



CHRONIC WASTING DISEASE (CWD) PROGRAM STANDARDS WORKING GROUP 2016

Veterinary Services (VS); Animal and Plant Health Inspection Service (APHIS);
U.S. Department of Agriculture (USDA)

Executive Summary

APHIS convened the Chronic Wasting Disease (CWD) Program Standards Working Group in June 2016. The group was composed of 12 members including State, Federal, and industry representatives and an internationally-recognized scientific expert on transmissible spongiform encephalopathies. The working group identified possible revisions for the CWD Program Standards and obtained information and viewpoints from individual attendees. This group could not provide a collective recommendation or consensus statement as it was not an official Federal Advisory Committee.

The Working Group discussed the following topics as they related to the CWD Program Standards: Goals and outcomes for the CWD Program; purpose and use of the Program Standards; susceptible species; definitions of terms; ante-mortem testing; epidemiological investigations; reporting; indemnity; surveillance in certified herds; fencing requirements; biosecurity requirements; carcass disposal; and requirements for interstate transport of wild caught cervids. Based on the group's discussions, as well as recommendations from an internal review, APHIS proposes a number of revisions to the CWD Program Standards, including:

- Revising the goal statement to focus on reducing the risk of interstate transmission of CWD.
- Clarifying that the Program Standards include detailed descriptions of suggested methods approved by the APHIS Administrator to meet the regulatory requirements.
- Making definitions of terms consistent between the Program Standards and the *Code of Federal Regulations* (CFR), which should provide the official definition for a term.
- Describing APHIS' intent to amend the CFR to define susceptible species based on scientific evidence of natural infection or experimental infections through natural routes and adding the genera *Rangifer* and *Muntiacus* to the list of susceptible species in the future.
- Implementing immunohistochemistry of rectal anal mucosa associated lymphoid tissue (RAMALT) and medial retropharyngeal lymph node (MRPLN) biopsies conducted as a whole-herd test concurrently with genotyping at PRNP codon 96 in white-tailed deer in trace back, trace forward, and CWD-exposed herds and for disease management in CWD-positive herds. At least 24 months should have passed after the last known exposure before conducting the initial whole-herd test. A second whole-herd test may be required at 36 or 42 months after the last known exposure as determined by the predominant genotype of the herd.

- Implement pilot projects using RAMALT and MRPLN biopsies conducted concurrently with genotyping at PRNP codon 132 in elk in trace back, trace forward and CWD-exposed herds and for disease management in CWD-positive herds to inform decisions about testing protocols.
- Clarifying the definitions and processes for performing epidemiological investigations.
- Replacing Appendix VI with a worksheet that States should submit for all positive herds enrolled in the HCP as part of their annual HCP report. Additionally, any herd receiving Federal indemnity will be required to complete a preliminary and final worksheet as part of its herd plan.
- Describing the factors that APHIS will consider when making decisions about providing indemnity for CWD-positive, -exposed, and -suspect animals and describing the relative priority of each.
- Clarifying the consequences of poor quality and missing post-mortem surveillance samples on herd status, as well as describing options States may consider as substitutions for these samples.
- Streamlining the description of fencing characteristics considered necessary to prevent ingress and egress of cervids for HCP-enrolled herds.
- Eliminating Appendix II, and making these scientific references available upon request.
- Removing Part B, Section 5. Sanitary Precautions and Biosecurity Practices for Herd Plans and Depopulations.
- Updating and streamlining Appendix IV.
- Consolidating the discussion of carcass disposal options in the main body of the Program Standards and deleting Appendix V.
- Describing options for using multiple methods with post-mortem testing to reduce the risk of environmental contamination for certain disposal methods.
- Add the content of the recently issued VS Guidance Document 8000.1 “Surveillance and Testing Requirements for Interstate Transport of Wild Caught Cervids” to the Program Standards.

APHIS will accept additional input from stakeholders on these proposed changes. Feedback may be submitted to vs.sprs.cervid.health@aphis.usda.gov through November 15, 2016. APHIS expects to publish a notice in the Federal Register in early 2017 that would ask for public comment on the draft revisions before subsequently issuing the revised CWD Program Standards.

CWD Regulations and Program Standards

The National CWD Herd Certification Program (HCP) was implemented in 2014. It is a voluntary Federal-State-industry cooperative program administered by APHIS and implemented by participating States. Participating States and herd owners must comply with requirements for animal identification, fencing, recordkeeping, and inspections/inventories, as well as animal mortality testing and response to any CWD-exposed, suspect, and positive herds. APHIS monitors the Approved State HCPs to ensure consistency with Federal standards through annual reporting by the States. With each year of successful surveillance, participating herds will advance in status until reaching 5 years with no evidence of CWD, at which time herds are certified as being low-risk for CWD. Only captive cervids from enrolled herds certified as low risk for CWD may move interstate. Currently, 29 States participate.

The CWD Program Standards provide guidance on how to meet CWD Herd Certification Program and interstate movement requirements. APHIS committed to an annual review of the Program Standards by industry and State and Federal agencies. The FY 2015 review did not occur due to APHIS' response to highly pathogenic avian influenza.

Industry and State partners have expressed several concerns about how the current CWD Program Standards have been implemented. In October 2015, the Committee on Captive Wildlife and Alternative Livestock of the United States Animal Health Association (USAHA) passed a resolution urging APHIS to amend the Program Standards.

Review of the Cervid Health Program

Before starting to revise the Program Standards, Veterinary Services conducted an internal evaluation of its Cervid Health Program in 2016. The evaluation identified the program's key strengths and areas where improvements were most needed or would be most beneficial. Internal and external stakeholders provided input to a core evaluation team comprised of seven VS staff members and one Wildlife Services staff member. Recommendations and stakeholder input regarding the CWD Herd Certification Program (HCP) from the review were provided to the CWD Program Standards Working Group.

