

Chronic Wasting Disease Industry/State/Federal Program Standards

September 20, 2022

Introduction

The purpose of these CWD Program Standards is to provide guidance to producers and regulatory officials on how to effectively control CWD and meet the requirements in 9 CFR parts 55 and 81. This document replaces all previous versions of the CWD Program Standards.

The CWD Herd Certification Program (HCP) provides a consistent national approach to certify deer, elk and moose herds as low risk for CWD (9 CFR 55.21-55.25). The interstate movement requirements for deer, elk and moose are designed to mitigate the risk of spreading CWD between states (9 CFR 81).

The animal health community has learned much about CWD in the last 50 years. Peer reviewed science indicates the following:

- (1) CWD does not affect humans.
- (2) CWD does not affect animals other than cervids.
- (3) CWD does not devastate wild deer and elk populations in areas where it is endemic.
- (4) CWD is now endemic in wild deer and elk populations in 29 states.
- (5) CWD will continue to spread in deer and elk populations despite efforts to control the disease.

When the CWD control program began, the prevalence of the disease was very low in both farmed and wild deer and elk populations. Strict regulations were implemented to eradicate the disease from farmed deer and elk herds. Since then, CWD has spread rapidly across the United States in both farmed and wild deer and elk populations. Even though CWD is now endemic in at least 29 states, the regulations for farmed deer and elk herds have remained strict. These strict regulations are no longer necessary or appropriate. It is now time to broaden the regulations for control of CWD and make allowance for continuity of business.

We have reached a tipping point in the CWD control program. Considering the ever-increasing prevalence of CWD in wild deer populations, we must now reevaluate our tactics. Depopulation of infected herds should no longer be the cleanup plan of choice, especially in areas of the country where CWD is established in wild cervid populations. Movement of animals from quarantined herds should be allowed under specific conditions. Live-animal tests should be used when possible and innovative testing protocols should be incorporated into case investigations and herd cleanup plans.

Regulations in 9 CFR 55 and 9 CFR 81 were written with enough flexibility to allow all these things to be done. The CFR does not need to be changed. These Program Standards provide further guidance on how to comply with the legal requirements in 9 CFR parts 55 and 81.

Part A of these Program Standards describes the voluntary Herd Certification Program and the requirements for interstate movement of cervids.

Part B of these Program Standards provides guidance on how to respond to the finding of CWD in farmed cervid herds.

Definitions

The following definitions and those in 9 CFR 55.1 and 81.1 apply to these CWD Program Standards.

Cervid. All members of the family Cervidae and hybrids, including deer, elk, moose, caribou, reindeer, and related species. For the purposes of this document, the term “cervid” refers specifically to cervids naturally (not experimentally) susceptible to CWD. These are animals in the genera *Odocoileus*, *Cervus*, and *Alces* and their hybrids, i.e., deer, elk, and moose.

Commingled. Animals are commingled if they have direct contact with each other, have less than 10 feet of physical separation, or share equipment, pasture, or water sources. Common ownership is not a factor in determining if animals are commingled.

CWD-exposed animal. An animal that is part of a CWD-positive herd, or that has been exposed to a CWD-positive animal or contaminated premises within the previous 5 years.

CWD-exposed herd. A herd in which a CWD-positive animal has resided within 5 years prior to that animal's diagnosis as CWD-positive.

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

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.

CWD-suspect animal. An animal that has tested positive on an unofficial CWD test and the test results have not yet been confirmed at NVSL, or an animal that has clinical signs of CWD.

Certified CWD Sample Collector: An individual who has completed appropriate training and is certified by a State to perform collection, submission, and preservation of samples for CWD testing.

Herd. One or more animals that are (1) under common ownership or supervision and are grouped on one or more parts of any single premises or (2) all animals under common ownership or supervision on two or more premises which are geographically separated but on which animals have been interchanged or had direct or indirect contact with one another.

Herd Inventory: A herd owner's written or electronic record of all the animals currently in the herd including each animal's species, date of birth, age, sex, date of acquisition, source and all individual identification numbers. A physical herd inventory is a process where a person physically counts the animals in the herd. A physical herd inventory may include inventory reconciliation where each animal and its identification numbers are examined and compared with current inventory records.

Official CWD test. Any test for the diagnosis of CWD approved by APHIS and conducted in a laboratory approved by APHIS in accordance with 9 CFR 55.8.

Owner: An individual, partnership, company, corporation, or other legal entity that has legal or rightful title to an animal or herd of animals.

Quarantine: An order issued by a State restricting movement of animals from or onto a premises to prevent the spread of disease or pests.

