VS Guidance 8003.1

Sampling Options for CWD Herd Certification Plan Compliant Herd Owners to Replace a Missed Mortality or Poor-Quality Sample Submission

1. Purpose and Background

This document provides a live animal chronic wasting disease (CWD) testing option for farmed white-tailed deer herd owners (referred to as owners hereafter) enrolled in the Chronic Wasting Disease Herd Certification Program (CWD HCP)[1]. State animal health officials (SAHOs) can provide this guidance to owners who otherwise comply with the CWD HCP requirements but have infrequent missed mortalities or poor-quality samples.

Animal and Plant Health Inspection Service (APHIS) regulations require certain cervid species moving interstate, other than for slaughter or research, be enrolled in the CWD HCP. The HCP provides a consistent national approach to controlling CWD in farmed cervids and prevents the interstate spread of the disease. To be enrolled in the CWD HCP, owners must conduct CWD sampling on all deaths of all cervids aged 12 months or older that occur on-farm, at slaughter, or at a hunt facility under the same ownership. Occasionally owners with herds in the CWD HCP have missed mortalities or submitted poor-quality samples. In response to this issue, APHIS developed a live animal testing option SAHOs can use in white-tailed deer herds when CWD samples are missed or of poor quality.

APHIS statisticians calculated the number of live white-tailed deer to biopsy to equal the diagnostic value of an on-farm mortality. To derive this number, they calculated the probability of detecting CWD in an on-farm mortality using immunohistochemistry (IHC) testing of the medial retropharyngeal lymph nodes and obex and compared it to the probability of detecting CWD in a live animal by rectal anal mucosal associated lymphoid tissue (RAMALT) biopsy using IHC. They also examined factors such as the proportion of positive mortalities in CWD-positive herds before depopulation[2], within-herd CWD prevalence at depopulation[3], sensitivity of on-farm mortality IHC testing[4], sensitivity of live animal IHC testing by genotype at codon 96[5], and size of the herd to be sampled. The proportion of white-tailed deer CWD-positive exclusively in the medial retropharyngeal lymph node, indicating the animal was in an early stage of infection, was incorporated into

[1] This program includes both herds directly enrolled in the CWD Herd Certification Program and herds included based on their participation in Approved State CWD Herd Certification Programs. These are programs operated by State governments for CWD certification of cervid herds the Administrator has determined to meet the requirements of title 9, *Code of Federal Regulations* (9 CFR) 55.23(a).

[2] For herds APHIS depopulated due to CWD, APHIS calculated the number of mortalities occurring from the time the herd was diagnosed to the time the herd was depopulated and showed 24.1 percent of these mortalities were CWD positive.

[3] For herds APHIS depopulated within 6 months of a CWD diagnosis, the average within herd CWD prevalence was 16.5 percent.

[4] Sensitivity is over 99 percent.

[5] Sensitivities range from 42 percent for 96GS deer to 76 percent for 96GG deer (Thomsen, et. al, 2012 and Keane et. al. 2009).

the calculation[6]. IHC of RAMALT biopsy performs poorly in early infection, resulting in missing early cases.

After accounting for these variables, APHIS determined that IHC of RAMALT biopsy on five white-tailed deer representative of the mortality is appropriate to replace a missed mortality or a poor-quality submission in a herd. This value is based on a herd composition of 70 percent genotype GG and 30 percent genotype GS at codon 96 and assumes the CWD-positive white-tailed deer in the herd are evenly divided between early- and late-stage CWD progression. This guidance document represents the Agency's position on this topic and is intended solely as guidance. It does not have the force and effect of law, does not create, or confer any rights for or on any person, and does not bind the U.S. Department of Agriculture (USDA) or the public. Language suggesting that this guidance is mandatory (e.g., "shall," "must," "required," or "requirement") should not be construed as binding unless the terms quote from a statutory or regulatory requirement. The information this document contains may be made available to the public. While this document provides guidance for users outside APHIS, APHIS employees may not deviate from the directions provided herein without appropriate justification and supervisory concurrence.

Pursuant to the Congressional Review Act (5 U.S.C. § 801 et seq.), the Office of Information and Regulatory Affairs designated this rule as a non-major rule, as defined by 5 U.S.C. § 804(2).

2. Document Status

A. Review date: 6/30/2025.

B. This is a new document.

3. Authority and References

A. Authorities (*Code of Federal Regulations* (CFR)):

1) 7 CFR 371.4
2) 9 CFR 55.23
3) 9 CFR 55.8

B. References:

1) Chronic Wasting Disease Program Standards

C. Definitions:

[6] Out of 588 accessions representing over 3,700 samples tested for CWD, 41 percent were early CWD cases (prion only detected in medial retropharyngeal lymph node) and 59 percent were late CWD cases (prion detected in the medial retropharyngeal lymph node and obex).

1) Approved State CWD HCP: A program operated by a State government for certification of cervid herds with respect to CWD that the Administrator has determined meets the requirements of 9 CFR 55.23(a).

2) CWD HCP: The Chronic Wasting Disease Herd Certification Program established by 9 CFR part 55.The CWD HCP includes both herds directly enrolled in the CWD HCP and herds included based on their participation in Approved State CWD HCPs.

