

# Proposed Rules

This section of the **FEDERAL REGISTER** contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 9 CFR Parts 55 and 81

[Docket No. 00-108-7]

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:** Proposed rule.

**SUMMARY:** We are proposing further amendments that would establish a herd certification program to eliminate chronic wasting disease from farmed or captive cervids in the United States. Under the 2006 Chronic Wasting Disease (CWD) rule, participating deer, elk, and moose herds would have to follow CWD Herd Certification Program requirements for animal identification, testing, herd management, and movement of animals into and from herds. This document proposes additional changes to the program regarding recognition of State bans on the entry of farmed or captive cervids for reasons unrelated to CWD, the number of years an animal must be monitored for CWD before it may move interstate, interstate movement of cervids that originated from herds in proximity to a CWD outbreak, herd inventory procedures, and several other matters. These actions are intended to help eliminate CWD from the farmed or captive cervid herds in the United States.

**DATES:** We will consider all comments that we receive on or before June 1, 2009.

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

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/fdmspublic/component/>

[main?main=DocketDetail&d=APHIS-2006-0118](http://main?main=DocketDetail&d=APHIS-2006-0118) to submit or view comments and to view supporting and related materials available electronically.

- Postal Mail/Commercial Delivery: Please send two copies of your comment to Docket No. 00-108-7, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 00-108-7.

**Reading Room:** You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

**Other Information:** Additional information about APHIS and its programs is available on the Internet at <http://www.aphis.usda.gov>.

**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, 2008, 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.

In the United States, CWD has been confirmed in free-ranging deer and elk in Colorado, Illinois, Kansas, Nebraska, New Mexico, New York, South Dakota, Utah, West Virginia, Wisconsin, and Wyoming, and, as of October 2008, in 32

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farmed elk herds and 11 farmed or captive white-tailed deer herds in Colorado, Kansas, Michigan, Minnesota, Montana, Nebraska, New York, Oklahoma, South Dakota, 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.

Under 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. The Animal and Plant Health Inspection Service's (APHIS') regulations in 9 CFR subchapter B govern cooperative programs to control and eradicate communicable diseases of livestock.

On July 21, 2006, we published a final rule in the **Federal Register** (71 FR 41682, Docket No. 00-108-3; "the CWD final rule") amending 9 CFR subchapter B by establishing regulations in part 55 for a Chronic Wasting Disease Herd Certification Program to help eliminate chronic wasting disease (CWD) from the farmed or captive cervid herds in the United States. Under that rule, owners of deer, elk, and moose herds who choose to participate would have to follow the program requirements of a cooperative State-Federal program for animal identification, testing, herd management, and movement of animals into and from herds. The CWD final rule also amended 9 CFR subchapter C by establishing a new part 81 containing interstate movement requirements to prevent the spread of CWD.

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

period until January 3, 2007, in a **Federal Register** notice published on November 21, 2006 (71 FR 67313, Docket No. 00-108-6).

We received 77 comments by that date. They were from cervid producer associations, individual cervid producers, State animal health agencies, State wildlife agencies, and others.

We have carefully considered the merits of the petitions and of the public comments received in response to them. We believe that the petitioners and commenters identified several areas where the CWD final rule could be more effective or less burdensome, and we believe the CWD final rule could be improved by making several changes to its requirements. We are therefore proposing certain changes to the CWD final rule, described below. We plan to withdraw the 2006 CWD final rule published on July 21, 2006 and issue a revised final rule based on this proposal and on the CWD final rule, after evaluating public comments on this proposal.

#### **Reconciling Federal and State Requirements for the Interstate Movement of Captive Cervids**

One goal of the CWD final rule was to provide a consistent, nationwide standard for the interstate movement of cervids, when such animals are allowed to move in interstate commerce. For that reason, the CWD final rule provided a single set of CWD requirements to follow when moving cervids interstate. These requirements, developed with input from States and producers, were meant to standardize a variety of differing CWD requirements and restrictions imposed by States that regulate the entry of cervids from other States. For example, different States have different requirements for how long a cervid must have been in a herd subject to CWD monitoring in order to move, and different requirements for the type of animal identification required for cervids moving interstate.

APHIS continues to believe that the Federal CWD regulations should provide a consistent, nationwide set of requirements designed to address CWD risk for cervids that move interstate. Where the Federal CWD final rule establishes a standard for a particular aspect of interstate movement of cervids—identification requirements, for example—the requirement in the Federal CWD final rule will preempt any inconsistent State requirement. However, as the petitions and several comments on the petitions stated, the CWD final rule did not clearly resolve the issue of whether a State has authority to ban the movement of any

farmed or captive cervids into the State due to reasons other than CWD risks.

APHIS has sought and received further information from States on the nature of their State CWD regulations and the reasons States have determined such requirements to be necessary. In States that allow farmed or captive cervids from other States to enter under restrictions, rather than prohibiting their entry entirely, we found that the purpose of the CWD restrictions and the methods they employed were similar to the purpose and methods of the CWD final rule. In almost all cases, we believe that the requirements in the Federal-State cooperative CWD final rule will achieve the State goal of allowing interstate movement of farmed or captive cervids under conditions sufficient to prevent the spread of CWD. In one case, discussed in the next section of this document titled “Monitoring Period Required to Move Cervids Interstate,” we believe the “monitoring period” requirement currently employed by some States is superior to the requirement in the CWD final rule, and accordingly we propose to revise the CWD final rule with respect to the length of time a farmed or captive cervid moved interstate must have spent in an approved CWD herd certification program, and thus the length of time it has been subject to monitoring for CWD and other herd requirements.

However, in the course of considering the petitions and comments on them, APHIS has found that a number of States prohibit the entry of farmed or captive cervids for a variety of reasons, and to control a variety of risks, which are unrelated to CWD. State-imposed bans on the movement of cervids that are unrelated to CWD risks will not be affected by the CWD final rule. While Federal CWD requirements preempt State CWD requirements when interstate movement of cervids is allowed, we do not believe it is necessary to preempt State laws or regulations that prohibit the entry of farmed or captive cervids for other reasons when States have articulated sound reasons for such bans. This would include a State that bans entry of cervids because the State does not have or is phasing out a farmed or captive cervid industry and States that impose restrictions to address diseases for which APHIS does not prohibit or restrict interstate movement.

Some States that ban the entry of farmed or captive cervids have cited concerns about the potential spread of CWD, brucellosis, and tuberculosis as one reason for the bans. This is not, in the agency's view, a persuasive reason to maintain a ban, because Federal

regulations<sup>1</sup> are specifically designed to allow the interstate movement of cervids without disseminating these diseases. We believe that the proposed Federal CWD requirements would be effective and, if finalized, would preempt conflicting State requirements. However, States also cite other reasons for their bans on the entry of farmed or captive cervids, such as risks from a number of diseases and parasites associated with cervids. Excluding examples for which there are already mandatory Federal testing or interstate movement requirements, the diseases and parasites that support the need for a ban in some States include epizootic hemorrhagic disease/bluetongue, Johne's disease, malignant catarrhal fever, and the meningeal worm (*Parelaphostrongylus tenuis*). States also base cervid bans on concerns that farmed or captive cervids could contain undesirable gene sequences that could be introduced into wild cervid populations if the cervids escape captivity. These States noted that maintaining the genetic purity of their native elk and deer populations was important to sportsmen and natural resource interests. More generally, States with bans cited concerns that escaped farmed or captive cervids would compete with wild populations for food and habitat. Some States also cited laws making it illegal to hold in captivity certain species or breeds of cervids covered by the CWD final rule. Some States imposed a ban partly to discourage high-fence trophy hunting operations that depend on continual restocking from out-of-State sources. Finally, some States cited environmental concerns, including ecosystem degradation resulting from cervids maintained in captivity or escaped cervids.