Trace back herd. A herd in which a CWD-positive animal formerly resided.

Trace forward herd. A herd that received exposed animals from a CWD-positive herd within 5 years prior to the diagnosis of CWD or from the identified date of entry of CWD into the positive herd.

Part A. Voluntary Herd Certification Program (HCP)

1. State Participation

Any state that operates a state program to certify the CWD status of cervid herds may request APHIS to designate the State program as an Approved State CWD Herd Certification Program. APHIS will approve or disapprove a state program in accordance with 9 CFR 55.23(a). An approved state must:

- (a) Have the authority to restrict the intrastate movement of all CWD-positive, CWD-suspect, and CWD-exposed animals.
- (b) Have the authority to require the prompt reporting of CWD test results and CWD-suspect animals.
- (c) Have a signed memorandum of understanding with APHIS that delineates the respective roles of the State and APHIS in CWD Herd Certification Program implementation.
- (d) Have placed all known CWD-positive, CWD-exposed, and CWD-suspect animals and herds under movement restrictions and allow movement of animals only under permit.
- (e) Conduct trace back investigations of CWD-positive animals and trace forward investigations of CWD-exposed animals and notify other states when appropriate.
- (f) Effectively enforce quarantines and laws and regulations for CWD.
- (g) Have designated an animal health official to coordinate CWD Herd Certification Program activities.
- (h) Have programs to educate those engaged in the interstate movement of cervids regarding requirements for animal identification and recordkeeping.
- (i) Require and enforce identification of animals in participating herds.
- (j) Maintain a database compatible with the CWD National Database and record information on premises, animals, and herd statuses.
- (k) Require CWD tests on all CWD-exposed and CWD-suspect animals that die and require proper disposal of all carcasses.

2. Herd Participation

Any owner of a farmed cervid herd may apply to enroll in the CWD Herd Certification Program by sending a written request to the appropriate state agency. Herd owners must agree to maintain their herds in accordance with the requirements specified in 9 CFR 55.23(b) and allow inspections by regulatory officials to verify that the herd meets these requirements. Herd owners who enroll in the CWD Herd Certification Program agree to maintain their herds in accordance with the following conditions:

- (a) Each animal in an enrolled herd must have at least two forms of identification (9 CFR 55.25). One must meet the requirements for official animal identification (9 CFR 55.1). The second must be unique for the individual animal within the herd. The means of identification may include electronic implant, flank tattoo, ear tattoo, tamper-resistant ear tag, or other means approved by APHIS. All animals in an enrolled herd must be identified before reaching 12 months of age or before leaving the herd, whichever occurs first. All animals in the herd, regardless of age, must be identified when a physical inventory is conducted that includes inventory reconciliation.
- (b) The herd premises must have perimeter fencing that meets state regulations and is adequate to prevent ingress or egress of cervids.
- (c) The owner must immediately report animals that escape or disappear, and all deaths (including

animals killed on premises maintained for hunting and animals sent to slaughter) of animals in the herd aged 12 months or older. For animals that die, the owner must make the carcasses of the animals available for tissue sampling and testing.

(d) The owner must maintain herd records that include a complete inventory of animals that states the species, age, and sex of each animal, the date of acquisition and source of each animal that was not born into the herd, the date of disposal and destination of any animal removed from the herd, and all individual identification numbers (from tags, tattoos, electronic implants, etc.) associated with each animal.

(e) If an owner wishes to maintain separate herds, there must be a buffer zone of at least 30 feet between the perimeter fencing around each herd and no commingling of animals may occur. Each herd must have its own inventory, working facilities, water sources and equipment.

3. Physical inventory

Upon request from a regulatory official, the owner must allow a regulatory official or a designated accredited veterinarian access to the premises and the herd to conduct a physical inventory. The inventory may consist of a review of herd records with visual examination of an enclosed group of animals or may include inventory reconciliation where each animal and its identification numbers are examined and compared with current inventory records. A physical inventory of a herd will not be requested more frequently than once per year, unless it is determined that a herd is not in compliance with CWD Herd Certification Program requirements. A physical inventory with inventory reconciliation must be performed on each enrolled herd at least once every 36 months.

The owner is responsible for assembling, handling, and restraining the animals and for all costs incurred to present the animals for inspection. When inventory reconciliation is required, the owner must present the entire herd for inspection under conditions where the designated official can safely read all identification on the animals.

4. Herd status

(a) Progression. When a herd is first enrolled in the CWD Herd Certification Program, it will be placed in First Year status. If the herd continues to meet the requirements of the CWD Herd Certification Program, each year, on the anniversary of the enrollment date the herd status will be upgraded by 1 year; i.e., Second Year status, Third Year status, Fourth Year status, and Fifth Year status. One year from the date a herd is placed in Fifth Year status, the herd status will be changed to Certified. The herd will remain in Certified status if it continued to meet the requirements of the program.