CWD Program Standards Working Group

APHIS convened the CWD Program Standards Working Group in June 2016 in response to our original commitment and the USAHA resolution. The Working Group was composed of 12 State, Federal, and industry representatives that included three representatives nominated by national organizations representing the farmed cervid industry; three State Veterinarians nominated by the National Assembly of State Animal Health Officials; two State Wildlife Officials nominated by the Association of Fish and Wildlife Agencies; three Veterinary Services representatives, and an internationally-recognized scientific expert on transmissible spongiform encephalopathies. The group obtained information and viewpoints from individual attendees. The group could not provide a collective recommendation or consensus statement as it was not an official Federal Advisory Committee.

APHIS asked the Working Group to identify technical corrections and/or clarifications needed in the Program Standards. Additionally, the Working Group was to identify revisions and/or amendments to be considered for the Program Standards with a focus on guidance that is impractical or impossible to implement in the field or guidance that conflicts with existing State laws, regulations, or actions. Further, the Working Group was to provide options for compliance with the requirements in 9 CFR 55

and 81 and update the guidance based on new scientific information.

On June 17, 2016, APHIS hosted a teleconference with six scientific experts on CWD and TSEs from the United States and Canada. Participants were asked to offer their scientific opinions on a number of questions that underlie a successful review of the current CWD Program Standards. One scientific expert provided opinions by email. Where possible, APHIS asked the experts to identify pertinent scientific citations that support their position. A summary of this discussion and the scientific articles that were cited were provided to the Working Group to inform their discussion.

The Working Group members participated in six conference calls from June to October 2016. Additionally, APHIS hosted a 3-day workshop in Frederick, MD in July 2016. During these meetings, group members discussed the following topics as they related to the CWD Program Standards:

1. Goals and Outcomes for the CWD Program
2. Purpose/Use of the CWD Program Standards
3. Definitions
4. Susceptible Species
5. Ante-mortem Testing
6. Epidemiologic Investigations, Information Sharing, and Reporting
7. Indemnity
8. Surveillance in Certified Herds
9. Fencing Requirements
10. Biosecurity Requirements
11. Carcass Disposal
12. Surveillance and Testing Requirements for Interstate Transport of Wild Caught Cervids

Summary of Discussion

1. Goals and Outcomes for the CWD Program

Current Status:

APHIS' goal for the CWD program, when the final rule was published in 2012, was to control the incidence of disease in farmed and captive cervids and prevent the interstate spread of CWD. However, the current version of the Program Standards states a broader goal of minimizing the introduction, transmission, and spread of CWD in captive cervid populations. Meanwhile, the Cervid Health 2016 Business Plan describes the program goal as one of prevention and control. Although these goals appear to be similar, stakeholders have expressed concern that APHIS' interpretation of the program goal has broadened over time and it is now being implemented as an eradication, not a control, program.

Discussion Summary:

The Working Group members agreed that the overarching goal of the HCP is to control the incidence of CWD in farmed and captive cervids and prevent the interstate spread of CWD. This discussion was consistent with a recommendation from our internal review that suggested APHIS focus its CWD program on reducing the risk of interstate transmission of CWD.

Achieving this goal will ultimately result in several important long-term outcomes, including:

- Healthy cervids (both farmed and wild populations) with a reduced risk of CWD.
- Increased confidence that HCP-certified herds are low risk for CWD infection.
- Strong trade of cervid animals and products (increase market confidence).
- Reduce risk of transmission from and the environmental contamination by CWD-infected herds.

Working Group members frequently referred to this overarching goal and the desired intermediate and long-term outcomes during subsequent discussions. This approach ensured that the revisions being considered for the Program Standards supported the overall goal and were aligned with important outcomes for the HCP.

APHIS's Proposed Changes to the Program Standards:

- Revise the goal statement to be consistent with the CFR. Describe the desired long-term outcomes of the HCP Program.
- When appropriate, show the alignment between other sections of the Program Standards and the overarching goal and desired outcomes.

2. Purpose/Use of the CWD Program Standards

Current Status:

The CWD Rule and accompanying Program Standards were one of APHIS's first attempts to develop a performance-based regulation for an animal health program. In this approach, the regulation states the required measurable or observable outcome and supporting documents such as a Program Standards provide details on how to achieve these required outcomes. This should provide more flexibility for regulated States and industry since the formal rulemaking process is only required to change the CFR text, not the more detailed Program Standards. Also, the Program Standards could allow for the approval of other methods to achieve the required outcomes. In contrast, earlier regulations contained design standards that provided prescriptive guidance on how to achieve the regulatory standards. This earlier approach was rather inflexible, and changes to the requirements involved a lengthy rulemaking process.

Discussion Summary:

APHIS has not clearly articulated this approach and the purpose of the Program Standards to our stakeholders. Working Group members acknowledged that it is confusing to regulated States and industry when APHIS refers to the current Program Standards as "optional guidelines." This misunderstanding about the role of the Program Standards appears to have created several instances of inconsistent interpretation and implementation of the program requirements.

APHIS's Proposed Changes to the Program Standards:

- Include a brief description of performance-based regulations and the role that supporting documents such as program standards serve when using this approach in the Introduction Section.
- Clarify that the CWD Program Standards include detailed descriptions of suggested methods that are approved by the APHIS Administrator to meet the regulatory requirements of the CWD regulations.
- Describe the process that States or industry may use to propose other methods/approaches to APHIS for approval to meet the regulatory requirements.

3. Definitions

Current Status:

Both the regulations and the Program Standards include a list of terms and their definitions. However, the Program Standards define some terms differently than they are defined in the CFR. The Program Standards also define additional terms that are not included in the CFR, but don't define others that should be. The definitions for some of these additional terms are not clear, and the same term may be used inconsistently within the Program Standards.

