

SUPPORTING STATEMENT
CENTER FOR EPIDEMIOLOGY AND ANIMAL HEALTH (CEAH)
***Mycoplasma Bovis* in Bison 2022 Case Control Study**
OMB Control No. 0579-0482

Part A

A. Justification

The Animal and Plant Health Inspection Service (APHIS) is requesting the renewal of an information collection request for a *Mycoplasma bovis* in bison Case Control Study, hereafter referred to as the Study.

USDA first recognized *Mycoplasma bovis* as an emerging pathogen in 2013. Since that time, few additional premises had been reported as affected until 2021, when multiple new premises and herds experienced significant losses attributed to the appearance of *Mycoplasma bovis* in the herds. These affected herds experienced 10 to 50% herd losses affecting multiple age classes, with reproductive aged cows suffering the most significant losses. Despite the unique and significant burden of this pathogen on bison, little information existed on the sources of infection to naïve herds. Once affected, bison producers reported significant recurrent losses in subsequent years, and producers first affected in 2013 continued to experience significant losses, particularly in 2021. No diagnostic testing was currently able to identify animals infected but not shedding the bacterium. This means that these animals can serve as a source of infection during subsequent years. Therefore, to limit additional herds becoming infected in the 2022 season, it was critical for APHIS to develop information on the potential sources of new infections in naïve herds.

The original study conducted in 2022 generated information needed to identify risk factors for this rapidly spreading pathogen. Identifying risk factors is critical for developing prevention and control recommendations. These recommendations are necessary because there are no effective treatments or vaccines currently for this pathogen and resulting mortality losses are high and recurring. The result for bison producers is significant economic losses, cultural losses for Native American tribes, and threatening conservation efforts for the Nation's wild bison populations.

APHIS collected data via telephone and email surveys from bison producers, and solicited study participation from a list of National Bison Association members and from affected producers who consent to having their identifications turned over by diagnostic laboratories.

This data collection supports the following general study objectives:

- Understand the burden of disease from *Mycoplasma bovis* in bison herds in the United States.
- Characterize disease presentation, impacts, and epidemiology of *Mycoplasma bovis* in bison

- Identify risk factors for the development of *Mycoplasma bovis* disease in bison herds
- Develop biosecurity recommendations to prevent *Mycoplasma bovis* infections in naïve bison herds.
- Support Tribal and other Federal partners in bison restoration and conservation goals.

In 2022, the Animal and Plant Health Inspection Service (APHIS) obtained approval for reinstatement of information collection 0579-0420, Bison 2022 Study. This periodic study is holistic and is focused on the state of the bison industry and general animal health. It involves approximately 2,000 bison producers in all 50 states. Information collection 0579-0482 is much more narrow than 0579-0420, focusing on the effects and remediation of the deadly *Mycoplasma bovis* disease in certain bison herds. It involves only approximately 200 respondents. That both studies are occurring approximately at the same time and involve the same animals is a coincidence.

APHIS is requesting an extension of approval of this case control study information collection request so that it might have approval in place to administer the survey for infected M. Bovis bison herds not in the initial study.

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

Collection and dissemination of animal health data and information is mandated by 7 U.S.C. § 391, the Animal Industry Act of 1884, which established the precursor of the APHIS, Veterinary Services, the Bureau of Animal Industry. Legal requirements for examining and reporting on animal disease control methods were further mandated by 7 U.S.C. § 8308 of the Animal Health Protection Act, “Detection, Control, and Eradication of Diseases and Pests,” May 13, 2002. This collection of bison data is consistent with the APHIS mission of protecting and improving American agriculture’s productivity and competitiveness.

The USDA Office of Tribal Relations requested that APHIS dedicate resources to understanding and responding to *Mycoplasma bovis* disease in bison. As an emerging disease threat with significant economic impacts to affected producers, information on the sources, impacts, and spread of this disease is critical for informing prevention and response efforts, such as biosecurity. As an emerging disease, little information currently exists on the epidemiology of *Mycoplasma bovis* in bison and no effective vaccines or therapeutics currently exist, making biosecurity measures one of the only prevention measures available to producers.

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

APHIS will use the data collected from the study to address the following goals.

1. Understand the burden of disease from *Mycoplasma bovis* in bison herds in the United States.
2. Characterize disease presentation, impacts, and epidemiology of *Mycoplasma bovis* in bison
3. Identify risk factors for the development of *Mycoplasma bovis* disease in bison herds
4. Develop biosecurity recommendations to prevent *Mycoplasma bovis* infections in naïve bison herds
5. Support Tribal and other Federal partners in bison restoration and conservation goals.