APHIS has concluded that many of the above concerns are substantive and that we should propose a way to accommodate State interests in these areas. APHIS believes that we can best address the concerns of States that have imposed a ban on the entry of farmed or captive cervids for reasons unrelated to CWD by changing the CWD final rule to recognize such a ban for those States. Therefore, we propose to add a new § 81.5 to the CWD final rule to clarify that state laws and regulations prohibiting the entry of farmed or captive cervids for reasons unrelated to CWD are not preempted by this part.

<sup>1</sup> For interstate movement requirements for cervids and other animals with respect to these diseases, see 9 CFR part 77 for tuberculosis, 9 CFR part 78 for brucellosis, and 9 CFR part 81 for CWD.

## Monitoring Period Required To Move Cervids Interstate

Under the CWD final rule, during its first year of implementation, cervids would be allowed to move interstate if they have been in an approved CWD Herd Certification program, and thus subject to monitoring for CWD and other requirements, for at least 1 year. The CWD final rule increased this length-of-time requirement in succeeding years of implementation, so the time animals would have had to be in a herd certification program in order to move interstate gradually increased to 2 years, then 3, then 4, then 5 years. It was the intent of the CWD final rule to provide a consistent, nationwide standard for the interstate movement of cervids. Existing State laws and regulations addressing movement of cervids vary in the amount of time that the animals must have been in a certification program prior to entry, and some States do not allow the entry of any cervids for non-CWD-related reasons, as discussed earlier. The gradual escalation of the Federal standard in the CWD final rule to 5 years was intended to achieve the desired level of risk control represented by 5 years of program participation and disease-free surveillance and monitoring, but to do so in a gradual manner that would not cause widespread economic harm to producers by making it impossible for some of them to move animals interstate until 5 years after they join the CWD Herd Certification Program.

The petitioners and many commenters on the petitions questioned whether the gradual approach reflected in the rule's Federal standard provided adequate protection, especially during the first 2 years of program implementation. The petitioners and most commenters suggested that the available science and the known epidemiology of CWD indicate that animals should be monitored for CWD for approximately 5 years before they can be considered safe to move interstate. Some commenters stated that studies of the natural incubation period in the wild are difficult to conduct and no comprehensive studies have been done; therefore, APHIS should not assume that most cervids will develop CWD within a year or two after infection. They noted that while animals developed signs of CWD within 1–2 years of infection in several cited research studies, these were studies of confined animals that were directly infected with large quantities of the CWD agent. This type of direct experimental infection is known to

result in minimum incubation periods for diseases in general.

In view of these uncertainties about the range of incubation periods for CWD, the commenters suggested that it would be prudent for the CWD program to monitor animals for 5 years before they can be considered safe to move interstate. The 5-year period was suggested because it is the period that most researchers and State CWD programs agree is a reasonable outer boundary for the incubation period for CWD.

In addition, comments on the petitions revealed that most State governments and industry representatives agree that many cervid producers who rely on moving animals interstate for the success of their businesses have already participated in a State CWD herd certification and monitoring program for 5 years or longer, would not be adversely affected by the adoption of a 5-year standard, and believe a 5-year standard would provide better protection against the spread of CWD than a lesser monitoring standard.

After considering comments, APHIS has concluded that the CWD program would be enhanced by requiring that farmed or captive cervid herds must have been monitored for at least 5 years before animals from such herds may be moved interstate. The CWD final rule discussed why it is important to consider possible exposure to CWD up to 5 years in the past when evaluating the CWD risk of a herd. The CWD final rule would have required 5 years of monitoring for a herd to reach the Certified level in the CWD program, although it would have established a gradually increasing timetable that, in early years of program implementation, would have allowed interstate movement of animals from herds with as little as 1 year of monitoring. We now believe that CWD incubation periods have not been sufficiently studied to justify using shorter monitoring periods initially and “ramping up” the monitoring requirement over time. Also, upon reexamining several research reports, we believe that they support the conclusion that natural incubation periods may last up to 5 years in enough cases to warrant revising the CWD program as designed in the CWD final rule. For example, the CWD final rule referred to a study<sup>2</sup> at the Colorado Division of Wildlife, Foothills Wildlife Research facility, which found that for a studied group of elk that were

naturally exposed to CWD in a contaminated environment, the average incubation time was 26 months and the incubation times ranged from 18 to 36 months. After the study ended, in the same group of elk held 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.<sup>3</sup> This could have been the result of a later environmental exposure, or it could represent a 5-year incubation period.

Further supporting the points made by the commenters, in other pathogenesis studies in mule deer and elk at the University of Wyoming,<sup>4</sup> high dose oral inoculation in mule deer produced an incubation period range of 15 months to over 25 months, with an average of 23 months. The researchers acknowledged that experimental infection (single-dose oral exposure to brain material) probably underestimates natural incubation times, as it is likely that greater exposure results in shorter duration of incubation. This supports the conclusion that incubation times for experimental infections most likely represent the range of minimum incubation times, so regulatory risk considerations should not be based solely on incubation periods demonstrated by experimental direct inoculations.

Based on our reevaluation of incubation studies, we believe that the longest incubation periods for regulated cervids will likely fall between 3 and 5 years. While a CWD program with a 3-year monitoring period might catch a large majority of infected animals, it appears that there would be enough animals that would become infected after a 4- or 5-year incubation period that a 3-year monitoring period would allow continued spread of CWD and reduce the effectiveness of the program.

Therefore, we are proposing to remove the gradual-escalation approach from the CWD final rule and replace it with a requirement that farmed or captive cervids moved interstate must be from herds that have had at least 5 years' monitoring for CWD (i.e., herds that have achieved “Certified” status in the certification program). This requirement is based on our interpretation of currently available research, and we may propose to modify it in the future if additional research provides a basis for doing so. This change would affect the requirements

<sup>3</sup> Miller, personal communication.

<sup>4</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.

<sup>2</sup> Miller *et al.*, 1998. Epidemiology of Chronic Wasting Disease in Captive Rocky Mountain Elk. *Journal of Wildlife Diseases*, 34:532–538.

for cervids moved interstate for non-slaughter purposes on the basis of their participation in the certification program; it would not affect the movement of cervids to slaughter.<sup>5</sup>

To make this change, we propose to amend paragraph (a) of § 81.3 as published at 71 FR 41706, which deals with interstate movement of animals from cervid herds that are enrolled in the CWD Herd Certification Program and are eligible for a certification status level based on the length of time they have successfully met program standards. We propose to amend this paragraph to state that the farmed or captive cervid must be enrolled in the CWD Herd Certification Program in a herd that has achieved Certified status, and must be accompanied by a certificate that states this and that also identifies the herd of origin and states that the animal does not show clinical signs associated with CWD.<sup>6</sup>

The change to the certificate requirement to indicate that the animal does not show clinical signs associated with CWD replaces a required statement that the animal is not a CWD-positive, CWD-exposed, or CWD-suspect animal. Requiring that the certificate state that the animal does not show clinical signs associated with CWD would be consistent with the information that can be obtained from an examination and with other interstate animal movement regulations. To complement this change, we would also remove the definitions of the terms *CWD-positive animal*, *CWD-exposed animal*, and *CWD-suspect animal* from § 81.1, because these terms would no longer be used in part 81.

