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**Part V**

## **Department of Agriculture**

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**Animal and Plant Health Inspection  
Service**

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**9 CFR Parts 55 and 81  
Chronic Wasting Disease Herd  
Certification Program and Interstate  
Movement of Farmed or Captive Deer,  
Elk, and Moose; Final Rule**

**DEPARTMENT OF AGRICULTURE****Animal and Plant Health Inspection Service****9 CFR Parts 55 and 81**

[Docket No. 00–108–3]

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:** Final rule.

**SUMMARY:** We are establishing a herd certification program to eliminate chronic wasting disease (CWD) from farmed or captive cervids in the United States. Participating deer, elk, and moose herds will have to follow program requirements for animal identification, testing, herd management, and movement of animals into and from herds. After 5 years of enrollment with no evidence of chronic wasting disease, a herd may be granted “Certified” status. Owners of herds may enroll in a State program that we have determined has requirements equivalent to the Federal program, or may enroll directly in the Federal program if no State program exists. We are also establishing interstate movement requirements to prevent the interstate movement of deer, elk, and moose that pose a risk of spreading CWD. These actions will help to eliminate CWD from the farmed or captive deer, elk, and moose herds in the United States.

**DATES:** *Effective Date:* October 19, 2006.**FOR FURTHER INFORMATION CONTACT:** Dr. Dean E. Goeldner, Senior Staff Veterinarian, Ruminant Health Programs, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737–1231; (301) 734–4916.**SUPPLEMENTARY INFORMATION:****Background**

Chronic wasting disease (CWD) is a transmissible spongiform encephalopathy (TSE) of cervids (members of Cervidae, the deer family) that, as of October 2005, 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. There is no known relationship between CWD and any other TSE of animals or people. Species known to be susceptible to CWD via

natural routes of transmission include Rocky Mountain elk, mule deer, white-tailed deer, black-tailed deer, and moose. Noncervid ruminant species, including wild ruminants and domestic cattle, sheep, and goats, have been housed in wildlife facilities in direct or indirect contact with CWD-affected deer and elk, and as of June 2005 there has been no evidence of transmission of CWD to these other species. Additional studies to delineate the host range of CWD are underway.

In the United States, CWD has been confirmed in free-ranging deer and elk in Colorado, Illinois, Nebraska, New Mexico, New York, South Dakota, Utah, West Virginia, Wisconsin, and Wyoming, and, as of October 2005, in 31 farmed or captive elk herds in Colorado, Kansas, Minnesota, Montana, Nebraska, Oklahoma, South Dakota, and Wisconsin, and in 8 farmed or captive deer herds in New York and Wisconsin. 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 Animal and Plant Health Inspection Service’s (APHIS’s) regulations in 9 CFR subchapter B govern cooperative programs to control and eradicate communicable diseases of livestock. In accordance with the Animal Health Protection Act (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, and to pay claims growing out of the destruction of animals.

On December 24, 2003, we published in the **Federal Register** (68 FR 74513–74529, Docket No. 00–108–2) a proposal to amend 9 CFR subchapter B by establishing regulations in part 55 for a CWD Herd Certification Program to help eliminate chronic wasting disease from the farmed or captive deer and elk herds in the United States. Under that proposal, deer and elk herd owners who choose to participate would have to follow program requirements for animal identification, testing, herd management, and movement of animals into and from herds. We also proposed to amend 9 CFR subchapter B by establishing a new part 81 containing interstate movement requirements to prevent the interstate movement of deer and elk that pose a risk of spreading CWD.

We solicited comments concerning our proposal for 60 days ending February 23, 2004. We received 105 comments by that date, from cervid ranches, national and State cervid

producer associations, national wildlife associations, State wildlife and agriculture agencies, and others. These comments are discussed below by topic. In response to these comments, APHIS has decided to amend the proposed rule by making the following changes:

- Adding moose to the animals covered by the regulations, in addition to deer and elk.
- Change the definition of *commingled*, *commingling* by replacing “30 feet of physical separation” with “10 feet of physical separation” and by eliminating the exception for animals in brief contact for less than 48 hours.
- Change the definition of *CWD-positive animal* to require two positive official CWD tests, rather than one.
- Change the definition of *CWD-suspect animal* to clarify that it would include animals that have tested positive to an unofficial CWD test.
- Change the definition of *herd plan* to specify that it must be signed by the herd owner, in addition to APHIS and the State, to emphasize the involvement of all three parties in a herd plan’s development.
- Change the requirements for animal identification to require that free-ranging animals captured for interstate movement and release, like other farmed or captive cervids, must have two forms of animal identification, including one form with a nationally unique animal identification number. Add “or other identification approved by APHIS” to the list of allowed identification devices we proposed (electronic implant, flank tattoo, ear tattoo, or tamper-resistant ear tag).
- Change the interstate movement restrictions for farmed or captive cervids to exempt cervids moving directly to slaughter from the requirements of § 81.3, “General restrictions,” when the sending and receiving States have agreed to the movement and certain other conditions are met.
- Change the responsibilities for herd owners participating in the program to require that they report animal deaths and make the carcasses available for testing for all animals 12 months and older, rather than 16 months as proposed. Also require herd owners to report any animals that escape or disappear.
- Change the inventory requirements for participating herds to specify that the “physical herd inventory with verification reconciling animals and identifications with the records maintained by the owner” must be conducted annually, rather than “upon request” as we proposed. Also change the inventory requirements to make it clear that 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 and liabilities incurred to present the animals for inspection.

- Add a requirement that cervids held for research purposes may only be moved interstate under a USDA permit. In the proposal, such animals were completely exempt from the requirements of the rule.

- Make minor changes to improve clarity in other sections of the rule.

### Comments on Definitions in the Proposed Rule

#### *Approved State CWD Herd Certification Program*

One commenter noted that although the term Approved State CWD Herd Certification Program appears in the regulations its meaning is not defined and must be derived from context. In response we have added a definition of this term that reads “A program operated by a State government for certification of cervid herds with respect to CWD that the Administrator has determined to meet the requirements of § 55.23(a).”

#### *Definition of Farmed or Captive*

Several commenters stated that when referring to cervids, the term “captive” should be changed to “privately owned,” “domestic,” or “farmed.” They stated that the term captive implies the animal was captured from the wild, but cervid ranches and farms primarily contain animals born on a commercial premises. Some commenters stated that the words “captive” or “captured” have a negative connotation about the cervid industry.

We understand that producers that maintain herds of cervids that were born in captivity and do not deal in animals captured from the wild believe that their industry is properly associated with other livestock industries, and that there may be negative connotations in any term that associates them with the capture of wild cervids. However, some herds of domesticated elk or deer do in fact contain some animals captured from the wild. While this is becoming less common, if our certification program only addressed herds in which all animals were born into captivity, the program would exclude too many herds, reducing the program’s effectiveness in controlling CWD. Many State CWD regulations and programs recognize the fact that a “captive” cervid may be

either born into a herd or introduced into it from the wild. Some States, in their requirements for allowing cervids to enter the State, require that the cervid must come from a herd that has been monitored for CWD for at least 5 years under a State program, but do not require that the cervid must have been born into a captive herd; instead, they require that all animals in the source herd must be either natural additions or have been in the herd for at least 1 year.

We believe that to effectively control CWD our certification program must address not only cervid herds containing solely domesticated cervids born into herds, but also must address herds that contain one or more animals introduced from the wild, cervids captured from the wild and temporarily maintained in captivity, and cervids maintained by zoos and other exhibitors. Also, the term captive cervids is already in use in a number of other Federal regulations (e.g., 9 CFR Part 77—Tuberculosis, 9 CFR Part 50—Animals Destroyed Because of Tuberculosis, and 9 CFR Part 91—Inspection and Handling of Livestock For Exportation). It is also used in several State laws, regulations, and policy statements. Using an alternate term such as “domestic cervid” or “farmed cervid” in our certification regulations would be inconsistent and could cause confusion.

However, we do agree that incorporating the term “farmed” along with the term “captive” would emphasize the fact that many cervids are domestic animals born in captivity. Therefore, we are replacing the term “captive” with the term “farmed or captive” throughout the regulations. We are making no change to the definition itself, so in this final rule, the term *farmed or captive* will read as follows: “Privately or publicly maintained or held for economic or other purposes within a perimeter fence or confined area, or captured from a free-ranging population for interstate movement and release.”

#### *Definition of Commingled, Commingling*

Several commenters stated that there is no scientific evidence supporting the idea that animals are commingled to the extent that disease transmission is possible when the animals are separated by less than 30 feet. These commenters stated that CWD transmission at this distance would be possible only through aerosol routes, and no evidence has ever been found that CWD passes via an aerosol spray from animal to animal. Commenters also stated that regulations for control of other diseases, e.g.,

tuberculosis, require separation of only 10 feet to prevent commingling.

Several commenters asked for clarification of how the commingling definition would apply to perimeter fencing issues, and whether a certified herd would lose its status (become an exposed herd) if its premises does not have a double fence with at least 30 feet between the fences and a wild cervid in the area is diagnosed with CWD. One commenter suggested that perimeter fences that maintain 30 feet of separation from wild animals should be clearly required for all farmed or captive cervid premises, because, otherwise, commingling with native animals could not be avoided, increasing both the risk that captive animals would contract CWD from free-ranging animals and the risk that farmed or captive animals would spread CWD to free-ranging native animals.

The term commingling is used in the regulations in two distinct contexts—that of temporary contact between animals (e.g., during sale or transport or at shows) and more long-term contact between animals (e.g., when an owner maintains two or more separate herds on one premises, in accordance with § 55.23(b)(5)). The criteria used to determine that commingling has occurred are especially important because if a herd was commingled with a CWD-positive animal, it can be declared to be a CWD-exposed herd.

We agree with the points made by several commenters that it would be both unnecessary and burdensome to say that animals are commingled if there is not a 30-foot buffer zone between animals at all times. We are changing this requirement in the definition of commingling to 10 feet of separation, and will make it clear that this separation distance is adequate for situations where animals are in temporary association, such as at auctions or during movement. We are making this change because our level of knowledge concerning transmission of CWD from animal to animal has increased since the proposed rule was written. In the proposed rule we stated “A buffer zone of 30 feet was chosen because in other APHIS disease control programs this distance has been shown to be effective in preventing aerosol transmission of infective agents from one animal to another. Because there is not yet a detailed model of how TSE’s are transmitted, APHIS believes it is prudent to assume that they might spread short distances as aerosols, rather than only through more direct contact.” Current evidence indicates that transmission is most likely to occur via an oral-fecal route, and that a 10-foot

buffer zone should prevent this. A buffer zone of 10 feet will prevent nose-to-nose contact, make accidental fecal contamination and transfer less likely, and is the standard distance we use to prevent ectoparasite transfer of other diseases. Ten to 12 feet is also the standard distance used for construction of alleyways on farms and animal holding facilities, so it will be relatively easy to comply with this standard when a producer needs to prevent commingling of animals.

However, we also believe that it is necessary for separate herds to have a buffer zone of more than 10 feet between them because risks of cross-herd contamination are increased when different herds are in close association for long periods. Therefore, in addition to changing "30 feet" to "10 feet" in the definition of *commingled*, *commingling*, we are also adding the following italicized words to the paragraph describing conditions for maintaining separate herds, § 55.23(b)(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."

Readers should note that this requirement that herds must be separated by 30 feet applies to cases where a single owner maintains separate herds, as well as to cases where different owners have adjacent herds.

Several commenters stated that since current scientific information indicates CWD is transmitted laterally, animal to animal, there is no basis for the "48-hour exemption." One commenter stated that all animals grouped together even briefly at a sale or auction should assume the status of the lowest program status animal in the group. Some commenters stated that the definition's exemption for animals commingled for less than 48 hours at sales or auctions is arbitrary, but if used, it should also apply to short-term commingling of animals outside sales or auction premises, when the owner can document that the commingling was for less than 48 hours.

A zoo association requested that APHIS establish an exemption similar to the 48-hour exemption for auctions and sales for zoo animals that briefly share holding or hospital pens for the purpose of cleaning enclosures or shifting animals.

The "48 hour exemption" exists in various forms in several other animal disease control programs, and is based on an assumption that transmission of disease between animals is most likely during periods of prolonged close contact. APHIS has reexamined this assumption with regard to CWD transmission, and has found that there are no completed studies of CWD transmission rates that definitively settle the question of what length of time contact between animals is needed before there is a significant risk of CWD transmission. Therefore, we are removing the "48 hour exemption" from the definition of *commingling*. We may address the risks associated with brief contacts again in future rulemaking if new studies of CWD transmission provide relevant data.

Commenters also noted that the rule did not clearly describe the actions APHIS would take to reduce a herd's program status if its animals commingled with animals from a lower-status herd. This reclassification of herd status becomes even more important now that we have eliminated the "48 hour exemption" for sales and auctions, where commingling is likely to occur. We agree that § 55.24, *Herd status*, does not sufficiently describe APHIS or State actions that may reduce herd status as a result of commingling. Therefore, we are adding a new paragraph § 55.24(b)(3) that reads: "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."

