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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 55 and 81

[Docket No. 00-108-8]

RIN 0579-AB35

Chronic Wasting Disease Herd Certification Program and Interstate Movement of Farmed or Captive Deer, Elk, and Moose

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim final rule and request for comments.

SUMMARY: We are amending a final rule, which will take effect when these amendments become effective, that will establish a herd certification program to control chronic wasting disease (CWD) in farmed or captive cervids in the United States. Under that rule, owners of deer, elk, and moose herds who choose to participate in the CWD Herd Certification Program would have to follow requirements for animal identification, testing, herd management, and movement of animals into and from herds. This document amends that final rule to provide that our regulations will set minimum requirements for the interstate movement of farmed or captive deer, elk, and moose but will not preempt State or local laws or regulations that are more restrictive than our regulations. This document requests public comment on that change. This document also amends the final rule to require farmed or captive deer, elk, and moose to participate in the Herd Certification Program and to be monitored for CWD for 5 years before they can move interstate, clarify our herd inventory procedures, establish an optional protocol for

confirmatory DNA testing of CWD-positive samples, add a requirement to continue testing cervids that are killed or sent to slaughter from Certified herds, and make several other changes. These actions will help to control the incidence of CWD in farmed or captive cervid herds and prevent its spread.

**DATES:** Effective Date: This interim final rule is effective August 12, 2012. Additionally, the effective date of FR Doc 06-6367, published on July 21, 2006 (71 FR 41682-41707), and delayed by FR Doc E6-14861, published on September 8, 2006 (71 FR 52983), is now August 12, 2012.

Compliance Date: The date for complying with 9 CFR part 81 is delayed until December 10, 2012. The compliance date for 9 CFR part 55 is August 12, 2012.

Comment Date: We will consider all comments on the subject of preemption of State and local laws and regulations regarding chronic wasting disease that we receive on or before July 13, 2012. We will consider comments we receive during the comment period for this interim final rule. After the comment period closes, we will publish another document in the Federal Register. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

**ADDRESSES:** You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2006-0118-0199>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. 00-108-8, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2006-0118> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Patrice Klein, Senior Staff Veterinarian, National Center for Animal Health Programs, Veterinary Services, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1231; (301) 851-3435.

#### SUPPLEMENTARY INFORMATION:

##### Comment Subject Area

This interim final rule with request for comments discusses our decision not to preempt State and local laws and regulations that are more restrictive than our regulations with respect to chronic wasting disease, except to allow transit of deer, elk, and moose that are otherwise eligible for interstate movement through States with more restrictive laws and regulations, in section III of the Background section under the heading "APHIS' Decision Not to Preempt More Restrictive State Requirements on Farmed or Captive Cervids With Respect to CWD." We will consider all comments that we receive on this subject that are received by the date and time indicated in the DATES section of this interim final rule with request for comments.

## Background

### I. Purpose of the Regulatory Action

#### a. Need for the Regulatory Action

Chronic wasting disease (CWD) is a transmissible spongiform encephalopathy (TSE) of cervids (members of Cervidae, the deer family) that, as of May 2011, has been found only in wild and captive animals in North America and in captive animals in the Republic of Korea. First recognized as a clinical “wasting” syndrome in 1967, the disease is typified by chronic weight loss leading to death. Species currently known to be susceptible to CWD via natural routes of transmission include Rocky Mountain elk, mule deer, white-tailed deer, black-tailed deer, sika deer, and moose.

In the United States, as of March 2012, CWD has been confirmed in wild deer and elk in 16 States and in 39 farmed elk herds and 15 farmed or captive white-tailed deer herds in 11 States. The disease was first detected in U.S. farmed elk in 1997. It was also diagnosed in a wild moose in Colorado in 2005.

The presence of CWD in cervids causes significant economic and market losses to U.S. producers. Canada prohibits the importation of elk from Colorado and Wyoming and now requires that other cervids be accompanied by a certificate stating that CWD has not been diagnosed in the herd of origin. The Republic of Korea has suspended the importation of deer and elk and their products from the United States and Canada. The domestic prices for elk and deer have also been severely affected by fear of CWD.

To help producers avoid the losses caused by CWD infection and risk, we determined that it was necessary to establish a program that would actively identify herds infected with

CWD and allow producers to manage these herds in a way that will prevent further spread of CWD. Specifically, on July 21, 2006, we published a final rule in the Federal Register (71 FR 41682-41707, Docket No. 00-108-3; “the July 2006 final rule”) that established the Chronic Wasting Disease Herd Certification Program in 9 CFR subchapter B, part 55. (That part had previously contained only regulations related to the payment of indemnity to the owners of CWD-positive captive herds who voluntarily depopulate their herds.)

Under the July 2006 final rule, owners of deer, elk, and moose herds who choose to participate would have to follow the program requirements of a cooperative State-Federal program for animal identification, testing, herd management, and movement of animals into and from herds. The July 2006 final rule also amended 9 CFR subchapter C by establishing a new part 81 containing interstate movement requirements designed to prevent the spread of CWD through the movement of farmed or captive deer, elk, or moose.

After publication of the July 2006 final rule, but before its effective date, APHIS received three petitions requesting reconsideration of several requirements of the rule. On September 8, 2006, we published a notice in the Federal Register (71 FR 52983, Docket No. 00-108-4) that delayed the effective date of the CWD final rule while APHIS considered those petitions. On November 3, 2006, we published another notice in the Federal Register (71 FR 64650-64651, Docket No. 00-108-5) that described the nature of the petitions and made the petitions available for public review and comment, with a comment period closing date of December 4, 2006. We subsequently extended that comment period until January 3, 2007, in a Federal Register notice published on November 21, 2006 (71 FR 67313, Docket No. 00-108-6).

We received 77 comments by that date. They were from cervid producer associations, individual cervid producers, State animal health agencies, State wildlife agencies, and others. We carefully considered the petitions and the public comments received in response to them.

On March 31, 2009, we published in the Federal Register (74 FR 14495-14506, Docket No. 00-108-7; "the March 2009 proposed rule") a proposal<sup>1</sup> to amend the July 2006 final rule. We proposed to amend the July 2006 final rule by recognizing State bans on the entry of farmed or captive cervids for reasons unrelated to CWD, increasing to 5 the number of years an animal must be monitored for CWD before it may be moved interstate; restricting the interstate movement of cervids that originated from herds in proximity to a CWD outbreak; changing herd inventory procedures; prohibiting the addition of animals to CWD-positive, -suspect, and -exposed herds; requiring States to conduct wildlife surveillance for CWD as part of their Approved State CWD Herd Certification Programs; providing for optional confirmatory DNA testing of CWD-positive samples; and making several other changes.

This final rule sets an effective date for the July 2006 final rule and makes changes to it based on the March 2009 proposal and on the comments we received on that proposal.

#### b. Legal Authority for the Regulatory Action

Under the Animal Health Protection Act (AHPA, 7 U.S.C. 8301 et seq.), the Secretary of Agriculture has the authority to issue orders and promulgate regulations to prevent the introduction into the United States and the dissemination within the United States of any pest or disease of livestock. The Animal and Plant Health Inspection Service's (APHIS') regulations in 9 CFR subchapter B govern cooperative programs to control and eradicate communicable

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<sup>1</sup> To view the proposed rule and the comments we received, go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2006-0118>.

diseases of livestock. The regulations in 9 CFR subchapter C establish requirements for the interstate movement of livestock to prevent the dissemination of diseases of livestock within the United States.

## II. Summary of the Major Provisions of the Regulatory Action

The CWD Herd Certification Program is a cooperative effort between APHIS, State animal health and wildlife agencies, and deer, elk, and moose owners. APHIS coordinates with these State agencies to encourage deer, elk, and moose owners to certify their herds as low risk for CWD by being in continuous compliance with the CWD Herd Certification Program standards.

Under subchapter B of part 55, States that participate in the CWD Herd Certification Program must establish State programs that are approved by APHIS. We will approve such programs if the State:

- Establishes movement restrictions on CWD-positive, CWD-suspect, and CWD-exposed animals, to prevent the spread of the disease, and requires testing of such animals.
- Conducts traceback on such animals, to determine what other animals may be affected.
- Requires testing of all animals that die or are killed. As we do not have live-animal tests for CWD, it is important to sample and test carcasses whenever possible to accurately evaluate the CWD risk in a herd.
- Maintain premises and animal identification for all herds participating in the CWD Herd Certification Program in the State. This is an integral part of being able to conduct traceback.

Herd owners will be approved to participate under State CWD Herd Certification

Programs if they:

- Identify each animal in their herds through approved means of identification and maintain a complete inventory of the herd. These requirements are also integral to conducting traceback. Upon request by APHIS or the State, owners must also allow officials to conduct a herd inventory to verify the records.
- Add to their herds only animals that are from herds enrolled in the CWD Herd Certification Program, to ensure that animals added to herds are of known risk.
- Maintain perimeter fencing adequate to prevent ingress or egress of cervids, to prevent CWD from being spread through contact with wild cervids.
- Report to APHIS or the State all animals that escape or disappear, and report to APHIS or the State all animals that die or are killed and make their carcasses available for tissue sampling and testing.

Herds are given a status based on the date they enrolled in the program. Herds that do not have any CWD-infected or CWD-exposed animals for 5 years will be granted Certified status. (Herd owners who participate in State CWD Herd Certification Programs that are approved by APHIS will be credited for the time they have participated in such a program towards the 5-year requirement.) Based on current science, 5 years of surveillance is a reasonable time period to determine whether the disease is present in the herd, as CWD has an incubation period. Thus, the movement of animals from a Certified herd poses a low risk of spreading CWD.

The movement restrictions in 9 CFR part 81 therefore allow deer, elk, and moose from Certified herds to move interstate. They also allow the interstate movement of wild animals captured for interstate movement or release, if identified with two forms of animal identification, including one official identification, and if the source population has been documented to be low risk for CWD based on a surveillance program. The part also allows the interstate movement of animals moved for slaughter; research animals; and other animals on a case-by-case basis. Finally, this part includes provisions under which deer, elk, or moose that are eligible to move interstate may transit a State that bans or restricts the entry of such animals en route to another State.

A detailed discussion of the provisions of 9 CFR part 55, subchapter B, and 9 CFR part 81 is available in the July 2006 final rule. This document concentrates on the changes we are making to the July 2006 final rule subsequent to the March 2009 proposed rule and in response to comments. The major changes we are making are:

- The March 2009 proposal indicated that the goal of the CWD program was to eliminate the disease in farmed or captive cervids. We have now determined that our goal is to control the spread of the disease. The persistence of CWD in wild cervid populations and our current lack of knowledge about the transmission of CWD have made the goal of eliminating CWD from farmed or captive cervids impractical.
- Our CWD regulations will set minimum standards for State CWD Herd Certification Programs and for the interstate movement of cervids. The March 2009 proposal indicated that we would preempt State and local laws and regulations that were more restrictive as well. However, we have since decided that our regulations will not preempt

State and local laws and regulations that are more stringent than our regulations, except that (as noted earlier) cervids that are eligible to move interstate may transit a State that bans or restricts the entry of such animals en route to another State. We are soliciting public comment on this decision, as described below under the heading "APHIS' Decision Not to Preempt More Restrictive State Requirements on Farmed or Captive Cervids With Respect to CWD."

- The March 2009 proposed rule included some proposed provisions designed to give States options to regulate CWD within the context of Federal preemption of State and local laws and regulations, such as allowing States to prohibit entry of cervids for reasons unrelated to CWD and because of proximity to findings of CWD in wildlife. We are not including those provisions in this final rule because they are no longer necessary given our decision on preemption.
- Because our goal is now to control the spread of CWD rather than to eliminate it, we are not requiring States to conduct surveillance for CWD in wild cervid populations or requiring States to prohibit the addition of animals to herds containing CWD-positive, CWD-exposed, or CWD-suspect animals.
- Based on comments on the March 2009 proposed rule, we are removing an exemption in the July 2006 final rule under which Certified herds were not required to make animals that were sent for slaughter or killed on shooter operations available for testing.

We are also making several minor changes to improve the clarity of the changes we proposed and of the regulations.

### III. Discussion of Comments

We solicited comments concerning the March 2009 proposal for 60 days ending July 1, 2009. We received 78 comments by that date. They were from producers, researchers, and representatives of State governments. They are discussed below by topic.

#### General Opposition to the CWD Herd Certification Program

Several commenters recommended that we withdraw the July 2006 final rule, rather than making changes to it as described in the proposal and issuing a revised final rule. These commenters stated that designing a Federal program for control of CWD in captive cervids is about a decade too late to be useful. The commenters doubted that, at this point in time, the Federal program as described would materially improve CWD control beyond what has already been achieved by the collective coordinated efforts of State animal health and wildlife management agencies. Rather, the commenters stated, options for providing Federal assistance to States would be most beneficial and efficient. Commenters also stated that, under this approach, many of the key elements of the Federal CWD Herd Certification Program could still be provided by APHIS to the States as guidance for establishing or refining their respective CWD control programs.

We have determined that a voluntary Federal CWD program is necessary to give States from which farmed or captive cervids are moved interstate and herd owners who move farmed or captive cervids interstate the opportunity to demonstrate that they meet minimum standards for CWD management. These minimum standards are necessary for an effective CWD program. Guidelines for a CWD program, rather than mandatory requirements, would not be sufficient to ensure that the CWD program is effective.

Accordingly, this final rule announces our intention to amend the July 2006 final rule and set an effective date for the amended final rule of August 12, 2012. The regulatory text at the end of this document includes the complete text of the July 2006 final rule, as amended by this final rule. The changes to the July 2006 final rule are described in the March 2009 proposed rule and the Background section of this document.

We agree with the commenters that circumstances relevant to a Federal CWD program have changed over time, necessitating a change in the objective of the CWD program. In the July 2006 final rule and the March 2009 proposed rule, as well as all our previous CWD-related rules, the stated objective of the CWD program was the elimination of CWD from captive and farmed cervids in the United States. We have now concluded, however, that our CWD objective should be to establish a herd certification program for herd owners and States to control the incidence of CWD in farmed and captive cervids and prevent the interstate spread of CWD. We have concluded that elimination of CWD from farmed and captive cervids is not practical given the persistence of CWD in wild cervid populations and our current lack of knowledge about how CWD may be transmitted between wild cervid populations and farmed and captive cervids. The CWD Herd Certification Program will allow States and herd owners to monitor herds of farmed and captive cervids to ensure that they are at low risk for CWD, and our regulations in part 81 will allow only farmed or captive deer, elk, and moose from herds that have reached Certified status in the CWD Herd Certification Program, after 5 years of monitoring, to be moved interstate, with limited exceptions.

A few commenters stated that the position that a Federal CWD program is unnecessary is in keeping with APHIS' overall intent to phase out regulatory efforts for "program diseases" in the coming decade.

We assume the commenters are referring to our plans for the strategic future of APHIS' Veterinary Services (VS) program,<sup>2</sup> in which we have stated that VS will increase its focus on disease prevention, preparedness, detection, and early response. Our plans also acknowledge that several major disease control and eradication programs are either complete or nearing completion. However, we do not contemplate APHIS phasing out administration of the disease control and eradication programs to which the commenters referred, but rather redirecting resources as necessary to accomplish new objectives based on new circumstances. We will continue to administer disease control and eradication programs, including the CWD Herd Certification Program.

One commenter stated that the proposed rule will fail to adequately control CWD in farmed or captive cervids in the United States. The commenter cited increases in positive tests of farmed and captive cervids for CWD and additional States in which CWD has been found in captive herds since December 2003, when the initial proposed rule to establish the CWD Herd Certification Program was published. The commenter stated that, if the goal of the CWD Herd Certification Program is to eliminate CWD from captive cervid herds, stricter controls must be in place to prevent further spread of the disease. For example, the commenter stated, it is possible for a captive cervid facility to earn Certified status, thus allowing animals from the herd to be moved interstate, without testing a single animal for CWD.

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<sup>2</sup> For more information on this plan, see [http://www.aphis.usda.gov/about\\_aphis/programs\\_offices/veterinary\\_services/vision\\_science.shtml](http://www.aphis.usda.gov/about_aphis/programs_offices/veterinary_services/vision_science.shtml).

The suspension of the effective date of the July 2006 final rule means that States and herd owners have not been required to comply with its provisions. The CWD Herd Certification Program we are establishing imposes new controls on the interstate movement of deer, elk, and moose. The requirements for interstate movement and herd certification in the July 2006 final rule, with the modifications discussed in the March 2009 proposal and in this document, will help prevent the spread of CWD.

With respect to the commenter's specific concern regarding the July 2006 final rule, § 55.23(b)(3) requires herd owners to inform an APHIS or State representative regarding all animals that die (including animals killed on premises maintained for hunting and animals sent to slaughter) and to make the carcasses of the animals available for tissue sampling and testing in accordance with instructions from the APHIS or State representative. We expect that we will test all samples that will be provided to us. If a herd had no mortality for 5 years, which is unlikely, it could reach Certified status without having animals tested. However, given our current knowledge about the biology of CWD, there is a low risk that CWD will be present in a herd after 5 years of monitoring with no mortality. In addition, continued surveillance will be required for any Certified herd to retain its Certified status.

#### APHIS' Decision Not to Preempt More Restrictive State Requirements on Farmed or Captive Cervids With Respect to CWD

In the Background section of the July 2006 final rule, under the heading "Executive Order 12988," we stated that the July 2006 final rule preempted all State and local laws and regulations that were in conflict with it. Our intent was to establish uniform requirements that would apply to the interstate movement of farmed or captive cervids to each of the States.

The petitions we received and made available with the November 2006 notice indicated strong opposition to Federal preemption of State restrictions on farmed and captive cervids with respect to CWD. We considered the petitions, and the comments on the petitions, in developing the proposed rule we published in the Federal Register on March 31, 2009. We also received several comments on the March 2009 proposal addressing whether the Federal CWD requirements should preempt inconsistent State requirements.

As discussed earlier, we have now concluded that our objective with respect to CWD should be to establish a herd certification program for herd owners and States to control the incidence of CWD in farmed and captive cervids and prevent the interstate spread of CWD, as elimination of CWD from farmed and captive cervids is not practical. Accordingly, these CWD regulations will set mandatory minimum requirements for interstate movement of farmed or captive cervids with respect to CWD; they will not preempt State and local laws and regulations on CWD in farmed or captive cervids when those laws and regulations are more restrictive than the Federal regulations. (The only exception is with respect to the movement of farmed or captive cervids through a State, as discussed later in this document.)

This approach will ensure that there are minimum requirements applicable to the interstate movement of farmed or captive cervids, while also allowing State and local laws, regulations, and policies to impose additional requirements on farmed or captive cervids as necessary to address local needs. We believe this approach is appropriate for CWD, where we have limited methods for diagnosing the disease and preventing its spread and where the goal of the program is to control, rather than eradicate, the disease.

Several commenters focused on the issue of State wildlife management authority. These commenters stated that States must retain authority to regulate and manage wildlife resources more stringently if they feel that risks are not adequately mitigated by the Federal program. The commenters specifically cited banning movement of captive cervids into a State for any reason, including risks related to CWD.