#### Proximity of Herd of Origin to CWD Occurrences and CWD History of an Animal's Herd

Some commenters also raised the concern that the CWD final rule would disrupt State program efforts to provide an additional level of protection against the spread of CWD by prohibiting entry of farmed or captive cervids from those areas where CWD has been detected. Several States currently implement such policies in various forms. The form of the State requirement is usually to list either counties, regions within a State, or entire States where CWD has been

<sup>5</sup> The final rule allows farmed or captive deer, elk, or moose to be moved to slaughter 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, if they have two forms of animal identification and are accompanied by a certificate issued in accordance with § 81.4.

<sup>6</sup> Later in this document, we also propose a change that would redesignate this paragraph (a) as paragraph (b).

detected and ban entry of cervids from the listed areas.

We believe this is a useful risk reduction approach for States that wish to add another level of protection to the requirements in the CWD final rule. However, not all States believe they need the additional risk reduction. Also, although all the States that use this method agree that its purpose is to prohibit entry of cervids from areas in proximity to occurrences of CWD, there is substantial variation in the details of such requirements for different States.

Therefore, we propose to change the CWD final rule to allow States to elect not to receive farmed or captive cervids from areas in proximity to occurrences of CWD in wild cervids. We also propose to establish a single Federal standard for such proximity in order to make the standard consistent among all States with such restrictions. We propose to do this by (1) establishing a list of States that do not accept entry of farmed or captive cervids from herds of origin in proximity to CWD occurrences in wild cervids and (2) changing the certificate requirement for interstate movement of farmed or captive cervids to document when animals are from herds that are in proximity to CWD occurrences in wild cervids.

Section 81.3(a)(2) of the CWD final rule requires that farmed or captive cervids that are moved interstate based on their participation in the CWD Herd Certification Program must be accompanied by a certificate issued by a State or Federal official or an accredited veterinarian. The certificate must contain information to help identify the animals and document their status in the certification program. The contents required for a certificate are set out in § 81.4 as published at 71 FR 41706.

To be consistent with the change discussed above that animals moved interstate must be from herds with Certified status, we propose to change the references in § 81.4 to herds “participating in the CWD Herd Certification Program” to instead refer to herds “that have achieved Certified status in the CWD Herd Certification Program.” We also propose to add the following requirements to this paragraph:

- The certificate would have to include a statement by the issuing accredited veterinarian, State veterinarian, or Federal veterinarian that the animals are not from farmed or captive herds where CWD has been diagnosed within the past 5 years or epidemiologically linked to herds where CWD has been diagnosed within the past 5 years.

The proposal to have a time limit of 5 years when considering CWD infection or epidemiological linkage is based on the same evidence cited in the CWD final rule and in this proposal to support the requirement for 5 years of monitoring before a cervid may be moved interstate. That decision was based on several factors, including the probable maximum incubation time for CWD and timespans realistically needed for reporting and evaluation of CWD occurrences.

- The certificate would have to also include a statement by the issuing accredited veterinarian, State veterinarian, or Federal veterinarian as to whether or not the animals' premises are within 25 miles (40 km) of a federally or State-identified case of CWD in wild deer, elk, or moose, or within 25 miles (40 km) of an area where CWD has become established in wild deer, elk, or moose, as defined by APHIS and the State.

We believe that this proposed requirement provides a reasonable standard that can be consistently applied and that provides the level of additional risk reduction that meets or exceeds that of similar current State requirements. The proposal to set the limits of proximity to CWD cases in the wild at 25 miles (40 km) is consistent with proximity guidelines used in some State CWD programs applicable to both captive and wild cervids, and is also consistent with the current international practice of several countries for importing and exporting elk. For example, the Quebec Department of Agriculture, Fisheries and Food requires a statement on certificates accompanying elk imported into Quebec that they are from a farm that “is located more than 40 km from an enterprise with an epidemiological link to a case of CWD.” The United States regulations for importing elk from Canada call for a similar statement.<sup>7</sup>

In addition to adding this proximity certification for moving farmed or captive cervids interstate, we propose to establish a list of States that do not accept entry of farmed or captive cervids from areas in proximity to CWD occurrences. This list, called “States That Limit Cervid Entry Based on Proximity to CWD Occurrences,” would be maintained and revised by APHIS, and would be made available by APHIS on its Web site and by mail upon

<sup>7</sup> In “Protocol Respecting The Importation Of Cervids From Other Provinces Or Countries Into Quebec Under The Animal Health Protection Act (R.S.Q., c. P-42)’ and “Protocol For the Importation of Farmed Cervids From Canada,” USDA, APHIS, Veterinary Services, National Center for Import and Export.

request. The initial list would include all States that currently have State laws or regulations that ban entry of farmed or captive cervids from areas in proximity to CWD occurrences in the wild. At any time, a State could request to be removed from the list if it changes to allow entry of farmed or captive cervids from areas in proximity to CWD occurrences in the wild. Any State not on the list could request to be added to the list by sending the Administrator a written request to be added and a copy of the State law or regulation that bans entry of farmed or captive cervids from areas in proximity to CWD occurrences in the wild.

This list of States, in conjunction with the new requirement of a certification regarding proximity, will allow State and Federal representatives to determine when a shipment of cervids may not be moved to a destination State due to proximity restrictions. To make it clear that these new requirements apply in two ways—animals that do not meet them may not be moved interstate to listed States, and animals that do meet them must have that fact documented in the certificate—we propose to redesignate the current introductory text of § 81.3 as paragraph (a) and add the new requirements in subparagraphs (a)(1) and (a)(2) as set out in the proposed regulatory text of this document.

We are proposing one more change related to the risks associated with maintaining a CWD herd in proximity to known occurrences of CWD in wild cervids. While the level of such risk is uncertain, it appears prudent to mitigate the risk. A number of herds have been long established in proximity to known occurrences of CWD in the wild; in most cases, the herd was established before CWD was found in wild animals in the area. Most of these herds have participated in State CWD programs and are eligible for the Federal-State cooperative CWD program. It would be very difficult to bar such herds from participation in the program. It would also be unnecessary if the herds have already effectively complied with program requirements for some years. However, we have determined that it would add to the effectiveness of CWD control if, in the future, no new herds were established in proximity to CWD occurrences in the wild.

Therefore, we propose to amend § 55.22(a), *Participation and enrollment*, by adding a provision that an application for participation may also be denied if APHIS or the State determines that the applicant's herd was established after the effective date of a final rule following this proposal on a

premises within 25 miles (40 km) of a Federally or State-identified case of CWD in wild deer, elk, or moose, or within 25 miles (40 km) of an area, as defined by APHIS and the State, where CWD has become established in wild deer, elk or moose.

#### **Monitoring and Surveillance of CWD in Wild Cervids**

The proposed changes discussed above concerning proximity of herds to known occurrences of CWD in wild cervids would only be practical if reliable data is available to identify areas where CWD occurs in the wild. States with significant wild cervid populations currently conduct monitoring and surveillance activities for CWD in the wild. These activities are often conducted by State wildlife agencies, though some involve agriculture agencies, and often Federal agencies provide assistance or technical support when resources are available to do so. The types and extent of surveillance for CWD in the wild vary. The most extensive surveys rely on testing samples submitted by hunters. Some States also employ surveillance methods such as harvesting and testing a geographically targeted random sampling of wild deer and elk, or testing vehicle-killed cervids, to estimate CWD distribution.

