can decide to use or reject the information. For the proposed study, both YNP and Montana Department of Livestock would assist APHIS in conducting the work.

Issue: The proposed study is for population control of bison. The EA should evaluate and disclose how APHIS bison population control program is in conflict with a stated purpose of the IBMP of maintaining a wild, free-ranging bison population in the ecosystem and describe how it is NOT population control.

Response: The proposed study is not designed to control the bison population. The study is designed to investigate the use of an immunocontraceptive vaccine (GonaCon™), a non-lethal technique, to reduce the shedding and transmission of *Brucella abortus*. While GonaCon™ will temporarily induce infertility, it would only be used on a small number of *Brucella*-positive animals to investigate whether it is a feasible option under field conditions. If agencies consider using GonaCon™ in YNP bison, the potential impacts that the use of GonaCon™ could have on bison population numbers would be evaluated.

Issue: How can brucellosis be eliminated from the Greater Yellowstone Area (GYA) by using GonaCon™ when nothing is being done about elk or other wildlife? Transmission from elk to cattle is documented, but transmission from bison to cattle is not. There is no evidence that brucellosis can be eliminated from wild populations, and this creates false hope for cattle producers.

Response: Transmission of brucellosis from bison to cattle is documented in studies (see Flagg, D.E. 1983. A case history of a brucellosis outbreak in a brucellosis free state which originated in bison. Proceedings of the U.S. Animal Health Association. 87:171−172; Davis et al., 1990. *Brucella abortus* in captive bison. I. Serology, bacteriology, pathogenesis, and transmission to cattle. Journal of Wildlife Disease, 26:360−361.) Brucellosis has successfully been eradicated from wild bison in the Henry Mountains herd, the Wind Cave herd, and others.

Effectively reducing the prevalence of brucellosis in the GYA, with a goal of eventual eradication of the disease from affected wildlife, requires a multi-pronged, integrated, disease-reduction strategy. Such a strategy is predicated on coordinated activities to reduce the prevalence of disease in elk and bison, increase herd immunity in cattle, and mitigate transmission of disease between wildlife and cattle. The proposed study investigates only one aspect of the strategy, that being reducing the prevalence of disease in bison. The results of the proposed study would be used to inform future decisions on longer-term management strategies.

Issue: Transmission of brucellosis from GYA bison is documented to be low by June 1 and extremely low by June 15, which conflicts with information on the transmission risk in the EA. APHIS should explain why the proposed study is necessary given this information.

Response: The time of year at which transmission occurs is irrelevant to the proposed study. As discussed in the EA, transmission of brucellosis occurs via abortion or parturition (i.e., the birth process). The birthing process in GYA bison is complete, except for a few animals, by June 15th; hence the greatest risk of transmission of brucellosis occurs before that date. Prevention of pregnancy and abortion or parturition in infected bison by the non-lethal technique of contraception in the proposed study may have the potential of halting transmission in bison. The proposed study would investigate whether or not contraception would reduce shedding of *Brucella* organisms.

Issue: APHIS should consider other methods of controlling brucellosis to prevent transmission, such as vaccinating cattle, removing livestock from public areas where wildlife is thriving, using dogs, using fencing to reduce wildlife-livestock interactions, shutting down government wildlife feedlots, addressing habitat issues where there is a conflict between bison and cattle, and using better cattle management practices (grazing systems, classes of livestock, fences, timing of use, etc.).

Response: Effectively controlling brucellosis and preventing transmission of disease between wildlife and cattle requires a multi-pronged, integrated disease-reduction strategy. The proposed study investigates only one aspect of the strategy, and the results of the proposed study would be used to inform future decisions on longer-term management strategies. Discussion of other options for brucellosis control or prevention of transmission is outside the scope of the EA for the proposed study.

APHIS recognizes the need to address the livestock-wildlife interface and to mitigate disease transmission between livestock and wildlife. Recent amendments to the federal brucellosis program regulations now require that any State in which it has been determined that wildlife are infected with *B. abortus* must develop and implement a brucellosis management plan. The brucellosis management plan must, among other things, describe epidemiologic assessment and surveillance activities to identify occurrence of *B. abortus* in domestic livestock and wildlife and potential risks for spread of disease, and describe mitigation activities to prevent the spread of *B. abortus* from domestic livestock and/or wildlife, as applicable, within or from the brucellosis management area.