The CWD Herd Certification Program seeks to control CWD in farmed or captive cervids. We are not imposing requirements on States with respect to management of wild cervid populations, except when those populations could pose a disease risk to farmed or captive cervids, such as the translocation of wild cervids from wild populations that have not been assessed for CWD. As long as they do not affect farmed or captive cervids, State and local laws and regulations related to management of wild cervid populations are not affected by the CWD regulations. The only provision of the July 2006 final rule that relates to wild cervids is a requirement that animals captured from wild populations for interstate movement and release be accompanied by a certificate documenting the source population to be low risk for CWD, based on a CWD surveillance program that is approved by the State government of the receiving State and by APHIS. This requirement is directly related to and necessary for preventing the introduction of CWD into farmed or captive cervid populations, although it provides some protection for wild cervid populations as well.

(NOTE: The July 2006 final rule contained requirements in § 81.3(b) for interstate movement of captive cervids that were captured from free-ranging populations. In this final rule, we are changing the description of these populations to "wild populations," as farmed or captive cervids may range freely on their premises without being considered "free-ranging" for the

purposes of the regulations. We are also replacing references to "free-ranging" in the definitions of farmed or captive in §§ 55.1 and 81.1 with references to "wild," changing the order of the wording in the phrase "captured for interstate movement and release from a wild population" in § 81.3(b) to "captured from a wild population for interstate movement and release," and clarifying § 81.3(b) to indicate that it requires a CWD surveillance program for wild cervid populations in order to allow the interstate movement of cervids captured from wild populations. These changes are intended to improve the clarity of the regulations. Discussions of wild cervid populations in the remainder of the Background section of this rule reflect this change.)

Several commenters also expressed concern regarding classifying farmed or captive cervids as livestock. These commenters noted that APHIS' authority to prevent, control, or eradicate diseases, pursuant to the AHPA, specifically refers to livestock. These commenters pointed out that the legal definition of livestock is highly variable among States; many States do not define captive native species as "livestock," since livestock is not always within the sole jurisdiction of their fish and wildlife agencies. Thus, the commenters stated, in some instances captive cervids of native species may not fall within the Federal definition of livestock. The commenters recommended removing the references to livestock in the regulations or yielding to a State's definition when referring to cervids in this way.

We appreciate the commenters' concerns. Clearly, farmed and captive cervids are not traditional livestock; they are often referred to as alternative livestock. We understand that State fish and wildlife agencies in many States are responsible for the management of all cervids within their State, not just those that are wild but also those held on farms or in other captive

situations. Nonetheless, these agencies may not have experience working within the context of a program designed to control an animal disease in farmed or captive animal populations.

The AHPA charges the U.S. Department of Agriculture with the responsibility of controlling or eradicating any pest or disease of livestock, and defines "livestock" broadly as "all farm-raised animals." This means that all farmed or captive cervids fall under the AHPA definition of livestock. Under this authority, we have determined that it is appropriate to establish requirements for the interstate movement of farmed or captive cervids to help prevent the spread of CWD. To the extent that State fish and wildlife agencies are responsible for farmed or captive cervids in their States, they will need to cooperate with APHIS in the administration of the CWD regulations. We will work with State fish and wildlife agencies to help them to understand their responsibilities and to ensure that we can cooperate well. It is important to reiterate that States retain the authority to manage fish and wildlife populations, including wild cervids, under this final rule.

Several commenters urged the adoption of regulations that would preempt State and local laws and regulations on farmed or captive cervids with respect to CWD. Commenters noted that the movement of farmed and captive deer and elk has been extremely difficult because of a variety of different rules at the State level, with some States banning the movement of farmed or captive deer and elk into or through their States altogether.

We understand the commenters' concerns with regard to facilitating the interstate movement of farmed and captive cervids. For the reasons set forth below, however, we have decided that our CWD regulations will not preempt State and local laws and regulations that are more restrictive than our regulations.

First, while the herd certification program and the requirements for interstate movement of farmed and captive cervids in the July 2006 final rule, as amended by this document, are supported by the best available science, we recognize that the methods for mitigating the disease are evolving; our current methods are limited by the current state of scientific knowledge. As such, it is not possible to create a uniform set of proven mitigations for CWD. We have determined that, in such circumstances, States should be able to implement more restrictive laws and regulations if they determine such laws and regulations to be appropriate.

For example, one commenter stated that States should be able to impose more restrictive requirements or prohibitions on the interstate movement of farmed or captive cervids because there is currently no practical live-animal test validated for white-tailed deer, in contrast to other diseases mentioned in the March 2009 proposed rule, such as tuberculosis and brucellosis. The lack of a live-animal test creates uncertainty about the disease-free status of herds, or animals moved interstate from herds.

We agree the lack of a live-animal test for CWD creates uncertainty. Our approach to establishing a greater degree of certainty involves monitoring all herds enrolled in the CWD Herd Certification Program for at least 5 years before allowing animals from those herds to move interstate. This approach uses surveillance over time to increase the certainty that animals from a herd are low risk; 5 years of testing all cervids that die in a herd without finding a CWD-positive animal provides substantial assurance that CWD is not present in the herd. However, surveillance in the CWD Herd Certification Program does not provide the same level of certainty with respect to the disease status of an individual animal that a live-animal test could provide.

Allowing States to impose more restrictive requirements than our requirements acknowledges that this uncertainty exists.

Another commenter stated that the industry in the commenter's State considers that State's CWD program to be a benchmark after which other States' programs could be modeled. The commenter stated that industry recognizes that a Federal rule is needed for interstate movement of registered animals, but expressed concern that not allowing the State to impose stricter requirements in some situations might not be appropriate.

We agree that States can serve as laboratories for different regulatory approaches. In the uncertain scientific environment surrounding CWD, we welcome any additional evidence we can gather about the effectiveness of regulatory approaches. Our decision to allow States to impose requirements that are more restrictive than our regulations will allow States to create and experiment with regulatory programs.

The other reason to allow States to develop and enforce laws and regulations that are more restrictive than our regulations is, as we noted above, inherent in the fact that our program objective has changed to reflect changes in conditions. When the objective of a program is to eliminate a disease, we impose requirements that are sufficient to achieve that objective, based on the best available science. If a State were to impose requirements that are more restrictive than our requirements in such a case, the additional State requirements would impede interstate commerce without advancing the objective of the program.

However, the objective of our regulations is now to assist in controlling CWD in farmed and captive cervids, rather than eliminating CWD in farmed and captive cervids. Eliminating CWD from farmed and captive cervids is not practical given the persistence of CWD in wild

cervid populations and our current lack of knowledge about how CWD may be transmitted between wild cervid populations and farmed and captive cervids. Other gaps in our scientific knowledge we have about CWD also impair our ability to achieve eradication, including the lack of certainty regarding the disease status of individual live animals, the lack of knowledge regarding how the disease is transmitted between wild and farmed or captive cervid populations, and our lack of knowledge regarding effective cleaning and disinfection measures for premises on which CWD has been found. (For example, we do not know any cleaning and disinfection measures that allow us to effectively address the persistence of CWD in substrates.)

For these reasons, the CWD Herd Certification Program and our interstate movement restrictions are designed to prevent the spread of CWD, rather than to eliminate it. Allowing States to establish more restrictive laws and regulations on farmed and captive cervids recognizes that States may want to establish a higher level of protection against the disease than the Federal program is designed to provide.

In this final rule, we are also establishing provisions for the interstate transportation of farmed or captive cervids through States in response to comments. These provisions will preempt State and local laws and regulations in addition to or different than the requirements set forth in this final rule. These provisions allow owners of farmed or captive cervids (including animals captured from wild populations for interstate movement and release) to move those cervids, without unloading and while en route to another State, through States that prohibit or restrict the entry of farmed or captive cervids into their State.

Specifically, 15 commenters asked us to address the issue of State bans or restrictions on the interstate movement of farmed or captive cervids through a State to another State of

destination. The commenters stated that States should not have the right to ban interstate movement through a State to another State when the farmed or captive cervids being moved meet the entry requirements of the destination State. Ten of the commenters specifically recommended defining "entry" and "import" as being received into a specific State and excluding from State regulation any movement through States that are not receiving farmed or captive cervids.

We agree with these commenters that the regulations should provide for movement through a State, even if the State bans movement of farmed or captive cervids into the State. While, as noted, our scientific knowledge about CWD is limited, the scientific knowledge we have suggests that CWD is not highly infectious. In general, the movement of animals through a State without unloading poses a low risk of spreading CWD, and the regulations in part 81 ensure that the animals moved interstate will themselves present a low risk of being infected with CWD.

Not providing for movement through States that ban or further restrict the entry of farmed or captive deer, elk, or moose would also raise several issues. The rerouting required to avoid such States may make transportation of farmed or captive cervids economically unfeasible. Even if such transportation is economically feasible, the additional time necessary to traverse a lengthy route may raise animal health or welfare issues for the cervids being transported; the cervids would need regular water, feed, and rest, as required for all livestock under the Twenty-Eight Hour Law (49 U.S.C. 80502). Captive cervids that needed to be offloaded for such purposes would not be easy to confine and to reload onto a conveyance. Given the low risk associated with this type of movement, we have determined that it is appropriate to provide for the

movement of farmed or captive cervids through States and localities whose laws or regulations on the movement of captive cervids are more restrictive than the regulations in part 81.

In this final rule, a new § 81.6 indicates that State and local laws and regulations that are more restrictive than the regulations in part 81 are not preempted by part 81, except for the regulations regarding interstate movement through a State to another State in § 81.5.

Section 81.5 sets out the following provisions for farmed or captive deer, elk, or moose to move through a State or locality whose laws or regulations are more restrictive than those in part 81 to another State:

- The farmed or captive deer, elk, or moose must be eligible to move interstate under § 81.3. This section requires animals that move interstate to be from Certified herds, to be from wild populations that have been documented to be low risk for CWD, or to be moved directly to slaughter. It also provides for movement of research animals under permit, which will only be issued if the movement authorized will not result in the interstate dissemination of CWD. Thus, movement of animals under § 81.3 already presents a low risk of spreading CWD, even without considering the low risk associated with the pathway of transportation through a State.
- The farmed or captive deer, elk, or moose must meet the entry requirements of the destination State listed on the certificate or permit accompanying the animal.
- Except in emergencies, the farmed or captive deer, elk, or moose must not be unloaded until their arrival at their destination. Emergencies might include a breakdown of the vehicle transporting the deer, elk, or moose or weather conditions that make it impossible or extremely unsafe for a vehicle to continue along its scheduled itinerary.

We recognize that the decision not to preempt State and local laws and regulations with respect to CWD, except for deer, elk, and moose that are moved through a State, represents a change in our preemption policy, as expressed in the July 2006 final rule and the March 2009 proposed rule. We believe the change is appropriate for the reasons discussed above. However, because the public has not previously had a chance to comment on this change in policy, we are requesting comment on our new policy, as well as the specific provisions of § 81.5. We will consider comments we receive during the comment period for this interim final rule. After the comment period closes, we will publish another document in the Federal Register. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Although we may make changes based on comments, the rest of the Background section of this document assumes that the preemption policy described above will continue to be effective.

#### Changes in the March 2009 Proposed Rule That Are Now Unnecessary

Because the objective of the CWD program have changed from elimination of the disease in farmed and captive cervids to control of the spread of the disease, several changes we proposed in March 2009 are no longer necessary:

Allowing States to prohibit entry of cervids for reasons unrelated to CWD. As noted earlier, we proposed to add to the July 2006 final rule a new § 81.5 indicating that State laws and regulations prohibiting the entry of farmed or captive cervids for reasons unrelated to CWD are not preempted by 9 CFR part 81. Since we are allowing States to prohibit the entry of farmed or

captive cervids for reasons related to CWD, except with respect to movement through a State, the proposed section is no longer necessary.

Allowing States to prohibit entry of farmed or captive cervids based on proximity to CWD in wild deer, elk, or moose. We proposed to add to the July 2006 final rule provisions allowing States to refuse entry to farmed or captive cervids that originated from premises within 25 miles (40 km) of a federally or State-identified case of CWD in wild deer, elk, or moose, or within 25 miles of an area, as defined by APHIS and the State, where CWD has become established in wild deer, elk, or moose. As States may now impose such requirements, as well as other additional requirements, under § 81.6, we are not including these changes in this final rule.

Requiring ongoing wildlife surveillance as part of an Approved State CWD Herd Certification Program. In the July 2006 final rule, paragraph (a) of § 55.23 lists aspects of a CWD program that the Administrator will evaluate when determining whether a State CWD program qualifies as an Approved State CWD Herd Certification Program. We proposed to add to this list that the Administrator will evaluate whether the State conducts monitoring and surveillance activities to estimate geographic distribution of CWD in the State. This requirement was included to ensure that States had data allowing them to certify that farmed or captive cervids moved interstate did not originate from premises in proximity to a known CWD outbreak, to support the proximity provisions in the March 2009 proposed rule. Since we are not including those provisions in this final rule, specifically requiring that States conduct monitoring and surveillance activities to estimate geographic distribution of CWD in the State is no longer necessary.

However, we continue to encourage States to conduct monitoring and surveillance for CWD in wildlife populations. Knowledge of the geographic distribution of CWD in wildlife that is generated through wildlife surveillance is valuable to both wildlife and domestic animal managers. The information helps both groups assess risk of animal movement and helps in other disease prevention and management planning.

In addition, for deer, elk, or moose captured from a wild population for interstate movement and release, the regulations in § 81.3(b) require the certificate accompanying those animals to document that the animals are from a source population that is low risk for CWD, based on a CWD surveillance program that is approved by the State Government of the receiving State and APHIS. States that want to facilitate such movement will need to have a CWD surveillance program in place for their wild populations.

In the past, APHIS has supported surveillance for CWD in wild cervid populations through cooperative agreements with State wildlife agencies and tribes. We hope that we will be able to continue to support wildlife surveillance. We anticipate that APHIS will receive flat or declining budgets for the next several years, which would likely substantially limit our support. Nonetheless, we will work with State wildlife agencies and tribes to develop more efficient and effective surveillance strategies for the future.

Not allowing herds to participate in the CWD Herd Certification Program based on proximity to CWD in wild deer, elk, or moose. In the July 2006 final rule, paragraph (a) of § 55.22, "Participation and enrollment," sets out procedures for owners to enroll and participate in the CWD Herd Certification Program. In the March 2009 proposed rule, we proposed to amend § 55.22(a) to state that an application for participation may be denied if APHIS or the

State determines that the applicant's herd was established after a subsequent final rule becomes effective on a premises within 25 miles of a federally or State-identified case of CWD in wild deer, elk, or moose, or within 25 miles of an area, as defined by APHIS and the State, where CWD has become established in wild deer, elk, or moose. The requirement was proposed in conjunction with the other proximity provisions that we are not including in this final rule. In the proposal, we also stated that, while the level of risk associated with maintaining a CWD herd in proximity to known occurrences of CWD in wild cervids is unknown, the proposed prohibition on establishing new herds in proximity to CWD occurrences in the wild would add to the effectiveness of CWD control.

However, commenters presented information indicating that the 25-mile distance was not necessarily enough to mitigate the risk of exposure to CWD, given the distribution and variation in home ranges of wild deer, elk, and moose, meaning that the standard might not effectively mitigate whatever risk may exist. Given that the primary impetus for potentially denying the application for participation of a herd in proximity to known occurrences of CWD in wild herds was to support the other proximity provisions in the March 2009 proposed rule, and given the information presented by the commenters, we are not including this provision in the final rule. However, under this final rule, States may choose to address the risk associated with premises in areas in proximity to CWD cases or areas where CWD has become established by placing their own restrictions on the establishment of premises in such areas, based on local conditions.

Finally, one commenter opposed preemption and specifically stated that States should be allowed to require written approval from the State veterinarian for any consignment of deer, elk, or moose to enter the State before it is moved interstate from its premises of origin. Another

commenter generally asked us to require the State agency overseeing captive cervids in the receiving State to be notified when captive cervids are moved to a State. Our decision to allow States to impose additional requirements on the entry of captive cervids beyond those in our regulations allows for States to keep such requirements in place, or to impose them, as they determine to be necessary.

#### Overlap of Federal and State Requirements

Two commenters stated that the March 2009 proposed rule included various provisions for inspections and certification requirements that are duplicative of their State's rules and regulations. The commenters asked whether the APHIS requirements are in addition to State regulations or if the State's current practices would satisfy the requirements. The commenters expressed concern about the burden that could result if the APHIS requirements were being imposed in addition to State requirements.

Another commenter requested that APHIS consider exemptions from Federal requirements for States which, now or in the future, develop comprehensive, risk-based regulatory CWD policies pertaining to confined cervid populations.

Several States already enroll deer and elk herd owners in programs based on these principles. We believe that it is better to build a Federal program that recognizes State activities than to replace them with a strictly Federal program. Therefore, the July 2006 final rule allows APHIS to recognize State regulations and procedures as satisfying APHIS requirements. We believe the States that have or are developing CWD programs can readily incorporate our proposed minimum criteria with few or no changes to State programs.

Specifically, in § 55.23, paragraph (a) sets out the elements necessary for a State to have an Approved State CWD Herd Certification Program. This paragraph sets general standards but does not prescribe the means for meeting them. If a State's CWD program meets the minimum requirements in § 55.23(a), we do not impose any further requirements on the State. Thus, State practices can satisfy APHIS requirements under the regulations.

It is not necessary to exempt States that have or develop comprehensive, risk-based CWD regulatory policies from Federal requirements; such a regulatory policy would be recognized under § 55.23(a) as an Approved State CWD Herd Certification Program. An Approved State CWD Herd Certification Program allows herds in that State that reach Certified status to move their animals interstate. Under this final rule, any farmed or captive cervids moved interstate will have to come from an Approved CWD Herd Certification Program, with limited exceptions.

#### Definition of Official Animal Identification

The July 2006 final rule included in §§ 55.1 and 81.1 a definition of official animal identification. In the March 2009 proposed rule, we proposed to amend this definition to indicate that the CWD program allows the use of either the eight-character or nine-character identification number format for cervids.

One commenter stated that approval for the animal identification tag in the commenter's State has been requested several times since 2008, without confirmation that the request has been received or is being considered. The commenter noted that the tag in question is a nine-character tag. Another commenter expressed general concern that our approval of State tags has not been forthcoming.

Until the publication of this final rule, there has been no CWD Herd Certification Program in place in the regulations, and we have been concentrating on determining the appropriate objectives and provisions of the overall program. We plan to evaluate State animal identification for use as official identification as part of the CWD Herd Certification Program implementation process. We will reach out to these commenters to ensure that we are addressing their concerns, and we invite others who may have similar concerns to contact the person listed under FOR FURTHER INFORMATION CONTACT.

#### Definition of National Uniform Eartagging System

The definition of official animal identification in the July 2006 final rule referred to the National Uniform Eartagging System as one or three systems of nationally unique animal identification that fulfilled the requirements of the definition. In the March 2009 proposed rule, we included a definition of National Uniform Eartagging System to help provide more information about this system, supporting the goal of standardizing animal identification and increasing animal traceability.