Discussion Summary:

Working Group members emphasized the importance of clear, understandable definitions that are consistent between the regulation and the Program Standards. They identified many examples where absent, unclear, or discrepant definitions created confusion and inconsistency in program implementation.

APHIS's Proposed Changes to the Program Standards:

- Make definitions of terms consistent between the Program Standards and the CFR, which should provide the official definition for a term.
- Clarify definitions of terms that are specific to the Program Standards.
- Ensure that defined terms are used consistently throughout the Program Standards.

4. Susceptible Species

Current Status:

The regulations in 9 CFR parts 55 and 81 define "cervid" as "All members of the family Cervidae and hybrids, including deer, elk, moose, caribou, reindeer, and related species. For the purposes of this rule, the term "cervid" refers specifically to cervids susceptible to CWD. These are animals in the genera *Odocoileus*, *Cervus*, and *Alces* and their hybrids, i.e. deer, elk, and moose." However, recent case reports and published scientific evidence support that reindeer (genus *Rangifer*) and Muntjac (genus *Muntiacus*) are also susceptible to and can transmit CWD.

Discussion Summary:

The scientific experts that participated in the conference call unanimously agreed that APHIS should consider both the *Rangifer* genus and muntjac as CWD-susceptible species. Further, these experts suggested that APHIS should be more conservative and assume that any species of cervid is susceptible to CWD rather than list specific species considered susceptible. Alternatively, industry representatives on the Working Group opposed adding new species to the program, while the wildlife and animal health officials on the group recognized that the addition of new species would likely be needed over time based on new information about the disease.

APHIS's Proposed Changes to the Program Standards:

- APHIS proposes to amend the CFR to give more flexibility in the process to change the list of species considered susceptible to CWD. We would define susceptible species based on scientific evidence of natural infection or experimental infections through natural routes. Instead of listing specific species in the regulation, we would include the list in future revisions to the Program Standards. Initially, we would add both the genera *Rangifer* and *Muntiacus* to the list of susceptible species.

- Because it will take time to implement this regulatory change, APHIS will include language in this revision to the Program Standards that acknowledges that the genera *Rangifer* and *Muntiacus* are susceptible to CWD and that APHIS intends to add them to the list of susceptible species in the future by changing the CFR.

5. Ante-mortem Testing

Current Status:

Several peripheral lymphoid tissues have been evaluated for their ability to permit an ante-mortem diagnosis of CWD. The interpretation of tests for CWD on these tissues is complicated by a long incubation period, the pattern of distribution of prions throughout the body, and the influence of genetics on the progression of disease in infected animals. As a result, a truly infected animal may not have prion detected in a certain tissue at the time of testing. In addition, the ante-mortem biopsy procedure provides a smaller sampling of the target tissue than what is typically evaluated post-mortem. Together, these factors make the implications for testing live animals for CWD very different than testing animals at the time of necropsy. Ante-mortem testing for CWD has important regulatory implications if it is used to permit the interstate movement of animals and/or release quarantines in CWD-infected or exposed herds as this testing may fail to detect infected animals.

Despite these concerns, the lack of an approved live animal, or ante-mortem, test for CWD remains a major impediment to the current CWD program. Without this option, we are limited in our ability to assess infection status of herds involved in epidemiological investigations. Further, the current Program Standards essentially restrict the management options for these herds to either whole-herd depopulation or 5-year quarantines. In light of these constraints, our internal review acknowledged that additional diagnostic tools are critically needed to manage CWD and encouraged APHIS to continue to fund and encourage research to develop ante-mortem tests.

Discussion Summary:

Working Group members identified two primary purposes for ante-mortem testing in the CWD Program:

- To inform epidemiological investigations and make risk-based decisions about quarantine release in trace back, trace forward and CWD-exposed herds.
- To provide tools to manage disease in CWD-positive herds, especially when depopulation is not logistically possible and/or economically feasible.

The Working Group spent a considerable amount of time discussing the potential role and use of ante-mortem testing in the CWD program. This topic was an integral component of other discussions the group had about epidemiological investigations, reporting, indemnity and even the possibility of using ante-mortem testing as an option for routine surveillance in herds participating in the HCP. These discussions were based on the following assumptions regarding ante-mortem testing:

- Ante-mortem testing should result in “low risk, not no risk” herd management decisions.
- Ante-mortem testing should be implemented based on the current available science. However, we need to regularly evaluate the approved tests as we gain experience using them to refine and improve testing protocols. We also need to continue to evaluate other test methods to determine suitability for use in the program.
- Ante-mortem testing will be approved for use in specific circumstances. It will not be appropriate in all herds/situations/species.
- Ante-mortem testing should be performed on whole herds or targeted high-risk groups of animals. They do not provide sufficient sensitivity to test an individual animal.

- Initially, immunohistochemistry of rectal anal mucosa associated lymphoid tissue (RAMALT) and medial retropharyngeal lymph node (MRPLN) biopsies will be considered official ante-mortem tests.
- The genotype at prion protein gene (PRNP) codon 96 in white-tailed deer and codon 132 in elk must be known to interpret the ante-mortem testing result.
- The time since last known exposure to CWD must be documented and should be used to determine when the initial whole-herd ante-mortem test is performed.
- More than one round of ante-mortem testing may be required, with an appropriate period of time between rounds of tests.
- Currently, we have sufficient scientific evidence to feel comfortable setting these time frames for testing in white-tailed deer. However, there are important differences between deer and elk in the distribution of prion in central nervous system versus peripheral lymphoid tissue. We have limited information about the time from CWD exposure until tests can detect prion in the rectal mucosal. Additional data and evaluation is needed before approving the RAMALT for official use in elk.
- For interstate movement, State Animal Health Officials need to be willing to consider options other than 5-year quarantine. Even so, performing ante-mortem tests may not reduce a herd's total time under quarantine to less than 5 years, but it could provide alternatives for intrastate movement.