3) Enrolled Herd: A herd that has enrolled in the CWD HCP and meets the minimum requirements defined in 9 CFR part 55.

4) CWD-positive animal: An animal that has had a diagnosis of CWD established through official confirmatory testing conducted by the National Veterinary Services Laboratories (NVSL).

5) CWD positive herd: A herd in which a CWD-positive animal resided at the time it was diagnosed and which has not been released from quarantine

6) SAHO: State animal health official or their designee.

7) AVIC: Area Veterinary in Charge or their designee.

4. Audience

VS employees, other federal and state agencies, and members of the public.

5. Guidance

A. General

This document describes the process for approving herd owners to test live white-tailed deer for CWD by IHC using RAMALT biopsy, in lieu of a missed mortality test and the number and type of deer that must be tested. This policy only applies to white-tailed deer because of the lower sensitivity of the test and prolonged incubation period in elk[7]. The SAHO must be agreeable to this option before it is offered to the owner. The AVIC or the SAHO must review this guidance with the owner.

B. Recordkeeping and Sampler Training

1) For each missing mortality or poor-quality sample submitted, the owner must document the reason it occurred, and the steps taken to prevent a recurrence.

2) Samples collectors with repeated poor-quality or unusable sample submissions must take training as specified by the SAHO. Following this training, if sampling errors continues, the SAHO should recommend the owner change sample collectors and advise them that ultimately, they are responsible for the quality of the samples submitted.

C. Approval to use antemortem testing

1) The AVIC and SAHO must review the previous 3 years of inspection reports and testing history and conclude the owner is compliant with CWD HCP requirements as outlined in 9 CFR part 55 and the CWD Program Standards before allowing the owner to follow the procedures outlined in this document. Specifically, owners with a history of repeatedly missing multiple mortalities and/or submitting poor-quality samples should not be considered for this deviation. The missing mortality and sample submission error should be 5 percent or less over 3 years (total number of missing mortalities + total number of poor-quality sample submissions) ÷ total number of mortalities × 100). For herds of 100 or fewer animals, the entire herd history of missed mortalities and sample submissions can be used to calculate this error. The overall compliance history of the herd should also be considered.

2) The AVIC and the SAHO must agree in writing that the herd meets the criteria to replace a missed mortality or poor-quality sample with live white-tailed

[7] Moore et al. 2018.

deer testing. Documentation of the decision, including rational, must be maintained in the herd file.

D. Sampling
   1) White-tailed deer should be tested, as described below, for ***each*** white-tailed deer with a missed mortality or poor-quality sample submission.

      a. If the genotype of the white-tailed deer to be biopsied is ***not known***:

         1. Sample five white-tailed deer that are between 2 to 4 years of age[8] *and* have the longest exposure to the white-tailed deer with the missed mortality or poor-quality sample submission. If there are not enough animals in this age group, sample animals nearest to that age range that are at least 2 years of age.

      b. If the genotype of the white-tailed deer to be biopsied is ***known***:
         1. The owner must provide genetic documentation and sample a total of five white-tailed deer with at least four white tailed deer with GG at codon 96.

         2. If the group of white-tailed deer does not contain four white-tailed deer with GG at codon 96, then the owner must test two white-tailed deer with GS at codon 96 to replace each codon 96GG white-tailed deer not tested.

         3. White-tailed deer that are antemortem sampled must be between 2 to 4 years of age ***and*** have the longest exposure to the white-tailed deer with the missed mortality or poor-quality sample submission. If there are not enough animals in this age group, sample animals nearest to that age range that are at least 2 years of age.

E. All submitted rectal biopsy samples must have a minimum of six lymphoid follicles to be considered a valid diagnostic sample, and if not, the animal must be resampled or a similar animal substituted.

F. Sample collection must be done by a state or federal veterinarian or a licensed, accredited veterinarian under the supervision of a state or federal veterinarian, as described in the CWD Program Standards Section 5.3, and be submitted within 7 days of collection.

G. Liability and Associated Costs

   1) The owner must pay all costs associated with sample collection, genetics, and diagnostic testing.

[8] The median age for white-tailed deer to be CWD-positive was 3 and average age 3.4 from over 1,600 samples taken from 2019 to the present. The range was 0.5 to 15 years of age.

2) The owner, and not the state, or APHIS, will bear the loss of any animal, function, or part of an animal that could arise because of handling or sample collection associated with the procedures specified in this document.
3) Any method of chemical restraint used for testing shall be performed or administered by an individual who can legally purchase and administer chemical restraints in the state at the owner's expense.

H. Testing and Results

1) Unless the State's NAHLN laboratory has a deviation approved by NVSL to test rectal biopsies the rectal biopsies must be sent to NVSL for CWD testing.

2) If a positive result is found on a RAMALT biopsy, the herd will be put under quarantine by the State and will be designated a CWD positive herd.

6. Inquiries

Please contact the APHIS Veterinary Services Ruminant Health Center, Cervid Health Program, at VS.SP.Cervid.Health@usda.gov with any questions about this guidance.