Several commenters expressed concern that State-approved animal identification might not be recognized as official animal identification under the definition of National Uniform Eartagging System. These commenters stated that all State-approved official identification that is in use should be approved, and updates to animal identification systems should be required for new herds only.

The proposed National Uniform Eartagging System definition did not affect the definition of official animal identification in the July 2006 final rule. The National Uniform Eartagging System is a numbering system, not a tagging system. With respect to identification

devices, animals in herds enrolled in the CWD Herd Certification Program must have at least two forms of animal identification attached to the animal, approved by APHIS. As stated above, we will evaluate State animal identification systems for approval as official identification as part of the implementation process for the CWD Herd Certification Program.

#### Definition of Premises Identification Number

The July 2006 final rule defined premises identification number (PIN) in §§ 55.1 and 81.1 as a unique number assigned by a State or Federal animal health authority to a premises that is, in the judgment of the State or Federal animal health authority, a geographically distinct location from other livestock production units. The PIN is associated with an address or legal land description and may be used in conjunction with a producer's own livestock production numbering system to provide a unique identification number for an animal. The definition stated that the PIN may consist of:

- The State's two-letter postal abbreviation followed by the premises' assigned number; or
- A seven-character alphanumeric code, with the right-most character being a check digit.

The check digit number is based upon the ISO 7064 Mod 36/37 check digit algorithm.

The definition of official animal identification, in turn, allows the use of a premises-based number system in which an official PIN is combined with a producer's livestock production numbering system to provide a unique identification number.

In the March 2009 proposed rule, we proposed to amend this definition by, among other things, removing the option to use the State's two-letter postal abbreviation followed by the premises' assigned number as a PIN. Under the proposed rule, PINs issued after the effective

date of a final rule following the March 2009 proposal would have had to consist of the seven-character alphanumeric code with the characteristics described above.

Four commenters raised concerns about this change. One stated that producers who use eartags numbered with a premises-based number system containing PINs with State two-letter postal abbreviations and unique identifiers can now purchase eartags from the company of their choice without the involvement of an accredited veterinarian. Under the proposed rule, the commenter stated, such purchases would have to involve an accredited veterinarian, which would make the system unnecessarily cumbersome.

Two commenters expressed concern that all currently used tags would need to be replaced. These commenters stated that the State identifier was preferable. One stated that the State authority issuing identifiers can more easily add to and update the system than the Federal Government can. The other stated that the State identifier can be tracked and updated better than a Federal identifier. A third commenter stated that, when State identifiers are used, purchasers can easily identify the State of origin of an animal, and stated that tracebacks are better handled by State veterinarians than by searching through a huge grouping of animals from all States.

It is important to note that the proposal would not have required any currently issued tags to be replaced; it only would have required that all new PINs conform to the seven-character alphanumeric standard, thus requiring newly issued official identification to reflect the new PINs. In addition, we do not agree that using the seven-character alphanumeric standard poses any difficulties for verification of origin, traceback, or modifications to the system; the seven-character alphanumeric standard has been in use for many years without encountering these

problems. Finally, the changes we proposed would not have required producers to purchase tags from an accredited veterinarian.

However, we appreciate that some States may want the flexibility to continue using their PIN issuance system in the future. As long as PINs issued by States meet the other standards in the revised definition of PIN, we do not anticipate any problems with allowing States to do so. Therefore, in this final rule, we are including the option from the June 2006 final rule to use a PIN that consists of the State's two-letter postal abbreviation followed by the premises' assigned number.

#### Credit for Herd Participation in States Without Approved State CWD Herd Certification Programs

In the July 2006 final rule, paragraph (a) of § 55.22 sets out procedures and conditions for herd owner participation and enrollment in the Federal CWD Herd Certification Program. Paragraph (a)(1)(ii) sets out the procedures and conditions for enrollment of herds that are in a State that does not have an Approved State CWD Herd Certification Program.

Under paragraph (a)(1)(ii)(B), if APHIS determines that the herd owner has maintained the herd in a manner that substantially meets the conditions specified in § 55.23(b) for herd owners, the enrollment date will be the first day that the herd participated in such a program. However, in such cases, the enrollment date may not be set at a date more than 2 years prior to the date that APHIS approved enrollment of the herd. This type of constructed enrollment date will be unavailable for herds that apply to enroll 1 year after the implementation of the CWD program, and herds that apply to enroll after that date will have an enrollment date of the date APHIS approves the herd participation.

In the March 2009 proposed rule, recognizing the delays in implementing the CWD program, we proposed to grant an additional year of credit for herds that had been maintained in a manner that substantially meets the conditions specified in § 55.23(b) for herd owners, for a total of 3 years' credit.

Four commenters stated that we should allow for 5 years' credit to be granted to herds whose owners have maintained them in a manner that substantially meets the conditions specified in § 55.23(b). Doing so would allow those herds to enter the program in Certified status and thus be eligible to move interstate. One commenter stated that providing a maximum of 3 years' credit would essentially shut down the industry for 2 years and that States have written rules that provide adequate CWD surveillance status and disease control in their captive cervids, allowing for the interstate movement of animals with an extremely low risk of CWD.

Three commenters stated that providing only 3 years' credit for herd owner participation outside the context of an Approved State CWD Herd Certification Program discriminates against persons or farms that have a proactive approach to testing and recordkeeping but have a laggard or nonexistent CWD program in their States. These commenters stated that herds meeting the standards of the certification program for any time period should be enrolled in the Federal CWD Herd Certification Program on the date they began meeting such standards, as shown in accurate herd records.

We appreciate the efforts of herd owners who maintain their herds in a manner that substantially meets the conditions specified in § 55.23(b) outside the context of a State CWD program, and we realize that limiting credit for such efforts to 3 years will temporarily prevent the interstate movement of animals from such herds until the herds can achieve Certified status.

However, as discussed in the June 2006 final rule, only State programs have the extensive infrastructure, enforcement mechanisms, and record systems that verify participation and support reasonable confidence that herds in these programs can fully meet the program requirements over long periods of time. (In response to the first commenter, if a State has put in place adequate rules for CWD surveillance and disease control, that State's CWD program would be eligible for recognition as an Approved State CWD Herd Certification Program under § 55.23(a), thus allowing participating herds to receive 5 years' credit.)

While individual herd owners may also devise or join non-State programs that meet the necessary animal identification, monitoring, and other requirements, and their compliance may be documented through herd records and animal records in various State and market records collections, it would be very difficult to establish with confidence that such herds comply with requirements over lengthy periods.

It should also be noted that herd owners who have been practicing CWD control and testing measures may not necessarily meet the criterion for granting credit that the herd has been maintained in a manner that substantially meets the conditions specified in § 55.23(b). We will individually review every application for enrollment credit under § 55.22(a)(1)(ii)(B) to determine whether credit should be granted.

We are making two changes to provisions involving enrollment dates in this final rule. In the July 2006 final rule, we provided in § 55.22(a)(1)(i) for herds to receive credit for having been enrolled in a State program that APHIS determines qualifies as an Approved State CWD Herd Certification Program. We indicated that such a "constructed enrollment date" would be unavailable for herds that applied to enroll 1 year after the effective date of the final rule.

However, such a determination would be contingent on a State applying for approval of its CWD program. If a herd participated in a CWD program that was eventually determined to qualify as an Approved State CWD Herd Certification Program, but that State did not apply to have its program approved within 1 year of the effective date of this rule, the herd owner would receive no credit for participation due to the State's inaction, despite the herd having been maintained consistent with the CWD Herd Certification Program. Accordingly, we are removing the provision in paragraph (a)(1)(i) that limited the availability of constructed enrollment dates. This will allow States to become approved at any time after the effective date of this final rule; herds enrolled and in good standing in their State program will maintain their State enrollment date in the Federal CWD Herd Certification Program provided they continue to meet our requirements.

Similarly, we are removing the provision limiting constructed enrollment dates in paragraph (a)(1)(ii)(B), which indicated that herds maintained in a manner that substantially meets the conditions specified in § 55.23(b) would receive credit for up to 3 years of program participation only if they apply to enroll within 1 year after the effective date of this final rule. There is no reason to deny a herd owner credit based on the date of enrollment if the herd has been maintained in a manner that substantially meets the conditions specified in § 55.23(b).

We are also switching the order of paragraph (a) of § 55.23, which discusses owner participation, and paragraph (b), which discusses State participation. As the provisions for owner participation discuss State participation, switching the order of these paragraphs will result in a more logical presentation.

### Movement of Animals into CWD-Positive, CWD-Exposed, and CWD-Suspect Herds

In the July 2006 final rule, paragraph (a) of § 55.23 lists aspects of a CWD program that the Administrator will evaluate when determining whether a State CWD program qualifies as an Approved State CWD Herd Certification Program. Paragraph (a)(4) stated that the Administrator will evaluate whether the State has placed all known CWD-positive, CWD-exposed, and CWD-suspect animals and herds under movement restrictions, with movement of animals from them only for destruction or under permit. (Movement under permit could include research animal movement, as provided in § 81.3(d) of the July 2006 final rule, or movement from a breeding herd to a shooter facility.)

In the March 2009 proposed rule, we proposed to amend this paragraph to require that States allow no movement of animals into such herds. We stated that such movement affects the CWD indemnity program, which makes indemnity available for eligible animals based on the inventory at the time the movement restrictions are imposed. An increase in the size of a herd under restriction due to CWD also causes a corresponding increase in the program resources devoted to the herd, and in the amount of work for Federal and State representatives working with the herd. For instance, if animals from several additional herds are added to a CWD-exposed or CWD-suspect herd that is later found positive for CWD, those additional herds must also be evaluated during traceback as possible sources of CWD. Also, increasing the herd size potentially increases the total number of infected animals, and the risk of CWD spread (e.g., more animals means more opportunities for an animal to escape confinement).

Several commenters stated that owners of some CWD-positive, CWD-exposed, or CWD-suspect herds that are part of hunting operations have in the past added animals to their herds and

need to continue adding animals in order to remain in business. These commenters stated that prohibiting movement of farmed or captive cervids to these farms would require these farms to breed all their animals, which in turn would require increasing the density of their cervid populations, to provide for both breeding cows and their male offspring. This would greatly increase the cost of doing business for these herds.

A few owners of such herds stated that they would be put out of business if they could not add animals to their herds. One expressed concern that meat producers might be affected by such a restriction as well.

Two commenters expressed concern that Certified herds might lose a valuable business opportunity if sales to herds with CWD-positive, CWD-exposed, and CWD-suspect animals were prohibited.

With respect to traceback, two commenters stated that epidemiologic investigations could be conducted from herds containing CWD-positive, CWD-exposed, or CWD-suspect animals in the same way that they are conducted to and from other herds.

With respect to transmission from the facility containing the CWD-positive, CWD-positive, CWD-exposed, or CWD-suspect animals, one commenter stated that State herd plans implemented at such facilities typically require double fences and double barriers designed to prevent contact between the farmed or captive cervids in the facility and wild cervids. Another commenter stated that the risk associated with escape of animals from a large herd containing CWD-positive, CWD-exposed, or CWD-suspect animals does not change when animals are added to that herd.

With respect to indemnity, three commenters suggested that animals introduced into herds containing CWD-positive, CWD-exposed, or CWD-suspect animals should not be eligible for indemnity. Another commenter suggested that we allow herds to apply for indemnity only within a certain timeframe following the identification of a CWD-positive, CWD-exposed, or CWD-suspect animal from the herd.

Based on these comments, we are not including this proposed change in this final rule. Our intent is to provide flexibility in the regulations to allow the operations described by commenters to remain economically viable. However, we note that, under this final rule, States will be allowed to restrict or prohibit the addition of animals to herds containing CWD-positive, CWD-exposed, or CWD-suspect animals. We also note that, when paying indemnity for a whole herd, we only make indemnity available for the animals that were part of the herd at the time we confirm the CWD diagnosis that leads us to pay indemnity for a herd.

We agree that epidemiologic investigations can be conducted from and to animals added to herds containing CWD-positive, CWD-exposed, or CWD-suspect animals, in the same way epidemiologic investigations are conducted in other circumstances. However, the owners of Certified herds need to be aware that selling animals to herds containing CWD-positive, CWD-exposed, or CWD-suspect animals (or selling to a third party who may sell to such herds) increases their risk of being linked to CWD-positive animals and herds. Owners of Certified herds that sell animals to herds containing such animals need to make sure that they have accurate, complete, and up-to-date inventories and records. Without such inventories and records, it will be difficult to determine with reasonable confidence whether a Certified herd was a source of infection, which could result in movement restrictions being placed on that herd and

the suspension or loss of the herd's status in the CWD Herd Certification Program. We will work with herd owners and States to ensure that all herd owners are aware of the type of information we need to facilitate successful epidemiological investigations.

With respect to additions to herds containing CWD-positive, CWD-exposed, or CWD-suspect animals increasing the density of the herd and therefore increasing the risk of spreading CWD to neighboring or surrounding populations, we agree that there are mitigations available for this risk, such as the double fencing that the commenters cite. For herds that are enrolled in the CWD Herd Certification Program, we would require such mitigations to be contained in a herd plan. Again, under this final rule, States will have the option to require such mitigations when animals are moved into herds containing CWD-positive, CWD-exposed, or CWD-suspect animals. States can also ban such movement altogether.

#### Herd Inventories

In the July 2006 final rule, paragraph (b) of § 55.23 lists responsibilities of herd owners who enroll in the CWD Herd Certification Program. Paragraph (b)(4) describes requirements for herd recordkeeping and annual inventories. Among other things, paragraph (b)(4) requires the owner to allow an APHIS employee or State representative access to the premises and herd, upon request, to conduct an annual physical herd inventory with verification reconciling animals and identifications with the records maintained by the owner. The owner must present the entire herd for inspection under conditions where the APHIS employee or State representative can safely read all identification on the animals. The owner will be responsible for assembling, handling and restraining the animals and for all costs incurred to present the animals for inspection.

In response to comments on the July 2006 final rule, we proposed in March 2009 to make changes to the annual inventory requirements to address their practicality. The changes we proposed were intended to clarify our intention to conduct an actual physical inventory of assembled animals when an APHIS employee or State representative finds it to be needed for program purposes. However, an actual physical inventory is not always necessary.

We proposed to indicate that the APHIS employee or State representative may order either an inventory that consists of review of herd records with visual examination of an enclosed group of animals or a complete physical herd inventory with verification to reconcile all animals and identifications with the records maintained by the owner. In the latter case, we proposed to require the owner to present the entire herd for inspection under conditions where the APHIS employee, State representative, or accredited veterinarian can safely read all identification on the animals. The proposed rule indicated that inventory of a herd would be conducted no more frequently than once per year, unless an APHIS employee, State representative, or accredited veterinarian determines that more frequent inventories are needed based on indications that the herd may not be in compliance with CWD Herd Certification Program requirements.

Ten commenters opposed removing the requirement for an annual physical herd inventory. Some cited specific issues. Two cited past experience in inspecting farmed or captive cervid herds as indicating that, without annual physical inspections, it is difficult to ensure that herds are in compliance. One stated that in the absence of annual inspections, recordkeeping issues escalate rapidly. The other stated that we should require two inspections per year, one physical and one nonphysical inventory.

Another commenter stated generally that the physical inventory requirement will help to ensure that adequate records are maintained, which will be vital in doing any necessary trace when an outbreak of CWD in a captive cervid herd occurs.

Another commenter stated that, when two of the acceptable forms of unique identification that may be used include microchips and tattoos, there can be no substitute for handling the animals if their true identity is to be verified.

The provisions we proposed give APHIS employees and State representatives the ability to require an annual complete physical herd inventory. The proposed provisions simply provide for an inventory of records as another option if no changes in the circumstances of a captive cervid herd indicate that a complete physical herd inventory is necessary. If an inventory indicates that a specific herd is not complying fully with the requirements of the program, the proposed regulations allow for more frequent physical inventories, at the discretion of APHIS employees and State representatives.

We have determined that a review of herd records will be adequate for an annual inventory, assuming that the herd owner maintains adequate records and that there have been no major changes in the composition of the herd. In addition, three commenters stated that physical inventories impose a significant financial impact on producers, suggesting that, to the extent possible, complete physical herd inventories should be conducted no more often than necessary.

Under this final rule, States have the option of requiring more frequent physical inventories for all herds in their States.

One commenter stated that a complete physical herd inventory should be required only when there is sufficient reason to expect that poor records are being kept.

We disagree. Although poor recordkeeping would be one reason we might require a complete physical herd inventory, there are other reasons as well. For example, if the facility containing the herd had experienced a fence breach, we might conduct a physical inventory. Large movements of animals in or out of the herd may result in enough uncertainty with respect to recordkeeping to warrant a physical inventory. Finally, physical inventories should be performed at intervals of no more than 3 years in order to ensure that recordkeeping is accurate. There may be other reasons to perform physical inventories as well.

In the March 2009 proposed rule, we stated in the Background section that complete physical herd inventories would usually be several years apart; we did not propose to include any provisions regarding the frequency of physical inventories in the regulatory text. To communicate our expectations more clearly, we are adding in this final rule a requirement that a complete physical herd inventory be performed for all herds enrolled in the CWD Herd Certification Program no more than 3 years after the last complete physical herd inventory for the herd.

In the Background section of the proposed rule, we stated that a physical assembly would be required at the time a herd is enrolled in the Federal-State cooperative CWD program, in order to provide a reliable baseline record for the herd's participation. Several commenters asked questions regarding whether inventories or inspections required by States could satisfy the requirement for an initial complete physical herd inventory. Twelve commenters stated that an initial physical inventory should only be required for those herds entering the CWD program that do not have a baseline record already on file with their State regulatory agency. Another commenter stated that it seems redundant and costly to require a physical inventory if a herd is

already enrolled in a State CWD program. Another commenter stated that the requirement for an initial physical inventory should apply to new breeders only and not to existing breeders. One commenter asked whether herds that are enrolled in a compliant State CWD Herd Certification Program but have never had a physical inventory need to have a physical inventory done retroactively.

In order to provide a reliable baseline record for the herd's participation, a herd on which a complete physical herd inventory had never been performed would need to undergo a physical inventory before beginning participation in the Federal CWD Herd Certification Program. However, we would accept a complete physical herd inventory performed by an APHIS employee, State representative, or accredited veterinarian not more than 1 year before the enrollment date of the herd as fulfilling the requirement for an initial physical inventory. Such inventories might be performed as part of an official herd test for tuberculosis or brucellosis, or as part of a State CWD Herd Certification Program.

We are making two changes related to this issue. To make our expectations clear, we are indicating in the regulations that a complete physical herd inventory must be performed at the time a herd enrolls in the CWD Herd Certification Program. We are also providing that APHIS may accept a complete physical herd inventory performed by an APHIS employee, State representative, or accredited veterinarian not more than 1 year before the herd's date of enrollment in the CWD Herd Certification Program as fulfilling the requirement for an initial inventory. We would not accept such an inventory if the inventory did not appear to provide an accurate and complete accounting of the animals in the herd, or if the composition of the herd

had changed substantially since the inventory was performed (for example, with large additions to or sales from the herd).