We expect States would continue such surveillance activities. Because several changes in this proposed rule rely on identifying areas where CWD occurs in the wild, we also propose to make such continued surveillance a requirement for a State program to become an Approved State CWD Herd Certification Program. Specifically, we propose to add this requirement to the list in § 55.23, *Responsibilities of States and enrolled herd owners*, as paragraph (a)(12).

Herd owners and Federal and State representatives would use reports from these monitoring and surveillance activities to determine, for purposes of the changes discussed above, when a premises is “within 25 miles (40 km) of a Federally or State-identified case of CWD in wild deer, elk, or moose, or within 25 miles (40 km) of an area, as defined by APHIS and the State, where CWD has become established in wild deer, elk, or moose.”

#### **Additional Changes to Responsibilities of States and Enrolled Herd Owners (§ 55.23)**

We propose to make several changes to § 55.23 to clarify the responsibilities of States and owners participating in the cooperative Federal-State CWD

program, and to reduce the compliance burden where it is practical to do so.

#### **State Enforcement of Quarantines**

Paragraph (a)(4) of § 55.23 requires States to place all known CWD-positive, CWD-exposed, and CWD-suspect animals and herds under movement restrictions, with movement of animals from those herds only for destruction or under permit. We now propose to expand this requirement to prohibit CWD-positive, CWD-exposed, and CWD-suspect herds from adding animals to the herd from outside sources. The CWD final rule did not include such a requirement because it seemed unlikely that many owners would choose to expand herds that were under restrictions and possibly destined for destruction. However, there have been some cases where the owners of CWD-positive, CWD-exposed, and CWD-suspect herds have added new animals. This affects the CWD indemnity program, which makes indemnity available for eligible animals based on the inventory at the time the movement restrictions are imposed. An increase in the size of a herd under restriction due to CWD also causes a corresponding increase in the program resources devoted to the herd, and in the amount of work for Federal and State representatives working with the herd. For instance, if animals from several additional herds are added to a CWD-exposed or CWD-suspect herd that is later found positive for CWD, those additional herds must also be evaluated during traceback as possible sources of CWD. Also, increasing the herd size potentially increases the total number of infected animals, and the risk of CWD spread (e.g., more animals means more opportunities for an animal to escape confinement).

To address this problem, we propose to change § 55.23(a)(4) to specifically state that no movement of animals into CWD-positive, CWD-exposed, and CWD-suspect herds is allowed.

#### **Herd Inventory Procedures**

We are also proposing to make changes to § 55.23 to address issues concerning the practicality and the burden on owners associated with paragraph (b)(4), which describes herd recordkeeping and annual inventory requirements.

Section 55.23(b)(4) of the CWD final rule requires owners to maintain herd records that include a complete inventory of animals, 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 each animal, and all

individual identification numbers (from tags, tattoos, electronic implants, etc.) associated with each animal. We do not propose to change this requirement. However, we do propose to change other requirements in this paragraph, which currently state that the owner must allow an APHIS employee or State representative access to the premises and herd to conduct an annual physical herd inventory to reconcile animals and identifications with the records maintained by the owner. The CWD final rule currently requires that the owner, when this physical inventory occurs, must assemble, restrain, and present the entire herd for inspection under conditions where the APHIS or State official can safely read all identification on the animals. The owner would be responsible for all costs incurred to present the animals for inspection.

Several commenters noted that it was unclear whether an actual physical inventory of assembled animals was required each year, or only "upon request." They also suggested that a physical inventory would impose a considerable burden if conducted on an annual basis. The CWD final rule estimated that for a herd of 50 elk, the annual physical inventory cost would be approximately \$1,000, including veterinary fees of approximately \$500 and hired labor costs of approximately \$500. This cost could be significantly higher in some cases; for example, labor costs for skilled cervid handlers are higher in some areas, and the physical assembly and restraint could cause injury to some cervids, with further costs to the owner for subsequent veterinary care or loss of the animal.

We agree that the CWD final rule language is unclear on the requirement for physical inventories. Our intention is to conduct an actual physical inventory of assembled animals when an APHIS employee or State representative finds it to be needed for program purposes. We propose that a physical assembly would be required at the time a herd is enrolled in the Federal-State cooperative CWD program, in order to provide a reliable baseline record for the herd's participation. After this initial physical assembly for inventory purposes, further physical inventories would be scheduled when the APHIS employee or State representative finds it necessary to verify herd compliance with program standards — for example, if there has been significant movement of animals into or from the herd, or if other conditions warrant a physical inventory to confirm the herd records. Physical inventories would usually be several

years apart, and would never be ordered more than once per year, unless we determine that more frequent inventories are needed based on indications that the herd may not be in compliance with CWD Herd Certification Program requirements.

However, some type of herd inventory would be performed annually. When the inventory does not include physical assembly of the entire herd, it would include, at a minimum, review of all owner records documenting animal identification and records of animals added to or removed from the herd. It would also include observation of the herd's unrestrained animals in a viewable, enclosed area or space where the inspector could reconcile all visible identification devices with prior records and check for any obvious inconsistencies between the number, age, and gender of animals observed and the animals documented in the owner records. During such inventories, the owner and the person performing the inventory would work together to resolve any discrepancies to the satisfaction of the person performing the inventory.

This proposed change should also make it possible in many cases to plan the timing of a physical assembly of a herd for inventory so that it is coordinated with cervid testing for brucellosis and tuberculosis. Such testing occurs for cervid herds participating in the cooperative State-Federal Cervid Brucellosis Program or Cervid Tuberculosis Program. The Uniform Methods and Rules for these programs describe when such herds must be assembled and tested for these diseases. For example, to maintain a herd's Certified status with regard to brucellosis, or its Accredited status with regard to tuberculosis, the herd must be retested for the relevant disease every 21 to 27 months under current brucellosis and tuberculosis regulations. This timetable may change in the future. We expect that, in many cases, when a cervid herd participates in the CWD program and one or both of the tuberculosis and brucellosis programs, any required physical assembly of the herd can be planned so that during a single assembly, requirements for all of the programs can be met. For example, the initial physical assembly would serve to establish and confirm the required inventory, records, and individual animal identification requirements for CWD, but it could also be used to conduct testing and any other requirements for the tuberculosis or brucellosis programs. If the APHIS employee or State representative later finds it necessary to schedule another

physical assembly for inventory, it is likely that it could be scheduled to allow any required tuberculosis or brucellosis testing to occur during the assembly.

APHIS plans to develop additional guidance in the future, after we gain additional experience working with herd inventories, to clarify when an actual physical inventory of assembled animals will be required, and to provide more information on the different activities involved in the different levels of a physical inventory of assembled animals. When developed, such guidance will be made available in the CWD program Uniform Methods and Rules or in other program guides. Readers should also note that in addition to Federal regulations concerning inventory requirements, individual States may have requirements in this area in State law or regulations.

In § 55.23(b)(4) on page 41704 of the final rule, we also inadvertently omitted accredited veterinarians as one of the types of officials authorized to conduct the herd inventory. Since accredited veterinarians play an important role in implementing the CWD program, we propose to change this reference to also allow access to the premises by an accredited veterinarian who has been designated to conduct an inventory. To implement these changes to inventory requirements, we propose to revise all but the first sentence of § 55.23(b)(4).