APHIS's Proposed Changes to the Program Standards:

- Implement RAMALT and MRPLN biopsies conducted concurrently with genotyping at PRNP codon 96 as official tests in white-tailed deer in trace back, trace forward and CWD-exposed herds and for disease management in CWD-positive herds.
- Implement pilot projects using RAMALT and MRPLN biopsies conducted concurrently with genotyping at PRNP codon 132 in elk in trace back, trace forward and CWD-exposed herds and for disease management in CWD-positive herds. APHIS, States, and industry will need to collaborate to collect and report testing data and other information about herds participating in these pilot projects to develop and refine testing protocols in elk.
- Describe when and how ante-mortem testing may be applied in the context of various situations in these herds.
- Describe the approved ante-mortem testing scheme that will incorporate animal genotype, time since last exposure to CWD, whole-herd testing, and in most cases, multiple tests conducted over time.
 - At least 24 months should have passed after the last known exposure before conducting the initial whole-herd test. A second whole-herd test may be required at 36 or 42 months after the last known exposure as determined by the predominant genotype of the herd.
- Describe the approved tissue types, the sample collection and submission process; tissue characteristics required for laboratory testing; test interpretation, and reporting requirements.
- Describe who is authorized to collect biopsy samples and under what conditions.
- Include diagrams/flow-charts to illustrate these descriptions where appropriate.

6. Epidemiologic Investigations, Information Sharing and Reporting

Current Status:

The current Program Standards use inconsistent definitions and terminology related to epidemiological investigations. This has resulted in confusion and, in some cases, inconsistent implementation of these investigations across States.

Further, States have not uniformly adopted the option to reduce the length of time of quarantines for CWD-exposed herds or herds under investigation to less than 60 months (5 years) from the last known case or exposure based on an evaluation of the case epidemiology. There are several factors that impact our ability to obtain comprehensive epidemiological information concerning these herds. Since APHIS prioritizes indemnity funds for depopulation of CWD-positive herds, we are often unable to remove critical exposed animals for diagnostic testing that would allow us to better understand the status of certain herds under investigation. The lack of an approved live animal test further limits epidemiological data from herds. Finally, there is not a standardized, transparent process used to collect and share available epidemiological findings across States. As a result, States may not have the information necessary to reduce quarantine requirements, they may be reluctant to do so without definitive guidance or specific instruction from VS, or both.

Discussion Summary:

Working Group members emphasized the importance of clear, understandable definitions that are consistent between the regulation and the Program Standards. They identified many examples where absent, unclear, or discrepant definitions created confusion and inconsistency in the implementation of epidemiological investigations. Both industry and State Animal Health Officials in the group discussed situations where herds were implicated in epidemiological investigations and quarantines were placed due to confusion about the definition of CWD-exposed animals. All group members agreed that clarification is needed about APHIS' requirements concerning epidemiological investigations.

Working Group members agreed it is critical to share accurate, timely, complete information about ongoing CWD epidemiological investigations among affected Federal and State Animal Health Officials. Doing so helps to control the spread of CWD by quickly and accurately identifying exposed animals and placing movement restrictions on animals and herds. Sharing this information will also facilitate continuity of business since State Animal Health Officials would have the information available to release or reduce quarantines for herds under investigation, as appropriate. Finally, the Working Group members recognized that local State and Federal Animal Health Officials needed flexibility in order to evaluate epidemiological information to make decisions about reducing or releasing quarantines in specific herds. They felt it was too prescriptive to identify specific factors to consider or their relative importance when making these decisions.

However, the Working Group members were less consistent in their opinions about a process to share epidemiological information. The Working Group reviewed Appendix VI. CWD Epidemiology Investigation and Report Template, along with a worksheet requesting similar information. Most preferred the worksheet format and felt that the content helped to guide thorough and consistent epidemiological investigations. However, the State Animal Health Officials on the group did not support requiring States to complete it or to provide other written summary reports regarding investigations to other States or APHIS. Instead, they suggested that the one-on-one conversations that already occur informally between State Animal Health Officials are adequate. They encouraged APHIS to facilitate discussions when multiple States become involved in investigations and to regularly post summary information about recent CWD investigations on the APHIS website.

APHIS's Proposed Changes to the Program Standards:

- Make definitions of terms consistent between the Program Standards and the CFR, which should provide the official definition for a term. Ensure that defined terms are used consistently throughout the Program Standards.
- Clarify the definitions and processes for performing epidemiological investigations. Include diagrams/flow-charts where appropriate.
- Replace Appendix VI with a worksheet that includes information about the owner and/or the producer of the herd, location of the herd, the premise, type of operation, test results, inventory

of animals, movements of animals in and out of the herd, trace information, index case history and other essential data. (See Appendix 1.)

- States should complete this worksheet for all positive herds enrolled in the HCP as part of their annual HCP report. Additionally, any herd that requests Federal indemnity must complete a preliminary and final worksheet. This reporting requirement will be specified in the herd plan.

7. Indemnity

Current Status:

In recent years, APHIS appropriated \$3 million to support cervid health activities, including \$1 million for CWD indemnity. Currently, APHIS prioritizes these limited indemnity funds for the depopulation of entire CWD-infected herds. Unfortunately, this amount of indemnity is often insufficient to depopulate all CWD-infected herds identified in a single year. Further, we are typically unable to remove critical exposed animals for diagnostic testing that would allow us to better understand the status of certain herds involved in epidemiological investigations. Despite concerns expressed by many stakeholders, the availability of funding for CWD indemnity is unlikely to increase in the near future.