We expect the two changes discussed above—removing the "48 hour exemption" and adding an explicit process to reduce the status of commingled herds—will result in operational changes at sales, auctions, and other sites where animals are at risk of commingling. Owners will probably find it useful to plan animal grouping at such sites so that only animals with equal program status are grouped together.

Based on some of the comments about commingling, some readers appear not to understand that the term is used in the regulations for distinct and limited purposes related to contact with other farmed or captive cervids, and not related to exposure to wild cervids in a farm's vicinity. The concept of commingling is used when determining whether groups of animals on a single premises qualify as separate herds or not, when determining whether animals have been exposed to animals from a

herd with a lower program status, and when determining whether animals in a suspect herd commingled with a CWD-positive animal, in which case the suspect herd will lose its program status and will be designated as a CWD-exposed herd. However, as discussed above regarding perimeter fence issues, there is nothing in the regulations that would reduce a herd's program status based on the lack of a 30-foot (10-foot, under this final rule) physical separation from animals in the wild. Although APHIS encourages double perimeter fencing, the requirement in the regulations is for single-fencing. In individual cases a herd plan developed to eradicate CWD from a CWD-positive herd, to control the risk of CWD in a suspect herd, or to prevent introduction of CWD into another herd, may specify double perimeter fencing for a particular herd, for example, when there is known CWD infection in adjacent captive or wildlife populations.

#### *Definitions of CWD-Exposed Animal and CWD-Exposed Herd*

One commenter pointed out that the defined terms for exposed animals and herds omitted cases where the exposure was not to a CWD-positive animal, but to a CWD-exposed animal (which may later prove to be CWD-positive). The commenter suggested creating and defining a term to cover such "exposed to exposed" contacts for epidemiology purposes.

We agree with the commenter that awareness of "exposed-to-exposed" contacts can help epidemiologic investigations and long-term tracking of patterns of CWD transmission. However, exposed animals and herds are already subject to restrictions under the regulations, and we do not believe that the regulations should impose any additional restrictions on "exposed-to-exposed" animals. We do plan to emphasize the importance of investigating "exposed-to-exposed" contacts in our nonregulatory guidance to APHIS and State veterinarians conducting epidemiologic investigations.

#### *Definitions of CWD-Positive Animal and CWD-Positive Herd*

Several commenters questioned the definition of a CWD-positive animal as one that "has had a diagnosis of CWD confirmed by means of an official CWD test." These commenters stated that at least two positive results from certified laboratories are needed to reliably identify a positive animal. The commenters said two tests should be required because they believe that errors in samples collected for CWD programs

have been found (e.g., mislabeling or collection of the wrong tissues) and that current CWD tests require evaluation of results in a manner that is subjective and may be subject to error. Some commenters stated that, after an animal tests positive, the owner should have the opportunity to have the sample's DNA matched to DNA from the owner's animal to prove that the correct sample was tested. One commenter added that a positive result on a CWD test is a major crisis to any deer farmer, and the expense of a second test and DNA verification is a small price to pay to ensure that the process has been free of human or other error.

We agree with the comments suggesting that a determination that an animal is CWD-positive should not be based on a single positive test result. We are amending the definition of *CWD-positive animal* to read: "An animal that has had a diagnosis of CWD confirmed by means of two official CWD tests." 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 the second, confirmatory test would be conducted at the National Veterinary Services Laboratories (NVSL). In some cases, both the initial and confirmatory test may be conducted at NVSL.

With regard to DNA matching to confirm that positive samples are indisputably associated with the correct animal, we plan to allow such confirmation, at the owner's expense, when the owner of the CWD-positive animal requests it. DNA verification will be possible because our instructions on how to collect and submit tissue samples will require submission of all manmade identification devices on the animal, with part of the ear or skin to which they are attached, in a manner that preserves the chain of custody.

#### *Definition of CWD-Suspect Animal and CWD-Suspect Herd*

Several commenters suggested that it was not clear whether the phrase "laboratory evidence or clinical signs suggest a diagnosis of CWD" in the definitions of CWD-suspect animal and CWD-suspect herd meant that an animal or herd could be found to be CWD-suspect based on the results of unofficial CWD tests.

We planned to include unofficial CWD test results as an indicator in this definition. To clarify this, we are changing the relevant phrase in both definitions to read "unofficial CWD test results, laboratory evidence, or clinical signs suggest a diagnosis of CWD."

One commenter pointed out that the definition of *CWD-suspect herd* in § 55.1 said the determination could be made by "an APHIS employee or State representative," but the definition of *CWD-suspect animal* in § 81.1 mentions only "an APHIS employee." This was an inadvertent omission, and we have added "or State representative" to the definition of *CWD-suspect animal*.

#### *Definitions of Deer, Elk, and Moose*

Some commenters noted that the proposed definitions of deer and elk were imprecise or incomplete, and there was some confusion about when hybrid animals would be considered deer and when they would be considered elk. Several commenters asked why certain species were not included in either definition when there is no conclusive scientific evidence that the species are not susceptible to CWD. Commenters asked in particular about sika deer (*Cervus nippon*), sambar (*Cervus unicolor*), rusa deer (*Cervus timorensis*), barasingha (*Cervus duvauceli*), and Pere David's deer (*Elaphurus davidensis*). Several commenters suggested that the definitions be expanded to include more deer and elk or other cervids.

We agree, and are replacing the term "deer and elk" with "deer, elk, and moose" and are defining the term to mean "all animals in the genera *Odocoileus*, *Cervus*, and *Alces* and their hybrids." This change expands coverage to all species of concern. This final definition 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. We have expanded coverage to include moose (genus *Alces*) because CWD was recently diagnosed in a moose for the first time. 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. This change should make it clear that the same program requirements apply to deer, elk, moose, and any hybrids of these animals.

#### *Definition of Herd Plan*

Several commenters addressed the part of the herd plan definition that said a herd plan, among other things, will specify "the time for which a premises must not contain cervids after CWD-positive, -exposed, or -suspect animals are removed from the premises." These commenters stated that there should be a permanent ban on raising cervids on any property that once contained CWD-positive animals, due to risks of environmental transmission of CWD.

We do not agree with these comments. 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. Establishing permanent restrictions on repopulating premises with cervids would be unnecessarily broad and harsh when, in most cases, tailored herd plans can be used to minimize both the risk of CWD transmission and the financial burden on owners of premises. The length of a ban on restocking may be stated as an actual time period in months or years, or it may be condition-dependent, e.g., a herd plan might prohibit restocking based on the presence or levels of CWD in surrounding herds or wildlife.

Some commenters suggested that the definition of a herd plan in part 55 should state that it must be approved and signed by all three involved parties—APHIS, the State, and the herd owner. As proposed, it seemed that the document was executed between APHIS and the State but affected the herd owner.

As described in the proposal, the herd plan will be developed with extensive input from the herd owner, because it will include procedures developed to address the particular risks and situation of a herd. We agree that, although the APHIS Administrator has the ultimate authority to determine that a herd plan is adequate, all three involved parties should approve and sign the herd plan. Therefore we have changed the language in the definition to state that a herd plan will become effective after "it has been reviewed and signed by the Administrator, the State representative, and the herd owner."

One commenter stated that the herd plan definition's requirement for "regular examination of animals in the herd by a veterinarian for clinical signs

of disease" was vague, and could mean veterinarians must examine animals once a year, every month, or any other frequency.

We intend to establish the frequency of veterinary examination for each herd in the body of the herd plan developed specifically for the herd. We did not specify a frequency in the rule because it will be set based on the particular circumstances and risk conditions associated with each herd.

A zoological association commented that the herd plan definition could impose a tremendous burden on zoos with its requirement for "reporting to a State or APHIS representative of any clinical signs of a central nervous system disease or chronic wasting condition in the herd." The association interpreted this to mean that zoo veterinarians would have to report every cervid that exhibits chronic weight loss or an unsteady gait, both of which are common in older animals.

We believe this commenter did not take into account that this requirement applies only to herds that are under a herd plan, and that most zoos will not be subject to herd plans. A zoo, like any herd, would become subject to a herd plan only after it is found to be CWD-positive, CWD-exposed, or CWD-suspect. This should happen to zoos only rarely, but when it does, it is important that all clinical signs that may indicate CWD be reported and investigated.

#### *Consistency Between CWD Regulations and Other TSE Regulations*

Several commenters stated that the regulations for CWD, BSE, and scrapie should have similar structures, accepted risk levels, and effects. They stated that TSE causal agents for each disease and their effects on ruminants are sufficiently similar to demand virtually complete compatibility between regulations. They said that the continuing risk of cross contamination between species also requires regulatory consistency. Another reason they provided for consistency between CWD, BSE, and scrapie regulations is that, without it, cervid producers may be subject to discriminatory, anti-farming regulatory pressures. Some commenters suggested that farmed or captive deer, and elk generally should be treated the same as other domestic livestock. Some commenters questioned why owners of farmed or captive cervids are expected to test 100 percent of on-farm mortalities, while owners of cattle (potentially affected by BSE) test very few on-farm mortalities and a fraction of downer animals sent to slaughter, and owners of sheep (potentially affected by

scrapie) usually test only animals exhibiting clinical signs of scrapie.

In responding to these comments, we emphasize that the TSE diseases that affect different species of domestic livestock are not all the same disease. They have different modes of transmission and different pathogenicity, and taking these facts into account means that we cannot have the same approaches for all of our TSE programs and still attain our goals. At this point in time, the BSE program is a surveillance and prevention program, not a disease control program like the CWD certification program, and, as such, requires completely different standards and testing levels. The scrapie program, like the CWD program, is a certification program for an endemic disease. Where possible, we have tried to make the CWD program consistent with the scrapie certification program. However, several factors make it necessary that participants in the CWD program, unlike the scrapie program, must make all herd mortalities (over 12 months of age) and all animals sent to slaughter available for sample collection and testing. The most obvious reason for this difference is that two powerful surveillance tools are available to the scrapie program that are not available to the CWD program, a live animal test for scrapie and scrapie susceptibility genotyping.

#### *The 5-Year Standard*

Many commenters addressed the provisions of the rule that use a 5-year standard regarding risks of CWD. Some commenters questioned the part of these definitions that would classify an animal or herd as exposed based on contact with a CWD-positive animal anytime within the preceding 5 years. These commenters stated that including exposure that occurred 5 years before is not based on known risk or scientific fact, and suggested that a 3-year limit would be sufficient.

The 5-year standard is used in the definitions of *commingled*, *CWD-exposed animal*, and *CWD-exposed herd*, and the progress of a herd to "Certified" status also requires 5 years of monitoring without evidence of CWD. All of these uses assume that a cervid that contracts CWD will develop signs of the disease—in fact will almost certainly die from the disease—in less than 5 years. Based on that assumption, the rule requires investigation of an animal or herd's exposure to incidents within the past 5 years and, if a herd is continually monitored for CWD for 5 years without positive test results, the CWD risk in the herds is considered low.

All commenters agreed that the incubation period for CWD is less than 5 years. The key question for many commenters is, how much less? The expense of participating in the CWD program increases incrementally with the length of time required to reach "Certified" status. Also, with regard to exposure to CWD, many more animals and herds must be considered exposed if we consider exposure that happened 5 years ago than if we consider only exposures that happened in the past 2 or 3 years.

Many commenters suggested that a 3-year standard for exposure and for reaching "Certified" status is adequate and is justified by scientific research on the CWD incubation period. A few commenters also suggested either shorter or longer periods than 3 years for this standard. In addition to citing scientific research that supported an incubation period of from 24 to 34 months, some commenters also referred to State animal health agency records as supporting a 3-year standard. They stated that records of trace-back and trace-forward investigations of animals associated with CWD-positive herds did not show any cases where a CWD-positive animal acquired the disease more than 30 months prior to diagnosis. Some commenters stated that using a 5-year standard is arbitrary and simply incorporates a 2-year safety margin. Some commenters stated that certain existing State CWD programs allow animals to move into their States after only 3 years of monitoring for CWD.

We are not changing the 5-year standard in response to these comments. The choice of 5 years was made based on several factors, including the probable maximum incubation time for CWD and program design decisions about time spans realistically needed for all the participants in a herd certification program (Federal and State animal health personnel, cervid producers, laboratories, and others) to perform all the duties required of them.

The goal of the CWD certification program is to rapidly eliminate a disease that is not currently widespread in the farmed cervid industries. It will take much longer to achieve this goal if the program standards are set too low at the outset and must be made more stringent later; if, for example, we applied a 3-year standard at the outset only to find that it allowed CWD-positive animals to further spread CWD without being detected. Until there is definitive data to allow for less stringent measures, we must use a conservative approach based on current knowledge.