One commenter asked whether inventories or inspections required by a State could satisfy the requirement for continuing inventories. In the commenter's State, unrestrained inventories are performed yearly with record verification.

We would accept a yearly State inventory of a herd in the Herd Certification Program as fulfilling this requirement, as it would be conducted by a State representative. The inventory would have to meet the other requirements of paragraph (b)(4). We will work with States as we implement the CWD Herd Certification Program to establish inventory procedures, where necessary. However, an inventory consisting of record verification would not satisfy the requirements for a physical inventory at the time of enrollment and once every 3 years thereafter.

In the Background section of the proposed rule, we stated that the proposed changes should also make it possible in many cases to plan the timing of a physical assembly of a cervid herd for inventory so that it is coordinated with testing for brucellosis and tuberculosis. We noted that, to maintain a herd's Certified status with regard to brucellosis, or its Accredited status with regard to tuberculosis, the herd must be retested for the relevant disease every 21 to 27 months under current brucellosis and tuberculosis regulations.

Several commenters emphasized that, to have a successful program with producer buy-in, complete physical herd inventories should coincide with other industry animal health programs. These commenters stated that the recertification frequency for cervids in the tuberculosis and brucellosis programs is 33 to 39 months.

The commenters are correct that the frequency at which captive cervid herds that are accredited for tuberculosis are tested for that disease is 33 to 39 months, under § 77.35(d). However, in the Uniform Methods and Rules for brucellosis in cervids,<sup>3</sup> all test-eligible animals in Certified Brucellosis-Free herds are required to have a negative test at intervals between 21 and 27 months. Both of these intervals may change in the future. Our intent was to indicate that there are already occasions at which the animals in a herd must be assembled, handled, and restrained, which are occasions at which a complete physical herd inventory could be conducted with minimal additional cost and disruption to the herd.

Commenters raised other concerns with respect to timing. Several commenters stated that whole herd assembly for handling should be consistent and within the established husbandry timeframe practiced by the industry for the species in question. One commenter stated that physical inventories inspections should be limited to those periods where animal health will not be endangered, e.g., cows in late stage of pregnancy and bulls in velvet or hard antler. Two commenters stated that complete physical herd inventories could be done during weaning and/or breeding. One commenter noted generally that there are many times during a year that it would be dangerous to handle deer.

We agree with these commenters that these issues should be taken into account when scheduling a complete physical herd inventory. We already take these issues into account when scheduling whole-herd tests for brucellosis and tuberculosis in farmed or captive cervids. In all cases, when scheduling a complete physical herd inventory, we will work with the owner of the

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<sup>3</sup> Available at [http://www.aphis.usda.gov/animal\\_health/animal\\_diseases/brucellosis/](http://www.aphis.usda.gov/animal_health/animal_diseases/brucellosis/).

herd to find a time that takes all relevant factors into account. We are providing a 3-year span in which a physical inventory may be conducted in order to allow for such flexibility of scheduling.

Several commenters stated that, if herd records indicate that a specific number of animals are in a pen, and the inspector can verify that amount, there should be no need for a visual inspection of each tag.

We disagree. Records could indicate that the number of animals in a pen was correct, but without verifying that the identification on each animal matches that reflected in the records, we cannot be certain that the animals in the pen are the same as the animals in the records. Another commenter noted that most forms of identification will not be readable from any distance unless the animal is restrained, which makes a hands-on physical inventory necessary.

The regulations in this final rule do provide for an inventory based on records, but we will need to conduct complete physical herd inventories occasionally, for the reasons discussed earlier.

Several commenters stated that whole herd inventories should be conducted during routine herd health procedures. If APHIS or another agency orders a physical inventory, these commenters stated, then APHIS or the ordering agency should be responsible for the costs, risks, and animal losses associated with handling the animals in the herd.

As discussed earlier, we will make every effort to conduct complete physical herd inventories at times coincident with whole-herd testing or other times when the herd is being restrained for another purpose. However, we will not guarantee that all complete physical herd inventories will be conducted at such times; when there are reasons to suspect that recordkeeping is deficient, for example, we may need to conduct a complete physical herd inventory in order to

provide assurance that the herd is in compliance with the CWD Herd Certification Program. In that case, owners will be responsible for all costs incurred to present the animals for inspection, a provision of the July 2006 final rule that we did not propose to change in March 2009. The CWD Herd Certification Program is a voluntary program for herd owners who wish to avail themselves of the opportunity presented by the program to demonstrate that the animals in their herds are low-risk for CWD. It is not appropriate to pay costs of participation in this voluntary program.

We note that keeping accurate, complete, and up-to-date records will make APHIS employees more confident that an inventory conducted by reviewing records, as opposed to a physical inventory, may be sufficient to fulfill the yearly inventory requirement.

Several commenters stated that the frequency of complete physical herd inventories must be consistent with animal health programs for other species, and that currently there is no annual herd inventory required for cattle herds in the tuberculosis or brucellosis programs.

For the other programs to which the commenters refer, complete physical herd inventories are conducted at the time the whole-herd test is conducted. As discussed in this document, we plan to schedule complete physical herd inventories so that they coincide with other occasions when the herd is assembled, such as whole-herd tests for tuberculosis and brucellosis. However, unlike brucellosis and tuberculosis, there is no approved ante-mortem test for CWD, meaning that we cannot use testing to determine the health status of individual animals when they are moved interstate. Instead, we establish that animals in a herd are at low risk of being infected with CWD through surveillance over time. As the animals' low-risk status is thus tied to their membership in a herd that has undergone 5 years of surveillance without finding

CWD, an annual inventory of the herd's records is necessary to validate those records. We note that the records inventory should be much less labor- and time-intensive than the physical herd inventory.

We also proposed to amend paragraph (b)(4) to include accredited veterinarians as people who can conduct a herd inventory, along with APHIS employees and State representatives. The July 2006 final rule allows accredited veterinarians to perform many other Herd Certification Program functions; allowing them to conduct inventories would be consistent with the rest of the program.

One commenter stated that States should be able to specify when and under what conditions accredited veterinarians are approved to conduct inventories. The commenter's State requires that a regulatory veterinarian conduct the first inventory; accredited veterinarians can conduct subsequent inventories.

Under this final rule, States are free to put in place requirements regarding when an accredited veterinarian is allowed to conduct a herd inventory, such as the one the commenter describes.

Several commenters expressed concern that the proposed rule did not prevent an accredited veterinarian from inventorying his or her own herd. Some of these commenters also stated that accredited veterinarians should not be able to issue certificates for the movement of animals from their own herds, as allowed by the July 2006 final rule under § 81.4.

Another commenter stated that accredited veterinarians should not be allowed to inspect their own herds to determine whether they are in compliance.

We disagree that such provisions are necessary for the regulations governing the CWD Herd Certification Program. Accredited veterinarians routinely perform accredited duties on their own animals in other Veterinary Services programs. Under our regulations in 9 CFR part 161, to maintain their accreditation, accredited veterinarians must comply with the standards for accredited veterinarian duties in § 161.4. If an accredited veterinarian conducted an irregular inventory of his or her own cervid herd, we would suspend or revoke the accreditation of that veterinarian. Although our experience indicates that the commenters' concerns are misplaced, nonetheless, under this final rule, States are free to impose restrictions on what duties an accredited veterinarian performs on his or her own animals in the State's CWD program should they choose to.

One commenter requested that we add a definition of accredited veterinarian.

We concur that providing such a definition would improve the clarity of the regulations, particularly when other, similar parts in subchapters B and C include such a definition. Accordingly, we are adding a definition of accredited veterinarian to §§ 55.1 and 81.1 in this final rule. The definition indicates that an accredited veterinarian is approved by the Administrator in accordance with 9 CFR part 161 to perform functions specified in subchapters B, C, and D of 9 CFR chapter I.

One commenter stated that the annual inspection of captive cervid facilities should include participation from wildlife professionals as well as accredited veterinarians.

Wildlife professionals could conduct inventories if they were State representatives with authority over farmed or captive cervids and involved in the oversight of the CWD Herd Certification Program. We note that the commenter is a representative of a State in which the

wildlife authority has jurisdiction over farmed and captive cervids, so it is likely that, in this commenter's State, wildlife professionals would conduct or assist in inventories.

One commenter recommended that we propose common inventory datasheets, allowing for States to design their own as localized issues may require some reasonable modifications.

The regulations in paragraph (b)(4) of § 55.23 already state the information that is required for an inventory: The 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. Under paragraph (a)(10) of § 55.23, States are required to maintain this information in a State database, pending the creation of the CWD National Database administered by APHIS.

In this final rule, we are amending the list of information required for each animal to include the species of the animal. This information will be useful in conducting inventories and confirming the accuracy of herd records.

One commenter noted that, in hunting preserves, there is no way possible to assemble the animals for inventory because they are lost in many acres of woodland, and there is no way to track births inside of a hunting preserve. The commenter stated that these premises should be exempt from the inventory requirements, as the animals never leave the preserve alive anyway.

Participation in the voluntary CWD Herd Certification Program will require maintenance of accurate, complete, and up-to-date herd records, and verifying those records when necessary. Such records are essential to allow a herd owner to demonstrate that animals in the herd are low

risk for CWD. As discussed earlier, the CWD Herd Certification Program establishes that animals are low risk through surveillance over time, making it crucial that we know which animals are included in the surveillance. Herd owners should consider whether they can comply with the requirements of the CWD Herd Certification Program before applying to enroll in the program.

One commenter stated that the regulations should require an adequate review of facility maintenance, animal health, and regulatory compliance during the nonphysical inventory.

We do not believe it is necessary to indicate in the regulations that such a review will take place. APHIS employees and State representatives will evaluate these facility conditions during inventories, as well as at other times. If we discover that the requirements of the regulations are not being complied with, we will take appropriate action.

#### Confirmatory DNA Testing of Official Test Samples

In the July 2006 final rule, § 55.24 sets out provisions for determining the status of a herd of farmed or captive cervids enrolled in the CWD Herd Certification Program. Paragraph (c)(1) provides for an owner to appeal cancellation of enrollment or suspension or loss of herd status. We proposed to amend paragraph (c)(1) to provide a process by which herd owners can appeal the designation of an animal as CWD-positive, based on DNA test results.

Several commenters stated that any process for confirmatory DNA testing should include not just the current owner of an animal but also the original owner of the animal, if any. Some commenters stated that, in the event of a traceback, original owners should be allowed to submit their own samples. Two commenters stated that many herd owners conduct DNA testing on their animals at birth, allowing for the use of these records. Commenters also stated generally

that many herd owners already have their animals' DNA profiled or recorded in a registry, meaning the confirmatory DNA testing process could make use of this information. Two commenters stated that owners should be allowed to keep DNA samples of animals they have sold for use in confirmatory DNA testing.

Other commenters stated that tissue for DNA testing should be required to accompany all samples sent for CWD testing, to protect previous owners who cannot submit tissues when animals are tested but who will be implicated in the event of a positive CWD test result.

We understand the concerns of the commenters that previous owners of an animal may be implicated in a traceback resulting from a CWD-positive animal, since such implication may lead to the suspension or loss of a herd's CWD status. However, the goal of the confirmatory DNA testing provisions is only to verify that the sample tested is a match for a particular animal.

The recordkeeping requirements in the regulations, if followed, will allow us to conduct tracebacks in the event of a positive CWD test result. As discussed earlier, we require an annual inventory in part to ensure that we can conduct an appropriate traceback.

Our regulations do not prevent owners of animals from retaining DNA samples of animals they sell. Sellers of animals are also free to contract with their buyers to provide that the buyers will submit a DNA sample for confirmatory testing if the animal is tested for CWD.

As discussed in the proposed rule, we have added the option of confirmatory DNA testing in response to commenters. However, we should note that we currently maintain rigorous chain-of-custody procedures for samples that are submitted for CWD testing, and we will continue to maintain these procedures both for samples that are not accompanied by tissue for confirmatory DNA testing and those that are. We are confident that our current processes ensure

that test results are correctly assigned to individual animals, as they do in other APHIS animal health programs.

We stated that our guidance on confirmatory DNA testing would allow an owner to reserve the option for confirmatory DNA testing by informing the Federal or State representative or accredited veterinarian who collects the tissues. To allow for later confirmatory DNA testing, we proposed that the person collecting the tissues would also collect from the animal some somatic tissue that contains an official identification device, along with the tissue samples routinely collected for CWD testing (brain stem, lymph nodes, etc.). Submitting tissues attached to an official identification device establishes a reliable chain of custody that allows later DNA tests to be compared to a tissue sample that verifiably comes from the owner's animal in question.

One commenter stated that the requirement to maintain an official identification device with every DNA sample is an absurd requirement designed to impede confirmatory activities, particularly if the samples are held by an independent third party. The commenter stated that APHIS itself does not require samples to be accompanied by official identification. Another commenter stated that, if an accredited veterinarian is submitting all samples, there should be no need to have tissue attached to the official identification.

The official identification device is necessary in order to ensure that there is an incontestable association between the tissue whose DNA is tested and the animal being tested. Without official identification attached to the tissue being tested, both APHIS and the owner would rely on APHIS' chain-of-custody processes to ensure that the identity of the animal is associated properly with the DNA test results of the tissue sample.

As discussed earlier, we are confident that our chain-of-custody processes are effective. However, as a request for confirmatory DNA testing indicates that the owner wants additional assurance regarding the effectiveness of those processes (including the submission of samples by an accredited veterinarian), it would not make sense to rely on that chain of custody for confirmatory DNA testing as well.

We discuss other comments related to third parties conducting CWD tests and holding samples later under this heading.

Several commenters expressed concern regarding the requirement to include somatic tissue with an official identification device. These commenters stated that it would be difficult to fulfill such a requirement, especially for male animals, where taxidermy work requires the head, shoulder, and neck areas to be left intact for the mounting process. In the trophy market, a missing piece of ear would devalue the animal. These commenters also stated that the requirement for tissue to be attached to the official identification is not practical when a microchip is the official identification device.

As explained earlier, we need an official identification device to be attached to the somatic tissue in order to establish an incontestable link between the two. The confirmatory DNA testing process is optional for owners. If owners believe that supplying the tissue necessary to conduct confirmatory DNA testing will result in an economically unacceptable devaluation of their animals, they should not choose to use this optional process.

Microchips that are used as official identification devices are designed so that some tissue adheres to the microchip. This is to prevent a person from moving an official identification

microchip from one animal to another. The somatic tissue that adheres to such microchips when removed from the animal will be usable in our confirmatory DNA testing process.

As an alternative to providing somatic tissue with official identification attached, several commenters suggested that accredited veterinarians collect DNA samples for each animal during the complete physical herd inventory and store them until the animals are tested for CWD. Some of these commenters stated that such samples should be held by a third party.

Our program resources are not sufficient to allow us to build or lease space in which to store sample tissue for DNA testing for each farmed or captive cervid that is identified in a complete physical herd inventory, or to contract for such storage. In any case, using DNA samples stored by APHIS or a third party for confirmatory testing would create chain-of-custody issues, rather than resolve them.

Several commenters stated that a neutral third party should maintain the tissue to be used for confirmatory DNA testing.

Most CWD samples are tested by third-party laboratories, either State or university laboratories. These third-party laboratories are approved to conduct CWD testing under § 55.8(d). We audit third-party laboratories to make sure they comply with the standards set out in § 55.8(d).

If an owner decides that DNA testing is necessary to confirm the identity of the animal that tested positive for CWD, tissue attached to an official identification device would be used for the testing, to ensure that the brain or lymph node sample that tests positive for CWD has the same DNA as the tissue attached to the official identification device. The sample used for

confirmatory DNA testing would accompany the sample of brain and lymph node tested for CWD to ensure that chain of custody is not broken.

The National Veterinary Services Laboratories (NVSL) is the only laboratory authorized to confirm a CWD-positive test result from a third-party laboratory, so any tissue to be used for confirmatory DNA testing for an animal that tested positive for CWD would have to accompany the suspect sample to NVSL from the third-party laboratory, in order to maintain chain of custody. We are planning to conduct the optional confirmatory DNA testing at NVSL or at a third-party laboratory authorized to perform such testing. The sample for CWD testing will be accompanied by the tissue for confirmatory DNA testing at all times. Therefore, the involvement of a neutral third party is not necessary and would in fact increase complications in maintaining chain of custody.

One commenter recommended that the cost of DNA testing be borne initially by APHIS, to show that positive tests truly came from the animals for which the positive test results were reported. If the association of the animal with the positive test results is confirmed, the commenter recommended, the owner's indemnity would be reduced by the cost of the testing. If the association is not confirmed, the animal would no longer be a CWD suspect and APHIS should be held responsible for all costs associated with such confirmatory testing and herd disruption. This commenter also stated that confirmatory DNA testing should be performed on all CWD-positive cervids, so as to remove the onus of possible Government error.

The commenter's recommendations are impractical in several respects. Not all herds in which animals are diagnosed as CWD-positive are subsequently depopulated, as discussed earlier in this document under the heading "Movement of Animals into CWD-Positive, CWD-

Exposed, and CWD-Suspect Herds." A CWD diagnosis in those herds would not result in the payment of indemnity, meaning that we could not recover the costs of confirmatory DNA testing. Performing confirmatory DNA testing on every CWD-positive sample we receive could thus require substantial resources. In addition, as discussed earlier, providing the necessary somatic tissue attached to official identification could be difficult for some herd owners, meaning they might not want to participate in confirmatory DNA testing.

Confirmatory DNA testing is an optional service we proposed to provide, based on the requests of commenters, only when herd owners request the service. We are confident that our chain-of-custody processes are effective. We do not believe it is an appropriate use of APHIS' limited resources to pay for confirmatory DNA testing. As noted earlier, the CWD Herd Certification Program is a voluntary program for herd owners who wish to avail themselves of the opportunity presented by the program to demonstrate that the animals in their herds are low-risk for CWD. It is not appropriate to pay any of the costs of participation in this voluntary program, such as costs associated with herd disruption. In any case, disruption in the circumstances the commenter cites would be temporary, as the herd's status would be restored after the error was found.

One commenter stated that allowing for confirmatory DNA testing would be contrary to current accepted procedures that allow for the immediate depopulation of herds in the event of a serious livestock disease outbreak. The commenter stated that delays inherent in DNA retesting potentially allow for continued disease exposure both to cohort animals, but also the continued contamination of the environment; in addition, the longer depopulation is delayed, the greater the risk that animals may escape or be illegally moved.

The available scientific evidence indicates that CWD is not an acute infectious disease; typically, by the time it is diagnosed in an animal, the disease has been present on a premises for a year or more. In addition, the confirmatory DNA testing is not expected to take more than a few days. Accordingly, we have determined that the risks the commenter identifies with respect to disease spread are unlikely. As the commenter notes, any movement from a herd in which an animal has been identified as CWD-positive would be illegal; we work with our State counterparts to ensure effective enforcement of this requirement. We are making no changes in response to this comment.