Several factors contribute to the imbalance between current indemnity funding versus needs: Large herd size, high market value of individual animals, and extensive movements of animals among herds resulting in a large number of herds involved in epidemiological investigations. Of course, the lack of an approved live animal test further limits epidemiological data and management options in these herds and places a higher demand on limited indemnity funding.

In light of these constraints, our internal review acknowledged that it is increasingly important for APHIS to prioritize the use of limited indemnity funds in a way to reduce the risk of disease transmission. Additionally, stakeholders have challenged APHIS, States, and industry to develop new approaches that will more equally share CWD depopulation and indemnity costs.

Discussion Summary:

Working Group members emphasized the importance of using indemnity to depopulate CWD-positive herds, particularly breeding herds, to reduce the potential for disease transmission and environmental contamination. Members agreed that ante-mortem testing could be used as a tool to manage disease and remove infected animals to reduce environmental in situations where whole-herd depopulation of CWD-positive herds is not logistically possible and/or indemnity is not available. Additionally, members acknowledged that indemnity funding could be used strategically to remove exposed animals in herds involved in epidemiological investigations to inform risk evaluation and decision making regarding movement restrictions and other risk mitigations.

There was less agreement among participants about the priority to place on factors other than herd status that APHIS should consider when making decisions about providing indemnity. The group generally favored prioritizing indemnity for breeding herds versus hunting preserves. The group also acknowledged that the risk for disease transmission to nearby captive cervid herds or wild populations of cervids should influence decisions about indemnity funding, with a higher priority given to depopulating CWD-positive herds in areas where CWD has not been detected in the wild and there is a local density of wild or captive cervids that makes transmission a concern.

The Working Group also discussed how APHIS might incorporate herd participation and compliance in the HCP when making indemnity decisions. Generally, the idea is that APHIS would prioritize indemnity for animals in enrolled herds that have been compliant with the program for some period of time. The cervid industry representatives stated that this approach would recognize the efforts of producers in

CWD control and give them an incentive to continue. The primary concern among group members was how to balance disease control goals against encouraging HCP participation. Members proposed several options for how APHIS could implement this approach: Limit indemnity funding to only HCP-enrolled/compliant herds; pay a reduced amount of indemnity for animals in non-participating herds; make decisions regarding indemnity for HCP-enrolled/compliant herds as they are needed, but delay decisions for animals in non-participating herds until the end of the fiscal year.

APHIS's Proposed Changes to the Program Standards:

- Add a new section regarding indemnity. Describe APHIS' goals for providing indemnity funding.
- Describe the factors that APHIS will consider when making decisions about providing indemnity for CWD-positive, -exposed, and -suspect animals and describe the relative priority of each (See Appendix 2).

8. Surveillance in Certified Herds

Current Status:

HCP enrolled herd owners are required to conduct CWD testing on all on-farm deaths of cervids aged 12 months or older. This essential surveillance provides confidence that HCP-certified herds are at low risk for CWD infection. However, recent investigations have identified certified herds in several States that have tested few (and in some cases no) animals. In most cases, the herd is complying with the surveillance requirements for herd certification. The low number of samples submitted for surveillance may be a consequence of small herd size, low death loss in the herd, a high number of animal movements in and out of the herd without much opportunity for surveillance, or a combination of these or other factors. Several stakeholders have expressed concerns about the level of routine surveillance in certified herds and a "loophole" in the surveillance requirements that certified herds do not have to test animals sent to hunt facilities or slaughter houses. APHIS' internal review also acknowledged this concern and recommended that the Program Standards be revised to require adequate surveillance testing and results reporting for herds to maintain their certification status.

Discussion Summary:

Working Group members agreed that surveillance was an underpinning of the HCP and that all herds should meet the current surveillance requirements. However, the industry representatives were adamantly opposed to the idea of adding specific sample number targets or herd surveillance minimums into the Program Standards. They believe that current requirement to submit 100 percent of on-farm deaths, combined with the length of time herds have been enrolled in the HCP, provides surveillance at a level sufficient to detect infection if it is present. They also felt that adding a sample number target or herd surveillance minimum would penalize herds with low death rates. State and Federal animal health representatives were less consistent in their comments. Some individuals provided specific examples where certified herds lacked robust sample numbers, despite meeting the HCP surveillance requirements. Others agreed with the industry's position and commented that as long as herd owners met the current surveillance requirements, there was sufficient evidence to support low risk of CWD.

The State Animal Health Officials on the Working Group contacted their fellow members of the National Assembly to obtain data to inform this discussion. Twenty-two States responded to the data request. Fifteen of these States had farmed cervids and submitted usable data. Overall, the majority of herds were testing more than 10 percent of the herd for CWD over a 5-year period. However, a few States had notable exceptions to this general trend.

Based on these data and the input from the group, APHIS will not propose changes to the requirements for post-mortem surveillance in the Program Standards at this time. However, APHIS will emphasize that States should continue to monitor surveillance in herds and include reporting on this metric in the annual report that approved States submit to APHIS.

APHIS's Proposed Changes to the Program Standards:

- Clarify the consequences of poor quality and missing samples on herd status. Describe options States may consider as substitutions for these samples.
- Streamline the text throughout this section to clarify and reduce unnecessary repetition.

9. Fencing Requirements

Current Status:

The CFR describes the performance standard for fencing required of herds that participate in the HCP – it is adequate to prevent ingress and egress of cervids. Part A of the current Program Standards includes the criteria that APHIS considers to meet this performance standard. It also includes considerable discussion about the use of “double fencing” or other mitigations. Part B discusses that fencing should be addressed in herd plans for CWD-positive or -exposed herds. It reiterates the general fencing requirements for HCP herds and the discussion about the use of “double fencing” or other mitigations. Appendix II provides scientific justification for APHIS’s decision regarding the minimum fence height of 2.4m (8 feet) along with other scientific references.