#### Enrollment Dates

Section 55.22(a)(1)(ii)(B) concerns setting an enrollment date for herds that enroll directly in the Federal CWD Herd Certification Program, and ensuring that the enrollment date gives some credit for the time period during which herds substantially met Certification Program standards before they could enroll in the Program. This paragraph reads, in part, "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."

We propose to change that requirement to allow APHIS to set an enrollment date for such herds that is up to 3 years prior to the date APHIS actually processed and approved enrollment. We propose this revision because implementation of the Certification Program has proceeded more slowly than planned, in part due to the need to resolve the issues

discussed in this proposed rule. To minimize possible losses to herd owners who have managed their herds in compliance with program requirements but could not be formally enrolled because no State CWD program was available and the CWD final rule was not in effect, we propose to allow up to 3 years' credit instead of 2. Since this rule also proposes to limit interstate movement to cervids that have been enrolled for 5 years and have achieved Certified status, we expect this change would affect a small number of herds that become enrolled directly in the Federal CWD program after the effective date of a final rule. If such herds qualify for 3 years' credit upon enrollment, animals from the herd could be moved interstate approximately 2 years later if and when the herd achieves Certified status.

#### Confirmatory DNA Testing of Official Test Samples

On page 41685 of the CWD final rule, we responded to comments that suggested that, after an animal tests positive for CWD, 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. In response, we stated, "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."

Since the CWD final rule was published, APHIS has discussed this issue with owners and laboratories and has developed procedures to work with owners who wish to order such confirmatory DNA testing. In this NPRM we propose to change paragraph (c)(1) of § 55.24 (71 FR 41705) of the final rule so that such testing would be available through the following arrangements.

At the time an owner allows tissue samples to be collected from an animal for official CWD testing, the owner would be able to reserve the option for DNA comparison testing by informing the Federal or State representative or accredited veterinarian who collects the tissues. To allow for later DNA comparison testing, the person collecting the tissues would have to also collect from the animal some somatic tissue (usually an ear) that contains an

official identification device, along with the tissue samples routinely collected for CWD testing (brain stem, lymph nodes, etc.). Submitting tissues attached to an official ID device establishes a reliable chain of custody that allows later DNA tests to be compared to a tissue sample that verifiably comes from the owner's animal in question.

If the CWD official tests show that owner's animal is CWD-positive, the owner could employ the appeal provisions of § 55.24(c) to request that the tissue samples that were tested for CWD be compared to the ear or other tissues submitted with the animal ID attached. If the DNA in the tissues tested for CWD and the DNA in the tissues attached to the ID device match, there is confidence that the positive CWD tests do in fact pertain to the correct animal. If the DNA in the respective test results does not match, that may justify the Administrator granting the appeal. In such cases the animal would be redesignated CWD-suspect pending further investigation to establish the final proper status of the animal and its herd.

We propose that if an owner requests confirmatory DNA testing, the owner would pay for the cost of the test. If this proposed rule is adopted as final, APHIS will publish additional guidance on how to request confirmatory DNA testing and how to arrange payment for such tests.

To recognize this procedure in the regulations, we propose making changes to the CWD final rule to document the owner's right to order and pay for confirmatory DNA testing when one or more of the owner's animals tests positive for CWD. We would change paragraph (c)(1) of § 55.24, which deals with an owner's right to appeal the designation of their herd's status, by adding a provision for appeals based on the results of a DNA test requested and paid for by the owner to determine whether previous official CWD test results were correctly associated with an animal that belonged to the owner.

#### Miscellaneous Changes

We also propose to change the definition of *premises identification number (PIN)* in parts 55 and 81 and to add a definition for *National Uniform Eartagging System* to both parts. These proposed changes are intended to achieve greater standardization and uniformity of official numbering systems and eartags used in the National Animal Identification System and in animal disease programs and to enhance animal traceability. We also propose to add the following sentence to the definition of *official animal*

*identification:* "The CWD program allows the use of either the eight-character or nine-character format for cervids." This proposed change would allow use of either larger eartags with nine-character unique numbers, or smaller eartags with eight-character numbers. We propose to allow use of both size tags because the use of the smaller eartags is sometimes advisable to reduce stress on younger elk and deer.

#### Executive Order 12866 and Regulatory Flexibility Act (RFA)

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with 5 U.S.C. 603, we have performed an initial regulatory flexibility analysis, which is set out below, regarding the potential effects of the proposed action on small entities. This initial analysis indicates that the benefits of the proposed action would exceed its costs. We do not currently have all the data necessary for a comprehensive analysis of the effects of this rule on small entities. Therefore, we are inviting comments concerning potential effects.

The changes proposed in this document would, if adopted, modify the requirements set forth in the CWD final rule.<sup>8</sup> For that reason, the economic analysis that follows considers the impact of the proposed changes using the CWD final rule as a baseline. An economic analysis was prepared for the CWD final rule, and that analysis is incorporated in this document by reference.

The proposed changes would have the most impact on cervid farms, most of which are believed to be small in size under the U.S. Small Business Administration's standards.

The proposal to remove the gradual-escalation monitoring period requirement for interstate movement and replace it with a 5-year minimum requirement would adversely impact current farmers with less than 5 years in the program who wish to ship at least some of their animals interstate for purposes other than slaughter. The number of such farmers is unknown, although it is estimated that many, if not most, herd owners who rely on interstate movement for the success of

<sup>8</sup> The effective date of the CWD final rule, which was published in the *Federal Register* on July 21, 2006 (71 FR 41682–41707, Docket No. 00–108–3), has been delayed pending consideration of the changes proposed in this document.

their businesses already meet the 5-year standard by way of their participation in an existing State CWD certification program. Under the proposal, time spent in an APHIS-approved State program would count towards the time needed to satisfy the 5-year requirement, and many farmers have participated in a State program for at least 5 years. It is estimated that at least 20 States have formal CWD certification programs for cervids in place.

Any adverse impact of the proposed 5-year standard on current farmers would be further muted to the extent that a number of States have already adopted that standard themselves. Currently, States have the authority to regulate farmed cervids, including the authority to establish requirements for entry of cervids. In response to APHIS' CWD proposed rule published in December 2003, and its CWD final rule published in July 2006, several States have decided to adopt a 5-year monitoring period requirement for cervids entering those States. Both the December 2003 proposed rule and the July 2006 final rule included an eventual 5-year monitoring period requirement for interstate movement.

For those farmers who would be adversely affected by a shift to a 5-year monitoring period requirement, the economic impact would vary depending on the circumstances of each—such as the time, if any, already spent in a State program, the number and value of animals that would otherwise be shipped interstate, and the alternative opportunities available for sales within the State. Although data for individual herd owners are not available, those who are located in States that do not now have a State program and who cannot qualify for a herd status upgrade would likely suffer the most severe economic consequences, since they would have to participate in the Federal program (or a newly established State program) for 5 years before they could move their cervids interstate.<sup>9</sup> Under the CWD final rule, these same herd owners would have been able to move their animals interstate after only 1 year in the program. (For these and other herd owners who do not meet the 5-year monitoring requirement, the only alternative under the proposal that would allow for earlier interstate movement would be to sell or otherwise dispose of their existing cervids and replace them with animals from a herd with higher status. However, this

alternative would not come without a price; all else being equal, the cost of each replacement cervid is likely to exceed the proceeds from the sale or disposition of each existing animal, given the former's higher status.) It is conceivable that the shift to a 5-year monitoring requirement could effectively force some farmers out of the cervid business, especially those with little or no time in State programs. On the other hand, the change that would allow APHIS to set an enrollment date for herds that is up to 3 years prior to the date APHIS actually processed and approved enrollment should preclude this outcome for most herds.