We agree that many studies suggest an average incubation period for CWD of

no more than 36 months. For example, a study<sup>1</sup> in captive elk at the Colorado Division of Wildlife, Foothills Wildlife Research facility, found that the average incubation period for elk in its herd that were naturally exposed to CWD in a contaminated environment was 26 months (range 18–36 months). However, in this same group of elk and in the same pens, there was a case of CWD in an individual animal that occurred 5 years after the last CWD death in the herd. This could have been the result of a later environmental exposure or it could represent a 5-year incubation period.<sup>2</sup> Preliminary reports from an ongoing APHIS and Agricultural Research Service research project in Ames, IA have also identified animals that did not show signs of disease until at least 4 years after infection, and animals that do not show signs of disease 4 years after infection but that test positive for CWD through unofficial tests such as rectal biopsy and the third eyelid test.

In pathogenesis studies<sup>3</sup> in mule deer and elk at the University of Wyoming, high dose oral inoculation produced an average incubation (from exposure to onset of clinical disease) of 23 months (range 15 months to >25 months) in mule deer. Similar work in elk showed the range of incubation was 12–34 months. The researchers acknowledged that experimental infections (single dose oral exposure to brain material) probably underestimate natural incubation times as it is likely that greater exposure results in shorter duration of incubation. In other words, experimental infections most likely represent the range of minimum incubation times. Maximum incubation times are not known but most likely exceed 25 months for mule deer and 34 months for elk.

For these reasons, we believe that incubation periods for low dose natural exposures may be longer than incubation periods for high dose oral inoculations used in most research. Based on the information we have now, the longest incubations likely fall between 3 and 5 years. This supports establishing the program with a 5-year timeframe for tracing animals and certifying herds to ensure the program locates CWD-positive animals.

We anticipate that research, monitoring, and surveillance will reveal

more precise data about CWD transmission over the next few years. If new data support changing the 5-year standard, APHIS will initiate rulemaking to modify it.

#### *Animal Identification*

Many commenters addressed the proposed animal identification requirements. Some requested more flexibility in the type of approved identification so that producers could make better economic decisions about what type of identification worked best for their herds. We agree, and have added the phrase “or other device approved by APHIS” to the lists of approved identification devices (electronic implant, flank tattoo, ear tattoo, or tamper-resistant ear tag) in § 55.25, *Animal identification* and § 81.2, *Identification of deer, elk, and moose in interstate commerce*. We will approve alternative identification on a case-by-case basis as the program is implemented. The criteria for approving identification devices will be whether they provide permanent, secure identification, are cost effective, and are practical for those who must apply and read the devices.

Many cervid producers commented that the proposal to require two forms of official identification would be very burdensome, due to the expense and difficulty of assembling and restraining an entire herd to apply the devices. This involves high labor costs, risks of harming the animals, and, if tranquilizer darts are used, dart drug costs of \$30 to \$35 per animal. Some commenters suggested that APHIS could mitigate this burden by phasing in the two identification requirements over the first 2 or 3 years of program participation. Some commenters also suggested that a second form of official identification should only be required when animals are moved from an owner's premises, not for every animal in the herd.

We are making several changes to the animal identification requirements, discussed below, in response to these comments. We also intend to work with producers when they enroll in the program to allow them to apply the required animal identification at a time and in a manner that minimizes the burden on the producer, who is responsible for ensuring that animals are identified when required and for the costs associated with identifying the animals.

When applying identification devices, producers may be able to schedule identification activities at a time when they already need to restrain animals, such as the annual physical inventory, or may be able to apply identification to

a few animals at a time over extended periods, or may find other ways to economize on the process. More information is being developed on flexible alternatives for accomplishing program requirements, including application of animal identification devices required by the program, and this information will be made available to the public when it is ready.

We are not eliminating the requirement for a second form of animal identification because accurate identification is a critical element of the program, and loss or obliteration of identification devices is quite common with cervids. A producer who can't logistically meet the identification and inventory standards will be unable to participate in the CWD Herd Certification Program. Participation must be contingent on ability to meet the requirements, or the program will lose effectiveness and industry confidence. Producers who want their herds to achieve “Certified” status may need to alter their management practices in order to meet program requirements.

However, we are changing the identification requirement so that only one of the two required identification devices attached to the animal must have a nationally unique animal identification number that is linked to that animal in the CWD National Database, where information on the animal's current herd may be cross-referenced. The other animal identification device need only be unique within the animal's herd; that is, it does not need a nationally unique number, but may instead merely identify the herd and distinguish different animals in the herd. Since the second means of animal identification is only required to be unique for the individual animal within its herd, this should allow continued use of most existing forms of animal identification as the required second means of identification.

To accomplish this change, we are separating the proposed defined term *official identification* into two new defined terms, *animal identification* and *official animal identification*. We are also retitling § 55.25, *Official identification*, as *Animal identification*, and are changing it as described below.

We define *animal identification* as a device or means of animal identification approved by APHIS for use under 7 CFR part 55. The definition also notes that examples of animal identification devices that APHIS has approved are listed in § 55.25.

We define *official animal identification* to mean devices or means of animal identification approved by

<sup>1</sup>Miller et al., 1998 Epidemiology of Chronic Wasting Disease in Captive Rocky Mountain Elk, *Journal of Wildlife Diseases*, 34:532–538.

<sup>2</sup>Miller, personal communication.

<sup>3</sup>Williams et al. 2002. Chronic Wasting Disease of Deer and Elk. A Review With Recommendations for Management. *Journal of Wildlife Management* 66(3): 551–563.

APHIS to uniquely identify individual animals, with examples provided in § 55.25. The definition states that official animal identification must include a nationally unique animal identification number that adheres to either the National Uniform Eartagging System, the AIN (Animal identification number) system, a premises-based numbering system that uses an official premises identification number (PIN), or another numbering system approved by the Administrator for the identification of animals in commerce.

Revised § 55.25, *Animal identification*, now says that each animal required to be identified must have at least two forms of animal identification attached to the animal, that the means of animal identification must be an electronic implant, flank tattoo, ear tattoo, tamper-resistant ear tag, or other device approved by APHIS. The revised section states that one of the animal identifications must be official animal identification as defined, with a nationally unique animal identification number that is linked to that animal in the CWD National 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.

The nationally unique identification number and all the animal's identification data from the second form of identification will be entered into the CWD National Database. This will allow an authorized user of the CWD National Database to use either identification number to retrieve all information on the animal and its herd and premises.

The nationally unique identification number approach is consistent with the national animal identification system (NAIS) that APHIS is in the process of developing and implementing in cooperation with States and animal industries. The NAIS is intended to be an effective, uniform, consistent, and efficient national animal identification system. An overview of the NAIS is available at <http://animalid.aphis.usda.gov/nais/index.shtml>.

To make our CWD regulations consistent with the NAIS approach that is under development, we are also adding a definition recently added to other APHIS domestic livestock regulations. On November 8, 2004, we published in the **Federal Register** an interim rule concerning livestock identification and the use of numbering systems for identification devices (69 FR 64644–64651; Docket No. 04–052–1). The interim rule amended the APHIS regulations that address interstate movement of livestock (9 CFR parts 71,

77, 78, 79, 80, and 85). One purpose of the interim rule was to authorize use of an alternative numbering system for individual animal identification that assigns a unique number to each animal identified under the system, to encourage consistency with the NAIS. The interim rule included definitions of *animal identification number (AIN)* and *premises identification number (PIN)*, which we are adding to the CWD regulations in 9 CFR parts 55 and 81. The definition of *animal identification number (AIN)* reads: “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.” The definition of *premises identification number* reads: “Premises identification number (PIN). 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 premises identification number 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 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.”

This definition of AIN is added to clarify the sentence in the new definition of *official animal identification* that reads: “The official animal identification for an animal must include a nationally unique animal identification number, such as an AIN number.” While the rule does not require use of an AIN—other nationally unique identification numbers can meet the requirement—we wanted to make it clear, in preparation for implementation of the NAIS, that NAIS-compliant individual animal identification will also meet the requirements of this CWD rule.

Some commenters suggested that the regulations should specifically “grandfather in” as animal identification any form of identification that is currently accepted by a State CWD program.

We are not giving blanket approval to all forms of identification currently used by a State CWD program because we may not be aware of the characteristics of all such devices in use, and a few may not be adequate for program purposes. We do expect to approve most, if not all, identification devices in use by State CWD programs, under the provision we are adding (discussed above) to allow identification by “any other device approved by APHIS.”

Some commenters suggested that cervids captured from a free-ranging population for interstate movement and release should also be required to have two forms of animal identification because such animals are not regularly observed and hence are more likely to lose one form of identification between extended observation periods.

We agree, and we are changing the requirements for animal identification to require that free-ranging animals captured for interstate movement and release, like other farmed or captive cervids, must have two forms of animal identification, one of which must be official animal identification. We are making this change by removing the phrase “except for free-ranging animals captured for interstate movement and release in accordance with § 81.3(b), which must have at least one form of identification” from § 81.2, *Identification of deer, elk, and moose in interstate commerce*, and revising the phrase “has at least one form of official identification” in § 81.3(b) to read, “has two forms of animal identification, one of which is official animal identification.”

Several commenters asked whether there was a specific age before which animals in participating herds must be officially identified.

The proposed rule did not establish a specific age by which animals must be identified. We did not do so because local herd conditions will affect both when identification is needed, and when it is practical to apply it. However, the commenters are correct that the rule should be more specific about when identification must be applied, both to help herd owners comply with the requirement and to ensure that the animals are officially identified before certain events that present risks of spreading CWD can take place, such as interstate or intrastate movement of the animal from the premises, which may result in exposure to other animals.

Therefore, we are adding the following sentences to paragraph (b)(1) of § 55.23, *Responsibilities of herd owners*: “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." We are using 12 months as the age by which animals must be identified because that age has been suggested before by industry members as a reasonable standard, and because the seasonal nature of livestock management means that herd management events where applying identification is feasible are likely to repeat on a 12-month cycle.

We expect that many herd owners will use the annual inventory process as an opportunity to apply animal identification to animals born into the herd in the previous year. The Uniform Methods and Rules for the Chronic Wasting Disease Herd Certification Program (UM&R) describes other situations where owners may wish to apply identification at other times.

#### *APHIS Authority To Regulate Wild Cervid Capture and Release*

Several commenters stated that APHIS is overstepping its authority by regulating interstate movement of cervids captured and released from a free-ranging population. The commenters believe that any regulation of such movement should be under the authority of the respective State wildlife agencies. The commenters did not oppose requiring animal identification and documentation that such animals are free from CWD for such movements, but they did oppose including such requirements in APHIS regulations.

APHIS works cooperatively on CWD issues with many State wildlife agencies and will continue to do so. We rely on these agencies to apply and administer their State authorities over wildlife in support of mutual State-Federal goals for CWD control. We will work cooperatively with these agencies to achieve safe, low-risk movement of cervids captured and released from a free-ranging population. APHIS shares with State wildlife agencies the goal of avoiding the establishment of CWD in wildlife in new areas.

APHIS does not agree that we are exceeding our authority in applying regulatory requirements in an APHIS rule to the capture and release of cervids from a free-ranging population. The Animal Health Protection Act of 2002

("the Act") grants the Secretary of Agriculture (and by delegation of authority, the Administrator of APHIS) ample authority to do so. Under the Act, the Secretary may prohibit or restrict the movement in interstate commerce of any animal if the Secretary determines that it is necessary to prevent the introduction or dissemination of any pest or disease of livestock.

Under the Act's definitions, it is clear that this authority extends to regulating the interstate movement of cervids captured from one free-ranging population for release in another such population. The Act broadly defines *animal* as "any member of the animal kingdom (except a human)," which includes wild cervids. The Act broadly defines *interstate commerce* to include "trade, traffic, or other commerce" between or through U.S. States, territories, and possessions. The act of capturing animals, moving them interstate, and releasing them falls within this scope. The Act's definition of *move* specifically covers, among other things, the act of transporting, and the act of releasing into the environment; both apply to the translocation of captured cervids. It is not uncommon for multiple governmental agencies to have authority over the same things or transactions for similar or different purposes. One agency having authority to regulate a thing or transaction for one purpose does not preclude another agency from having authority over the same thing for a similar or different purpose. This is especially true when dealing at different levels of government, but is also true when dealing within the Federal government or within a State's or other jurisdiction's regulatory scheme. Nothing precludes such multiple authorities over the same thing or transaction, if each agency exercising authority with regard to the thing or transaction in question has the requisite jurisdiction to do so. The Secretary (and by delegation of authority, the Administrator of APHIS) has clearly been granted that authority under the Animal Health Protection Act.

#### *Applicability To Hunting Operations*

Several commenters suggested that hunting ranches should be regulated in an alternate manner that recognizes the constraints that exist for these farms. According to the commenters, most hunting operations are very large premises that do not normally restrain their animals' movements within the premises, making identification and inventory very difficult. Commenters said that detection of incidental mortalities throughout the year in order to make tissues available for testing

would be difficult and that dead animals in such facilities might not be located quickly enough to obtain samples suitable for testing. Commenters said that hunting operations are also seasonal, meaning that the requirement that all animals that die on the premises must be made available for testing would mean a flood of sampling for 4 to 5 months each year when hunters kill animals on the premises. They said that the volume of work during this period could adversely affect the quality of tissue collection, recordkeeping, and laboratory analysis. These commenters suggested that instead of the CWD Certification program as proposed, hunting operations could participate in a surveillance and monitoring program that was harvest-based, without strict animal identification and inventory requirements but including testing a statistical sample of each year's harvest for 3 to 5 years.