(b) Newly formed herds. If a newly formed herd is composed solely of animals obtained from herds already enrolled in the Program, the new herd will have the same program status as the lowest status of any herd that provided animals for the new herd. The enrollment date of the new herd will be the latest enrollment date for any of the source herds.

(c) Addition of animals. Animals may be added from herds with the same or a higher CWD program status with no negative impact on the herd certification status. If animals are added from or commingled with animals from a herd with a lower program status, the herd's status must be changed to the lower status.

(d) Semen and embryos. Additions of genetic material (germplasm) to a herd will not affect the herd's CWD status. There is currently no scientific evidence that CWD can be transmitted in germplasm.

(e) Cancellation. The CWD program status of a herd may be cancelled if the owner does not fully comply with program requirements for animal identification, animal testing, and recordkeeping. Following cancellation, the owner may apply to have the herd reinstated to the program at First Year status level with a new enrollment date. The owner of a herd that is cancelled due to noncompliance may apply to enroll a newly formed herd, but any such herd must start at First Year status regardless of the status of the animals from which the herd is composed.

5. CWD testing requirements

Animals in farmed cervid herds that are 12 months of age and over that die or are slaughtered must be tested for CWD with an official CWD test. Tissue samples must be collected by State or APHIS officials, accredited veterinarians, or certified CWD sample collectors. Alternatively, owners may remove and submit the entire head with all attached identification devices to an approved CWD laboratory for tissue collection.

Normal sanitary precautions should be used during sample collection. Gloves should be worn, but use of extensive personal protective equipment (PPE) is not required. Formalin (10 percent neutral buffered formalin) should be handled in a well-ventilated area. If rabies is suspected, samples should not be collected and state regulatory officials should be notified.

6. Missed CWD tests

A “missed test” occurs when a test-eligible animal is lost, dies or is slaughtered and is not successfully tested for CWD. There is no guidance in 9 CFR 55 or 81 on how to handle missed CWD tests. State regulatory officials are to develop state-specific protocols for responding to missed tests. When a missed test occurs, a state representative should conduct a CWD risk assessment of the herd and determine if the herd’s program status will be affected. Risk assessments should take into consideration the status level of the herd, the amount of surveillance testing that has been performed, the length of time the herd has met surveillance requirements, and the number of tests that have been missed.

One missed test should not result in a reduction or suspension of herd status if a herd has certified status and no other CWD tests were missed in the previous 24 months. Otherwise, each missed test should result in a reduction in herd status by one level unless additional animals are tested to supplement CWD surveillance in the herd.

To supplement CWD surveillance in a herd, four (4) additional animals may be tested using live-animal tests to make up for each test that is missed. The four animals to be tested should be of the same sex and species as the untested animal, should have been housed near the untested animal, and should have resided in the herd for approximately the same length of time. Live-animal tests should be allowed for supplemental testing of cervids using rectal biopsy, tonsil biopsy, medial retropharyngeal lymph node biopsy, or other tissue as approved by the state.

Exceptions for missed tests may be made if animals die from anthrax or from another disease where necropsy is contraindicated due to public health risks or if they are lost due to an act of vandalism or natural disaster such as a tornado or flood. An exception may also be granted when multiple animals die during an epidemic disease event. Such exceptions are to be made at the discretion of state regulatory officials.

7. Official CWD tests

(a) Official CWD tests. An official CWD test is one that meets the requirements in 9 CFR 55.8 and includes (1) histopathological examination of central nervous system (CNS) tissues from the animal for characteristic microscopic lesions of CWD using test protocols provided by the National Veterinary Services Laboratories (NVSL), (2) proteinase-resistant protein analysis methods including but not limited to immunohistochemistry (IHC) and/or western blotting on CNS and/or peripheral tissue samples from a live or a dead animal, using test protocols provided by NVSL, or (3) any other test method approved by APHIS.

(b) Postmortem tests. When animals are tested postmortem, collection and submission of both the obex and a medial retropharyngeal lymph node (MRPLN) is recommended. Submission of both tissue samples is not required but it may ensure that a definitive diagnosis can be made. Although submission of both samples is recommended, the value of testing each sample type individually must not be diminished or discounted. At this point in the CWD control program, it is time to use a broader variety of tests and recognize that tests do not have to be perfect to be valuable.