Issue: Expanding bison habitat available to herds is becoming increasingly recognized by IBMP partners and public. There are significant areas of bison-friendly private land as well as public lands that are currently unoccupied by bison (examples include Dome Mountain Ranch, Dome Mountain Wildlife Management Area and the Gallatin National Forest lands, Madison Valley, and Elk Meadows Ranch). Translocation/restoration and conservation of bison to historic habitat within the Upper Gallatin watershed is an alternative to bison slaughter or sterilization.

Response: Although these alternatives are outside the scope of the proposed study, APHIS notes that expanding bison habitat without also addressing issues relating to

disease reduction at the same time merely expands the disease on the landscape. Bison from the proposed study and their offspring that remain negative for brucellosis in both serology and culture tests for the duration of the study that satisfy existing bison quarantine requirements may be used for bison conservation purposes. The decisions on conservation would take place closer to the end of the study.

Issue: What authority does APHIS have to control wild bison? APHIS lacks congressionally delegated jurisdictional authority over bison.

Response: APHIS has the authority to take measures in order to ensure that livestock that move in interstate commerce do not introduce or disseminate diseases of livestock within the United States. Accordingly, if wildlife could serve as a means of introducing diseases of livestock into livestock that will move in interstate commerce, APHIS can take measures to evaluate and mitigate the risk of disease introduction. APHIS is authorized under the Animal Health Protection ACT (AHPA, 7 U.S.C. 8301 et. seq.) to take these measures.

Issue: Frequently, APHIS proposes studies on bison and then fails to release agency findings or subject them to peer review and publication in independent journals. How will the results of this study be made available?

Response: When the proposed study is complete, the results will be published in a peer-reviewed scientific journal. At this time, it is not possible to identify the specific journal in which the results would be published.

Issue: In the 2000 final EIS, BMP and associated ROD, agencies rejected population control as an alternative because the impacts of it were thought to be too significant. Also, those documents stated that contraception may make bison more susceptible to disease, significant behavioral changes could occur, social bonds between animals could be disrupted, or breeding or birthing seasons could be altered or extended.

Response: Although the previous documents did discuss contraception as a proposed option that was dismissed at the time, when the EIS and ROD were finalized, no specific information on the potential use of GonaCon™ as a non-lethal immunocontraceptive option for brucellosis management existed. At the time the EIS and ROD were finalized, the available contraception options were different from GonaCon™ because they caused repeated and prolonged breeding activity, difficulties with administering them to bison, and questions about potential impacts to the immune system that could make bison more susceptible to disease.

The proposed study would evaluate GonaCon™ as a non-lethal technique for safety and efficacy under field conditions and the information from this initial study would be used to inform later, larger-scale brucellosis management options. The ROD and the BMP advocate the concept of adaptive management, which allows for changes in bison management options as newer information becomes available. Previous studies of the immunocontraceptive GonaCon™ in bison under non-field conditions have not showed any of the problems listed (disease susceptibility, behavioral changes, etc.) but the bison

in the proposed study would be monitored for any adverse or unexpected effects and appropriate decisions concerning the larger-scale use of GonaCon™ in the future would take this information in to account.

Issue: Serology tests would not give APHIS adequate proof of whether or not bison used for the study have an active infection of brucellosis that would make disruption of their breeding and reproductive cycles effective in preventing transmission. The proposed serology testing described in the EA would not reveal recovered animals or animals with active infections. APHIS needs to evaluate how the inaccuracies in finding active infections with serology testing would impact useable and meaningful data gathered from this study and disclose these findings to the public.

Response: The use of repeated serologic tests and culture as described in the EA document are the best tools available to determine the infection status of living bison. Conducting repeated serologic tests during the proposed study allows for the most accurate characterization of the test animals' brucellosis status.

Issue: APHIS should use a domestic source of bison to conduct the study so as not to destroy GYA bison.

Response: This suggestion is not a viable option because there is no longer any source of naturally-infected bison in the United States other than GYA bison. Additionally, research using study animals other than GYA bison has been criticized as not being applicable to the GYA due to potential genetic differences in the herds.

Issue: APHIS should include a discussion of the current science on the male-to-female transmission potential to address the question of whether bison or elk bulls can transmit brucellosis to females during breeding. There is no evidence that this cannot happen and bulls have transmitted *B. abortus* in their semen at low levels. How would transmission of *B. abortus* by male bison to female bison affect this study?

Response: If bull-to-cow sexual transmission commonly occurs, then disease reduction by the use of immunocontraception would not be efficacious. It has long been assumed that sexual transmission does not occur to any significant degree in bison, as is the case in cattle. A single, limited study (Robison et al., 1998. Conservation of germplasm from bison infected with *Brucella abortus*. Journal of Wildlife Disease, 34:582−589.) failed to demonstrate bull-to-cow sexual transmission. APHIS is currently conducting a series of studies to confirm the conclusion that the sexual route is not a significant means of transmission of brucellosis in bison.