APHIS is willing to work with hunting premises owners and States to consider and evaluate suggested alternative approaches for hunting premises to meet program requirements. However, none of the approaches suggested in comments would be adequate to detect the presence of CWD with sufficient confidence to allow certification of the herd or to control the spread of CWD in hunting premises effectively. We believe that identification of all animals, an annual herd inventory, and extensive testing are the keystones of an effective CWD program, and these are the requirements that hunting premises owners asked us to reduce or eliminate. Alternative surveillance programs that sample a percentage of animals in hunting herds and that do not include identifying and inventorying all animals might ameliorate some concern about the presence of CWD, but we do not believe such an approach could provide the same degree of confidence that the CWD certification program requirements provide. If hunting premises owners want their herds to be certified, they must meet the requirements for the certification program.

#### *Eligibility of Cervid Owners To Participate in the Program and Enrollment Dates*

Some commenters suggested that CWD Certification Program participation should be limited to herd owners with no prior violations of State laws and regulations for livestock and animal care.

We agree with the spirit of this comment but believe that banning producers with "any violation" would

be too severe and could unnecessarily reduce participation in the program and program effectiveness. While sometimes APHIS officials may have information about relevant violations by applicants, we believe the enforcement and recordkeeping activities of State governments usually make them the best level to address questions about when particular producers have committed violations that indicate they are unlikely to comply with CWD Certification Program requirements fully and honestly. State veterinarians and other officials can address this question when deciding whether to admit a herd to their Approved State CWD Herd Certification Program or, in cases where there is no approved State program, the State veterinarians can still advise APHIS officials about violations by applicants applying to enter the Federal program directly. If an applicant has committed relevant violations, this may be cause to refuse consideration of the application if the violations are known at the time of application, or to deny the application if the violations are discovered later during evaluation of the application. To make this clear, we are adding the following sentence to § 55.22, *Participation and enrollment*: “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.”

Several commenters addressed procedures for “grandfathering” herds already in State CWD programs into the APHIS CWD Certification Program. Some believe that herds that have complied with a State program should be grandfathered in with the status they have achieved, even if their State program has not been designated as an Approved State CWD Herd Certification Program under APHIS regulations. Commenters stated that producers should not be penalized simply because their State, for whatever reason, did not, does not, or will not cooperate to get Federal recognition for the State program. Commenters also addressed the problem of “grandfathered” credit for herd owners who wish to enroll directly in the Federal CWD program because there is no State program available to them. Such owners may have maintained their herds for some time, in some type of voluntary individual or other non-State program, under conditions equivalent to the Federal program standards (animal

identification, monitoring, testing of suspect animals, restrictions on animals added to the herd, etc.), and should receive some sort of credit for this.

We generally agree that herd owners should be given appropriate credit for time their herds were maintained under restrictions equivalent to those in the Federal CWD program, whether that time was spent enrolled in a State program that later becomes an Approved State CWD Herd Certification Program, in a State program that does not choose to apply to be approved, or in some other program that nevertheless applied the same sort of herd maintenance conditions. Whenever we evaluate an existing State CWD program that has applied for approval and participation in the National CWD Program, we will carefully compare the requirements of the program as followed by that State to determine that the State, and thus herds in good standing in the State’s program, have met the minimum standards of our program. For herds in States that have not applied to become Approved State CWD Herd Certification Programs, appropriate credit will be granted for periods when the herd was complying with standards equivalent to the APHIS CWD Certification Program requirements, regardless of whether or not there is a State CWD program or whether the relevant State has formally requested status as an Approved State CWD Herd Certification Program.

However, we are imposing one limit on credit for herds that enroll directly in the Federal CWD program and have not participated in a State CWD program. If APHIS determines that the owner of such a herd has maintained the herd in a manner that substantially meets the conditions specified in § 55.23(b), the owner will be granted up to a maximum of 2 years’ credit. That is, in cases where a herd directly enrolls in the Federal CWD program and the herd is given credit for participation in an individual or other non-State CWD program, the herd’s enrollment date may not be set at a date more than 2 years prior to the date that APHIS approves enrollment of the herd.

We are prepared to grant unlimited credit for time spent in certain Approved State CWD programs but only a maximum of 2 years for time spent in an individual or other non-State CWD programs because 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. 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 is simply harder to establish with confidence that such herds comply with requirements over lengthy periods. We have chosen to limit the credit granted to such herds to 2 years because such a policy also has been used in the Canadian program for granting credit to herds.

One commenter stressed the importance of requiring that enrolling herds with pre-existing State status levels into the Federal program should be done only after inventory reconciliation with death records and review of mortalities and test results by APHIS to ensure that these “grandfathered” herds do, in fact, meet the same regulatory standards as the Federal program. We agree and intend to carefully evaluate existing State CWD programs and carefully compare the requirements of the program to the requirements of this rule before establishing herd enrollment dates and determining if herds may be enrolled at an advanced status.

Some commenters suggested that the granting of “grandfathered” credit should be something that occurs only during the early stages of program implementation. They suggested that it would be unwise to allow herds to enter the Federal program several years from now and to grant them credit for time the herds spent in some other type of CWD program, while at the same time the Federal CWD program existed and was available.

We agree. We have always intended that “grandfathered” credit be a transitional tool used in early stages of program implementation. Once the Federal CWD program and Approved State CWD Herd Certification Programs are fully implemented, they should be the only way to accrue program status because they will have the most extensive and reliable enforcement and records systems. To make this intent clear, we are stating in paragraph (a)(1)(i) of § 55.22, *Participation and enrollment*, that constructed enrollment dates (grandfathering) will be unavailable for herds that apply to enroll more than 1 year after the effective date of this rule, and the enrollment date for herds that apply after that date will be the date APHIS approves the herd participation.

In an issue similar to the grandfathering policy, the proposed rule did not clearly state how the enrollment date or the herd status would be set

when a newly-formed herd enrolls and the herd contains only animals from herds that were already enrolled in the Program. Throughout this rule a guiding principle is that the status of herds is determined by the lowest status animal contained in the herd. To make it clear that this also applies in situations where herds are formed using animals from herds that have already achieved some status in the program, we are adding the following language to the sections addressing enrollment dates and herd status.

In § 55.22(a)(1), *Participation and enrollment*, we are adding a new paragraph (ii) to read “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.”

In § 55.24(a), *Initial and subsequent status*, we are adding the phrase “except that; if the herd is comprised 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.”

One comment noted that the proposal said a CWD-positive or -exposed herd may not apply to enroll, and suggested that it would be better to allow these herds to apply and develop a herd plan than to have them remain unmonitored and outside the system.

We agree that it would benefit program goals to include such herds. To do so, we are revising paragraph (a) of § 55.22, *Participation and enrollment*. The proposed first sentence of this paragraph read “Any owner of a captive deer or elk herd (except for CWD-positive herds, CWD-exposed herds, and CWD-suspect herds) may apply to enroll in the CWD Herd Certification Program by sending a written request to the State animal health agency, or to the veterinarian in charge if no Approved State CWD Herd Certification Program exists in the herd’s State.” We are removing the phrase “(except for CWD-positive herds, CWD-exposed herds, and CWD-suspect herds).” We are also adding the following sentence later in the paragraph: “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.”

A zoological association recommended that those zoological institutions that possess reliable traceback capabilities on cervid necropsy samples should be grandfathered into the certification program with an enrollment date set at

the date in which the first samples (if properly saved, stored, and representative of all cervid deaths in the collection) were obtained and archived.

We believe that the regulations as proposed will allow us to take such necropsy sampling evidence and other zoo disease control program activities into account when setting the enrollment date for zoos and similar institutions. There are several problems associated with enrolling zoos into the certification program, and the special circumstances associated with zoos may be the subject of future rulemaking addressing the certification program. For example, many zoos have not been considered eligible to enroll in State CWD programs and, consequently, there may be few State records documenting CWD monitoring at zoos. On the other hand, the records maintained by individual zoos for their disease control programs may sometimes provide documentation equivalent to State CWD program records. APHIS recognizes that most zoos have very active programs to prevent the spread of diseases such as CWD within their animal collections and to prevent the spread of disease to other sites when animals are removed from the zoo. If other program requirements have been met and documented by a zoo through appropriate recordkeeping, up to 2nd year status in the CWD Herd Certification Program can be granted.

#### *Economic Effects*

Several commenters questioned some of the figures and assumptions in the proposed rule’s economic analysis. Most of these commenters expressed concern that the analysis underestimated the degree of adverse impact; some were concerned that the additional costs of program participation would drive many cervid producers out of business. Some commenters suggested the analysis overestimated the price owners can currently get when they sell animals, and underestimated the annual costs of compliance in estimating “increased direct costs totaling about \$1,600 annually for the “average” elk herd owner (i.e., one with a herd of 50 elk).” One commenter stated that, based on his experience, it was possible to participate in his State herd surveillance program for CWD at an annual cost of a fraction of \$1,600. Several commenters stated that herds participating in the program would be essentially unable to sell animals or do business for 5 years, until the herd achieved “Certified” status, and that herds could not survive without income for this long.

We used the best economic data available at the time the proposed rule

was written. The cervid market is volatile, and some cost, price, and inventory data has changed since that time. We have updated the economic analysis for this final rule with data from several sources, including the 2002 Census of Agriculture. While some of the dollar estimates in the analysis have changed, its overall conclusion remains the same. The rule should have a positive economic effect on deer and elk farmers, both large and small, over the long term, with collateral benefits due to a decreased risk of spreading CWD from farmed or captive to wild cervids. There is currently no significant moose farming industry in the United States, and if one develops in the future, the economic effects of this rule on moose farming should be similar to its effects on deer and elk farming. The effects on herd owners will vary depending on their circumstances. In many cases the annual costs for an owner will not increase significantly because the herd is already participating in a State CWD program with similar requirements and costs. It is not true that participating herds will be unable to generate any income until 5 years pass, or until they are certified. First, many herds that participate will enter at a higher herd status than First Year because they retain their status from a State program when such programs are “grandfathered” into the Federal program. Second, participating herds that enroll at the beginning of the program and attain Second Year or above herd status can sell animals interstate to herds of an equal or lower status. Finally, this final rule establishes an exemption (discussed below) from the requirements of § 81.3 for animals moved interstate for slaughter.

#### *Herd Owner Responsibilities*

Numerous commenters addressed the description of the responsibilities of enrolled herd owners in § 55.23(b). One commenter stated that the requirement setting the minimum age over which animals that die are subject to testing at 16 months is arbitrary and unscientific. This commenter stated that, since infection seems to predominately emanate from calfhood, a more realistic age estimate is perhaps 9 months, and suggested that younger animals are carrying the disease but are just not being tested for it.

The proposed minimum age of 16 months (which is changed to 12 months in this final rule) was based both on testing practices in most existing State CWD programs and on average minimum incubation times observed in experimental inoculation of elk and deduced from surveillance records.

While we might be able to detect CWD in younger animals if all ages were tested, and while we would like to detect CWD as early as possible, the goals of the program are to control the spread of the disease through consistent and economically practical herd testing and certification over longer periods of time. Testing very young animals imposes additional costs on producers, States, and APHIS in exchange for additional epidemiological information of minimal value to the program goals. However, we agree that the best available scientific knowledge concerning the age when animals may be infected and the age that tests can reveal infection suggest that testing animals somewhat younger than 16 months could provide additional epidemiological data useful to controlling CWD. Therefore, we are changing the rule to require testing of animals 12 months or older. 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 believe this standard will not significantly increase costs for producers. We also note that this change only affects activities after the effective date of this rule—that is, existing State programs that tested animals 16 months and older prior to this date will still be eligible to be “grandfathered in” as Approved State CWD Herd Certification Programs, provided they meet the other eligibility requirements.

One commenter suggested that, in addition to being required to report all deaths of herd animals, the owner should also be required to report all animals that escape or disappear. This would ensure program officials were aware when unusually large losses might indicate either the presence of disease or inaccurate recordkeeping. This would also allow the program to address the risks associated with reintroduction of an accidentally released deer or elk back into the farm. We agree, and have added this requirement to § 55.23(b)(3).

One commenter questioned the requirement that owners must make available for tissue sampling and testing the carcasses of all herd animals that die aged 16 months or older. The commenter stated that there needs to be an allowance for a percentage of mortalities not discovered in time to preserve the carcass. The commenter believes this should be allowed because CWD is highly contagious and missing a percentage of the herd should not

result in the overall testing program missing the disease in the herd.