(c) Live-animal tests. It is time to incorporate and use live-animal tests whenever possible for whole-herd tests, statistical sample tests, and individual animal tests. Live-animal tests currently include the rectal biopsy (rectoanal-associated mucosa-associated lymphoid tissue (RAMALT)), the tonsil biopsy, and the MRPLN biopsy.

(d) Rejection of samples. Samples may be unsuitable for CWD testing if the wrong tissue is submitted, an insufficient amount of tissue is submitted, or the samples are severely autolyzed. If a brain stem sample is submitted and the obex is not visually apparent on histopathology, every attempt should be made to recut the sample to validate the test. When a brain stem sample is submitted and the dorsal motor vagus nucleus cannot be demonstrated on histopathology, a location issue (LOC) should be noted, but test results should still be reported. When lymph nodes or rectal biopsy samples are submitted that contain fewer than six lymphoid follicles, an insufficient follicle issue (ISF) should be noted, but test results should still be reported.

It is recommended that a piece of fresh (not in formalin) tissue attached to an official animal identification device be submitted with each sample that is submitted for CWD testing. When removal of a piece of the ear is problematic, a new identification tag may be affixed to the hide skin and submitted with the specimens. This practice allows APHIS to perform DNA comparison testing and genotyping if an animal tests positive for CWD. Failure to submit an identification device is not a reason to reject a sample.

(e) Sensitivity and specificity. It is imperative that we know the sensitivity and specificity of each type of CWD test so that regulatory officials and producers can choose the appropriate testing method. The sensitivity and specificity for each type of CWD test is listed in the following table. (Values for sensitivity and specificity are to be added to the table by APHIS and the appropriate research scientists.)

Sensitivity and Specificity of CWD Tests

Test Type	Animal Type	Sensitivity	Specificity
Western blot – obex or MRPLN	all cervids		
IHC – obex	all cervids		
IHC – MRPLN	all cervids		
IHC – obex and MRPLN	all cervids		
IHC – RAMALT biopsy	elk		
IHC – RAMALT biopsy	white-tailed deer		
IHC – RAMALT biopsy	white-tailed deer Genotype codon 96		
ELISA (Bio-Rad) – obex	all cervids		
ELISA (Bio-Rad) – MRPLN	all cervids		

8. Interstate movement

(a) Deer, elk, or moose moved interstate must meet the requirements in 9 CFR 81, be accompanied by a certificate of veterinary inspection, and meet the import requirements of the receiving state.

(b) Farmed deer, elk or moose moved interstate must originate from a herd with certified status or move directly to a recognized slaughtering establishment. Federal regulations (9 CFR 81) do not restrict interstate movement of cervids based on the location of the herd of origin. Movement is not restricted from CWD-endemic areas, nor is it restricted based on proximity to CWD cases in farmed or wild cervids. With CWD now endemic in 29 states, state regulators should be encouraged to allow importation of

animals from CWD-certified herds regardless of proximity to CWD cases in farmed or wild deer.

(c) Wild deer, elk, or moose captured in one state for release in another must originate from a source population that is documented to be low risk for CWD based on a CWD surveillance program that is approved by the receiving state and by APHIS.

(d) Notwithstanding any provision in this part, interstate movement of farmed or wild deer, elk, and moose may be allowed under permit on a case-by-case basis when the receiving state and APHIS determine that adequate survey and mitigation procedures are in place to prevent dissemination of CWD. Under this provision, interstate movement of animals that originate from CWD-exposed herds, CWD-positive herds, or herds with less than certified status could be allowed, especially if animals move to destinations where CWD is already endemic.

Part B. Guidance on Responding to Cases of CWD

States that participate in the voluntary CWD herd certification program are required to place all known CWD-positive, CWD-exposed, and CWD-suspect animals and herds under movement restrictions and allow movement of animals from such herds only under permit (9 CFR 55.23). Movement of animals from CWD-positive or CWD-exposed herds is not prohibited. It is only to be restricted as determined by the affected state and allowed only under a state issued permit.

Participating states are required to conduct trace back investigations of CWD-positive animals and trace forward investigations of CWD-exposed animals from CWD-positive herds. They are required to notify other states that may have received trace animals. They are required to have the authority to effectively enforce quarantines.

CWD is now endemic in 29 states and will continue to spread in wild deer and elk populations regardless of how cases of CWD in farmed deer and elk herds are handled. It is time to change the response to cases of CWD in farmed herds. Live-animal tests should be used whenever possible. Movement of animals from herds that are not infected with CWD should not be restricted. New methods to clean up CWD-positive herds other than depopulation should be used. Movement of animals from CWD-positive herds to areas where CWD is already endemic in wild deer should be considered. Deer and elk farmers should not be put out of business unnecessarily. Creative new ways should be developed control CWD.