Data Collection Form

Mycoplasma bovis in Bison Case Control Survey; (Private Sector)

A survey that participating bison producers will complete either by phone with an enumerator or through self-administration. Participants will email self-administered surveys to the APHIS study team who will share survey data with US National Park Service (NPS) collaborators. Survey data will be stored and maintained on secure USDA and Department of Interior networks. No personally identifiable information are included with the survey data.

The data collected, analyzed, and interpreted are disseminated to a wide variety of stakeholders. Producers, including Tribal entities, may utilize the study findings to develop herd biosecurity practices to reduce the risk from *Mycoplasma bovis*. Producer groups, academicians and extension specialists, state and federal animal health officials, and veterinarians may use summary estimates of disease and associated operation characteristics to improve health management, disease prevention measures, disease response measures, and information outreach efforts. Pharmaceutical and biologics companies might use estimates of the burden of disease to direct new research and development resources towards *Mycoplasma bovis* diagnostics, vaccines, and therapeutics. State and Federal officials responsible for regulatory veterinary medicine may use estimates reflecting disease and disease prevention to gain a more complete picture of animal health as a basis for program planning and funding. Research scientists may also use summary point estimates to design their research efforts. Veterinary and agricultural students in universities may use the reports for training in health management, animal welfare, and other agriculturally based careers. Additionally, students may participate in the data collection and analysis process, furthering their training.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology(e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection). Also describe any consideration of using information technology to reduce burden.

APHIS uses electronic technologies to help promote and administer the study. Identified National Bison Association members and affected producers receive an email with a copy of the

survey, but respondents have the option to complete the survey themselves and email their responses back or submit them over the phone with a study team member.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in “item 2” above.

APHIS staff collaborated with NPS staff to perform literature searches for existing data relevant to the Study. Available data were reviewed and compiled from all known sources. Sources reviewed include cooperative state research, private industry and professional publications, diagnostic laboratories, other Federal and State agencies, universities, and the National Bison Association. APHIS staff consulted employees from federal agencies, industry representatives, and academicians to identify areas of potential duplication. Based on this effort, APHIS is convinced that no other entity/source is collecting and analyzing this type of nationally representative information regarding *Mycoplamsa bovis* impacts to the U.S. bison industry with publicly available results.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

The bison industry is not as well studied as larger livestock commodity industries, and publicly available NASS data on indicators of the size of bison operations is not explicitly available. We use the total sales value of bison farms collected every 5 years in the NASS Census of Agriculture (last collected in 2017) as a baseline for assessing impacts to small businesses ([NASS 2017 Census of Agriculture - Bison](#)). The Small Business Administration’s Federal Government standards outlined in the North American Industry Classification Systems Codes defines a small agricultural business as having annual business receipts of \$750,000 or less.

The NASS 2017 Census of Agriculture indicates that 1,775 farms in the U.S. had at least one bison, but only 1,049 farms reported sales of bison or bison products. We assume that the 726 farms that did not report any sales of bison are small businesses because we would expect any non-small business to have some sales in a calendar year period. The 1,049 farms that had sales had a total sales value of \$120,186,000 in calendar year 2017, which is an average of \$114,572 total sales value per farm. Given the skewed nature of business size commonly observed in other livestock commodities (i.e. a small number of massive businesses with a large number of small businesses) and counterbalanced by the previous assumption that all the bison farms without sales are small farms, we assume that 90% of the 1,049 farms with sales are small businesses, which equals 944 farms. Adding this to the 726 farms without any recorded sales totals to 1,670 estimated small businesses out of the 1,775 farms with any bison inventory. We account for possible growth in the number of farms from 2017 (the previous NASS Census of Agriculture data collection) to 2022 (the Study’s data collection) by estimating a total of 2,000 farms with any bison inventory in 2022. Proportionally adjusting the total farms with any inventory from 1,775 to 2,000 brings the estimated total number of small businesses impacted by the Study from 1,670 to 1,882, or about 94% of the study population.

The Study is designed to collect data from selected producers who are willing to participate and thus not burden producers who feel they do not have the time to participate. Producers who choose to participate will be able to complete the survey by whichever mode (email or telephone) is most convenient for them, which will minimize potential impacts on business operations. In addition, the Study doesn't require any enumerator to set foot on a producer's operation, so producers do not need to set aside time and physical space to meet face-to-face with enumerators. Industry and producer input into the survey has been solicited to ensure that information collected is relevant, timely, and of appropriate complexity. Response to any portion of the Study is voluntary.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