Discussion Summary:

Industry representatives stated that the section on fencing in the current Program Standards was in excess of the CFR. Specifically, they felt that the discussion about “double fencing” and the inclusion of scientific references in Appendix II encouraged States to implement fencing requirements in excess of what is appropriate. They also objected to the term “double fencing” and preferred “secondary barriers.”

The industry representatives also suggested removing statements about the discretion of State officials and the mention of additional barriers/other mitigations to reduce the risk of CWD transmission in herd plans. However, several representatives from other stakeholder groups indicated it was important to retain language about fencing in the context of a herd plan, but that it should be reworded to better reflect APHIS’s intent. They also emphasized the importance of allowing the State, APHIS, and the herd owner to jointly evaluate whether to use fencing as a mitigation for disease transmission on a case-by-case basis when developing herd plans.

APHIS's Proposed Changes to the Program Standards:

- Streamline the description of fencing characteristics considered necessary to prevent ingress and egress of cervids for HCP enrolled herds.
- Retain the description of fencing requirements in the context of herd plans for CWD-positive and CWD-exposed herds. Reword the text so that the decision to require additional mitigations in a herd plan is made on a case-by-case basis and is not stated as a blanket recommendation.
- Eliminate Appendix II, and make these scientific references available upon request.

10. Biosecurity Requirements

Current Status:

The regulations require cleaning and disinfection of premises, conveyances, and other materials to receive Federal indemnity when animals are destroyed due to CWD. The regulations also state that herd plans for CWD-positive or -exposed herds may include requirements for cleaning and disinfection and restrictions on the movement and/or sharing of possibly contaminated equipment. This regulatory requirement is restated in the Program Standards, which also provide a list of several best management practices that are generally applicable to CWD-positive herds. Appendix IV provides an overview of the principles and approach used to determine the degree of environmental contamination on a premises. It also provides recommended disinfection and decontamination procedures for each category of environmental contamination.

Discussion Summary:

As with the discussion about fencing, several Working Group members felt that the biosecurity information in the Program Standards was being over-interpreted. One member gave an example where individuals not well versed in the CWD Program insisted on following the recommended safety precautions described for sample collection in Appendix III while on a visit to a premises involved in a CWD epidemiological investigation. This example emphasized the importance of clear descriptions about the purpose and context for any recommendations included in appendices. Some members felt that Appendix IV should be removed, while others felt that it was important to include as long as APHIS' intent for the recommendations was clear. Some members suggested that APHIS should include a new section in the Program Standards listing best management practice for biosecurity in herds participating in the HCP, while others felt this exceeded the current regulation.

APHIS's Proposed Changes to the Program Standards:

- Remove Part B Section 5. Sanitary Precautions and Biosecurity Practices for Herd Plans and Depopulations.
- Review Appendix IV to determine if any changes are needed based on recent scientific evidence. Make these scientific references available upon request. Streamline and revise the text to clarify intent and recommendations.

11. Carcass Disposal

Current Status:

The CFR describes the performance standard for disposal of carcasses from animals infected with CWD and animals from CWD-positive or exposed herds. The regulations specifically list incineration and alkaline hydrolysis tissue digestion as approved methods of disposal, but allow other methods authorized by APHIS as permissible in accordance with local, State, and Federal laws. The current Program Standards also list landfill and on-site burial as other APHIS-approved disposal methods. Appendix V lists additional disposal options and provide further explanation of each approved method.

Discussion Summary:

State Animal Health Officials in the group emphasized that flexibility in the Program Standards is essential to allow for local decision making regarding carcass disposal. Both State Animal Health Officials and industry representatives expressed concern about the references to Federal laws in both the regulation and the Program Standards. They prefer revising the Program Standards section about disposal by removing Appendix V, avoiding referencing the Environmental Protection Agency, and

removing specific approved disposal methods. Alternately, other group members commented that the Program Standards should retain an appendix that includes basic information about the approved methods of disposal. This is especially helpful when CWD is detected in a new location. Further, in these cases, local State and Federal animal health personnel may need additional technical support and guidance to identify and implement a disposal plan.

APHIS's Proposed Changes to the Program Standards:

- Consolidate the discussion of carcass disposal options in the main body of the Program Standards. List all approved disposal options. Describe options for using multiple methods with post-mortem testing to reduce the risk of environmental contamination for certain disposal methods.
- Remove Appendix V.
- Describe the process that States or industry may use to propose other methods or approaches to APHIS for approval to meet the regulatory requirements.
- Indicate that APHIS can provide additional technical support and guidance, available upon request, to assist in identifying and implementing a local disposal plan.

12. Surveillance and Testing Requirements for Interstate Transport of Wild Caught Cervids

Current Status:

Any wild cervid that has been captured is considered to be a “captive cervid” under the current CFR definition. As such, wild-caught cervids that are transported from one State or Tribal location to another for release must meet interstate movement requirements for identification and chronic wasting disease (CWD), bovine tuberculosis (TB), and brucellosis. APHIS collaborates with States to approve these movements. However, APHIS did not have a formal policy describing the process. Recently, stakeholders asked APHIS to develop a guidance document about this process that specifically described how APHIS would determine risk levels for CWD in these wild-caught cervids.

In September 2016, Veterinary Services issued Guidance Document 8000.1 “Surveillance and Testing Requirements for Interstate Transport of Wild Caught Cervids.” This document establishes a recommended minimum standard for testing and a uniform process of disease risk assessment to help prevent the spread of cervid diseases such as chronic wasting disease (CWD), bovine tuberculosis (TB), and brucellosis when wild cervids are captured for interstate movement and release. It also describes the process for submission and approval of these requests.