1. CWD Case Investigations

CWD case investigations are conducted under state authority. The purpose of a CWD case investigation is to identify CWD-exposed animals and place movement restrictions on them until it is determined if such animals are infected with CWD. During an investigation, the following guidelines should be followed.

(a) CWD-positive herd. All animals in a CWD-positive herd are considered CWD-exposed animals. It is imperative that such animals be tested using live-animal tests as quickly as possible to determine their CWD status and remove CWD-positive animals from the herd. Rapid identification of additional CWD-positive animals will also help to identify additional trace back herds.

(b) Trace forward herds. Trace forward herds are those that have received animals from a CWD-positive herd within 5 years prior to the positive diagnosis or from the identified date of entry of CWD into the herd. Animals received from a positive herd are considered CWD-exposed animals. The most probable date of entry of CWD into the positive herd may be less than five years, especially in cases where a CWD certified herd with a good surveillance history becomes infected or the positive animal is less than five years of age. In such cases, only animals that left the positive herd after the probable date of infection should be designated as CWD-exposed animals. It is imperative that such animals be tested using live-animal tests as quickly as possible to determine their CWD status and remove restrictions on the trace forward herd. It is not necessary to euthanize these animals to determine CWD status.

(c) Trace back herds. A trace back herd is one where a CWD-positive animal resided within five years prior to that animal's positive diagnosis. All animals in a trace back herd are considered CWD-exposed

animals. It is imperative that such herds be tested using live-animal tests as quickly as possible to determine the CWD status of the herd. It is not necessary to euthanize the animals in these herds to determine CWD status. It is not appropriate to trace animals forward from a trace back herd unless a CWD-positive animal was very recently (within the previous six months) in the herd.

2. Herd plans

A herd plan is not a quarantine. States are required to effectively monitor and enforce quarantines (9 CFR 55.23), but the authority to issue and administer quarantines belongs exclusively to the states.

A herd plan is required under two very specific circumstances. A herd plan is required as part of an agreement to depopulate a herd when federal indemnity is to be paid (9 CFR 55.7). A herd plan is also required to reinstate a herd's certification status when it is designated as CWD-positive or CWD-exposed (9 CFR 55.22) or when its status is lost or suspended (9 CFR 55.24).

A herd plan is written agreement developed to control the spread of CWD from a CWD-positive herd or to determine the CWD status of a trace back or a trace forward herd. A valid herd plan must be signed by APHIS, a state representative, and the herd owner. A herd plan may include specific requirements for movement of animals, CWD testing animals (using live-animal or postmortem tests), selective culling of animals, or depopulation of the herd.

A herd plan for a CWD-positive herd that is depopulated may also include requirements for (1) placement of animals back on the premises, (2) maintenance of fencing, (3) sharing and moving equipment, and (4) premises cleaning and disinfection.

3. Herd Cleanup

Participating states may consider releasing CWD quarantines by any of the following methods. Live-animal tests should be used in all cases except for depopulation.

- (a) Test exposed animals. The quarantine on a trace forward herd must be released immediately if all exposed animals in the herd are tested and CWD is not detected. The quarantine on a trace back herd must be released immediately following a whole-herd test if CWD is not detected.
- (b) Test and removal. Whole-herd tests may be conducted on CWD-positive herds every 12 months and CWD-positive animals may be removed from the herd. The quarantine on a CWD-positive herd must be released immediately following two consecutive annual whole-herd tests if no CWD is detected.
- (c) Test for 60 months. If all animals 12 months of age or older that die or are slaughtered are tested with an official CWD test for a period of 60 months following the last possible exposure and CWD is not detected, the quarantine must be released.
- (d) Depopulation. Depopulation of a herd should be used as a last resort. To release a quarantine by depopulation, all cervids in the herd must be euthanized and tested with an official CWD test. Quarantines on CWD-exposed herds must be released immediately following depopulation if no CWD-positive animals are identified. Quarantines on CWD-positive herds must be released 60 months following depopulation and cleaning and disinfection.
- (e) Other procedures. Quarantines may be released by other methods approved by state authorities.

5. Carcass disposal

Unless prohibited by state laws, cervid carcasses may be burned, buried, digested by alkaline hydrolysis or disposed of at approved landfills. The prions that cause CWD are not a danger to human health or to animals other than cervids. Prions that cause CWD are like the prions that cause scrapie in sheep and are not a danger to the environment. CWD prions are currently widespread in the environment of at least 29 states. As CWD continues to spread in wildlife populations, the distribution of CWD in the environment will continue to expand.