The rapid emergence and spread of *Mycoplasma bovis* in naïve bison herds in 2021 has resulted in significant economic losses for producers and lost conservation potential for public land managers. Without information on the most likely routes disease transmission and spread, herd managers are unable to implement any science-informed approaches to preventing disease emergence and spread. Because this disease can cause the loss of up to 50% of reproductive cows in an affected herd and 30% of the overall herd, combined with its tendency to recur in subsequent years once a herd is infected, the lack of rapid prevention and control measures has significant economic impacts to the bison industry and threaten the conservation of this species as wildlife.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5, such as:

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than 3 years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security**

policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

No special circumstances exist that would require this collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

The following people were consulted during planning and development of the Study:

- Dr. Danielle Buttke, National Park Service Wildlife Health Branch, 1201 Oakridge Drive, Fort Collins, CO 80524

Dr. Buttke initially proposed the study and developed the draft survey tool and assembled a team of experts to inform research goals and address information gaps.

- Dr. Lee Jones, United States Fish and Wildlife Service Natural Resources Program Center, 10 E. Babcock, Rm 105 Bozeman, MT 59715

Dr. Jones discussed the need for the survey, reviewed multiple drafts of the survey tool, and provided input on the research gaps for *Mycoplasma bovis* in bison.

- Dr. Jeff Martin, South Dakota State University Bison Center of Excellence, Rapid City, SD 57703

Dr. Martin discussed the need for the survey and reviewed the survey tool and study objectives.

APHIS published in the Federal Register a notice with 60-day public comment period on June 7, 2022 (see 87 FR 34633). One comment was received but it concerned returning captive bison to the wild and was not relevant to this information collection request.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.

APHIS will provide no direct payments or gifts to respondents. The information collected will be valuable to inform best management practices to prevent disease occurrence and understand the burden of disease.

Because no personally identifiable information will be collected, survey respondents cannot be contacted to share study results directly. Study results will be provided in aggregate to the National Bison Association membership, presented at the annual conference, and published in a scientific or trade journal to disseminate findings.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

APHIS will protect the data from this study as Confidential Business Information (CBI) as defined in 19 CFR 201.6. Respondent information will be protected by ensuring that no identifying information is linked to the data. The key linking the unique participant ID with respondent information will be used only to email the questionnaire to participants. APHIS will store the key in password protected files on USDA and Department of Interior computer networks. APHIS will ensure that these key files are destroyed as soon as possible after data validation.

Only summary estimates based upon the inference population will be reported. While every effort will be made to ensure respondent confidentiality, it is possible that information could be released as required by a Freedom of Information Act, or in the case of required disease reporting. However, names, addresses, and personal information will not be linked with the survey.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

There are no questions of a sensitive nature used in this collection activity.

12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.**

See APHIS Form 71 for hour burden estimates.

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.**

The total annualized cost to respondents is \$2,084.82 computed by multiplying the estimated average hourly wage (\$26.16) by the total number of burden hours needed to complete the work (55), and then multiplying the product (\$1,438.80) by 1.449 to capture benefit costs.

The average hourly rates used to calculate the estimate are for first-line supervisors of farming, fishing, and forestry workers (SOCC 45-1011, \$26.16), using information found at the U.S. DOL Bureau of Labor Statistics occupational employment statistics website at http://www.bls.gov/current/oes_stru.htm.

According to DOL BLS news release USDL-22-0469 released March 18, 2022, employee benefits account for 31 percent of employee costs, and wages account for the remaining 69 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.449.

13. Provide estimates of the total annual cost burden to respondents or recordkeepers resulting from the collection of information (do not include the cost of any hour burden shown in items 12 and 14). The cost estimates should be split into two components: (a) a total capital and start-up cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.

There are no capital/startup costs or ongoing operations and maintenance costs for respondents or record keepers associated with this information collection. Questions in this study may reference operation records, but APHIS does not require producers to maintain or provide these records to answer questions.

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

See APHIS 79. The annualized cost to the Federal government is estimated at \$34,893.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

This request is for an extension without change of the emergency information collection request approved by OMB. There are no changes to the estimates.

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

Depending on the findings, APHIS and partners may summarize information from this survey immediately following the data collection and validation phases. APHIS and NPS employees may enter data into electronic databases and perform statistical calculations such as descriptive statistics including frequency distributions, prevalence, and odds ratios. Standard errors and point estimates may be published for aggregated statistical measures.

To disseminate findings and recommendations, APHIS and partners will provide study results in aggregate to the National Bison Association membership, and recommendations based on the data will be shared with Department of Interior and Tribal partners.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

APHIS is not seeking an exemption to display the expiration date for OMB approval.

18. Explain each exception to the certification Statement in the "Certification for Paperwork Reduction Act."

APHIS is able to certify compliance with all provisions in the Paperwork Reduction Act.