Issue: There are findings that the shedding of *B. abortus* decreases with age, so APHIS should include in the proposed study whether the advancing age of seropositive female bison injected with GonaCon™ results in some immunity or at least lack of shedding *B. abortus* at subsequent births after the GonaCon™ is no longer effective. If this is proven to be correct, it could be a good tool for decreasing bison herd seroprevalence if GonaCon™ was aggressively applied to young females.

Response: The proposed study should, in part, address this hypothesis. GonaCon™-treated bison will be monitored for shedding in calvings after the period of reversible infertility produced by the contraceptive and compared to the untreated bison. All bison in the proposed study will begin the study as young females, so tracking the shedding over time as the bison age will be possible during the period of time that the proposed study is being conducted.

Issue: APHIS cites a Miller et al. 2004 study (Miller, L.A., J.C. Rhyan, and M. Drew. 2004. Contraception of bison by GnRH vaccine: a possible means of decreasing transmission of brucellosis in bison. Journal of Wildlife Diseases. 40(4):725-730) in the EA but only cites information that supports the proposed study. The Miller et al. 2004 study reports the possibility of abortion when GonaCon™ is given early to mid-pregnancy. This side-effect was not disclosed to the public.

Response: The GYA bison used in the proposed study would be injected with GonaCon™ in the spring as young, non-pregnant animals, so there is no concern about the potential for abortion from injection of GonaCon™ to bison that are already pregnant in the proposed study. APHIS is currently conducting ongoing research in another bison herd to investigate whether or not the vaccine induces abortions when administered in early pregnancy, and this information would be used to inform future decisions on the utility of GonaCon™ as a disease management tool.

Issue: APHIS has not provided the public with necessary information concerning the placement of bison at the conclusion of the proposed study. The EA states that all animals that test negative will be used for conservation purposes, and the acquisition permit says seronegative bison should be consigned to a quarantine location for further diagnostics, to a managed public trust conservation program to supplement genetic diversity of bison populations, or to private not-for-profit bison conservation programs. If none of these options are possible, the bison should be given to any private not-for-profit bison conservation program. APHIS should disclose the possible locations where the study bison will be placed, disclose the process for how these locations are selected, and how it will be decided where they will go.

Response: The EA describes how animals treated with GonaCon™ will be handled at the conclusion of the study. Animals from the study that were not treated with GonaCon™ that satisfy existing bison quarantine requirements will be used for bison conservation. It is impossible to anticipate at this time the demand and options for bison genetics conservation that will be available at the conclusion of the study. APHIS' intention is that these animals will be used for bison conservation through one or more channels. These potential channels include translocation to tribal or public premises to form or augment a bison herd with pure bison genetics; formation or augmentation of a foundation herd by a conservation non-governmental organization; or formation or

augmentation of a herd through embryo transfer. The disposition of animals or genetic materials from the study will be made after consultation with bison experts at YNP and conservation organizations such as the American Bison Society, the International Union for Conservation of Nature, or other applicable organizations.

Issue: APHIS has outlined plans in the EA that will lead to unsafe study conditions for bison and humans, as well as creating inhumane conditions for the bison during the proposed study. Capture, captivity, slaughter, constant testing, poking, prodding, immobilization drugs, and reversal agents are not humane treatment. Repercussions to bison from repeated use of immobilization narcotics and reversal agents can produce effects that are dangerous to unconfined bison and seemingly disastrous in an area confined with other bison. The EA should evaluate the risks associated with immobilization and reversal and contingency plans for the likelihood that there will be behavioral side effects to ensure safety of staff and animals.

Response: As discussed in the EA, restraint or chemical immobilization would only be used as needed. Restraint for the infrequent required testing of bison in the proposed study will usually be accomplished by means of a bison chute. Only after calving is it anticipated that animals will be chemically immobilized with a narcotic. This is to protect the calf from injury that might occur if the cow were restrained in the chute. APHIS' experience with restraint and chemical immobilization in numerous field studies and the quarantine feasibility study has been that periodic restraint in a chute or chemical immobilization have not routinely resulted in untoward behavioral effects that put animals or study personnel at increased risk. APHIS acknowledges that whenever bison congregate, in nature during the rut or migrations, or due to human intervention, there is increased risk of injury. APHIS' procedures and methods of handling bison are based on years of experience and are designed to minimize the risk of injury to animals and study personnel.