However, we are making two changes to the proposed protocol in this final rule. As proposed, the protocol indicated that a Federal or State veterinarian or accredited veterinarian would collect the tissue for testing. However, we do not plan to require that a veterinarian collect samples for CWD testing, so it would be inappropriate to require that a veterinarian also collect tissue for DNA testing. Therefore, we are removing the references in the proposed rule to the persons who can collect the samples. In addition, we are clarifying that the tissue tested for comparison to a CWD sample must have been collected from the same animal.

#### Monitoring Period Required to Move Deer, Elk, and Moose Interstate

In the July 2006 final rule, part 81 contains restrictions on the interstate movement of farmed or captive deer, elk, and moose that are designed to prevent the spread of CWD. Paragraph (a) of § 81.3 contains general restrictions on the interstate movement of deer, elk, and moose in the CWD Herd Certification Program. Under the July 2006 final rule, during its first year of implementation, cervids would be allowed to move interstate if they have been in an approved CWD Herd Certification program, and thus subject to monitoring for CWD and other

requirements, for at least 1 year. The CWD final rule increased this length-of-time requirement in succeeding years of implementation, so the time animals would have had to be in a herd certification program in order to move interstate gradually increased to 2 years, then 3, then 4, then 5 years.

In response to the petitions and many comments we received on the petitions, and based on a review of the available scientific evidence regarding the range of incubation periods for CWD, we proposed to remove the gradual escalation of the length-of-time requirement for farmed or captive deer, elk, or moose moved interstate. We instead proposed to require farmed or captive deer, elk, or moose moved interstate to be from herds that have had at least 5 years' monitoring in the CWD Herd Certification Program and have achieved Certified status. We stated that this requirement is based on our interpretation of currently available research, and we may propose to modify it in the future if additional research provides a basis for doing so.

One commenter stated that the 5-year monitoring period seems reasonable at this time, but there should be flexibility to immediately extend that period should science dictate such an extension is warranted. Another commenter stated that any regulation, Federal or State, should allow for rapid modification of such a requirement as new scientific information becomes available.

We agree. If the scientific evidence regarding the range of incubation periods for CWD advances and indicates that the 5-year monitoring requirement is either longer than necessary or not long enough, we will promptly propose appropriate changes to the regulations.

One commenter supported the 5-year monitoring requirement, but stated that there needs to be a way a new farmer can immediately achieve Certified status by purchasing a new herd from a farm or farms that are certified 5 years or more.

The regulations in § 55.24, which govern herd status, provide for the creation of a herd in the manner the commenter describes. Specifically, paragraph (a) of § 55.24 states that when a herd is first enrolled in the CWD Herd Certification Program, if the herd is composed solely of animals obtained from herds already enrolled in the program, the newly enrolled herd will have the same status as the lowest status of any herd that provided animals for the new herd. Therefore, if a new farmer purchased only farmed or captive cervids from herds that have achieved Certified status, and if the new herd met the other requirements in part 55 for herd participation, that herd would enter the program at Certified status.

One commenter stated that, in 9 years of raising elk, no CWD cases have been found in his herds. The commenter currently has a small herd that was established in 2006. The commenter stated that he would like to begin selling breeding stock and hunting bulls to other ranches, but the new 5-year requirement would prevent his ranch and all other ranches from doing this.

As discussed in response to the previous comment, if the commenter's herd is composed solely of animals obtained from herds already enrolled in the CWD Herd Certification Program, he may be able to get credit for those animals' statuses that would allow him to reach Certified status and thus move his animals interstate. We believe that many cervid producers who rely on moving animals interstate for the success of their businesses have already participated in a State CWD herd certification and monitoring program for 5 years or longer, and thus would not be

adversely affected by the adoption of a 5-year standard. In any case, in our review of the scientific evidence regarding the range of incubation periods for CWD, we determined that requiring 5 years of monitoring in order for animals in the CWD Herd Certification Program to move interstate was appropriate. The commenter did not provide any evidence to the contrary.

In a related change, we proposed to add two general requirements in a new § 81.3(a) for certification of all deer, elk, and moose moved interstate, not just those in the CWD Herd Certification Program. One requirement was that no deer, elk, or moose originating from a premises that was within 25 miles (40 km) of a federally or State-identified case of CWD in wild deer, elk, or moose, or within 25 miles (40 km) of an area where CWD has become established in wild deer, elk, or moose, as defined by APHIS and the State, could be moved into a State that did not accept such animals. We are not including this requirement in the final rule for reasons discussed in the section "Changes in the March 2009 Proposed Rule That Are Now Unnecessary."

The other requirement, which we proposed to add as a new paragraph (a)(1), was that no farmed or captive deer, elk, or moose may be moved interstate from farmed or captive herds infected with CWD, or epidemiologically linked to herds infected with CWD within the past 5 years.

Several commenters asked us to clarify the meaning of the term "epidemiologically linked" in proposed paragraph (a)(1). Two commenters expressed specific concerns regarding the scenario of a Certified herd selling animals to another herd, following which CWD is discovered in the receiving herd; the commenters wanted to know whether the Certified source herd would qualify as "epidemiologically linked" in this case. Two other commenters asked

whether, if an animal is linked through epidemiological investigation to a CWD-positive herd, but the animal in question is tested for CWD and found not to be CWD-positive, the herd containing that animal would be epidemiologically linked to the herd infected with CWD.

We understand the potential confusion associated with our use of the term "epidemiologically linked" in proposed § 81.3(a)(1). For herds in the CWD Herd Certification Program, we have a full description of how epidemiological linkages are investigated and how herd status may be suspended or lost in § 55.24(b), but our proposed requirement in paragraph (a)(1) would have applied to all deer, elk, and moose moved interstate.

In light of our not including the proposed proximity provisions in the final rule, we examined proposed paragraph (a)(1) and found it to be unnecessary. The regulations provide for the interstate movement of farmed or captive deer, elk, and moose in five circumstances. In each of these circumstances, it is unnecessary to require separately that the animal being moved interstate not be from a herd where CWD has been diagnosed in the past 5 years or that is epidemiologically linked to herds where CWD has been diagnosed in the past 5 years.

- Animals in the CWD Herd Certification Program. We proposed to require that such animals come from herds that have achieved Certified status. In order to achieve Certified status, the herd must not contain CWD-positive animals or be epidemiologically linked to a CWD-positive herd, as described in § 55.24. Therefore, having a separate requirement regarding epidemiological linkage is superfluous for these animals.
- Animals captured from wild populations for interstate movement or release. The July 2006 final rule requires that such an animal must have two forms of animal identification, one of which is official animal identification, and a certificate accompanying the animal

must document the source population to be low risk for CWD, based on a CWD surveillance program that is approved by the State Government of the receiving State and by APHIS. As such animals do not originate from farmed or captive herds, it would be impossible to certify that they are not from a CWD-positive herd or that they are not epidemiologically linked to such a herd.

We are making changes related to the movement of animals captured for interstate movement or release in this final rule. In the July 2006 final rule, the requirements for issuance of certificates for all captive cervids in § 81.4(a) included a requirement that the certificate include a statement that the animals are from a herd that has achieved Certified status in the CWD Herd Certification Program, and must provide the herd's program status; no exception was made for animals captured from wild populations for interstate movement and release. However, it is impossible to provide that information for such animals, which is why the regulations in § 81.3(b) include the alternative requirement to document the animals' source population as low risk for CWD. We are amending § 81.4 to remove the requirement for documentation of the captured wild animals' Certified status in the CWD program. We are also making minor editorial changes to § 81.3(b) to indicate that the certificate must state that the source population has been documented to be low risk for CWD, rather than indicating that the certificate itself must provide this documentation.

- Animals moved to slaughter. The July 2006 final rule requires that these animals have two forms of identification and be moved interstate with a certificate. There is no need

for further restriction of animals moved to slaughter based on epidemiological linkage, as animals moved to slaughter are a low-risk pathway for the spread of disease.

- Research animals. Such animals are moved under special permits for research purposes. It may well be valuable to move animals interstate for research that are from or are epidemiologically linked to CWD-positive herds.
- Interstate movements approved by the Administrator. It would be inappropriate to limit the Administrator's authority to approve interstate movement of animals to animals that are not from CWD-positive herds or epidemiologically linked to CWD-positive herds.

Therefore, we are not including proposed paragraph (a)(1) in this final rule. Section 81.3 in this final rule resembles the section as it appeared in the July 2006 final rule, except that paragraph (a), the paragraph describing interstate movement restrictions for farmed or captive deer, elk, and moose in the CWD Herd Certification Program, now indicates that such animals must come from a herd that has achieved Certified status in accordance with § 55.24. We are also not including a provision we proposed to add in § 81.4 that would have required a certificate for the interstate movement of deer, elk, or moose to include a statement that the animal being moved interstate are not from farmed or captive herds infected with CWD, or epidemiologically linked to herds infected with CWD within the past 5 years.

#### Certification that Deer, Elk, and Moose Moved Interstate Do Not Show Clinical Signs of CWD

In the July 2006 final rule, paragraph (a)(2) of § 81.3 requires a farmed or captive deer, elk, or moose that is moved interstate and that is from a herd in the CWD Herd Certification Program to be accompanied by a certificate issued in accordance with § 81.4 that identifies its

herd of origin and its herd's CWD Herd Certification Program status, and states that it is not a CWD-positive, CWD-exposed, or CWD-suspect animal.

We proposed to change these requirements. Because we proposed to require that all animals from the CWD Herd Certification Program moved interstate to be monitored for 5 years, we proposed to change the requirement to indicate that the herd status must be Certified. We also proposed to require that the certificate indicate that the animal does not show clinical signs associated with CWD, rather than that the animal is not a CWD-positive, CWD-exposed, or CWD-suspect animal. Requiring the certificate to state that the animal does not show clinical signs associated with CWD is consistent with information that can be obtained from an examination and with other interstate animal movement regulations.

One commenter asked whether fulfilling this requirement would necessitate a veterinary inspection prior to movement. If so, the commenter stated, then the requirement is extremely burdensome. The commenter's State requires a brand inspector to inspect all animals prior to movement, meaning that having a veterinarian conduct an additional inspection is unnecessary if the herd has been certified. The commenter stated that the brand inspector would easily recognize CWD symptoms.

Requiring a veterinarian to inspect animals moved interstate is standard in all APHIS disease programs, and a veterinary inspection for farmed or captive deer, elk, and moose moved interstate is essential to ensure that the animal being moved interstate is apparently healthy and meets the requirements of the regulations. Both State veterinarians and accredited veterinarians who perform this certification must comply with certain standards of practice and are accountable to APHIS. Allowing some other agency to inspect and certify animals for interstate

movement would not provide the assurance that the requirement for a veterinary inspection does. (We note that the July 2006 final rule also required the certificate accompanying a farmed or captive deer, elk, or moose moved interstate to be issued by a Federal veterinarian, State veterinarian, or accredited veterinarian, as discussed in § 81.4, "Issuance of certificates.")

#### Comments Not Related to the March 2009 Proposed Rule

Commenters on the March 2009 proposed rule raised several issues not related to the changes discussed in that document.

Some commenters stated that it was difficult to understand the full scope and content of the proposed CWD Herd Certification Program from the March 2009 proposed rule because the full text of the rule was not included. The commenters stated that they had raised concerns regarding aspects of the July 2006 final rule that were not addressed in the March 2009 proposed rule. The commenters stated that the incomplete text left uncertainty about other aspects of the program.

We developed the March 2009 proposed rule to address issues with respect to the July 2006 final rule that were raised in the petitions or in response to the petitions. Accordingly, the March 2009 proposed rule set out only the changes that we proposed to make to the July 2006 final rule. However, we understand that this could be confusing. To aid the reader, in this final rule we are setting out the entirety of the regulatory text in the July 2006 final rule, with the changes discussed in the March 2009 proposed rule and in this document. When this final rule becomes effective, the provisions in the regulatory text at the end of this document will be added to the Code of Federal Regulations. In addition, we are responding in this document to the

comments we received on aspects of the July 2006 final rule that were not included in the March 2009 proposed rule, as well as other aspects of the regulations.

The regulations currently include in § 55.1 a definition of herd. A herd is defined as a group of animals that are under common ownership or supervision and are grouped on one or more parts of any single premises (lot, farm, or ranch), or 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.

One commenter stated that this definition permits the intrastate, and depending on proximity to a State border perhaps even the interstate, transportation of animals from one facility to another regardless of their status in the program.

Any deer, elk, or moose moved interstate must meet the requirements of part 81. If they are moved intrastate, they must meet applicable State requirements; Federal regulations do not restrict intrastate movement, although we do require States that participate in the CWD Herd Certification Program to have the authority to restrict intrastate movement of cervids. The definition of herd in part 55 does not have any bearing on the movement restrictions in part 81.

The July 2006 final rule included a definition of herd plan. Such a plan sets out steps to be taken to eradicate CWD from a CWD-positive herd, to control the risk of CWD in a CWD-exposed or CWD-suspect herd, or to prevent the introduction of CWD into that herd or any other herd.

Several commenters stated that herd plans should not allow reintroduction of cervids into a facility previously inhabited by CWD-positive animals, given evidence about the persistence of

CWD in the environment and the lack of validated methods for decontaminating facilities that have housed CWD-positive animals.

One commenter expressed concern about the threat a premises that has held CWD-positive animals poses to wild cervids. This commenter stated that fences should remain in place on CWD-positive farms until a scientifically proven method has been developed for decontaminating facilities. Another stated that any premises that has held a CWD-positive animal should be quarantined for 5 years after the herd is depopulated, with no livestock allowed on the premises, followed by a reevaluation of the land and any environmental risk factors.

We note that all herds that participate in the CWD Herd Certification Program are required to have perimeter fencing under § 55.23(b)(2). As discussed in the July 2006 final rule, the definition's language will allow a herd plan to prohibit cervids from a premises for an appropriate period based on the specific risks and conditions of the individual herd. Ongoing and future research may help resolve many questions about environmental transmission of CWD and establish reasonable standards for when it is safe to repopulate a previously contaminated premises.

We do not consider it necessary to require permanent fencing of premises that contained CWD-positive herds for the purposes of preventing the interstate spread of CWD through the movement of farmed or captive cervids. However, under this final rule, States may impose requirements that are more restrictive.

As discussed earlier in this document, in the July 2006 final rule, paragraph (a)(4) of § 55.23 requires States to place all known CWD-positive, CWD-exposed, and CWD-suspect

animals and herds under movement restrictions, with movement of animals from them only for destruction or under permit.

One commenter stated that all CWD-positive herds should be immediately quarantined and automatically depopulated upon verification of CWD-positive test results from two USDA-approved laboratories, as well as any herds traced forward or backward from a CWD-positive herd. The commenter stated that all cervids in such herds and on such premises should be destroyed on site. Another commenter stated that all animals on game farms should be tested for CWD, with any positive test resulting in complete herd eradication.

We do not consider it necessary to immediately depopulate CWD-positive herds for the purpose of preventing the interstate spread of CWD through the movement of farmed or captive cervids. Animals from such herds will not be allowed to be moved interstate under this final rule, except directly to slaughter or under a research animal permit. We note that, under this final rule, States may require depopulation of CWD-positive and CWD-exposed herds.

In the July 2006 final rule, paragraph (b)(3) of § 55.23 requires herd owners participating in the CWD Herd Certification Program to make the carcasses of all animals that die (including animals killed on premises maintained for hunting and animals sent to slaughter) available for tissue sampling and testing in accordance with instructions from the APHIS or State representative.

One commenter asked us to consider herd plans that do not require 100 percent testing of all animals that die or are killed when developing the guidance for implementing the CWD regulations. The commenter stated that 100 percent compliance may not always be possible, and expressed concern that Certified herds would lose their status by failing to provide samples.

Another commenter stated that the regulations need to provide allowances for when animals escape or other factors make it impossible to provide a sample.

Testing all animals that die for CWD is necessary to establish, through surveillance over time, that animals in a particular herd are low risk for CWD. However, the regulations in § 55.23(b)(3) do provide that, in cases where animals escape or disappear and thus are not available for tissue sampling and testing, an APHIS representative will investigate whether the unavailability of animals for testing constitutes a failure to comply with program requirements and will affect the herd's status in the CWD Herd Certification Program, meaning we have provided the appropriate degree of program discretion in cases where a herd owner finds it impossible to provide samples.

In this final rule, we are amending § 55.23(b)(3) to indicate that we will also investigate program compliance when the samples provided are of poor quality, thus making it impossible to test them for CWD. Providing samples of poor quality causes the same problems as not providing a sample, and we need to be able to test all animals that die in a herd that is enrolled in the CWD Herd Certification Program.

One commenter stated that the regulations should provide a maximum time limit within which carcasses must be tested. In the commenter's State, for example, all licensees must submit carcasses for testing within 48 hours of the cervid's death to ensure that our agency can collect acceptable tissue samples for laboratory testing.

APHIS and the States are responsible for collecting the sample, once the owner makes it available, and testing it. We do so in accordance with guidelines that ensure that we have usable samples. The regulations in § 55.23(b)(3) require herd owners to immediately report deaths of

deer, elk, or moose 12 months of age or older, which will give us adequate time to collect and test samples.

One commenter stated that the July 2006 final rule does not prevent the owner from removing animal identification prior to making cervid carcasses available to the State for CWD testing. The commenter stated that, if tags are removed before testing, cervid carcasses cannot be accurately identified nor can the movement history of individual animals be determined.

The regulations in § 55.23(b)(1) require all animals in a herd that is participating in the CWD Herd Certification Program to be identified. Paragraph (b)(3) requires all reports of animals that die to include the identification numbers of the animals involved. Section 55.25 requires animals in the program to be identified with an electronic implant, flank tattoo, ear tattoo, tamper-resistant ear tag, or another device approved by APHIS. Such identification cannot be removed from the animal without leaving evidence that the identification has been removed, thus indicating noncompliance with the regulations. These requirements, taken together, address the commenter's concern.

Several commenters noted that, under § 55.24(a), Certified herds are not required to conduct slaughter surveillance and surveillance of animals killed in shooter operations. One commenter recommended that we require all animals that die to be tested for CWD in order to ensure that any CWD present in captive cervid facilities is detected.

Some commenters focused on shooter operations as a potential risk, stating that such facilities tend to be large, which creates more potential for ingress and egress of cervids, and are difficult to accurately inventory. These commenters stated that such circumstances make it even more important to maintain surveillance in those facilities.

Another commenter noted generally that there are data indicating that CWD prevalence is higher in adult male deer.<sup>4</sup> Since CWD can occur at a low prevalence and is difficult to detect, the commenter stated, excluding any animal from the testing requirement decreases the chances of detecting the disease when present. Thus, the commenter stated, excluding adult male deer that die or are killed on a premises would not be appropriate.

We agree that CWD can be difficult to detect even in infected animals. For example, in one herd that was depopulated in Minnesota, multiple elk that had shown no clinical signs of CWD turned out to be CWD-positive after testing. Animals in such a circumstance and in a Certified herd would not have been required to be tested for CWD under § 55.24(a). This indicates that we need to continue slaughter surveillance and surveillance of animals killed in shooter operations in order to provide additional certainty that Certified herds contain only animals that are low risk for CWD. Therefore, we are removing the provision in § 55.24(a) allowing Certified herds not to conduct slaughter surveillance and surveillance of animals killed in shooter operations.