Discussion Summary:

Industry representatives raised their concerns about these movements with APHIS and State Wildlife Officials participating in the group several times. The Working Group did not discuss this issue in detail because APHIS intended to issue the Guidance Document.

APHIS's Proposed Changes to the Program Standards:

- Add the content of the recently issued VS Guidance Document 8000.1 “Surveillance and Testing Requirements for Interstate Transport of Wild Caught Cervids” to the Program Standards.

Next Steps

APHIS will present this summary document at the 2016 USAHA Annual Meeting in October 2016 and will accept additional input from stakeholders on these proposed changes. Feedback may be submitted to vs.sprs.cervid.health@aphis.usda.gov through November 15, 2016. APHIS will revise the Program Standards in light of the feedback we receive on this summary document. APHIS expects to publish a notice in the Federal Register in early 2017 that would ask for public comment on the draft revisions to the CWD Program Standards before issuing the revised Program Standards.

Appendix 1: Epidemiological Investigation Worksheet

State ____ County _____ Herd _____ Owner _____

Please complete one form for each CWD positive herd that you have identified in your state.

Index Case (defined as the first positive case in a herd) check if traced from another positive herd

1. Age at the time of death/euthanasia? ____ Yr ____ Mo
2. Sex? ____ M ____ F
3. Species? _____
4. Was the index case a natural addition? ____ or a purchased addition? ____ (check one)
If natural addition, date of birth ____/____/____
If purchased, date added to herd ____/____/____
If purchased, from where? _____ (herd/name) ____ (state)
5. Date of death/euthanasia? ____/____/____
6. Date CWD samples were taken? ____/____/____
7. Was the index case exhibiting clinical signs at the time of death/euthanasia? Y/N/Don't know
8. Obex test result? Positive ____ Not detected ____ Location ____ Not sampled ____
Lymph node test result? Positive ____ Not detected ____ Location ____ Not sampled ____
_____ test result? Positive ____ Not detected ____ Location ____
Genetics testing results? ____@codon____ ____@codon____ Not tested ____

Positive Premises (defined as the premises on which the index case resided at the time of diagnosis)

1. Date cervid herd was established? ____/____/____
2. Type of operation (check all that apply)? ____ Breeding ____ Hunting ____ Other
(If Other, specify type _____)
3. Total size of the area where captive cervids were held? _____ Acres
4. Size of the enclosure where the index case was held? _____ Acres
5. Were animals from the index herd housed on more than one location? Y/N/Don't know
If yes, please explain _____
6. Was the premises double-fenced at the time the index case was diagnosed? Y/N/Don't know
7. Was the premises managed as a closed herd at the time of diagnosis? Y/N/Don't know
If yes, for what length of time prior to the index case diagnosis? ____ Yr ____ Mo
If not managed as a closed herd, how many other herds were cervids sourced from in the 5 year period prior to the index case diagnosis?
In-State sources # _____ Out-of-State sources # _____
8. Were any ancillary businesses associated with the positive premises? (e.g. urine collection, taxidermy, wildlife rehabilitation, fawn raising)? Y/N/Don't know
(If Yes, specify type(s) _____)

9. Was the index herd enrolled in a herd certification program (HCP) at the time that the index case was diagnosed? Y/N If yes, date of enrollment? ___/___/___

If yes, was the herd in compliance with the requirements of the HCP at the time the index case was diagnosed? Y/N/Don't know

If the herd was not in HCP compliance at the time the index case was diagnosed, please explain: _____

10. At the time that the index case was diagnosed, was the index herd located:

Within 10 miles of known CWD positives in wildlife? Y/N/Don't know

Between 11 and 50 miles of known CWD positives in wildlife? Y/N/Don't know

11. At the time that the index case was diagnosed, was the index herd located:

Within 10 miles of known CWD positives in other captive cervids? Y/N/Don't know

Between 11 and 50 miles of known CWD positives in other captive cervids? Y/N/Don't know

12. Most recent known/reported captive cervid inventory at the time the index case was diagnosed (or at the time of depopulation): Date of inventory ___/___/___

Cervid Herd Inventory at the Time of Index Case Diagnosis					
Species	1 year old and over		Under 1 year old		Total Inventory
	Males	Females	Males	Females	
Elk					
Whitetail deer					
Other (Please identify)					

13. Was this herd depopulated? Y/N If yes, date of depopulation? ___/___/___
 If no, date quarantined? ___/___/___

14. If this herd was depopulated, inventory at the time of depopulation:

Date of inventory ___/___/___

Check box if same as inventory listed in item 12 above:

Cervid Herd Inventory at the Time of Depopulation					
Species	1 year old and over		Under 1 year old		Total Inventory
	Males	Females	Males	Females	
Elk					
Whitetail deer					
Other (please identify)					

CWD Test results from the depopulated inventory (rows below should sum to total inventory in item above):

Obex test results? #Positive ___ #Not detected ___ #Location ___ #Not sampled ___
 Lymph node test result? #Positive ___ #Not detected ___ #Location ___ #Not sampled ___
 _____ test result? #Positive ___ #Not detected ___ #Location ___ #Not sampled ___

15. Did any cervids die prior to depopulation of the herd or while the herd was being held under quarantine (including euthanasia deaths)? Y/N/Don't know

If yes, how many? (please complete the following table):

Number of Cervids that Died or were Euthanized prior to Depopulation or while held under Quarantine					
Species	1 year old and over		Under 1 year old		Total
	Males	Females	Males	Females	
Elk					
Whitetail deer					
(please identify)					

CWD Test results (rows below should sum to total above):