We do not agree with the reasoning of the commenter and do not think it is necessary to make any change to the rule in response to this comment. While a herd owner will be in violation of a requirement if he or she does not provide a carcass for testing, we realize that there may be certain situations where a herd owner will not be able to provide a fresh carcass or a high quality sample. Program officials have ample flexibility to deal with such situations without adversely affecting the enrolled herd’s status.

Several commenters questioned the requirement in proposed § 55.23(b)(3) that the owner must “immediately report to an APHIS employee or State representative all animals that escape or disappear, and all deaths of deer, elk, and moose in the herd aged 16 months or older.” The commenters suggested that the meaning of “immediately” be clarified, perhaps to mean “within 24 hours,” and also asked for further details on what information should be included in such a report. A zoological association and a State agency also noted that hundreds of individual notifications could overwhelm APHIS and State personnel and suggested that, since there are many causes of mortality within farmed or captive cervid populations that involve nervous system complications and chronic weight loss unrelated to CWD, submission of periodic cervid mortality reports might be allowed for herds where CWD is not known to occur.

APHIS deliberately used the word “immediately” for the notification requirement because we want owners to notify the APHIS employee or State representative as soon as possible in every case. Immediate notification is required because the quality of tissue samples and related test results are directly related to the length of time that elapses between death and sample collection, and it takes time to arrange for sample collection after notification. We did not use a standard such as “within 24 hours” because in some cases owners may then wait nearly 24 hours to notify us, even if it was possible to notify us within an hour after the animal’s death or disappearance was discovered. In enforcing the “immediately” standard, APHIS will allow for reasonable delays due to such things as the time it takes an owner to consult inventory records to determine the identity of the animal, or the possibility that the APHIS employee or State representative is not available to receive notice when the animal is discovered. For example, if a dead

animal is discovered early in the morning, APHIS would expect to be notified that day, not the next; but if the animal were discovered late in the evening, and the APHIS employee or State representative had not supplied the owner a means of giving notice at any time (e.g., a 24-hour telephone number for notifications), then the next morning would be considered soon enough for “immediate notice.”

Regarding the comment requesting what information should be contained in the notice, we have added in § 55.23(b)(3) a requirement that the notice must include the identification numbers of the animal involved and the estimated time and date of the death, escape, or disappearance.

In response to the zoological association and State agency’s requests that periodic cervid mortality reports might be allowed instead of immediate notification in some cases, we believe that, in a very few situations, such arrangements might work depending on the particular situations of herds (including zoo collections) and their respective APHIS employees or State representatives. In this final rule, § 55.23(b)(3) provides 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. We are also willing to receive and evaluate suggestions for how the regulations could be changed in future rulemaking to provide additional flexibilities for cervid herds or collections in special circumstances that justify alternative approaches to issues such as animal mortality reporting.

To accomplish these changes, we are revising proposed § 55.23(b)(3) to read as follows: “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. A herd owner may make arrangements as to what constitutes immediate notification with the APHIS employee or State representative responsible for the herd, who may, at his or her discretion, allow delays in notification caused by extenuating circumstances such as weather or other conditions beyond the control of the herd owner. 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 make the carcasses of the animals available for tissue sampling and testing. 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."

#### *Herd Status, Suspension, and Appeals*

Some commenters stated that the proposed procedure to appeal herd status decisions is unfair because the hearing would be held by the Administrator rather than an independent third party. One stated that "the herd plan suspension procedures are an invitation to litigation as the determination and hearing the appeal is made by the undefined Administrator who always has the last word." Commenters stated that this would not be considered fair by any farmer or producer, and suggested that APHIS should use more sophisticated arbitration procedures with independent third parties as judges.

The appeal and hearing provisions in § 55.24(c)(1) are virtually identical to provisions in other APHIS regulations, and meet the legal requirements for appealing decisions at the agency level. We believe that hundreds of previous administrative hearings conducted by APHIS provide ample evidence that the rules of practice employed by the Administrator for hearings provide a fair and impartial hearing opportunity. Herd owners who do not agree with the decision of the Administrator after a hearing can exercise their due process legal rights to pursue redress in Federal court.

One commenter stated that the requirement that herd owners must make their appeal in writing to the Administrator within 10 days does not allow owners sufficient time to gather the information that is required in the formal appeal. The commenter suggested that, after requesting a hearing, the owner should be granted additional time to organize a defense.

We believe that 10 days is sufficient time for herd owners to prepare a simple letter of appeal that states all of the facts and reasons upon which the herd owner relies to show that the reasons for the proposed action are incorrect or do not support the action. The form and content of the appeal letter do not need to follow any requirements for rules of evidence or legal briefs; the letter simply needs to

state the basis for the appeal. If the appeal letter also identifies a conflict as to any material fact, then a hearing will be scheduled and the owner will have additional time to prepare for the hearing.

One commenter addressed the proposed requirement in § 55.24(b)(2)(ii) that a suspended herd that is reinstated into the program after a herd plan is developed for it "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." The commenter stated that setting a new enrollment date for these herds and making them lose their accrued program status would often be unfair, because herds may be placed in Suspended status even if they faithfully comply with program requirements for several years. The commenter believed that time spent complying with program requirements without signs of CWD in the herd decreases the herd risk and should be reflected in the herd status. For example, consider a herd that has spent 3 years in the program and has complied with all identification, testing, and other requirements. Suppose that 6 months before joining the program, the herd acquired an animal from another herd, and the animal died shortly after arriving in the herds and was not tested. Today, APHIS discovers that the source herd for that animal is positive for CWD. Therefore, the herd that received an animal from it, and is now in Fourth Year status in the CWD Herd Certification Program, is suspended. If that herd is reinstated with a new enrollment date and First Year status, that amounts to saying that it has the same risk as a herd that is enrolling for the first time and which has absolutely no previous history of monitoring and testing for CWD. This is inconsistent with the principle in the rest of the rule that regulatory requirements should decrease proportional to the amount of time a herd has spent monitoring and testing for CWD.

We agree and have made corresponding changes to § 55.24(b)(2)(ii). The changes allow reinstatement of a Suspended herd with its original enrollment date if the herd is in good standing in the program and has complied with its requirements. All Suspended herds that are reinstated still must comply with a herd plan developed to address the possible risks that caused their suspension. The relevant new language reads: "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 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."

#### *Interstate Movement Restrictions*

Several commenters stated that it is critical that the regulations establish a consistent nationwide standard for interstate movement that preempts State rules where needed. For example, some States only allow entry of animals that have been monitored for 5 years, regardless of the status of the herd to which the animals are moved. They said that current State-established interstate movement requirements are inconsistent and often not based on science, and that it is difficult to make business plans when movement requirements vary from State to State.

This rule will preempt State requirements for movement of cervids into States to the extent that the State requirements are in conflict with this rule. In addition, we expect that all States with significant cervid industry will develop Approved State CWD Herd Certification Programs, meaning that their requirements will be consistent with those of the Federal program, i.e., that State programs will have similar definitions and applicability and will impose requirements that are consistent with the Federal program. With regard to requirements for moving cervids into a State, we believe the requirements of this rule provide appropriate protection against the risk of spreading CWD through such movements. The gradual increase in program status required by § 81.3 to move cervids interstate will mean that eventually all cervids moved interstate must be from herds that have reached "Certified" status, entailing at least 5 years of monitoring.

One commenter stated that allowing facilities to move animals before reaching "Certified" status will have two negative effects. First, it is a disincentive for herds to reach "Certified" status if they can move animals without doing so. Second, it encourages States to maintain their own, stricter, movement requirements if they believe movements from lower-status herds present risks.

We do not agree and believe the commenter has misstated the effects of the rule. There are significant limits on moving animals before a herd reaches "Certified" status. Animals may not be moved interstate while the herd is in

First Year status, and after that animals may only be moved to herds with equal or lesser status (the receiving herd reverts to the lower status). There is also the gradual escalation of the status required to move animals interstate, so that 63 months after this rule takes effect, only animals from certified herds may move interstate. We also believe that States will find it to their economic benefit to allow movement of cervids into their States as long as they are moving to herds of equal program status and, therefore, similar risk levels.

One commenter suggested that an interstate movement requirement in proposed § 81.3(a)(1)(ii), requiring that “the herd is accompanied by a certificate \* \* \*” should read “the animals are accompanied by a certificate \* \* \*” because whole herds are not usually moved interstate. We agree, and have corrected this misstatement in the final rule. The language is corrected to read “the farmed or captive deer or elk is accompanied by a certificate \* \* \*” and is now located in § 81.3(a)(2).

#### *Interstate Movement Restrictions—Exemption for Slaughter Animals*

Many commenters stated that there should be an exemption to interstate movement restrictions to allow any cervid, whether or not enrolled in the program, to move interstate directly to slaughter. Some of these comments compared the risks of CWD to BSE, where younger animals may be moved to slaughter in the traditional feed lot and food chain situation because the age of the animals precludes significant risk.

Several commenters also suggested that cervids moved interstate for placement on a shooting preserve should be exempted from interstate movement restrictions if there were a guarantee that the animal would not come off the preserve alive.

In response to these comments, we have decided to create a partial exemption for animals moved directly to slaughter. We believe that doing so will not significantly increase the risk of spreading CWD since slaughter animals will be removed from contact with other animals, and we understand that increasing the opportunity to move animals to slaughter will provide economic relief for some owners. However, we need to monitor the movement of these animals to ensure that they do, in fact, move only to slaughter. We also wish to be kept informed when farmed or captive deer, elk, and moose are moved to slaughter, especially from herds not in the certification program or from herds that have not yet attained “Certified” status in the program, so we can arrange to

collect samples for testing, as appropriate, from these higher-risk animals. Therefore, we are adding a new paragraph § 81.3(c) to the interstate movement restrictions section to allow farmed or captive deer, elk, or moose, regardless of whether or not their herds are enrolled in the certification program, or, if enrolled in the program, regardless of their status relative to movement requirements, to move interstate directly to a recognized slaughtering establishment for slaughter if they have two forms of animal identification and are accompanied by a certificate issued in accordance with § 81.4. The required certificate is similar to the certificate used to move animals in the certification program interstate, in that it states the animal identification numbers of each animal moved, the number of animals covered by the certificate, the purpose of the movement, the points of origin and destination, the consignor, and the consignee. A certificate used to move animals to slaughter differs from the certificate used to move certification program animals interstate in that it does not need to state that the animals are from a herd participating in the CWD Herd Certification Program.

Instead, a certificate for movement to slaughter must state that an APHIS employee or State representative has been notified in advance of the date the animals are being moved to slaughter. This requirement will ensure that APHIS or the State can collect samples from these animals at slaughter when needed.

We are not creating an interstate movement exemption for cervids moved interstate for placement on a shooting preserve. Some commenters stated that the risk level of such animals is similar to that of slaughter animals, but the situations and risks are not similar. Animals moved to slaughter are kept from contact with other (nonslaughter) animals, and are slaughtered within a short time following movement. Animals moved to shooting preserves may live for years after movement and may come in contact with other domestic or wild cervids frequently during that time. The strong restrictions on slaughter animals result in lower risk levels than the minimal restrictions on shooting preserve animals. If exempted from the regulations’ controls, movement of shooting preserve animals would present a continuing risk because there is no guarantee that the animal would actually be hunted and killed on the new premises—or if the animal has CWD, that it would be killed before spreading the disease. CWD positive

animals inadvertently moved to a hunting premises could thus spread the disease to new populations of captive or wild animals, and without the paper trail created by interstate movement restrictions, Federal or State animal health officials would have no opportunity to prevent it, and might be unable to determine the source of the new disease locus.

We did determine, however, that we needed to provide, when the Administrator’s evaluation of the specific circumstances of a herd justifies it, greater flexibility in the interstate movement regulations to allow for movement of animals from herds that have not attained “Certified” status but whose surveillance and mitigation procedures are adequate to prevent the spread of CWD. We are, therefore, adding a new § 81.3(e), which states that notwithstanding any other requirements in the rule, interstate movement of farmed or captive deer, elk, and moose may also be allowed on a case-by-case basis under permit as approved by the Administrator, provided that adequate survey and mitigation procedures are in place to prevent dissemination of CWD.

#### *Recordkeeping and Inventory*

Several commenters stated that the regulations should clarify how and by whom registration and certification records will be maintained. Some commenters also stated that they understood that an annual physical inventory of herd animals would be required, but they did not see this requirement in the section describing herd owner responsibilities. One commenter stated that, when the proposal discussed the need for a physical inventory of animals, there was no discussion of the owner’s responsibility to ensure that State or APHIS representatives could conduct the inventory without substantial risk of injury to animals or workers. The commenter suggested that the final rule clarify the owner’s responsibility to gather the herd and sufficiently restrain each animal to allow inventory and verification of identification.

The UM&R includes descriptions of the procedures we expect to employ for recordkeeping and the annual physical inventory. We have also slightly revised § 55.23(b)(4) to clarify the owner’s responsibilities for recordkeeping and for the annual physical inventory. As revised, the paragraph reads: “The owner must maintain herd records including a complete inventory of animals that records 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. Upon request, the owner must allow an APHIS employee or State representative access to the premises and herd 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.”