We will, however, continue to evaluate the effectiveness of these regulations and will revisit this issue after the program has been established for some reasonable period of time. More scientific research may become available that guides our thinking on the most efficient, cost-effective forms of CWD surveillance.

With respect to the concerns specific to shooter operations, we note that, for herds in the CWD Herd Certification Program, herd premises must have perimeter fencing adequate to prevent ingress and egress of cervids under § 55.23(b)(2). The herd owner must also allow for

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<sup>4</sup> Miller, M. W., and M. M. Conner. 2005. Epidemiology of chronic wasting disease in free-ranging mule deer: spatial, temporal, and demographic influences on observed prevalence patterns. *Journal of Wildlife Diseases* 41: 275–290.

an inventory, as described in § 55.23(b)(4). Herds that cannot meet these requirements would not be eligible for the program.

One commenter stated that the final rule requires testing only of cervids 16 months of age or older. The commenter stated that cervids are apparently susceptible to CWD at birth and CWD has been documented in cervids as young as 9 months of age. In the commenter's State, licensees are required to test all captive cervids 6 months of age or older that die for any reason. The commenter suggested that we change our requirement to apply to all cervids 6 months of age or older.

As mentioned earlier, our regulations require that herd owners report the deaths of all cervids 12 months of age or older, not 16 months, and make the carcasses of those animals available for tissue sampling and testing. As discussed in the July 2006 final rule, the 12-month standard is based on our best approximation of the point where the value of additional epidemiological information exceeds the costs to producers and to program administration of testing younger animals. We will continue to review this standard as we gain more experience with the CWD Herd Certification Program and as new scientific information becomes available.

One commenter stated that paragraph (b)(3) of § 55.23 in the July 2006 final rule identifies APHIS employees and State representatives as people who can collect CWD test samples. The commenter stated that there is no definition of a State representative. Facing large volumes of CWD test samples, the commenter's State has established a formal program to certify private-sector collectors to provide routine surveillance samples for CWD program herds. The commenter stated that this program has the full confidence of APHIS staff in the State and that the regulations should recognize the program by defining "State representative" as a designated

individual trained by the State in addition to accredited veterinarians and State or Federal officials.

The commenter is mistaken about the requirements of paragraph (b)(3); they do not discuss sample collection or testing, but merely require the owner to notify an APHIS employee or State representative of animals that escape, disappear, or die, and to make the carcasses of animals that die available for tissue sampling and testing in accordance with instructions from the APHIS or State representative.

However, we will work out procedures for sample collection and testing with States that have Approved State CWD Herd Certification Programs under § 55.22(b). In general, we would require that any private-sector collectors of CWD samples operate within a structure that provides accountability to the State and APHIS, as the program in the commenter's State does.

It should also be noted that § 55.1 does contain a definition of State representative, which reads as follows: "A person regularly employed in the animal health work of a State and who is authorized by that State to perform the function involved under a cooperative agreement with the United States Department of Agriculture." We are amending this definition in this final rule to remove the reference to performing functions under a cooperative agreement, as not all functions performed by a State representative under the regulations will be performed under a cooperative agreement.

In the July 2006 final rule, paragraph (c) of § 55.24 provides that the Administrator may cancel enrollment after determining that the herd owner failed to comply with any requirements of § 55.24.

One commenter stated that the final rule does not include definitive actions or mechanisms to decertify captive herds if the owners fail to meet the program's requirements after they have been certified. These should include actions that will be taken if, for example, animals are not properly tagged, animals are not tested, fences are not maintained, or if the required records are incorrect, mishandled, or not provided.

We intended that paragraph (c) indicate that the Administrator may cancel enrollment after determining that the herd owner failed to comply with any requirements of subpart B in part 55. This would include failure to comply with the requirements the commenter mentioned, as well as failure to comply with herd plans and other important provisions of the CWD Herd Certification Program. Accordingly, this final rule corrects that provision of the regulations.

As the commenter implies, sometimes we may take actions short of cancellation in response to a failure to comply with the regulations. Because individual cases of failure to comply with the regulations will be different, we believe it is appropriate to make decisions on a case-by-case basis. However, with this change, we will make clear that the consequences of violations of the requirements can include cancellation of enrollment if the Administrator should determine that it is necessary and appropriate.

Paragraph (c) also provides that, in the event that a herd's enrollment is canceled, the herd owner may not reapply to enroll in the CWD Herd Certification Program for 5 years from the effective date of the cancellation. One commenter expressed concern that, because it takes 5 years for a herd to achieve Certified status, a herd owner whose enrollment was canceled would need 10 years to return a herd to Certified status. The commenter recommended allowing re-enrollment of canceled herds immediately.

We have reevaluated the provision and determined that the 5-year enrollment waiting period is not necessarily appropriate. While the animals from a herd whose enrollment has been canceled should not be moved interstate, it increases the strength of the CWD Herd Certification Program to have monitoring in place for those animals through the program. In addition, under the July 2006 final rule, after the 5-year waiting period is up, the owner of a herd whose enrollment is canceled could assemble a new herd composed of animals from Certified herds and thus be granted Certified status immediately, with no opportunity to monitor the owner's compliance before animals begin moving interstate from the herd.

To provide for monitoring of both types of herds, we are changing § 55.24(c) to indicate that any herd enrolled in the CWD Herd Certification Program by an owner whose herd's enrollment has been canceled may not reach Certified status until 5 years after the herd owner's new application for enrollment is approved by APHIS, regardless of the status of the animals of which the herd is composed. This change will provide for herds whose enrollment is canceled to immediately re-enter the program and thus be subject to monitoring. It will also ensure that newly assembled herds whose owners' enrollment was previously canceled are subject to thorough monitoring before animals from those herds can move interstate.

In the July 2006 final rule, § 55.25 set out requirements for animal identification for herds enrolled in the CWD Herd Certification Program. One commenter stated that the identification of individual cervids could be problematic, especially if animals have to be physically or chemically restrained. The commenter stated that animals would be put at serious risk of stress and injury, and identification could be cost-prohibitive if large quantities of immobilizing drugs are necessary. The commenter asked that we consider a redundant system of

two industry-accepted herd identification methods, which may include ear notches, ear tattoos, ear tags, and transponders.

As discussed earlier, identification of animals in herds enrolled in the CWD Herd Certification Program is essential in order to allow for accurate inventory and tracking of the interstate movement of animals moved from enrolled herds. Without such information, we cannot conduct the surveillance and epidemiological investigations that are necessary to determine whether animals from a herd are low risk for CWD. We consider the requirements in § 55.23 for two approved forms of identification, one of which meets the definition of official animal identification in § 55.1, essential to ensure the integrity of the animal identification used by herds enrolled in the program. Herds that cannot comply will not be eligible to participate in the voluntary CWD Herd Certification Program.

In the July 2006 final rule, part 81 contained restrictions on the interstate movement of deer, elk, and moose. The July 2006 final rule included in § 81.1 a definition of deer, elk, and moose that includes all animals of the genera *Odocoileus*, *Cervus*, and *Alces* and their hybrids. This definition is important in part 81 because the movement restrictions in that part apply only to deer, elk, and moose.

One commenter stated that all species in the family Cervidae should be included in the rule and in the CWD Herd Certification Program, stating that it is prudent to include all cervids until further research indicates that such deer cannot be infected with or spread CWD.

We have not expanded coverage to genera in which no species has demonstrated susceptibility via natural routes of transmission. To do so would extend the requirements of this rule without a sound basis, unnecessarily increasing the burden on regulated parties, especially

zoos with large and varied animal collections. We are prepared to extend the definition in the future if new research demonstrates additional species in other genera are susceptible to CWD by natural routes of transmission. For example, we made a change in the July 2006 final rule to add moose to the animals covered by the regulations.

One commenter asked why all deer, elk, and moose herds need to be enrolled in the CWD program in order to move interstate when only a limited number of cervid species within those respective genera have been identified as being CWD susceptible.

As discussed in the July 2006 final rule, the definition of deer, elk, and moose was developed by identifying the species known to be susceptible to natural spread of CWD and then expanding coverage to the complete genera that include these species, under the assumption that related animals in a genus may share similar susceptibility to CWD even when all species in the genus have not been shown to be susceptible. Based on the progress of knowledge about susceptible species over recent years, we believe this to be a scientifically sound and prudent assumption. We will continue to evaluate scientific evidence on this issue; if necessary at some point in the future, we will adjust the scope of our regulations.

One commenter suggested that we include in § 81.1 a definition of certificate, to complement the requirements for a certificate in part 81. The commenter suggested that the definition be similar to the definition of origin health certificate in 9 CFR part 91, which deals with export certification.

The regulations in § 81.4(a) describe in detail the information required on certificates issued for interstate movement in accordance with part 81. The definition of origin health

certificate in part 91 is largely devoted to explaining what information must be included on such a certificate. Consequently, we do not see a need to add such a definition to part 81.

In the July 2006 final rule, § 81.3 contains general restrictions on the interstate movement of deer, elk, and moose. Paragraph (b) of § 81.3 contains restrictions on the interstate movement of captive deer, elk, or moose that are captured from a wild population for interstate movement and release. Such animals must have two forms of animal identification, one of which is official animal identification, and a certificate accompanying the animal must document the source population to be low risk for CWD, based on a CWD surveillance program that is approved by the State Government of the receiving State and by APHIS.

Several commenters expressed concerns about these provisions. These commenters largely stated that the interstate movement of animals from wild populations should be subject to the same requirements as the interstate movement of animals from farmed or captive herds. Some commenters stated that captive animals are more thoroughly and continually monitored and restricted in their movement, and the percentage of infection with CWD in wildlife is much higher than in captive cervids. Another commenter noted that State fish and wildlife agencies may lack the funding and manpower necessary to conduct surveillance, meaning that some States may not be able to monitor the animals once they are released in the destination State.

The requirements for translocation are minimum requirements intended to regulate a practice that has been occurring. Without the provisions in § 81.3(b), there would have been no Federal CWD-related restrictions on the interstate movement of such animals. As one commenter pointed out, translocation can spread CWD; therefore, we determined that it was appropriate to put in place some restrictions on this movement.

We do not consider it practical to make the interstate movement of animals from wild populations subject to the same requirements as the interstate movement of animals from farmed or captive herds. Animals moved interstate from farmed or captive herds must come from a Certified herd, meaning they have been inventoried and monitored for 5 years to determine that they are low risk for CWD. It would be impossible to monitor wild animals in the same way we monitor farmed or captive animals. We note that, under this final rule, any State will be able to further restrict, or prohibit, the movement of animals captured from wild populations into the State.

As discussed earlier in this document, we encourage States to continue to perform surveillance in wild populations, both to facilitate the interstate movement of animals from wild populations and to understand the presence of CWD in their States generally.

In the July 2006 final rule, paragraph (c) of § 81.3 contained requirements for the interstate movement of deer, elk, and moose to slaughter. Two commenters asked that States be allowed to place additional requirements on such movement; one asked for a requirement that States be notified of such movement, and another asked that States be allowed to require a permit to ensure that the animals are moved directly to a slaughter facility.

Under this final rule, States can impose both of these additional requirements, as well as any other additional requirements they determine to be necessary, on movement to slaughter.

Some commenters asked questions regarding participation in the program. One requested that all nonsusceptible species be permitted to participate in the CWD Herd Certification Program on a voluntary basis, as movement restrictions imposed by States have had economic impacts on industry. If this change was made, the commenter asked that visible identification

not be required for reindeer used for exhibition purposes. Another asked why reindeer are not included in the indemnity provisions in part 55.

We did not provide for the participation of species not known to be susceptible to CWD in the CWD Herd Certification Program because their interstate movement does not pose a risk of spreading CWD. Under this final rule, States will continue to be free to impose restrictions on the interstate movement of farmed or captive cervids for any reason, not just related to CWD.

We recognize that the regulations may have created some confusion on this point. We published an interim rule in the Federal Register on February 8, 2002 (Docket No. 00-108-1, 67 FR 5925-5934) that established part 55. This rule defined animal as any captive cervid and stated that we would pay indemnity for CWD-positive animals, CWD-exposed animals, and CWD-suspect animals. However, of the animals in the family Cervidae, only deer, elk, and moose are known to be susceptible to CWD. We have not provided in our regulations for payment of indemnity for animals that are not susceptible to CWD, and we do not provide for their participation in the CWD Herd Certification Program, which is limited to deer, elk, and moose.

Accordingly, this final rule amends the definition of animal in § 55.1 to read: "Any farmed or captive deer, elk, or moose." This clarifies the regulations in part 55 and makes the definition of animal in that part consistent with the definition of animal in § 81.1.

The February 2002 interim rule also defined cervid as all members of the family Cervidae and hybrids, including deer, elk, moose, caribou, reindeer, and related species. While this is an accurate definition of the word "cervid," it may have created confusion; the provisions of part 55 contain several references to cervids in the context of payment of indemnity, but only animals

that are susceptible to CWD are eligible for indemnity. Accordingly, we are amending the definition of cervid as well, to indicate that for the purposes of part 55, the term "cervid" refers to animals in the genera *Odocoileus*, *Cervus*, and *Alces* and their hybrids, i.e., deer, elk, and moose. As the July 2006 final rule included an identical definition of cervid in part 81, we are amending that definition as well.

Two commenters expressed concern that the July 2006 final rule and the March 2009 proposed rule did not include specific details on how the CWD Herd Certification Program will operate. One stated that the rule should refer to a document that specifies the proper management of captive herds. Both of these commenters expressed specific concern about the lack of information about sample collection and testing.

Another commenter asked that we provide detailed information on how infected herds will be dealt with, i.e., quarantine and testing, depopulation, cleaning and disinfection, and fence maintenance requirements.

The optimal methods for most specific aspects of the CWD Herd Certification Program will vary among States. For States that already have CWD programs, we will review their specific methods and determine whether they are adequate to meet the performance standards set out in § 55.23(a). We will also develop a program standards document that will provide detailed guidance on the implementation of and compliance with the regulations, including sample collection and testing and the actions taken when a herd is quarantined. This approach gives States and herd owners flexibility to achieve performance-based standards and will allow us to update the guidance whenever it becomes necessary. For example, in the future, new scientific

evidence about CWD may indicate that different testing or cleaning and disinfection methods are appropriate; we will update our guidance if such evidence becomes available.

With respect to sample collection and testing, these activities will be overseen by APHIS employees and State representatives. We will have systems in place to ensure that people who collect samples are performing these activities correctly. Standards for approval of CWD testing laboratories are already found in § 55.8(d).

One commenter expressed concern about zoos' continued ability to hold and transport deer, elk, and moose for the purposes of public display, outreach education, and cooperative breeding programs. The commenter stated that the proposed rule is specific to the deer, elk, and moose farming community and does not address the specific needs and unique circumstances of the accredited zoo community. The commenter proposed that a method be developed to allow the movement of captive deer, elk, and moose by and between zoos that are accredited by the Association of Zoos and Aquariums, based on that association's guidelines for CWD surveillance in captive cervids in zoos.

The regulations in § 81.3(e) provide for the Administrator to issue a permit for the interstate movement of captive deer, elk, or moose in cases where the Administrator determines that adequate survey and mitigation procedures are in place to prevent dissemination of CWD. If a zoo presents evidence establishing that its survey and mitigation procedures are adequate to prevent dissemination of CWD, we will allow the interstate movement of animals from that zoo. We plan to work with zoos on how such movement might occur, and we may develop a proposal for stakeholder consideration to establish a zoo movement protocol in the future.

We note that, as this final rule does not preempt State laws and regulations that are more restrictive than our regulations, the interstate movement of captive deer, elk, and moose between zoos may be subject to additional State restrictions or prohibitions.

One commenter stated that the interstate movement of deer body parts should be restricted so that hunted deer parts from areas where CWD is endemic do not enter nonendemic areas.

The movement of deer parts in interstate commerce for human or animal consumption is regulated by the Food and Drug Administration. States may also have restrictions on the entry of deer parts and products.

One commenter, noting that we stated in the July 2006 final rule that there exists no live animal test for CWD, stated that there are two live-animal tests available: Tonsillar and rectal biopsies. The commenter stated that the tests are currently not recognized by all government entities, but could be a beneficial tool for research and whole herd surveillance. The commenter also recommended that we require all deer, elk, and moose moved interstate to have a live-animal test performed at least 30 days before transport. Two commenters stated that the regulations should take into account the possibility of an accepted live-animal test becoming available.

These tests have not yet been determined to be effective at detecting CWD in live animals, and thus we do not recognize them as official tests for use in the CWD Herd Certification Program. We certainly encourage research into methods for live-animal CWD detection. If and when an official live-animal test becomes available, we will amend the regulations to take its availability into account.

One commenter encouraged us to work with the U.S. Department of the Interior to develop disease eradication plans in U.S. wildlife, since it is obvious that domestic animal diseases, such as brucellosis in bison and elk, bovine tuberculosis in deer and elk, CWD in cervids, and scrapie in Big Horn sheep, can greatly impact wildlife and result in devastating economic loss to domestic livestock industries and business communities that depend on hunting for an economic base.

Wild deer and elk, as well as other wild animals, are State resources, unless they are on Federal land, in which case the Department of the Interior may be involved. We work with the States and with the Department of the Interior on research and mitigation development to help prevent disease transmission between wildlife and livestock.

Two commenters addressed importation of deer, elk, and moose. One stated that we should prohibit the importation of cervids from countries where CWD is present until those countries develop a herd monitoring and certification program that is equivalent to our program. The other stated that CWD-free countries are not likely to have an ongoing CWD surveillance program, meaning that it would be appropriate to allow the importation of cervids from CWD-free countries without requiring a herd surveillance program in the country of origin.

We restrict the importation of ruminants generally in 9 CFR part 93, Subpart D, which covers the importation of all ruminants. We plan to implement CWD-specific import requirements in the future; when we do, they will be equivalent to our requirements for interstate movement, in keeping with our commitments as a member of the World Trade Organization. Therefore, we agree with the first commenter. With respect to the second commenter's recommendation, one component of maintaining disease-free status is performing ongoing

surveillance to confirm continued freedom from the disease, and we would require such surveillance for imported cervids.

#### Miscellaneous Changes

In the July 2006 final rule, paragraph (b) of § 55.22 indicated that owners of farmed or captive deer, elk, or moose herds could apply to enroll in a Federal CWD Herd Certification Program if no State CWD Herd Certification program exists in the herd's State. Although we were prepared to establish such a program in 2006, changes in appropriated funds for the CWD program may make it impossible to do so in the future. We are amending paragraph (b) to indicate that the option of a Federal CWD Herd Certification Program will be subject to the availability of appropriated funds. If a Federal CWD Herd Certification Program cannot be made available to herd owners, they will have to participate in an Approved State CWD Herd Certification Program in order for their herds to achieve Certified status and thus be eligible to move interstate under part 81.