The adoption of the proposed 5-year monitoring period requirement could also impact prospective new entrants into the cervid farming business, to the extent that it requires them to acquire higher status, and presumably more costly, animals when initially stocking their herds. Under the proposal, for example, new entrants would be eligible to ship their animals interstate immediately only if they stocked their herds with cervids from certified herds. By contrast, the CWD final rule would have allowed new entrants to ship interstate immediately with animals acquired from herds having as low as Second Year status.

Relative to the CWD final rule, the impact on farmers of the proposal to give States the option to ban the entry of certain farmed and captive cervids is uncertain. We propose to allow States that completely prohibit the entry of farmed or captive cervids for reasons which are unrelated to CWD (e.g., for genetic purity or environmental reasons) to continue to do so. We also propose that States may decline to accept cervids from areas in proximity to CWD outbreaks. In both cases, impacts on States that have either type of ban would be nonexistent or minimal. The difference in impacts regarding State bans between this proposal and the final rule may be considered as follows. On the one hand, the CWD final rule would have given farmers with potentially risky animals access to markets in other States that are currently closed to them. On the other hand, there is no assurance, even if the CWD final rule had been in effect, that farmers would have been able to sell a significant number of their high-risk animals in those markets anyway. The market for cervids that are near CWD occurrences is limited, given the animals' added disease risk, and the absence of a ban option in the CWD final rule would not have removed that risk.

Relative to the current situation, the proposal to give States the option to ban

the entry of certain cervids would have no impact, since all States have that option now. Currently, several States have elected not to accept cervids if they came from areas in proximity to CWD in the wild.

The proposal to prohibit the program participation of herds established in the future in areas in proximity to CWD occurrences in wild cervids should have little or no impact. There are two reasons. First, the proposal affects newly established herds only, so no current farmers would be affected. Second, it is likely that few, if any, farmers would want to establish a new herd in areas in proximity to CWD in the wild, given the added disease risk and the attendant adverse marketing consequences noted above.

The proposal to define "proximity" as within 25 miles (40 km) of a CWD occurrence should benefit herd owners and the States, to the extent that it removes uncertainty that may now exist surrounding the definition of that term. The proposed definition is also consistent with current international practice for importing and exporting elk.

The proposal to require States to conduct monitoring and surveillance for CWD in wild cervids in order to become an approved State CWD program should have little or no impact. This is because such monitoring and surveillance is already being conducted by those States with significant cervid populations, including those without a CWD program.<sup>10</sup>

The proposal to prohibit CWD-positive, -exposed, and -suspect herds that are under State quarantine from adding animals to the herd from outside sources should have little impact, since few herds would be affected. It is estimated that, over the last several years, no more than about two or three cervid herds under quarantine have added animals from outside sources, usually for hunting purposes.

The proposal to modify the herd inventory requirements has the potential to favorably impact herd owners. Under the CWD final rule, herd owners would be required to conduct a physical inventory of assembled and restrained cervids annually. Under this proposed revision to the final rule, a physical inventory would be required at

<sup>9</sup> Herd owners who are not in a State program but who can demonstrate that they have maintained their herds in a manner that would substantially meet the program conditions established by APHIS may qualify for up to 3 years' enrollment credit.

<sup>10</sup> These activities are often conducted by State wildlife agencies, though some involve agriculture agencies, and often receive assistance or technical support from Federal agencies. If Federal assistance or support is reduced or withdrawn altogether in the future, the States would have to bear more or all of the cost of surveillance activities if they wanted to remain an approved State CWD program. At this time, there is no reason to believe that Federal assistance or support will be reduced or withdrawn in the future.

the time a herd is enrolled in a CWD program, and then only on an as-needed basis thereafter to verify compliance with program standards.<sup>11</sup> The proposed rule would still require an annual herd inventory—including a review of owner records and an observation of the herd's unrestrained animals in a viewable, enclosed area—but it would not require that the animals be physically assembled and restrained.

Since herd owners are responsible for all costs incurred in conducting a herd inventory, the proposal has the potential to offer them significant ongoing annual savings. This is because a herd inventory that does not require that the animals be physically assembled and restrained is less costly than one that does. The CWD final rule estimated that for a herd of 50 elk, the annual physical inventory (with the animals assembled and restrained) would cost approximately \$1,000, including veterinary fees of approximately \$500 and hired labor costs of approximately \$500. This cost could be significantly higher in some cases; for example, labor costs for skilled cervid handlers are higher in some areas, and the physical assembly and restraint could cause injury to some cervids, with further costs to the owner for subsequent veterinary care or loss of the animal. By contrast, a “nonphysical” herd inventory can be scheduled at a time when it is likely to add only minimally to herd owner operating costs, since most of the activities required for such an inventory are performed from time to time as part of routine herd management.

This proposed change to the herd inventory requirements should also make it possible in many cases to plan the timing of a physical inventory so that it is coordinated with cervid testing for brucellosis and tuberculosis. Such testing occurs for cervid herds participating in the cooperative State-Federal Cervid Brucellosis Program or Cervid Tuberculosis Program. The Uniform Methods and Rules for these programs describe when such herds must be assembled and tested for these diseases. For example, to maintain a herd's Certified status with regard to brucellosis, or its Accredited status with regard to tuberculosis, the herd must be retested for the relevant disease every 21 to 27 months (under current brucellosis

<sup>11</sup> APHIS has not yet developed guidelines for determining when a post-initial enrollment physical inventory would be required. The agency plans to do so in the future, after it gains additional experience working with herd inventories. When developed, such guidance will be made available in the CWD program Uniform Methods and Rules or in other program guides.

and tuberculosis regulations; this timetable may change in the future). We expect that, in many cases, when a cervid herd participates in the CWD program and one or both of the tuberculosis and brucellosis programs, any required physical inventory can be planned so that the requirements for all of the programs can be met during a single animal assembly. The initial and any subsequent physical inventories required for CWD purposes could also be used to conduct testing and any other requirements for the tuberculosis or brucellosis programs.

A very small number of herd owners may benefit from the new confirmatory DNA test provisions for animals that test CWD positive, in cases where a low-cost confirmatory test shows that positive test results were not associated with the correct animal. The number of herd owners who would benefit from the proposal to modify the herd inventory requirements is unknown.

The changes proposed in this document could be expected to have both positive and negative economic consequences for cervid farmers. Potentially, more cervid farmers stand to benefit than not, given that the proposal to modify the herd inventory requirements has the potential to offer significant ongoing annual cost savings to all program participants, but any adverse impact stemming from the proposed shift to a 5-year monitoring period requirement would be temporary and probably affect far fewer farmers.

The proposed rule has no new mandatory reporting, recordkeeping, or other compliance requirements for U.S. entities. Requirements associated with the earlier final rule were discussed in that rule.

The RFA requires agencies to identify, to the extent practicable, any Federal rule that may duplicate, overlap, or conflict with the proposed rule. APHIS has not identified any duplication, overlap, or conflict of the proposed rule with other Federal rules.

Finally, the RFA requires agencies to describe any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and that minimize any significant economic impact of the proposed rule on small entities. 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.

Of the proposed changes, the shift to a 5-year monitoring period requirement for interstate movement has the potential to have the most significant adverse impact on both small and large cervid farmers. However, leaving the gradual-escalation monitoring period requirement in place would be unsatisfactory, because the available research suggests that it may not provide an adequate level of protection against the spread of CWD. Most researchers and State CWD programs agree that 5 years is a reasonable upper bound for the incubation period for CWD.