#### *Reduced Testing Requirements for Certified Herds*

Several commenters suggested that, instead of the proposed herd certification program, APHIS should implement a surveillance program that relies on statistical sampling of a fraction of the cervids that die or are sent to slaughter. Some suggested that this approach, coupled with a requirement that herds maintain good records on animal acquisitions, could be effective and much less burdensome, especially for hunting operations.

We are not making any change based on this comment. Partial surveillance of mortalities in a herd, whether of a portion of the natural mortalities, of slaughtered animals, or of a combination, is not an effective approach for identifying and controlling a very low prevalence disease like CWD. Our epidemiological analyses show that while these surveillance strategies, especially combined with slaughter testing, could identify some affected herds, the disease would likely spread faster than containment resulting from the commenter's proposed surveillance strategy. Effective control requires animal identification, monitoring, recordkeeping, surveillance of all mortalities of animals 12 months and older, and interstate movement restrictions for as many herds as possible.

#### *Surveillance as an Alternative to Herd Certification*

Two commenters noted that § 55.24(a) of the proposal stated that, when a herd reaches “Certified” status, testing is no longer required for animals that are sent to slaughter or are killed on the premises of hunting or “shooter” operations. The commenters stated that such testing is good continuing

surveillance for CWD and recommended continued testing at a certain percentage.

We are not making any change based on this comment. While such testing is not required for animals in certified herds, the herd owners must still submit samples for all animals that die on the premises (not including animals killed by hunting as part of “shooter” operations or animals sent to slaughter). Testing these animals provides a better basis for continuing monitoring for CWD than would testing a percentage of random animals sent to slaughter or killed by hunters. Studies have shown that, when scrapie is present, it is found in a higher percentage of dead animals than in live animals, and we assume this is also the case with CWD, so testing all animals that die in a certified flock is likelier to disclose an outbreak than testing a percentage of all animals sent to slaughter or killed by hunters.

#### *Perimeter Fencing Requirements*

Several commenters asked for clarification regarding perimeter fencing requirements. They were unsure whether APHIS expected single fences, double fences for all herds, double fences in areas where CWD was endemic in wild cervids nearby, or something else.

The basic requirement of the regulation is for a single perimeter fence. As discussed above, two separate fenced areas with at least a 30-foot gap between them would be needed if an owner wanted to maintain two separate herds side-by-side. (See the discussion of the definition of *commingling* above.) Individual herd plans may also specify double perimeter fences for some herds, on a case-by-case basis, to address conditions such as CWD in nearby wild cervids or in farmed or captive cervids on adjacent premises. We plan to develop additional examples and guidance to help herd owners better understand this issue.

#### *Program Administration*

One commenter noted that proposed § 55.21, *Administration*, described the CWD Herd Certification Program as “a cooperative effort between APHIS, State animal health agencies, and deer and elk owners.” The commenter suggested that State wildlife agencies also be mentioned, since the program involves cooperation with such agencies for the capture and release of wild cervids and other matters.

We agree and have changed § 55.21 accordingly. Cooperation with State wildlife agencies is an important part of the program, as described in the preamble of the proposed rule. We

recognize that these agencies have regulatory authority for all or part of the farmed or captive cervids in some States.

Another commenter noted that proposed § 55.21 was the only part of the proposed rule that mentioned certifying herds as “free of CWD” and suggested that, consistent with the rest of the proposal, this reference should be to certifying herds as “low risk for CWD.” We agree, and have made the requested change.

#### *Research Animal Exemption*

At least 10 commenters stated that the proposed requirements would be incomplete and ineffective if the rule exempted cervids at research facilities from all requirements, which would be the effect of the proposed definition of *captive*. These commenters stated that CWD is known to have spread from research animals to wild cervids, and probably to captive cervids, either through release or escape of research animals or contact between research and wild cervids. Commenters variously suggested that interstate movement of research animals should be “monitored and controlled” or “closely regulated” and that “their destination research facilities should be known.” A commenter also stated that “an approval process should be identified” for research animal movement.

Although it is still unproven that CWD has spread from research animals to wild cervids in the past, we agree that research animals should not be totally exempted from movement requirements and have made changes to address this problem. We believe it would be unworkable to simply change the definition of *farmed or captive* to include research animals, and then allow research herds to enroll in the Certification program, due to the different nature and purpose of research herds. However, we can exercise close control over interstate movement of research animals by requiring a USDA permit for their movement. We have added this requirement to new § 81.3(d) of this final rule. We are also removing from the definition of *farmed or captive* the following sentence: “Animals that are held for research purposes by State or Federal agencies or universities are not included.”

The new research animal permit requirement in § 81.3(d) states that the Administrator may issue a permit if he or she determines that the movement authorized will not result in the interstate dissemination of CWD, and requires applicants to submit the following information when applying for a permit: The name and address of

the persons seeking the permit, the persons holding the research cervids to be moved interstate, and the person receiving the cervids to be moved interstate; the number and type of cervids; the reason for the interstate movement; any safeguards in place to prevent transmission of CWD during movement or at the receiving location; and the date on which movement will occur. The new requirement also states that 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.

#### *State Responsibilities*

Several commenters asked whether the scant availability of funds for program activities in various States could keep States from meeting their responsibilities under the proposed program. They stressed that if the program is to succeed, States need adequate funds to enforce quarantines, participate in developing herd plans, and conduct the necessary tracebacks.

We agree that active participation by States is important to the success of the certification program. That is why the description of State responsibilities in § 55.23(a) requires that States must have "effectively implemented" policies and programs to carry out the necessary quarantine enforcement, tracebacks, epidemiologic investigation, and other activities that rely on State involvement. If APHIS determines that a State has not devoted sufficient funds or personnel to perform these activities, APHIS will not be able to certify the State's CWD program as an Approved State CWD Herd Certification Program.

#### **Executive Order 12866 and Regulatory Flexibility Act**

This final rule has been reviewed under Executive Order 12866. The 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.

For this final rule, we have prepared an economic analysis. The economic analysis provides a cost-benefit analysis as required by Executive Order 12866, as well as an analysis of the potential economic effects of this final rule on small entities, as required under 5 U.S.C. 604. The economic analysis is summarized below. Much of the data regarding the cervid industry was provided by the two major industry

associations, the North American Elk Breeders Association (NAEBA) and the North American Deer Farmers Association (NADeFA). See the full analysis for the complete list of references used in this document. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**, or from this final rule's docket at the Federal Rulemaking Portal at <http://www.regulations.gov>.

Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture is authorized to regulate the movement in interstate commerce of any animal if the Secretary determines it necessary to prevent the introduction or dissemination of a livestock pest or disease; to hold, seize, quarantine, treat, destroy, dispose of, or take other remedial action with respect to such animals; to carry out operations and measures to detect, control, or eradicate diseases of livestock; and to cooperate with States or political subdivisions of States in programs to control livestock diseases.

#### *Alternatives Considered*

In assessing the need for this final rule, we identified three alternatives. One was to maintain the status quo, where State efforts are supported by Federal technical assistance and compensation programs. We rejected this alternative because it does not fully address disease risk, i.e., the possibility of disease spread through interstate movement. The current patchwork of State regulations hinders movement of animals believed to be at low risk for CWD and hence hinders growth of the industry. Also, this alternative does not give herd owners in States that do not have certification programs the opportunity to participate in such programs if they so desire. The status quo alternative would have no cost effects for APHIS but over time would impose additional costs on herd owners, who would face costs due to loss of animals from increased spread of CWD, loss of interstate and international markets, and possibly increased compliance costs for stricter State CWD programs as States react to CWD spread.

Another alternative was to simply prohibit the interstate movement of deer, elk, and moose altogether, without establishing a Federal herd certification program. This alternative would not significantly increase costs to APHIS, and would help reduce costs due to loss of animals caused by disease spread through interstate movement. However, this alternative does not afford producers the opportunity to seek the best-paying market for their animals in

any State. Accordingly, this alternative was rejected.

The third alternative, the one that we chose, was the establishment of a Federal herd certification program with interstate movement of animals contingent on participation in that program (with certain exceptions such as slaughter and research animals). This alternative substantially reduces the risk of exporting CWD from one state to another—because only deer, elk, and moose that have been subject to certain minimum surveillance criteria can be moved interstate—but at the same time allows producers the opportunity to seek the best-paying market for their animals. The costs and benefits of this alternative are discussed below.

#### *Summary of Economic Analysis*

This final rule will establish a CWD Herd Certification Program for farmed or captive deer, elk, and moose, and prohibit the interstate movement of deer, elk, and moose that are not enrolled in the program, with certain exceptions such as slaughter and research animals. Herds that participate will have to follow program requirements for animal identification, testing, herd management, and movement of animals to and from herds. Herd owners will be able to enroll in an Approved State CWD Herd Certification Program that meets minimum standards established by APHIS, or enroll directly in the Federal CWD Herd Certification Program if there is no approved State program in their location.

The following analysis is based largely on data collected from industry associations and sources of agricultural statistics, including census data. Prior to this rule, there were no Federal requirements regarding CWD for the interstate movement of deer, elk, and moose. However, at least 23 States have banned cervid introductions from other States, and at least 20 States have formal CWD certification programs for cervids in place, with requirements similar to the Federal requirements in this rule. The Federal program is designed to build on, rather than replace, existing State programs or State programs that are currently being developed. Herd owners in States that do not have an APHIS-approved program will be able to enroll in the Federal program.

This rule is intended to help eliminate CWD from farmed or captive cervids in the United States. It will support an existing APHIS program that pays indemnities to owners of CWD-positive herds who voluntarily depopulate their herds.

The final rule will primarily affect deer and elk farms and other cervid

facilities including zoos. In 2002 in the United States, there were an estimated 97,901 elk on 2,371 farms, and 286,863 deer on 4,901 farms. There are no known commercial moose farming operations, though some may emerge in the future. Without improved CWD control efforts, the disease could eventually infect almost all U.S. farmed or captive elk, deer and moose herds.

The final rule should have a positive economic effect on farmed and captive cervid operations, both large and small, over the long term. In the shorter term, the economic effect on deer and elk facilities will vary depending on the circumstances of each. Some operations, especially those who already participate in State programs and who take advantage of the increased access to out-of-State markets, should benefit immediately. Conversely, some operations could experience a significant adverse effect, especially those who cannot afford to pay the program's annual costs. However, given the available data, there is no basis to conclude that the final rule will have a significant negative economic impact on a substantial number of small entities in the short term.

The economic importance of the farming industries notwithstanding, the rule's primary benefits appear to lie in its ability to reduce the potential for the introduction or spread of CWD. However, it is difficult to translate that reduced potential into a dollar benefit.

#### *The Deer, Elk, and Moose Industries and the Impact of CWD*

The number of deer, elk, and moose in the United States that have died as a result of contracting CWD is unknown, largely because there is no way to track deaths among the free-ranging segment of the population. However, sampling has suggested infection rates ranging from less than 1 percent among wild white-tailed deer in Wisconsin to up to 15 percent among wild mule deer in northeastern Colorado. For farmed animals, the number of deaths directly attributed to CWD to date has been relatively low. However, for every infected animal, far more have been exposed to the disease.

Deer and elk are farmed for breeding stock, velvet antler, meat, and sales to game parks, hunting facilities, and exhibits. Velvet antler, considered a medical or dietary aid, is produced primarily for Asian markets. Deer and elk meat is a low-fat, low-cholesterol product, and when it is derived from farmed or captive herds (as opposed to meat harvested directly by hunters from wild populations) it is marketed primarily to gourmet restaurants, for

consumption by health-conscious dieters. The breeding stock market satisfies the need for replacement animals.

The most recent census data shows that there were 97,901 elk on 2,371 U.S. farms in 2002. The number of elk per farm varies, from a high of "500 plus" (for commercial farms) to a low of about 10 (for hobby farms). The value of each elk held also varies, depending on the type of animal (e.g., bull, cow, or calf), market conditions, and other factors. The average value of each elk is roughly estimated at \$2,000, with the typical high end value at about \$5,000. (The more valuable trophy animals hunted on game farms tend to be worth more than this average.) Based on the estimated average of \$2,000 per animal, the value of all 97,901 elk on U.S. farms is estimated at about \$196 million (97,901 × \$2,000). In 2001, gross receipts for members of the North American Elk Breeders Association (NAEBA), an industry group, totaled an estimated \$44.3 million.

The most recent census data shows that, in 2002, there were 286,863 deer on 4,901 U.S. farms. The number of deer per farm varies, from a high of about 3,000 (for commercial farms) to a low of about 5 (for hobby farms). The value of each deer also varies, depending on such factors as the type of animal and market conditions. An earlier estimate by the North American Deer Farmers Association put the average per animal value of all deer on member farms at \$1,687, which would make the estimated value of all 286,863 deer on U.S. farms about \$484 million (286,863 × \$1,687). As of January, 2002, capital investment (including land, fencing) in white-tailed deer farms totaled an estimated \$2.5 billion.