In the July 2006 final rule, paragraph (a)(10) of § 55.23 indicates that States are responsible for maintaining certain data in the CWD National Database administered by APHIS, or in a State database approved by the Administrator as compatible with the CWD National Database. However, references to the CWD National Database in §§ 55.25 and 81.2 do not also provide for the use of a State database that is compatible with the CWD National Database. Accordingly, we are amending those references to the CWD National Database to indicate that the required data may be found either in the CWD National Database or in an approved State database.

In this final rule, we are revising the definition of Administrator in § 55.1 to read: "The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator." The definition of Administrator in § 55.1 currently limits those who can act for the Administrator to APHIS employees, but State representatives may be authorized in some cases to fulfill tasks assigned to the Administrator in the context of operating their State CWD Herd Certification Programs. We are also adding this definition of Administrator to § 81.1.

In the July 2006 final rule, we revised the definition of CWD-positive animal to state that such an animal must have its diagnosis confirmed by means of two official CWD tests. In the Background section of that final rule, we stated that we expect that, in most cases, the first test would be conducted by a State, Federal, or university laboratory approved to conduct CWD official tests in accordance with § 55.8, and, if the first test was positive, a second, confirmatory test would be conducted at NVSL to confirm the diagnosis of CWD. In some cases, both the initial and confirmatory test may be conducted at NVSL.

However, stating that two official tests are conducted could indicate to readers that two different types of official tests must be conducted in order for an animal to be determined to be CWD-positive, which is not correct; our intent was to indicate that there must be two positive results, which may be from the same type of test. The definition also does not indicate that NVSL is the confirmatory laboratory. The intent behind our changes was to indicate that an animal will be determined to be a CWD-positive animal only after an initial positive result and subsequent official confirmatory testing conducted by NVSL. As indicated in the July 2006 final rule, official confirmatory testing by NVSL is required whether the initial test was conducted by an approved laboratory or by NVSL itself. Therefore, we are amending the definition of CWD-

positive animal to indicate that such an animal must have its diagnosis of CWD established through official confirmatory testing conducted by NVSL.

We are also reorganizing § 55.25 by moving the second sentence to the end of the section, to improve clarity.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

#### IV. Compliance with Other Statutes and Executive Orders

##### Executive Orders 12866 and 13563 and Regulatory Flexibility Act

This final rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also provides a final regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

This final rule amends a suspended final rule published in July 2006, for the control of chronic wasting disease (CWD) in farmed or captive cervids (deer, elk, and moose) in the United States. The July 2006 final rule established a voluntary Herd Certification Program that included CWD monitoring and testing requirements and set interstate movement restrictions. APHIS suspended the July 2006 final rule indefinitely to reconsider several of its requirements in response to petitions from the public and comments on those petitions. In this document, we examine expected benefits and costs of the July 2006 final rule, as amended by this final rule. With publication of this final rule and concurrent removal of the suspension of the July 2006 final rule, farmed or captive deer, elk, and moose herd owners who choose to participate in the Herd Certification Program will have to meet program requirements for animal identification, testing, and herd management. With certain exceptions, only deer, elk, and moose from Certified herds will be eligible for interstate movement.

Amendments to the July 2006 final rule include the following: (i) the Federal CWD regulations will set minimum requirements for interstate movement, while States will be allowed to impose additional requirements; (ii) cervids allowed to be moved interstate (other than ones moving to slaughter or for research), must be from certified herds that have been monitored for a period of at least 5 years and that have not been epidemiologically linked to herds where CWD has been diagnosed, or captured from a wild cervid population that has been documented to be low risk for CWD based on a surveillance program; (iii) farmed or captive cervids, when en route to another State, will be allowed to transit through States that otherwise ban or restrict their entry; (iv) a physical inventory of the animals will be required at the time a herd is enrolled in a CWD certification program and thereafter the animals will need to be physically assembled

for inventory within 3 years of the last physical inventory; (v) certified cervids that die or are killed at slaughter or on shooter operations will be required to be tested for CWD; and (vi) there will be optional confirmatory DNA test provisions for animals that test CWD-positive.

Implementation of the July 2006 final rule as amended by this final rule is expected to result in both positive and negative economic effects for herd owners and States, with benefits and costs depending on herd owners' existing management practices and marketing activities and States' current provisions with respect to CWD control. Overall benefits of the rule are expected to exceed its costs. Foremost, the July 2006 rule, as amended, will help prevent the spread of CWD among States and facilitate interstate movement of healthy cervids. The Herd Certification Program will also promote U.S. producers' access to international markets for cervid products such as antler velvet.

The regulations will provide uniform minimum requirements for interstate movement. This final rule will allow States to enact and administer stricter CWD status requirements for cervids entering from other States. As at present, herd owners' interstate marketing decisions may need to account for dissimilar State CWD certification regulations.

Some herd owners also may be adversely affected by the 5-year monitoring requirement for interstate movement; however, available research indicates that this minimum period of monitoring is necessary to provide an adequate level of protection against the spread of CWD. Most researchers agree that CWD manifests itself within 5 years if the disease is present in a herd of farmed or captive cervids. Many herd owners have been participating in state level CWD HCP's for at least 5 years and will have met this requirement as a result of being enrolled in a state program that becomes an Approved State HCP in the national CWD HCP program.

Producers who participate in the Herd Certification Program will be required to maintain a complete inventory of their herds, with verification by APHIS or State officials. The annual inventory cost is estimated to average about \$25 to \$30 per deer or elk, including the animals' physical inventory once every three years and use of eartags for identification. (We do not know of any farmed or captive moose herds.) Values of farmed or captive deer and elk range widely, depending on the type of animal and market conditions. Based on average per animal values of \$2,000 for deer and \$2,200 for elk, annual inventory costs are estimated to average between 1.25 and 1.50 percent of the value of a farmed or captive deer and to between 1.14 and 1.36 percent of the value of a farmed or captive elk.

The requirement that cervids from herds participating in the certification program be tested for CWD when they die or are killed (including slaughter) will entail submission of the carcass or whole head for tissue sampling and testing or collection of the tissue sample by an approved veterinarian. The estimated cost is about \$150 per sample, equivalent to about 8 percent of the average value of a farmed or captive deer and about 7 percent of the average value of a farmed or captive elk. CWD testing of cervids is recognized by APHIS, the States, and cervid herd owners as essential to successful control of this disease.

Herd owners will have the option of using confirmatory DNA testing provisions to verify that the sample tested is from the animal in question, although APHIS is confident that the existing chain-of-custody processes for CWD testing are effective. Owners who choose confirmatory DNA testing will consider it a benefit, as evidenced by their voluntary payment for this test.

Most cervid operations are small entities. The rule will have a positive overall economic impact on affected entities large and small, and the U.S. cervid industries generally, in controlling the spread of CWD and facilitating interstate and international trade in cervids and cervid products.

#### Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

#### Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

#### Executive Order 13175

APHIS sent a letter notifying all 565 federally recognized Tribes of the proposed changes to the CWD regulations. APHIS requested from Tribes all comments based on potential impacts and outcomes concerning the March 2009 proposed rule. APHIS offered to conduct conference calls or formal consultations with Tribal leaders if requested. APHIS did not receive any comments from Tribes regarding the March 2009 proposed rule.

#### Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), we published a notice in the Federal Register on January 24, 2012 (77 FR 3434-

3435, Docket No. APHIS-2011-0032), announcing our intention to reinstate the information collection associated with the July 2006 final rule and soliciting comments on it. We are asking the Office of Management and Budget (OMB) to approve our use of this information collection for 3 years. When OMB notifies us of its decision, we will publish a document in the Federal Register providing notice of the assigned OMB control number or, if approval is denied, providing notice of what action we plan to take.

#### E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

#### List of Subjects

##### 9 CFR Part 55

Animal diseases, Cervids, Chronic wasting disease, Deer, Elk, Indemnity payments, Moose.

##### 9 CFR Part 81

Animal diseases, Cervids, Deer, Elk, Moose, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, for the reasons set forth in the preamble under the authority at 7 U.S.C. 8301-8317 and 7 CFR 2.22, 2.80, and 371.4, we are announcing the effective date of

the final rule published on July 21, 2006 (71 FR 41682) and further amending 9 CFR Chapter I as follows:

#### PART 55—CONTROL OF CHRONIC WASTING DISEASE

1. The authority citation for part 55 is revised to read as follows:

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

2. Section 55.1 is amended as follows:

a. In the definition of State representative, by removing the words "under a cooperative agreement with the United States Department of Agriculture".

b. By revising the definitions of Administrator, animal, cervid, CWD-exposed animal, CWD-positive animal, CWD-suspect animal, herd plan, official animal identification, and premises identification number (PIN) to read as set forth below.

c. By adding definitions for accredited veterinarian and National Uniform Eartagging System, in alphabetical order, to read as set forth below.

#### § 55.1 Definitions.

Accredited veterinarian. A veterinarian approved by the Administrator in accordance with part 161 of this chapter to perform functions specified in subchapters B, C, and D of this chapter.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal. Any farmed or captive deer, elk, or moose.

\* \* \* \* \*

Cervid. All members of the family Cervidae and hybrids, including deer, elk, moose, caribou, reindeer, and related species. For the purposes of this part, 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.

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

\* \* \* \* \*

CWD-suspect animal. An animal for which an APHIS employee or State representative has determined that unofficial CWD test results, laboratory evidence or clinical signs suggest a diagnosis of CWD, but for which official laboratory results have been inconclusive or not yet conducted.

\* \* \* \* \*

Herd plan. A written herd and/or premises management agreement developed by APHIS in collaboration with the herd owner, State representatives, and other affected parties. The herd plan will not be valid until it has been reviewed and signed by the Administrator, the State representative, and the herd owner. A herd plan sets out the steps to be taken to eradicate CWD from a CWD-positive herd, to control the risk of CWD in a CWD-exposed or CWD-suspect herd, or to prevent introduction of CWD into that herd or any other herd. A herd plan will require specified means of identification for each animal in the herd; regular examination of

animals in the herd by a veterinarian for clinical signs of disease; reporting to a State or APHIS representative of any clinical signs of a central nervous system disease or chronic wasting condition in the herd; maintaining records of the acquisition and disposition of all animals entering or leaving the herd, including the date of acquisition or removal, name and address of the person from whom the animal was acquired or to whom it was disposed; and the cause of death, if the animal died while in the herd. A herd plan may also contain additional requirements to prevent or control the possible spread of CWD, depending on the particular circumstances of the herd and its premises, including but not limited to depopulation of the herd, specifying the time for which a premises must not contain cervids after CWD-positive, -exposed, or -suspect animals are removed from the premises; fencing requirements; selective culling of animals; restrictions on sharing and movement of possibly contaminated livestock equipment; premises cleaning and disinfection requirements; or other requirements. A herd plan may be reviewed and changes to it suggested at any time by any party signatory to it, in response to changes in the situation of the herd or premises or improvements in understanding of the nature of CWD epidemiology or techniques to prevent its spread. The revised herd plan will become effective after it is reviewed by the Administrator and signed by the Administrator, the State representative, and the herd owner.

\* \* \* \* \*

National Uniform Eartagging System. A numbering system for the official identification of individual animals in the United States providing a nationally unique identification number for each animal. The National Uniform Eartagging System employs an eight- or nine-character

alphanumeric format, consisting of a two-number State or territory code, followed by two or three letters and four additional numbers. Official APHIS disease control programs may specify which format to employ.

\* \* \* \* \*

Official animal identification. A device or means of animal identification approved for use under this part by APHIS to uniquely identify individual animals. Examples of approved official animal identification devices are listed in § 55.25. The official animal identification must include a nationally unique animal identification number that adheres to one of the following numbering systems:

(1) National Uniform Eartagging System. The CWD program allows the use of either the eight-character or nine-character format for cervids.

(2) Animal identification number (AIN).

(3) Premises-based number system. The premises-based number system combines an official premises identification number (PIN), as defined in this section, with a producer's livestock production numbering system to provide a unique identification number. The PIN and the production number must both appear on the official tag.

(4) Any other numbering system approved by the Administrator for the identification of animals in commerce.

\* \* \* \* \*

Premises identification number (PIN). A nationally unique number assigned by a State, Tribal, and/or Federal animal health authority to a premises that is, in the judgment of the State, Tribal, and/or Federal animal health authority, a geographically distinct location from other

premises. The premises identification number is associated with an address, geospatial coordinates, and/or location descriptors which provide a verifiably unique location. The premises identification number may be used in conjunction with a producer's own livestock production numbering system to provide a unique identification number for an animal. It may also be used as a component of a group/lot identification number. The premises identification number may consist of:

(1) The State's two-letter postal abbreviation followed by the premises' assigned number;

or

(2) A seven-character alphanumeric code, with the right-most character being a check digit. The check digit number is based upon the ISO 7064 Mod 36/37 check digit algorithm.

\* \* \* \* \*

3. In part 55, subpart B is revised to read as follows:

## Subpart B—Chronic Wasting Disease Herd Certification Program

Sec.

55.21 Administration.

55.22 Participation and enrollment.

55.23 Responsibilities of States and enrolled herd owners.

55.24 Herd status.

55.25 Animal identification.

## Subpart B—Chronic Wasting Disease Herd Certification Program

### § 55.21 Administration.

The CWD Herd Certification Program is a cooperative effort between APHIS, State animal health and wildlife agencies, and deer, elk, and moose owners. APHIS coordinates with these State agencies to encourage deer, elk, and moose owners to certify their herds as low risk for CWD by being in continuous compliance with the CWD Herd Certification Program standards.

### § 55.22 Participation and enrollment.

(a) Participation by States. Any State that operates a State program to certify the CWD status of deer, elk, or moose may request the Administrator to designate the State program as an Approved State CWD Herd Certification Program. The Administrator will approve or disapprove a State program in accordance with § 55.23(a). In States with an Approved State CWD Herd Certification Program, program activities will be conducted in accordance with the guidelines of that program as long as the State program meets the minimum requirements of this part. A list of Approved State CWD Herd Certification Programs may be obtained by writing to

the National Center for Animal Health Program, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1235.

(b) Participation by owners. Any owner of a farmed or captive deer, elk, or moose herd may apply to enroll in an Approved State CWD Herd Certification Program by sending a written request to the appropriate State agency. Subject to the availability of appropriated funds for a Federal CWD Herd Certification Program, the owner may apply to the APHIS veterinarian in charge if no Approved State CWD Herd Certification Program exists in the herd's State. APHIS or the State will determine the herd's eligibility, and if needed will require the owner to submit more details about the herd animals and operations. An application for participation may be denied if APHIS or the State determines that the applicant has previously violated State or Federal laws or regulations for livestock, and that the nature of the violation indicates that the applicant may not faithfully comply with the requirements of the CWD Herd Certification Program. If the enrolling herd is a CWD-positive herd or CWD-exposed herd, immediately after enrollment it must begin complying with a herd plan developed in accordance with § 55.24. After determining that the herd is eligible to participate in accordance with this paragraph, APHIS or the appropriate State agency will send the herd owner a notice of enrollment that includes the herd's enrollment date. Inquiries regarding which herds are participating in the CWD Herd Certification Program and their certification should be directed to the State representative of the relevant State.

(1) Enrollment date. With the exceptions listed in this paragraph, the enrollment date for any herd that joins the CWD Herd Certification Program after August 12, 2012, will be the date the herd is approved for participation.

(i) For herds already participating in State CWD programs, the enrollment date will be the first day that the herd participated in a State program that APHIS subsequently determines qualifies as an Approved State CWD Herd Certification Program in accordance with § 55.23(a) of this part.

(ii) For herds that enroll directly in the Federal CWD Herd Certification Program, which is allowed only when there is no Approved State CWD Herd Certification Program in their State and which is subject to the availability of appropriated funds, the enrollment date will be the earlier of:

(A) The date APHIS approves enrollment; or

(B) If APHIS determines that the herd owner has maintained the herd in a manner that substantially meets the conditions specified in § 55.23(b) for herd owners, the first day that the herd participated in such a program. However, in such cases the enrollment date may not be set at a date more than 3 years prior to the date that APHIS approved enrollment of the herd.

(iii) For new herds that were formed from and contain only animals from herds enrolled in the CWD Herd Certification Program, the enrollment date will be the latest enrollment date for any source herd for the animals.

(2) [Reserved]

(Approved by the Office of Management and Budget under control number 0579-0237)

§ 55.23 Responsibilities of States and enrolled herd owners.

(a) Approval of State programs and responsibilities of States. In reviewing a State program's eligibility to be designated an Approved State CWD Herd Certification Program, the Administrator will evaluate a written statement from the State that describes the State's CWD

control and deer, elk, and moose herd certification activities and that cites relevant State statutes, regulations, and directives pertaining to animal health activities and reports and publications of the State. In determining whether the State program qualifies, the Administrator will determine whether the State:

(1) Has the authority, based on State law or regulation, to restrict the intrastate movement of all CWD-positive, CWD-suspect, and CWD-exposed animals.

(2) Has the authority, based on State law or regulation, to require the prompt reporting of any animal suspected of having CWD and test results for any animals tested for CWD to State or Federal animal health authorities.

(3) Has, in cooperation with APHIS personnel, drafted and signed a memorandum of understanding with APHIS that delineates the respective roles of the State and APHIS in CWD Herd Certification Program implementation.

(4) Has placed all known CWD-positive, CWD-exposed, and CWD-suspect animals and herds under movement restrictions, with movement of animals from them only for destruction or under permit.

(5) Has effectively implemented policies to:

(i) Promptly investigate all animals reported as CWD-suspect animals;

(ii) Designate herds as CWD-positive, CWD-exposed, or CWD-suspect and promptly restrict movement of animals from the herd after an APHIS employee or State representative determines that the herd contains or has contained a CWD-positive animal;

(iii) Remove herd movement restrictions only after completion of a herd plan agreed upon by the State representative, APHIS, and the owner;

(iv) Conduct an epidemiologic investigation of CWD-positive, CWD-exposed, and CWD-suspect herds that includes the designation of suspect and exposed animals and that identifies animals to be traced;

(v) Conduct tracebacks of CWD-positive animals and traceouts of CWD-exposed animals and report any out-of-State traces to the appropriate State promptly after receipt of notification of a CWD-positive animal; and

(vi) Conduct tracebacks based on slaughter or other sampling promptly after receipt of notification of a CWD-positive animal at slaughter.

(6) Effectively monitors and enforces State quarantines and State reporting laws and regulations for CWD.

(7) Has designated at least one State animal health official, or has worked with APHIS to designate an APHIS official, to coordinate CWD Herd Certification Program activities in the State.

(8) Has programs to educate those engaged in the interstate movement of deer, elk, and moose regarding the identification and recordkeeping requirements of this part.

(9) Requires, based on State law or regulation, and effectively enforces identification of all animals in herds participating in the CWD Herd Certification Program;

(10) Maintains in the CWD National Database administered by APHIS, or in a State database approved by the Administrator as compatible with the CWD National Database, the State's:

(i) Premises information and assigned premises numbers;

(ii) Individual animal information on all deer, elk, and moose in herds participating in the CWD Herd Certification Program in the State;

(iii) Individual animal information on all out-of-State deer, elk, and moose to be traced;  
and

(iv) Accurate herd status data.