Obex test results? #Positive ___ #Not detected ___ #Location ___ #Not sampled ___

 Lymph node test result? #Positive ___ #Not detected ___ #Location ___ #Not sampled ___
 _____ test result? #Positive ___ #Not detected ___ #Location ___ #Not sampled ___

16. For **all CWD POSITIVE cervids** (TOTAL herd numbers) that died or were euthanized following the index case diagnosis (during depopulation or otherwise AND including the index case), please provide:

- a. TOTAL number of CWD positive animals: _____
- b. Of the Total number of CWD positive animals above, how many were:
 - 0 - 24 months of age? : _____
 - 25 - 48 months of age? : _____
 - 49+ months of age? : _____
- c. Total number of positive males: _____
- d. Total number of positive females: _____
- e. Were all positives the same species? Yes / No
 - i. If no, please provide the total number of positive:
 - Elk ___ Whitetail deer ___ Other (_____) ___
- f. Total number of positive natural additions: _____
- g. Total number of positive purchased additions: _____
 - i. Were all positive purchased animals from the same place? Yes / No
 1. If yes, total number of animals purchased? _____
 From herd _____ in state _____
 2. If no, number of facilities from which positive animals were purchased?

Provide number of animals purchased from each herd and the state of origin

- h. Total number of animals showing clinical signs at time of death: _____
- i. Genetics testing results on positives? Y/N/Don't know
 If yes (WTD), # GG @ codon 96? ____ # GS @ codon 96? ____ # SS @ codon 96? ____
 If yes (Elk), # LL @ codon 132? ____ # LM @ codon 132? ____ # MM @ codon 132? ____

17. How many *trace-forward* cervids were identified in the epidemiological investigation?

In-State trace-forwards # ____ Out-of-State trace-forwards # ____

Check box if unable to trace due to poor records, etc.

How many of the identified trace-forward cervids were tested for CWD? ____

Were any trace-forward cervids diagnosed as positive for CWD? Y/N/Don't know

If yes, how many were diagnosed as positive for CWD? ____

18. How many *trace-back* cervids were identified in the epidemiological investigation?

In-State trace-backs # ____ Out-of-State trace-backs # ____

Check box if unable to trace due to poor records, etc.

How many of the identified trace-back cervids were tested for CWD? ____

Were any trace-back cervids diagnosed as positive for CWD? Y/N/Don't know

If yes, how many were diagnosed as positive for CWD? ____

For the most recent years prior to the index case being diagnosed, please provide:

Number of Years Prior to CWD Index Case Diagnosis	Reported Inventory	# Sold or transferred from herd	Purchases (or other Non-natural additions)	Slaughtered and/or hunter harvested (and # CWD sampled)	# Natural deaths (and # CWD sampled)	# Valid Reported CWD Test Results (i.e. do not count location or untestable results)
1 Yr Prior				(____)	(____)	
2 Yrs Prior				(____)	(____)	
3 Yrs Prior				(____)	(____)	
4 Yrs Prior				(____)	(____)	
5 Yrs Prior				(____)	(____)	

Please include a copy of any epidemiologic report(s) conducted on this herd and copies of any lab test results or other pertinent findings.

Appendix 2: Proposed Priority Matrix for CWD Indemnity Decision Making.

Priority for Indemnity	Herd/Animal Status	Type of Herd	HCP Status	Risk of disease transmission in the local area	Value of animal post-mortem testing to understand epidemiology/inform decision making
High	CWD-Positive Herd	Breeding	Enrolled and compliant	CWD not detected in wildlife; high to moderate cervid density; and/or other risk factors	Not applicable
High	CWD-Exposed or Suspect Animals	Breeding	Enrolled and compliant	CWD not detected in wildlife; high to moderate cervid density; and/or other risk factors	Important or informative; Will likely impact knowledge/decisions about multiple herds.
High	CWD-Positive Herd	Hunt preserve	Enrolled and compliant	CWD not detected in wildlife; high to moderate cervid density; and/or other risk factors	Not applicable
Medium	CWD-Positive Herd	Breeding	Enrolled and compliant	CWD detected in wildlife; moderate to low cervid density; and/or few other risk factors	Not applicable
Medium	CWD-Exposed or Suspect Animals	Breeding	Enrolled and compliant	CWD not detected in wildlife; high to moderate cervid density; and/or other risk factors	Important or informative; Will likely impact knowledge/decisions about multiple herds.
Medium	CWD-Positive Herd	Hunt preserve	Enrolled and compliant	CWD detected in wildlife; moderate to low cervid density; and/or	Not applicable

				few other risk factors	
Medium	CWD-Positive Herd	Breeding	Not enrolled or Enrolled but not compliant	CWD not detected in wildlife; high to moderate cervid density; and/or other risk factors	Not applicable
Medium	CWD-Exposed or Suspect Animals	Breeding	Not enrolled or Enrolled but not compliant	Not applicable	Important or informative; Will likely impact knowledge/decisions about multiple herds.
Low	CWD-Positive Herd	Breeding	Not enrolled or Enrolled but not compliant	CWD detected in wildlife; moderate to low cervid density; and/or few other risk factors	Not applicable
Low	CWD-Exposed or Suspect Animals	Breeding	Not enrolled or Enrolled but not compliant	Not applicable	Important or informative; Will likely impact knowledge/decisions about multiple herds.
Low	CWD-Positive Herd	Hunt preserve	Not enrolled or Enrolled but not compliant	CWD not detected in wildlife; high to moderate cervid density; and/or other risk factors	Not applicable
Low	CWD-Positive Herd	Hunt preserve	Not enrolled or Enrolled but not compliant	CWD detected in wildlife; moderate to low cervid density; and/or few other risk factors	Not applicable