APHIS invites public comment on the rule's expected economic impacts, including any comment on the impact for 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 proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

#### **Paperwork Reduction Act**

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### **Lists 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 propose to amend 9 CFR parts 55 and 81 as previously amended at 71 FR 41682–41707 on July 21, 2006, as follows:

## PART 55—CONTROL OF CHRONIC WASTING DISEASE

1. The authority citation for part 55 continues 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 adding a definition for *National Uniform Ear Tagging System*, in alphabetical order, to read as set forth below.

b. In the definition of *official animal identification*, by adding at the end of paragraph (1) the sentence “The CWD program allows the use of either the eight-character or nine-character format for cervids.”

c. By revising the definition for *premises identification number (PIN)* to read as set forth below.

### § 55.1 Definitions.

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

*Premises identification number (PIN).* A nationally unique number assigned by a State, Tribal, and/or Federal animal health authority to a premises that is, in the judgment of the State, Tribal, and/or Federal animal health authority, a geographically distinct location from other premises. The premises identification number is associated with an address, geospatial coordinates, and/or location descriptors which provide a verifiably unique location. The premises identification number may be used in conjunction with a producer's own livestock production numbering system to provide a unique identification number for an animal. It may also be used as a component of a group/lot identification number. Premises identification numbers issued on or after [Insert effective date of final rule] shall consist of a seven-character alphanumeric code, with the right-most character being a check digit. The check

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

\* \* \* \* \*

3. Section 55.22 is amended as follows:

a. In the introductory text of paragraph (a), by adding a sentence following the third sentence to read as set forth below.

b. In paragraph (a)(1)(ii)(B), by removing the words “2 years prior” and adding the words “3 years prior” in their place.

### § 55.22 Participation and enrollment.

(a) \* \* \* An application for participation may also be denied if APHIS or the State determines that the applicant's herd was established after [insert effective date of final rule] on a premises within 25 miles (40 km) of a Federally or State-identified case of CWD in wild deer, elk, or moose, or within 25 miles (40 km) of an area, as defined by APHIS and the State, where CWD has become established in wild deer, elk, or moose. \* \* \*

\* \* \* \* \*

4. Section 55.23 is amended as follows:

a. By revising paragraph (a)(4) to read as set forth below.

b. By adding a new paragraph (a)(12) to read as set forth below.

c. By revising paragraph (b)(4) to read as set forth below.

### § 55.23 Responsibilities of States and enrolled herd owners.

(a) \* \* \*

(4) Has placed all known CWD-positive, CWD-exposed, and CWD-suspect animals and herds under movement restrictions, with no movement of animals allowed into such herds and with movement of animals from them only for destruction or under permit.

\* \* \* \* \*

(12) Conducts monitoring and surveillance activities to estimate geographic distribution of CWD in the State.

(b) \* \* \*

(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 by an APHIS employee or State representative, the owner must allow either of these officials or a designated accredited veterinarian access to the

premises and herd to conduct an inventory. The owner will be responsible for assembling, handling, and restraining the animals and for all costs incurred to present the animals for inspection. The APHIS employee or State representative may order either an inventory that consists of review of herd records with visual examination of an enclosed group of animals, or a complete physical herd inventory with verification to reconcile all animals and identifications with the records maintained by the owner. In the latter case the owner must present the entire herd for inspection under conditions where the APHIS employee, State representative, or accredited veterinarian can safely read all identification on the animals. During inventories, the owner must cooperate with the inspector to resolve any discrepancies to the satisfaction of the person performing the inventory. Inventory of a herd will be conducted no more frequently than once per year, unless an APHIS employee, State representative, or accredited veterinarian determines that more frequent inventories are needed based on indications that the herd may not be in compliance with CWD Herd Certification Program requirements.

\* \* \* \* \*

5. In § 55.24, paragraph (c)(1) is revised to read as follows:

### § 55.24 Herd status.

\* \* \* \* \*

(c) \* \* \*

(1) Herd owners may appeal designation of an animal as CWD-positive, cancellation of enrollment of a herd, or loss or suspension of herd status by writing to the Administrator within 10 days after being informed of the reasons for the action. The appeal must include all of the facts and reasons upon which the herd owner relies to show that the reasons for the action are incorrect or do not support the action. Specifically, to appeal designation of an animal as CWD-positive, the owner may present as evidence the results of a DNA test requested and paid for by the owner to determine whether previous official CWD test results were correctly associated with an animal that belonged to the owner. If the owner intends to present such test results as evidence, he or she shall request the tests and state this in the written notice sent to the Administrator. In such cases the Administrator may postpone a decision on the appeal for a reasonable period pending receipt of such test results. To this end, approved laboratories are authorized to conduct DNA tests to compare tissue samples tested for CWD

to samples from tissues that were collected at the same time by the accredited veterinarian or Federal or State veterinarian and are attached to an official identification device. Such DNA tests are available only if the animal owner arranged to submit animal tissue attached to an official identification device along with the other tissues that were collected for the official CWD test. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision. If the Administrator grants an appeal of the status of a CWD-positive animal, the animal shall be redesignated as CWD-suspect pending further investigation to establish the final status of the animal and its herd. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator.

\* \* \* \* \*

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

6. The authority citation for part 81 continues to read as follows:

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

7. Section 81.1 is amended as follows:

a. By removing the definitions for *CWD-positive animal*, *CWD-exposed animal*, and *CWD-suspect animal*.

b. By adding a definitions for *National Uniform Eartagging System*, in alphabetical order, to read as set forth below.

c. In the definition of *official animal identification*, by adding at the end of paragraph (1) the sentence “The CWD program allows the use of either the eight-character or nine-character format for cervids.”

d. By revising the definition of *premises identification number (PIN)* to read as set forth below.

##### **§ 81.1 Definitions.**

\* \* \* \* \*

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

\* \* \* \* \*

**Premises identification number (PIN).** A nationally unique number assigned by

a State, Tribal, and/or Federal animal health authority to a premises that is, in the judgment of the State, Tribal, and/or Federal animal health authority, a geographically distinct location from other premises. The premises identification number is associated with an address, geospatial coordinates, and/or location descriptors which provide a verifiably unique location. The premises identification number may be used in conjunction with a producer's own livestock production numbering system to provide a unique identification number for an animal. It may also be used as a component of a group/lot identification number. Premises identification numbers issued on or after [Insert effective date of final rule] shall consist of 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.

8. Section 81.3 is amended as follows:

a. By redesignating paragraphs (a), (b), (c), (d), and (e) as paragraphs (b), (c), (d), (e), and (f), respectively.

b. By redesignating the introductory text as paragraph (a) introductory text and adding new paragraphs (a)(1) and (a)(2) to read as set forth below.

c. By revising newly designated paragraph (b) to read as set forth below.

##### **§ 81.3 General restrictions.**

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

(1) No farmed or captive deer, elk, or moose may be moved interstate from farmed or captive herds where CWD has been diagnosed within the past 5 years or epidemiologically linked to herds where CWD has been diagnosed within the past 5 years.