#### *Benefits of Rule*

The final rule will benefit the national cervid industry, cervid product consumers, individual herd owners, and individual States. The effects on each are discussed below, and benefits for small businesses are directly addressed in the section "Analysis of the Economic Effects on Small Entities."

The interstate movement restrictions that allow only "program" deer, elk, and moose to be moved interstate will help to prevent the spread of CWD among both the farmed and wild populations. Participation in a certification program substantially reduces the risk of spreading CWD from one State to another, because only deer, elk, and moose that have been subject to certain minimum surveillance and other criteria can be moved interstate.

Preventing the spread of CWD among deer, elk, and moose benefits entities and individuals that rely on those animals for their income. These include cervid farms, State agencies that sell hunting licenses, and employees of motels and restaurants in hunting areas. It also benefits individuals that rely on those animals for recreation and food. A study by a sociologist in Wisconsin found that when the disease seems contained there is little hunter effect. However, if the disease becomes widespread, data in his study suggest that hunters will abandon the sport. Also, hunters from counties in which CWD-positive animals were found were more likely to skip the 2002 gun season than were hunters from non-CWD counties.

Preventing disease spread also offers the potential for other, more far-reaching benefits. Although there is no known relationship between CWD and other spongiform encephalopathies of animals or humans, bovine spongiform encephalopathy (BSE) has had an immense negative impact upon European livestock systems. Action by USDA on CWD will demonstrate to our trading partners the seriousness with which we view the prevention and control of these types of diseases.

The outbreak of CWD in wildlife and farmed herds has motivated States to restrict the movement of elk and deer into States; and to start programs to control the disease within States. Prior to this rule, the various States did not follow a standard interstate movement policy, nor were there standards to ensure equivalency between State CWD programs. This resulted in a failure to maintain a nationwide marketing system under which healthy farmed elk and deer can be bought and sold throughout the United States. Producers of elk and deer are, therefore, generally limited to sales in their local marketing areas. The lack of a Federal CWD program has also limited U.S. producers' access to international markets for products such as antler velvet.

Based on the rate of increase in the number of infected herds in recent years, it is estimated that, without improved CWD control efforts, the disease could eventually infect almost all U.S. farmed and captive elk herds. Large movements of animals between herds exacerbate risks of disease spread. In Canada, after CWD was discovered in 1996, movements of animals from one herd resulted in the infection of 38 other herds, which caused the Canadian Government to buy and destroy 7,400 animals. While it is risky to extrapolate from limited data covering only a few

years, the few herds studied in detail do suggest that CWD is easily spread through unrestricted commerce in deer and elk, and could readily become established in most U.S. herds. The rule, therefore, could serve to protect substantial cervid industry livestock assets, valued at an estimated \$196 million for elk and \$484 million for deer.

For farmers with infected cervids, the losses can extend far beyond the direct loss of livestock. They can also incur costs for the disposal of the animal carcasses, as well as costs for cleaning and disinfecting their premises. In some areas, positive animals have to be disposed of through costly incineration or digestion, since even landfills require a negative test before accepting a carcass for disposal. Perhaps most important of all, owners of infected herds may also face State-imposed quarantines and State-imposed restrictions on the subsequent agricultural use of their land, actions which many view as tantamount to closure.

Even farmers with animals that have not been infected or exposed to CWD are affected, as evidenced by recent action taken by the Republic of Korea. That country recently suspended all imports of deer and elk, and their products, from the United States, due to concern that there may be a link between CWD and other transmissible spongiform encephalopathies of animals or humans. The precise impact of Korea's suspension is unknown, because data that are compiled on U.S. exports do not provide the level of detail necessary to identify deer and elk and their products. However, New Zealand is a major competitor to U.S. producers in the area of deer antler exports to Korea, and in 2001 the value of New Zealand antler exports to Korea increased from NZ\$34 million to NZ\$37 million. In 1998, Canada, another major competitor, sold 100,000 kg. of elk velvet, worth about CA\$13 million, to the Republic of Korea; Canada's sales dropped by 80 percent the next year, after CWD was introduced into Korea from Saskatchewan.<sup>4</sup> To the extent that the Federal certification program will reassure foreign trading partners that all State programs meet a standard for effectiveness, increased international sales are likely.

The rule's primary benefits are to help prevent the spread of and eradicate CWD in farmed deer, elk, and moose; assist efficient domestic elk and deer

marketing; maintain and enhance export markets of cervid products; protect wildlife resources; and obviate the need for greater public and private expenditures related to CWD in the future. The introduction of an aggressive control program now, when the number of known infected herds is small, reduces the risk of higher future Federal eradication program costs, such as Canada faced in 1996 when it had no certification program and CWD infection in one herd quickly spread to 38 herds, causing 7,400 elk to be destroyed.

The rule also demonstrates to our trading partners that the United States is able and willing to take early and aggressive action to protect the health of its animal and animal industries, making it easier for U.S. exporters to negotiate access to foreign markets.

#### *Costs of Rule*

The final rule has cost implications for herd owners, individual States, and APHIS. The impact on each is discussed below, and cost effects for small businesses are directly addressed in the section "Analysis of the Economic Effects on Small Entities."

#### *Cost for Herd Owners*

Participation in a State, or Federal, certification program will require that herd owners employ certain minimum disease preventative measures established by APHIS. The cost to comply with these minimum requirements will vary among individual herd owners, depending on the circumstances of each. Many herd owners, especially the larger ones, are likely to already be in at least partial compliance with one or more of the requirements on a voluntary basis, since they constitute sound management practice. Perimeter fencing is a case in point. Most herd owners already have perimeter fencing in place, if for no other reason than to keep animals from escaping.

The certification program requires that herd owners must make available for sample collection and testing the carcasses of all dead deer, elk, and moose 12 months of age or older (including animals killed on hunting premises). Many herd owners will hire an accredited veterinarian to remove and submit the required tissue samples. Collecting a sample and packing it for submission usually takes under an hour. Veterinarians charge herd owners about \$100 to collect each sample.

Participating herd owners will have to identify each animal uniquely, using two approved forms of identification, such as tattoos, ear tags, or electronic

implants. Although many herd owners already identify their animals, only a few are likely to use two forms of identification. The cost of identifying an animal will vary, depending on the type of identification used and other factors, including any costs associated with "rounding up" the animals for installation of the identification. The rules allow for the multiple use of the same form of identification, so, conceivably, each animal could have two ear tags, potentially the least costly form of identification. Ear tags cost about \$2 each. By comparison, veterinarians could be expected to charge herd owners at least about \$25 to implant each microchip.

It has been estimated that the program's minimum disease preventative measures will result in increased direct costs totaling about \$1,600 annually for the "average" elk herd owner (i.e., one with a herd of 50 elk), exclusive of any costs stemming from a CWD discovery within the herd. It is assumed that deer herd owners would face similar costs. The annual cost of \$1,600 includes \$1,000 for the annual inventory, \$100 for the maintenance of program records, \$250 for tagging, and \$200 for sample collection by a veterinarian, and \$50 for ancillary costs. The annual inventory cost of \$1,000 assumes veterinary fees to "read" tags (\$500) and hired labor (\$500). The sample collection cost of \$200 assumes that 2 animals over 12 months of age die per year. It is expected that the cost of sample collection will be less of a burden for hunting premises than for production or breeding herds, because of the relatively high per-animal profit margin for hunting premises, and because these businesses are already organized to pass on fees (e.g., for State-required tagging) to their customers. The price these premises charge to hunt an elk varies with the quality of the animal, and ranges from about \$3,000 for a lesser-quality bull elk to about \$10,000 for bull elk that score over 375 by the Boone and Crockett scoring system (i.e., an animal with an exceptional antler rack). Because these businesses generally schedule their hunts well in advance, it should be possible for them to schedule a veterinarian to collect samples at appropriate times without disrupting business or customer schedules.

Participating herds that are found to have CWD-positive or CWD-exposed animals will immediately lose their program status, and could reenroll only after entering into a herd plan. (A herd plan is a written herd management agreement, developed by APHIS with input from the herd owner, State

<sup>4</sup> Elk Production; Economic and Production Information for Saskatchewan Producers, Saskatchewan Agriculture and Food, November 2000.

representatives, and other affected parties, which sets forth the steps to be taken to eradicate CWD from a positive herd.) It is estimated that, in about 90 percent of herd plans, herd owners will agree to depopulate their herds, for which APHIS will pay eligible owners indemnities of up to \$3,000 per animal. Two likely consequences for a positive herd are State-imposed quarantines that can last several years, and State-imposed restrictions on the repopulation of cervids on the same premises. Fortunately, herd infection is rare. As of October 2005, only 31 farmed elk herds and 8 farmed deer herds have been found positive, representing less than 2 percent of all elk farms and much less than 1 percent of all deer farms. We estimate that 20 currently infected elk herds will be detected over the next 2 years after this rule is adopted.

Finally, the certification program will establish herd status, based on the number of years of enrollment in the program with no evidence of disease. Herd status will affect the movement of animals, since additions from a herd with a later enrollment date will cause the acquiring herd to revert to the status of the herd from which the deer, elk, and moose were acquired. Herd status, therefore, will tend to make animals from lower status herds less valuable than those from higher status herds, due to the reduced marketability of the former. This will be an issue for new (or short-term) participants in a certification program. Because they would have little or no previous surveillance history, their herds would be accorded lower status, an action that would likely cause a decline in the market value of their animals. This effect will decline over time as herds accumulate years in the program. Also, the "grandfather" provision for Approved State CWD programs means that in many cases the time herds spent in a State program, prior to adoption of this rule, will count toward their program status. Herd owners who choose not to participate in a certification program could also face a loss in animal value, since participating herds will be less likely to acquire animals from nonparticipating herds, due to penalties.

#### *Cost for States*

After this rule is adopted, we expect that all States which permit cervid farming will participate by developing approved State CWD programs under the regulations. Many of these States will likely make participation mandatory for all in-State herd owners.

States that do establish a certification program will incur the costs of setting

up and administering that program, including costs for the development of legislative/regulatory authority, surveillance and monitoring, recordkeeping and data sharing, disease research, and education and outreach to farmers. As a point of reference in this regard, it has been conservatively estimated that such costs for establishing and maintaining a CWD program for farmed elk will amount to \$47,000 per State per year.

In addition, States may also incur costs stemming from a possible disease discovery, such as costs for: the maintenance of quarantines, diagnostic testing, disposition of positive/exposed herds, and carcass disposal. The costs associated with a discovery of the disease can vary significantly, depending on the number of animals in an affected herd, the herd plan developed to deal with the disease, the type of carcass disposal, and other factors. Based on the experience of 5 of the States with farmed elk that have tested positive for CWD, the cost of responding to a disease finding is estimated at \$20,285 per herd, on average.

APHIS assists the States in their CWD eradication efforts by conducting testing and supporting surveillance and other activities that the States would otherwise have to fund themselves. Through fiscal year 2002, \$17.3 million of Commodity Credit Corporation funding was transferred to APHIS for CWD eradication activities. In addition, \$0.8 million of APHIS contingency funds were used for CWD eradication efforts. In FY 2003, APHIS received its first appropriated funding for CWD of \$14.9 million. That figure was \$17.8 million in FY 2004, \$17.9 million in FY 2005, and \$18.5 million in FY 2006.

#### *Cost for APHIS*

The direct costs APHIS will incur from this rule are the costs of approving and monitoring CWD programs established by States and the costs associated with establishing and administering a Federal program for herd owners who wish to participate but who are not located in States with programs. Both costs should be relatively insignificant increases, since APHIS already works closely with States on their CWD programs, and direct enrollment of herds into a Federal program is expected to be needed in no more than a few States with only a few cervid herds in each. APHIS may also incur some costs to the extent that it assists in the design and implementation of State programs that are established (or modified) in response to the rule.

APHIS' liability for indemnities could also be affected, if the newly established State programs result in the detection of more positive animals than would otherwise be the case. To date, APHIS has paid out more than \$12.5 million for CWD indemnities.

#### *Cost for Others*

It is likely that many hunting operations may elect not to participate in the program, especially those with large premises that do not normally restrain their animals, a situation that makes animal identification and inventory difficult. For hunting operations, any negative impact of not participating in the program should be minimal. First of all, most hunting operations are animal importers, not exporters; hunting operations—as distinct from separate breeding operations located nearby that support the hunting operations—generally do not ship their animals interstate. Second, those who pay thousands of dollars to hunt at hunting premises generally are in search of trophy antlers, not food; accordingly, hunters who patronize hunting premises may not be as concerned about CWD as hunters elsewhere. The fact that hunting operations do not participate in the program, therefore, should not be a significant issue for most prospective hunters at those facilities, especially if the facilities conduct alternative surveillance and monitoring activities or if the States where the hunting operations are located require CWD testing.

The final rule also adds a new requirement that animals moved for research purposes must be moved under a USDA permit. Owners of research animals should be only minimally affected by the rule, since few, if any, research animals are moved interstate. Furthermore, the permit that owners of research facilities would need in order to move their animals interstate should be easily obtainable, since the permit application requires only rudimentary information regarding the movement, i.e., information that should be readily available to animal owners at no cost to them to generate.