(11) Requires that tissues from all CWD-exposed or CWD-suspect animals that die or are depopulated or otherwise killed be submitted to a laboratory authorized by the Administrator to conduct official CWD tests and requires appropriate disposal of the carcasses of CWD-positive, CWD-exposed, and CWD-suspect animals.

(b) Responsibilities of enrolled herd owners. Herd owners who enroll in the CWD Herd Certification Program agree to maintain their herds in accordance with the following conditions:

(1) Each animal in the herd must be identified using means of animal identification specified in § 55.25. All animals in an enrolled herd must be identified before reaching 12 months of age. In addition, all animals of any age in an enrolled herd must be identified before being moved from the herd premises. In addition, all animals in an enrolled herd must be identified before the inventory required under paragraph (b)(4) of this section, and animals found to be in violation of this requirement during the inventory must be identified during or after the inventory on a schedule specified by the APHIS employee or State representative conducting the inventory;

(2) The herd premises must have perimeter fencing adequate to prevent ingress or egress of cervids. This fencing must also comply with any applicable State regulations;

(3) The owner must immediately report to an APHIS employee or State representative all animals that escape or disappear, and all deaths (including animals killed on premises maintained for hunting and animals sent to slaughter) of deer, elk, and moose in the herd aged 12 months or older; Except that, APHIS employees or State representatives may approve reporting schedules other than immediate notification when herd conditions warrant it in the opinion of both APHIS and the State. The report must include the identification numbers of the animals involved and the estimated time and date of the death, escape, or disappearance. For animals that die (including animals killed on premises maintained for hunting and animals sent to slaughter), the owner must inform an APHIS or State representative and must make the carcasses of the animals available for tissue sampling and testing in accordance with instructions from the APHIS or State representative. In cases where animals escape or disappear and thus are not available for tissue sampling and testing, or when the owner provides samples that are of such poor quality that they cannot be tested for CWD, an APHIS representative will investigate whether the unavailability of animals or usable samples for testing constitutes a failure to comply with program requirements and will affect the herd's status in the CWD Herd Certification Program;

(4) 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. Upon request by an APHIS employee or State representative, the owner must allow either of these officials or a designated accredited

veterinarian access to the premises and herd to conduct an inventory. The owner will be responsible for assembling, handling, and restraining the animals and for all costs incurred to present the animals for inspection. The APHIS employee or State representative may order either an inventory that consists of review of herd records with visual examination of an enclosed group of animals, or a complete physical herd inventory with verification to reconcile all animals and identifications with the records maintained by the owner. In the latter case, the owner must present the entire herd for inspection under conditions where the APHIS employee, State representative, or accredited veterinarian can safely read all identification on the animals. During inventories, the owner must cooperate with the inspector to resolve any discrepancies to the satisfaction of the person performing the inventory. Inventory of a herd will be conducted no more frequently than once per year, unless an APHIS employee, State representative, or accredited veterinarian determines that more frequent inventories are needed based on indications that the herd may not be in compliance with CWD Herd Certification Program requirements. A complete physical herd inventory must be performed on a herd in accordance with this paragraph at the time a herd is enrolled in the CWD Herd Certification Program; Except that, APHIS may accept a complete physical herd inventory performed by an APHIS employee, State representative, or accredited veterinarian not more than 1 year before the herd's date of enrollment in the CWD Herd Certification Program as fulfilling the requirement for an initial inventory. In addition, a complete physical herd inventory must be performed for all herds enrolled in the CWD Herd Certification Program no more than 3 years after the last complete physical herd inventory for the herd;

(5) If an owner wishes to maintain separate herds, he or she must maintain separate herd inventories, records, working facilities, water sources, equipment, and land use. There must be a buffer zone of at least 30 feet between the perimeter fencing around separate herds, and no commingling of animals may occur. Movement of animals between herds must be recorded as if they were separately owned herds;

(6) New animals may be introduced into the herd only from other herds enrolled in the CWD Herd Certification Program. If animals are received from an enrolled herd with a lower program status, the receiving herd will revert to that lower program status. If animals are obtained from a herd not participating in the program, then the receiving herd will be required to start over in the program.

(Approved by the Office of Management and Budget under control number 0579-0237)

§ 55.24 Herd status.

(a) Initial and subsequent status. When a herd is first enrolled in the CWD Herd Certification Program, it will be placed in First Year status; except that, if the herd is composed solely of animals obtained from herds already enrolled in the Program, the newly enrolled herd will have the same status as the lowest status of any herd that provided animals for the new herd. 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, and the herd will remain in Certified status as long as it is enrolled in the program, provided its status is not lost or suspended in accordance with this section.

(b) Loss or suspension of herd status. (1) If a herd is designated a CWD-positive herd or a CWD-exposed herd, it will immediately lose its program status and may only reenroll after entering into a herd plan.

(2) If a herd is designated a CWD-suspect herd, a trace back herd, or a trace forward herd, it will immediately be placed in Suspended status pending an epidemiologic investigation by APHIS or a State animal health agency. If the epidemiologic investigation determines that the herd was not commingled with a CWD-positive animal, the herd will be reinstated to its former program status, and the time spent in Suspended status will count toward its promotion to the next herd status level.

(i) If the epidemiologic investigation determines that the herd was commingled with a CWD-positive animal, the herd will lose its program status and will be designated a CWD-exposed herd.

(ii) If the epidemiological investigation is unable to make a determination regarding the exposure of the herd, because the necessary animal or animals are no longer available for testing (i.e., a trace animal from a known positive herd died and was not tested) or for other reasons, the herd status will continue as Suspended unless and until a herd plan is developed for the herd. If a herd plan is developed and implemented, the herd will be reinstated to its former program status, and the time spent in Suspended status will count toward its promotion to the next herd status level; Except that, if the epidemiological investigation finds that the owner of the herd has not fully complied with program requirements for animal identification, animal testing, and recordkeeping, the herd will be reinstated into the CWD Herd Certification Program at the First Year status level, with a new enrollment date set at the date the herd entered into Suspended

status. Any herd reinstated after being placed in Suspended status must then comply with the requirements of the herd plan as well as the requirements of the CWD Herd Certification Program. The herd plan will require testing of all animals that die in the herd for any reason, regardless of the age of the animal, may require movement restrictions for animals in the herd based on epidemiologic evidence regarding the risk posed by the animals in question, and may include other requirements found necessary to control the risk of spreading CWD.

(3) If an APHIS or State representative determines that animals from a herd enrolled in the program have commingled with animals from a herd with a lower program status, the herd with the higher program status will be reduced to the status of the herd with which its animals commingled.

(c) Cancellation of enrollment by Administrator. The Administrator may cancel the enrollment of an enrolled herd by giving written notice to the herd owner. In the event of such cancellation, any herd enrolled in the CWD Herd Certification Program by that herd owner may not reach Certified status until 5 years after the herd owner's new application for enrollment is approved by APHIS, regardless of the status of the animals of which the herd is composed. The Administrator may cancel enrollment after determining that the herd owner failed to comply with any requirements of this subpart. Before enrollment is canceled, an APHIS representative will inform the herd owner of the reasons for the proposed cancellation.

(1) Herd owners may appeal designation of an animal as CWD-positive, cancellation of enrollment of a herd, or loss or suspension of herd status by writing to the Administrator within 10 days after being informed of the reasons for the action. The appeal must include all of the facts and reasons upon which the herd owner relies to show that the reasons for the action are

incorrect or do not support the action. Specifically, to appeal designation of an animal as CWD-positive, the owner may present as evidence the results of a DNA test requested and paid for by the owner to determine whether previous official CWD test results were correctly associated with an animal that belonged to the owner. If the owner intends to present such test results as evidence, he or she shall request the tests and state this in the written notice sent to the Administrator. In such cases the Administrator may postpone a decision on the appeal for a reasonable period pending receipt of such test results. To this end, laboratories approved under § 55.8 are authorized to conduct DNA tests to compare tissue samples tested for CWD to samples from tissues that were collected at the same time from the same animal and are attached to an official identification device. Such DNA tests are available only if the animal owner arranged to submit animal tissue attached to an official identification device along with the other tissues that were collected for the official CWD test. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision. If the Administrator grants an appeal of the status of a CWD-positive animal, the animal shall be redesignated as CWD-suspect pending further investigation to establish the final status of the animal and its herd. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator.

(2) [Reserved]

(d) Herd status of animals added to herds. A herd may add animals from herds with the same or a higher herd status in the CWD Herd Certification Program with no negative impact on

the certification status of the receiving herd.<sup>5</sup> If animals are acquired from a herd with a lower herd status, the receiving herd reverts to the program status of the sending herd. If a herd participating in the CWD Herd Certification Program acquires animals from a nonparticipating herd, the receiving herd reverts to First Year status with a new enrollment date of the date of acquisition of the animal.

(Approved by the Office of Management and Budget under control number 0579-0237.)

§ 55.25 Animal identification.

Each animal required to be identified by this subpart must have at least two forms of animal identification attached to the animal. One of the animal identifications must be official animal identification as defined in this part, with a nationally unique animal identification number that is linked to that animal in the CWD National Database or in an approved State database. The second animal identification must be unique for the individual animal within the herd and also must be linked to that animal and herd in the CWD National Database or in an approved State database. The means of animal identification must be approved for this use by APHIS, and must be an electronic implant, flank tattoo, ear tattoo, tamper-resistant ear tag, or other device approved by APHIS.

(Approved by the Office of Management and Budget under control number 0579-0237)

4. Part 81 is revised to read as follows:

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<sup>5</sup> Note that in addition to this requirement, § 81.3 of this chapter restricts the interstate movement of farmed and captive deer, elk, and moose based on their status in the CWD Herd Certification Program.

## PART 81– CHRONIC WASTING DISEASE IN DEER, ELK, AND MOOSE

Sec.

81.1 Definitions.

81.2 Identification of deer, elk, and moose in interstate commerce.

81.3 General restrictions.

81.4 Issuance of certificates.

81.5 Movement of deer, elk, or moose through a State to another State.

81.6 Federal preemption of State and local laws and regulations with respect to CWD.

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

§ 81.1 Definitions.

These definitions are applicable to this part:

Accredited veterinarian. A veterinarian approved by the Administrator in accordance with part 161 of this chapter to perform functions specified in subchapters B, C, and D of this chapter.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal. Any farmed or captive deer, elk, or moose.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

Animal identification. A device or means of animal identification approved for use under this part by APHIS. Examples of animal identification devices that APHIS has approved are listed in § 55.25 of this chapter.

Animal identification number (AIN). A numbering system for the official identification of individual animals in the United States. The AIN contains 15 digits, with the first 3 being the country code (840 for the United States), the alpha characters USA, or the numeric code assigned to the manufacturer of the identification device by the International Committee on Animal Recording.

APHIS employee. Any individual employed by the Animal and Plant Health Inspection Service who is authorized by the Administrator to do any work or perform any duty in connection with the control and eradication of disease.

Cervid. All members of the family Cervidae and hybrids, including deer, elk, moose, caribou, reindeer, and related species. For the purposes of this part, 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.

Chronic wasting disease (CWD). A transmissible spongiform encephalopathy of cervids. Clinical signs in affected animals include, but are not limited to, loss of body condition, behavioral changes, excessive salivation, increased drinking and urination, depression, and eventual death.

CWD Herd Certification Program. The Chronic Wasting Disease Herd Certification Program established in part 55 of this chapter.

Deer, elk, and moose. All animals in the genera *Odocoileus*, *Cervus*, and *Alces* and their hybrids.

Farmed or captive. Privately or publicly maintained or held for economic or other purposes within a perimeter fence or confined area, or captured from a wild population for interstate movement and release.

National Uniform Eartagging System. A numbering system for the official identification of individual animals in the United States providing a nationally unique identification number for each animal. The National Uniform Eartagging System employs an eight- or nine-character alphanumeric format, consisting of a two-number State or territory code, followed by two or three letters and four additional numbers. Official APHIS disease control programs may specify which format to employ.

Official animal identification. A device or means of animal identification approved for use under this part by APHIS to uniquely identify individual animals. Examples of approved official animal identification devices are listed in § 55.25 of this chapter. The official animal identification must include a nationally unique animal identification number that adheres to one of the following numbering systems:

(1) National Uniform Eartagging System. The CWD program allows the use of either the eight-character or nine-character format for cervids.

(2) Animal identification number (AIN).

(3) Premises-based number system. The premises-based number system combines an official premises identification number (PIN), as defined in this section, with a producer's livestock production numbering system to provide a unique identification number. The PIN and the production number must both appear on the official tag.

(4) Any other numbering system approved by the Administrator for the identification of animals in commerce.

Premises identification number (PIN). A nationally unique number assigned by a State, Tribal, and/or Federal animal health authority to a premises that is, in the judgment of the State, Tribal, and/or Federal animal health authority, a geographically distinct location from other premises. The premises identification number is associated with an address, geospatial coordinates, and/or location descriptors which provide a verifiably unique location. The premises identification number may be used in conjunction with a producer's own livestock production numbering system to provide a unique identification number for an animal. It may also be used as a component of a group/lot identification number. The premises identification number may consist of:

(1) The State's two-letter postal abbreviation followed by the premises' assigned number;

or

(2) A seven-character alphanumeric code, with the right-most character being a check digit. The check digit number is based upon the ISO 7064 Mod 36/37 check digit algorithm.

§ 81.2 Identification of deer, elk, and moose in interstate commerce.

Each animal required to be identified by this part must have at least two forms of animal identification attached to the animal. The means of animal identification must be approved for this use by APHIS, and must be an electronic implant, flank tattoo, ear tattoo, tamper-resistant ear tag, or other device approved by APHIS. One of the animal identifications must be an official animal identification as defined in this part, with a nationally unique animal identification number that is linked to that animal in the CWD National Database or in an

approved State database. The second animal identification must be unique for the individual animal within the herd and also must be linked to that animal and herd in the CWD National Database or in an approved State database.

(Approved by the Office of Management and Budget under control number 0579-0237)

§ 81.3 General restrictions.

No farmed or captive deer, elk, or moose may be moved interstate unless it meets the requirements of this section.

(a) Animals in the CWD Herd Certification Program. The captive deer, elk, or moose is:

(1) Enrolled in the CWD Herd Certification Program and the herd has achieved Certified status in accordance with § 55.24 of this chapter; and

(2) Is accompanied by a certificate issued in accordance with § 81.4 that identifies its herd of origin and that states that the animal's herd has achieved Certified status and that the animal does not show clinical signs associated with CWD.

(b) Animals captured for interstate movement and release. If the captive deer, elk, or moose was captured from a wild population for interstate movement and release, each animal must have two forms of animal identification, one of which is official animal identification, and the certificate issued in accordance with § 81.4 that accompanies the animal must state that the source population has been documented to be low risk for CWD, based on a CWD surveillance program in wild cervid populations that is approved by the State Government of the receiving State and by APHIS.

(c) Animals moved to slaughter. The farmed or captive deer, elk, or moose must be moved directly to a recognized slaughtering establishment for slaughter, must have two forms of

animal identification, one of which is official animal identification, and must be accompanied by a certificate issued in accordance with § 81.4.

(d) Research animal movements and permits. A research animal permit is required for the interstate movement of cervids for research purposes. The permit will specify any special conditions of the movement determined by the Administrator to be necessary to prevent the dissemination of CWD. The Administrator may, at his or her discretion, issue the permit if he or she determines that the destination facility has adequate biosecurity and that the movement authorized will not result in the interstate dissemination of CWD.

(1) To apply for a research animal permit, contact an APHIS employee or State representative and provide the following information:

(i) The name and address of the person to whom the special permit is issued, the address at which the research cervids to be moved interstate are being held, and the name and address of the person receiving the cervids to be moved interstate;

(ii) The number and type of cervids to be moved interstate;

(iii) The reason for the interstate movement;

(iv) Any safeguards in place to prevent transmission of CWD during movement or at the receiving location; and

(v) The date on which movement will occur.

(2) A copy of the research animal permit must accompany the cervids moved, and copies must be submitted so that a copy is received by the State animal health official and the veterinarian in charge for the State of destination at least 72 hours prior to the arrival of the cervids at the destination listed on the research animal permit.

(e) Interstate movements approved by the Administrator. Notwithstanding any other provision of this part, interstate movement of farmed or captive deer, elk, and moose may be allowed on a case-by-case basis when the Administrator determines that adequate survey and mitigation procedures are in place to prevent dissemination of CWD and issues a permit for the movement.

§ 81.4 Issuance of certificates.

(a) Information required on certificates. A certificate must show any official animal identification numbers of each animal to be moved. A certificate must also show the number of animals covered by the certificate; the purpose for which the animals are to be moved; the points of origin and destination; the consignor; and the consignee. The certificate must include a statement by the issuing accredited veterinarian, State veterinarian, or Federal veterinarian that the animals were not exhibiting clinical signs associated with CWD at the time of examination. The certificate must also include a statement that the animals are from a herd that has achieved Certified status in the CWD Herd Certification Program, and must provide the herd's program status, with the following exceptions:

(1) Certificates issued for animals captured from a wild population for interstate movement and release do not need to state that the animals are from a herd that has achieved Certified status in the CWD Herd Certification Program but must include the statement required in § 81.3(b); and

(2) Certificates issued for animals moved directly to slaughter do not need to state that the animals are from a herd that has achieved Certified status in the CWD Herd Certification

Program and must state that an APHIS employee or State representative has been notified in advance of the date the animals are being moved to slaughter.

(b) Animal identification documents attached to certificates. As an alternative to typing or writing individual animal identification on a certificate, another document may be used to provide this information, but only under the following conditions:

(1) The document must be a State form or APHIS form that requires individual identification of animals;

(2) A legible copy of the document must be stapled to the original and each copy of the certificate;

(3) Each copy of the document must identify each animal to be moved with the certificate, but any information pertaining to other animals, and any unused space on the document for recording animal identification, must be crossed out in ink; and

(4) The following information must be typed or written in ink in the identification column on the original and each copy of the certificate and must be circled or boxed, also in ink, so that no additional information can be added:

(i) The name of the document; and

(ii) Either the serial number on the document or, if the document is not imprinted with a serial number, both the name of the person who issued the document and the date the document was issued.

(Approved by the Office of Management and Budget under control number 0579-0237)

§ 81.5 Movement of deer, elk, or moose through a State to another State.

Farmed or captive deer, elk, or moose may be moved through a State or locality whose laws or regulations on the movement of those animals are more restrictive than this part to another State under the following conditions:

(a) The farmed or captive deer, elk, or moose must be eligible to move interstate under § 81.3.

(b) The farmed or captive deer, elk, or moose must meet the entry requirements of the destination State listed on the certificate or permit accompanying the animal.

(c) Except in emergencies, the farmed or captive deer, elk, or moose must not be unloaded until their arrival at their destination.

§ 81.6 Federal preemption of State and local laws and regulations with respect to CWD.

State and local laws and regulations on farmed or captive deer, elk, or moose with respect to CWD that are more restrictive than the regulations in this part are not preempted by this part, except as described in § 81.5.

Done in Washington, DC, this May 31, 2012.

Edward Avalos

Under Secretary for Marketing and Regulatory Programs.