(2) No farmed or captive deer, elk, or moose may be moved interstate to any State listed on the list of States That Limit Cervid Entry Based on Proximity to CWD Occurrences<sup>1</sup> unless the certificate accompanying the animal states that its premises are at least 25 miles (40 km) from any location where a Federal or State agency identified a case of CWD in wild deer, elk, or moose, and from any area, as defined by APHIS and the State, where CWD has become established in wild deer, elk, or moose. This list is maintained by the Administrator, and a State will be added to or removed from the list after the Administrator receives a written request to do so from the State government, documenting that State law or regulation bans the movement into the

State of farmed or captive cervids from herds in proximity to CWD occurrences, or documenting that such a ban in State law or regulation has been repealed.

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

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

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

\* \* \* \* \*

9. In § 81.4, paragraph (a) is revised to read as follows:

##### **§ 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 that has achieved Certified status 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 that has achieved Certified status in the CWD Herd Certification Program and must state that an APHIS employee or State representative has been notified in advance of the date the animals are being moved to slaughter. The certificate must also include a statement by the issuing accredited veterinarian, State veterinarian, or Federal veterinarian that the animals are not from farmed or captive herds where CWD has been diagnosed within the past 5 years or epidemiologically linked to herds where CWD has been diagnosed within the past 5 years. The certificate must also include a statement by the issuing accredited veterinarian, State veterinarian, or Federal veterinarian as to whether or not the animals' premises are within 25 miles (40 km) of a Federally or State-identified case of CWD in wild deer, elk, or moose, or within 25 miles (40 km) of an area, as defined by APHIS and the State,

<sup>1</sup>This list will be maintained on the APHIS Web site at <http://www.aphis.usda.gov>.

where CWD has become established in wild deer, elk or moose.

\* \* \* \* \*

10. A new § 81.5 is added to read as follows:

**§ 81.5 State prohibitions on cervid movement not related to CWD.**

State laws and regulations prohibiting the entry of farmed or captive cervids for reasons unrelated to CWD are not preempted by this part.

Done in Washington, DC, this 25th day of March 2009.

**Kevin Shea,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. E9-7026 Filed 3-30-09; 8:45 am]

**BILLING CODE 3410-34-P**

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**DEPARTMENT OF THE TREASURY**

**Alcohol and Tobacco Tax and Trade Bureau**

**27 CFR Parts 40, 41, 44, 46, and 71**

**[Docket No. TTB-2009-0001; Notice No. 93; Re: T.D. TTB-75]**

**RIN 1513-AB70**

**Increase in Tax Rates on Tobacco Products and Cigarette Papers and Tubes; Floor Stocks Tax on Certain Tobacco Products, Cigarette Papers, and Cigarette Tubes; and Changes to Basis for Denial, Suspension, or Revocation of Permits (2009R-118P)**

**AGENCY:** Alcohol and Tobacco Tax and Trade Bureau, Treasury.

**ACTION:** Notice of proposed rulemaking; cross-reference to temporary rule.

**SUMMARY:** Elsewhere in this issue of the **Federal Register**, the Alcohol and Tobacco Tax and Trade Bureau is issuing a temporary rule implementing certain provisions of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA). The text of the regulations in the temporary rule published in the Rules and Regulations section of this issue of the **Federal Register** serves as the text of the proposed regulations.

**DATES:** Comments must be received on or before June 1, 2009.

**ADDRESSES:** You may send comments on this notice to one of the following addresses:

- <http://www.regulations.gov> (via the online comment form for this notice as posted within Docket No. TTB-2009-0001 at "Regulations.gov," the Federal e-rulemaking portal);

- Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and

Trade Bureau, P.O. Box 14412, Washington, DC 20044-4412; or

- *Hand Delivery/Courier in Lieu of Mail:* Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Suite 200-E, Washington, DC 20005.

See the **Public Participation** section of this notice for specific instructions and requirements for submitting comments, and for information on how to request a public hearing.

You may view copies of this notice, any comments received, and the related temporary rule at <http://www.regulations.gov>. A direct link to the appropriate [Regulations.gov](http://www.regulations.gov) docket is also available under Notice No. 93 on the TTB Web site at [http://www.ttb.gov/regulations\\_laws/all\\_rulemaking.shtml](http://www.ttb.gov/regulations_laws/all_rulemaking.shtml). You also may view copies of these documents by appointment at the TTB Information Resource Center, 1310 G Street, NW., Washington, DC 20220. To make an appointment, call 202-927-2400.

**FOR FURTHER INFORMATION CONTACT:** For questions concerning floor stocks tax, contact the National Revenue Center, Alcohol and Tobacco Tax and Trade Bureau ([FloorStocksTax@ttb.gov](mailto:FloorStocksTax@ttb.gov), 513-684-3334 or 1-877-TTB-FAQS (1-877-882-3277)); for other questions concerning this document, contact Amy Greenberg, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau (202-927-8210).

**SUPPLEMENTARY INFORMATION:**

**Background**

In the Rules and Regulations section of this issue of the **Federal Register**, we are publishing a temporary rule setting forth regulatory amendments to implement certain provisions of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA). The temporary rule amends the existing regulations to reflect increases in the tax rates on tobacco products and cigarette papers and tubes, revising existing floor stocks tax regulations to reflect the scope of the CHIPRA floor stocks tax provisions, and revising existing regulations to include the new statutory criteria for denial, suspension, or revocation of tobacco permits.

The Alcohol and Tobacco Tax and Trade Bureau (TTB) is responsible for the administration of the Internal Revenue Code of 1986 provisions relating to qualification of manufacturers of tobacco products and cigarette papers and tubes, importers of those products, and export warehouses for those products. TTB is also responsible for collecting the excise taxes on tobacco products and cigarette papers and tubes removed from

domestic production facilities and brought to the United States from Puerto Rico. In addition, TTB is responsible for collecting the floor stocks tax imposed by CHIPRA on tobacco products (except large cigars) and cigarette papers and tubes held for sale on April 1, 2009.

The temporary regulations published elsewhere in this issue of the **Federal Register** involve amendments to parts 40, 41, 44, 46, and 71 of the TTB regulations (27 CFR parts 40, 41, 44, 46, and 71). The text of the temporary regulations serves as the text of these proposed regulations. The preamble to the temporary regulations explains the proposed regulations.

**Public Participation**

*Comments Invited*

We invite comments from interested members of the public on this proposed rulemaking.

*Submitting Comments*

You may submit comments on this notice by one of the following three methods:

- *Federal e-Rulemaking Portal:* You may electronically submit comments on this notice through "Regulations.gov," the Federal e-rulemaking portal. A direct link to the [Regulations.gov](http://www.regulations.gov) docket containing this notice and its related comment submission form is available on the TTB Web site at [http://www.ttb.gov/regulations\\_laws/all\\_rulemaking.shtml](http://www.ttb.gov/regulations_laws/all_rulemaking.shtml) under Notice No. 93. You may also reach this notice and its related comment form via the [Regulations.gov](http://www.regulations.gov) search page at <http://www.regulations.gov>. Supplemental files may be attached to comments submitted via [Regulations.gov](http://www.regulations.gov). For complete instructions on how to use [Regulations.gov](http://www.regulations.gov), visit the site and click on "User Guide" under "How to Use this Site."

- *Mail:* You may send written comments to the Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 14412, Washington, DC 20044-4412.

- *Hand Delivery/Courier:* You may hand-carry your comments or have them hand-carried to the Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Suite 200-E, Washington, DC 20005.

Please submit your comments by the closing date shown above in this notice. Your comments must reference Notice No. 93 and include your name and mailing address. Your comments also must be made in English, be legible, and be written in language acceptable for public disclosure. We do not