#### *Analysis of the Economic Effects on Small Entities*

The Regulatory Flexibility Act requires that agencies consider the economic effects of rules on small entities. This final rule primarily affects deer and elk farms, because they are most likely to be affected by the program's requirements and the interstate movement restrictions.

We do not have details about the size of the 2,371 elk farms and 4,901 deer farms in the United States. However, it is reasonable to assume that most are small in size, under the U.S. Small Business Administration's (SBA) standards. This assumption is based on composite data for providers of the same and similar services. In 2002, there were 41,238 U.S. farms in NAICS 11299, a classification comprised solely of establishments primarily engaged in raising certain animals (including deer and elk but excluding cattle, hogs and pigs, poultry, sheep and goats, animal aquaculture, apiculture, horses and other equines, and fur-bearing animals). For all 41,238 farms, the per farm average gross receipts in 2002 was \$39,868, well below the SBA's small entity threshold of \$750,000 for farms in that NAICS category.

To the extent that the rule prevents the spread of—and perhaps eliminates altogether—CWD in farmed cervids in the United States, small herd owners should benefit over the long term. The rule will also provide herd owners with increased access to potentially better-paying out-of-State markets. By establishing equivalency between State programs, and replacing the current patchwork of State regulations, the rule will reduce the cost of complying with multiple sets of requirements and facilitate the safe movement of animals between States. Even herd owners who sell their animals in-State only stand to benefit, since the program reduces their disease risk when importing animals from other States.

The benefits, however, do not come without a price. As indicated above, it is estimated that the direct cost to satisfy the program's prescribed minimum disease preventative measures will total about \$1,600 annually for the average elk herd owner (i.e., one with a herd of 50 elk), exclusive of any costs stemming from a CWD discovery within the herd. However, the annual cost does not appear to be particularly burdensome, since it is equivalent to 4 percent of the 2002 per farm average gross receipts for all U.S. farms in NAICS 11299 (\$1,600/\$39,868). Those herd owners who have the option and elect not to participate will avoid the program's annual costs but they will see the value of their animals discounted in the marketplace, since "non-program" animals will likely carry a stigma of inferiority. As discussed below, the discount is likely to exceed the program's annual cost for most herd owners, making participation mandatory from a practical economic standpoint for those who are not

required by their respective State to participate.

According to NAEBA, all herd owners sell breeding quality animals, and it is not unusual for the average elk herd owner to sell 10 or more breeding quality animals per year, commonly in the range of between \$2,500 and \$5,000 per animal. NAEBA estimates that, with a Federal certification program in place, non-program breeding quality animals could be sold in-State for breeding purposes, but only at a discount of about 50 percent from their value as program animals. By electing to participate, therefore, the average elk herd owner would more than offset the \$1,600 in added program costs with the sale of just 1 high value, or 2 low value, breeding animals per year. From an economic standpoint, therefore, most "elective" herd owners would be better off participating in the program than not participating.

The previous discussion assumes, of course, that the herd owners wished to continue in the cervid business. It is possible that the investment returns experienced by some herd owners are already so low that paying the added costs to join the program would not make economic sense. These herd owners, therefore, would effectively be forced out of the cervid business by the rule. The number of such herd owners is unknown but it is likely to be small, given that the added costs are equivalent to 4 percent of 2002 average annual gross receipts for farms in NAICS 11299, a category that includes deer and elk farms.

The presence of CWD in a herd is more likely to be detected if the herd is a participating herd, given the increased surveillance. For herd owners who are found to have positive animals, the negative impact of State-imposed quarantines and State-imposed restrictions on the repopulation of cervids on the same premises would likely more than offset the benefits of any indemnity payments. Indeed, it is very likely that most would elect to cease cervid production altogether. Fortunately for herd owners, the likelihood of a herd becoming infected has been rare, as only 31 farmed elk herds and 8 farmed deer herds have been found positive as of October 2005, representing less than 2 percent of all elk farms and much less than 1 percent of all deer farms in the United States in 2002. It is estimated that additional CWD-positive deer and elk herds will be detected over the next 2 years, after which a drop off in detection will occur. This drop off will be the result of reduced movement of infected animals

between herds due to the program's operations.

All in all, the rule can be expected to have a positive economic effect on deer and elk farmers, both large and small, over the long term. In the shorter term, the economic effect on farmers will vary depending on the circumstances of each. Some farmers, especially those who already participate in State programs and who take advantage of the increased access to out-of-State markets, could benefit immediately. Conversely, a small number of farmers could experience a significant adverse impact, especially any farmers whose revenue is so small they cannot afford to pay the program's annual costs. There is no basis to conclude that the rule will have a significant economic impact on a substantial number of small entities.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

#### **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 all 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.

#### **Paperwork Reduction Act**

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579-0237.

This final rule includes certain regulatory provisions that differ from those included in the December 2003 proposed rule. Some of those provisions involve minor changes from or additions to the information collection requirements set out in the December 2003 proposed rule. These changes include the following:

Two changes were made regarding animal identification requirements. One change required that free-ranging

animals captured, moved, then released must have two forms, rather than one form, of official animal identification. The other change set a definite age (12 months) by which animals in the certification program must first be officially identified. While the proposed rule required animal identification, these particular changes are new requirements in the final rule.

The final rule also requires a research animal permit for the interstate movement of cervids for research purposes. The permit contains information about the animals, their movement, and their destination and also specifies any special conditions of the movement determined by the Administrator to be necessary to prevent the dissemination of CWD.

*Estimate of burden:* The public reporting burden for the new or changed collections of information is estimated to average 0.4 hours per response.

*Respondents:* Federal and State wildlife management agencies, researchers, universities, and any other parties who move and release wild cervids or move cervids for research purposes.

*Estimated annual number of respondents:* 12.

*Estimated annual number of responses per respondent:* 15.

*Estimated annual number of responses:* 180.

*Estimated total annual burden on respondents:* 72 hours.

**Government Paperwork Elimination Act Compliance**

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

**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, we are 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. By removing the definition of *captive*.

■ b. In the definition of *herd*, by removing the words "A group of animals" and adding in their place the words "One or more animals".

■ c. By revising the definitions of *animal*, *CWD-exposed animal*, *CWD-positive animal*, *CWD-suspect animal*, and *herd plan* to read as set forth below.

■ d. By adding definitions for *animal identification*, *animal identification number (AIN)*, *Approved State CWD Herd Certification Program*, *commingled*, *commingling*, *CWD-exposed herd*, *CWD Herd Certification Program*, *CWD-source herd*, *CWD-suspect herd*, *deer*, *elk*, and *moose*, *farmed or captive*, *herd status*, *official animal identification*, *premises identification number (PIN)*, *trace back herd*, and *trace forward herd*, in alphabetical order, to read as set forth below.

**§ 55.1 Definitions.**

\* \* \* \* \*

*Animal.* Any farmed or captive cervid.

\* \* \* \* \*

*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.

*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.

\* \* \* \* \*

*Approved State CWD Herd Certification Program.* A program operated by a State government for certification of cervid herds with respect to CWD that the Administrator has determined to meet the requirements of § 55.23(a).

\* \* \* \* \*

*Commingled, commingling.* Animals are commingled if they have direct contact with each other, have less than 10 feet of physical separation, or share

equipment, pasture, or water sources/watershed. Animals are considered to have commingled if they have had such contact with a positive animal or contaminated premises within the last 5 years.

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

*CWD-exposed herd.* A herd in which a CWD-positive animal has resided within 5 years prior to that animal's diagnosis as CWD-positive, as determined by an APHIS employee or State representative.

*CWD Herd Certification Program.* The Chronic Wasting Disease Herd Certification Program established by this part. This program includes both herds that are directly enrolled in the CWD Herd Certification Program and herds that are included based on their participation in Approved State CWD Herd Certification Programs.

*CWD-positive animal.* An animal that has had a diagnosis of CWD confirmed by means of two official CWD tests.

\* \* \* \* \*

*CWD-source herd.* A herd that is identified through testing, tracebacks, and/or epidemiological evaluations to be the source of CWD-positive animals identified in other herds.

*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.

*CWD-suspect herd.* A herd for which unofficial CWD test results, laboratory evidence, or clinical signs suggest a diagnosis of CWD, as determined by an APHIS employee or State representative, but for which official laboratory results have been inconclusive or not yet conducted.

*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 free-ranging population for interstate movement and release.

\* \* \* \* \*

*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.

*Herd status.* The status of a herd assigned under the CWD Herd Certification Program in accordance with § 55.24, indicating a herd's relative risk for CWD. Herd status is based on the number of years of monitoring without evidence of the disease and any specific determinations that the herd has contained or has been exposed to a CWD-positive, -exposed or -suspect animal.

\* \* \* \* \*

*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.
- (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 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 premises identification number 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 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.

\* \* \* \* \*

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

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

\* \* \* \* \*

■ 3. In part 55, a new subpart B is added 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 owners.* Any owner of a farmed or captive deer, elk, or moose herd may apply to enroll in the CWD Herd Certification Program by sending a written request to the appropriate State agency, or to the 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 the effective date of this rule 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. This type of constructed enrollment date will be unavailable for herds that apply to enroll after October 19, 2007, and herds that apply to enroll after that date will have an enrollment date of the date APHIS approves the herd participation.

(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, 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 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 after October 19, 2007, and herds that apply to enroll after that date will have an enrollment date of the date APHIS approves the herd participation.

(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]*

(b) *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) of this subpart. 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.

(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 State 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 of this subpart. 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, 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;

(4) The owner must maintain herd records that include a complete inventory of animals that states 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. Upon request, the owner must allow an APHIS employee or State representative access to the premises and herd 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;

(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.

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#### **§ 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 comprised 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. Once the herd has received "Certified" status, slaughter surveillance and surveillance of animals killed in shooter operations will no longer be required, but other requirements of the program will remain in force.

(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, the herd owner may not reapply to enroll in the CWD Herd Certification Program for 5 years from the effective date of the cancellation. The Administrator may cancel enrollment after determining that the herd owner failed to comply with any requirements

of this section. Before enrollment is canceled, an APHIS representative will inform the herd owner of the reasons for the proposed cancellation.

(1) Herd owners may appeal cancellation of enrollment or loss or suspension of herd status by writing to the Administrator within 10 days after being informed of the reasons for the proposed action. The appeal must include all of the facts and reasons upon which the herd owner relies to show that the reasons for the proposed action are incorrect or do not support the action. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision. 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. However, cancellation of enrollment or loss or suspension of herd status shall become effective pending final determination in the proceeding if the Administrator determines that such action is necessary to prevent the possible spread of CWD. Such action shall become effective upon oral or written notification, whichever is earlier, to the herd owner. In the event of oral notification, written confirmation shall be given as promptly as circumstances allow. This cancellation of enrollment or loss or suspension of herd status shall continue in effect pending the completion of the proceeding, and any judicial review thereof, unless otherwise ordered 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>2</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. 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 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. 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.

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

■ 4. A new part 81 is added to read as follows:

### 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.

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

#### § 81.1 Definitions.

*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.

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

*CWD-positive animal.* An animal that has had a diagnosis of CWD confirmed by means of two official CWD tests as defined in § 55.1 of this chapter.

*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.

*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 free-ranging population for interstate movement and release.

*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.

(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 unique number assigned by a State or Federal animal health authority to a premises that is, in the judgment of the

<sup>2</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.

State or Federal animal health authority, a geographically distinct location from other livestock production units. The premises identification number 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 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 subpart 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. 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.

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#### **§ 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:

(i) If the movement occurs between October 19, 2006 and January 19, 2009, the herd has achieved at least Second Year status in accordance with § 55.24 of this chapter;

(ii) If the movement occurs between January 19, 2009 and January 19, 2010, the herd has achieved at least Third Year status in accordance with § 55.24 of this chapter;

(iii) If the movement occurs between January 19, 2010 and January 19, 2011, the herd has achieved at least Fourth Year status in accordance with § 55.24 of this chapter;

(iv) If the movement occurs between January 19, 2011 and January 19, 2012, the herd has achieved at least Fifth Year status in accordance with § 55.24 of this chapter;

(v) If the movement occurs after January 19, 2012, the herd has achieved Certified status in accordance with § 55.24 of this chapter; and

(2) The farmed or captive deer, elk, or moose is accompanied by a certificate issued in accordance with § 81.4 of this part 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.

(b) *Animals captured for interstate movement and release.* If the captive deer, elk, or moose was captured for interstate movement and release from a free-ranging population, each 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.

(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 and that the animals are from a herd participating in the CWD Herd Certification Program, and must provide the herd's program status; *Except that*, certificates issued for animals moved directly to slaughter do not need to state that the animals are from a herd participating 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)

Done in Washington, DC, this 14th day of July 2006.

**Charles D. Lambert,**

*Acting Under Secretary for Marketing and Regulatory Programs.*

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