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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 55 and 81

[Docket No. 00-108-2]  
RIN 0579-AB35

Chronic Wasting Disease Herd Certification Program and Interstate  
Movement of Captive Deer and Elk

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

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SUMMARY: We are proposing to establish a herd certification program to eliminate chronic wasting disease from captive cervids in the United States. Participating deer and elk herds would 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 would be granted ``certified'' status. Owners of herds could enroll in a State program that we have determined has requirements equivalent to the Federal program, or could enroll directly in the Federal program if no State program exists. We are also proposing to establish interstate movement requirements to prevent the interstate movement of deer and elk that pose a risk of spreading CWD. These actions are intended to eliminate CWD from the captive deer and elk herds in the United States.

DATES: We will consider all comments that we receive on or before February 23, 2004.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 00-108-2, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 00-108-2. If you use e-mail, address your comment to [regulations@aphis.usda.gov](mailto:regulations@aphis.usda.gov). Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ``Docket No. 00-108-2'' on the subject line.

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.

APHIS documents published in the Federal Register, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

FOR FURTHER INFORMATION CONTACT: Dr. Lynn Creekmore, Staff Veterinarian, VS, APHIS, 2150 Centre Avenue, Fort Collins, CO 80526, telephone (970) 494-7354.

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#### SUPPLEMENTARY INFORMATION:

##### Background

Chronic wasting disease (CWD) is a transmissible spongiform encephalopathy (TSE) of cervids (members of Cervidae, the deer family) that as of November 2002 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 include Rocky Mountain elk, mule deer, white-tailed deer, and black-tailed deer. Non-cervid 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 November 2002 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, South Dakota, Utah, Wisconsin, and Wyoming, and in 27 captive (farmed) elk herds in Colorado, Kansas, Minnesota, Montana, Nebraska, Oklahoma, South Dakota, and Wisconsin, and in 2 captive deer herds in Wisconsin. The disease was first detected in U.S. farmed elk in 1997.

Research is being conducted to develop live-animal diagnostic tests for CWD. Currently, definitive diagnosis is based on postmortem examination (necropsy) and testing of postmortem samples. On microscopic examination, lesions of CWD in the central nervous system resemble those of other TSE's. In addition, using a technique called immunohistochemistry, scientists test brain tissues for the presence of the protease-resistant prion protein.

The origin and mode of transmission of CWD is unknown. Animals born in captivity and those born in the wild have been affected with the disease. Based on epidemiology, transmission is thought to be lateral, or from animal to animal. Although maternal transmission may also occur, it appears to be a relatively uncommon form of transmission.

Surveillance for CWD in free-ranging deer and elk in Colorado and Wyoming has been ongoing since 1983 and has defined the endemic areas

in those States. CWD was detected in 2000 and 2001 in free-ranging deer in western Nebraska. The source of the disease is believed to be natural spread from the Colorado and Wyoming endemic area. More intensive surveillance to better define the prevalence and distribution of the disease in free ranging deer in these States is underway. However, in 2002, CWD was detected in wild cervids in northwestern Colorado, southern New Mexico, southwestern South Dakota, and south central Wisconsin. Detection of disease in these unexpected areas has led to increased surveillance to better define the limits of the endemic area and to determine the nationwide distribution and prevalence of CWD in wild cervids. This surveillance effort is a two-pronged approach consisting of hunter-harvest cervid surveys conducted in many States, as well as surveillance targeting deer and elk exhibiting clinical signs suggestive of CWD throughout the entire country. Surveillance for CWD in captive elk began in 1997. Captive cervid surveillance has increased each year since 1997 and will be an integral part of the U.S. Department of Agriculture (USDA) program to eliminate CWD from captive cervids. Surveillance in both wild and captive animals has been a cooperative effort involving State agriculture and wildlife agencies, USDA, elk and deer producers, and hunters.

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

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. Animal health regulations administered by the Department under this authority include those specifically addressing control programs and indemnity payments for tuberculosis (part 50), brucellosis (part 51), pseudorabies (part 52), and scrapie (part 54), and regulations in part 53 regarding payment of claims for other diseases. We have already promulgated regulations to pay indemnity to the owners of CWD-positive captive herds who voluntarily depopulate their herds. These indemnity regulations, contained in 9 CFR part 55 and referred to below as the indemnity interim rule, were published in the Federal Register on February 8, 2002 (Docket No. 00-108-1, 67 FR 5925-5934).

While the indemnity program should contribute greatly to the eventual eradication of CWD in the United States, it will not achieve this goal unless it is supported by programs to actively identify herds infected with CWD, and to manage these herds in a way that will prevent further spread of CWD. To that purpose, we are proposing to create a CWD Herd Certification Program to help eliminate chronic wasting disease from the captive deer and elk herds in the United States. 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 are also

proposing to establish interstate movement requirements to prevent the interstate movement of deer and elk that pose a risk of spreading CWD.

APHIS has established herd or flock certification programs in the past to monitor animals for disease and eventually certify a herd or flock as disease-free or low risk. Notably, we established the Scrapie Flock Certification Program, which is described in 9 CFR part 54, subpart B. The CWD Herd Certification Program that we are proposing in this document has many features in common with the scrapie program. Because both diseases are caused by TSE's and often have a long incubation period, both programs require closely monitoring animals over a period of years and restricting movements of animals into and from herds.

#### Proposed CWD Herd Certification Program

We are proposing to create a cooperative Federal-State-private sector program to contribute to the eradication of CWD from captive deer and elk herds in the United States.

Jurisdiction over captive deer and elk varies from State to State. The vast majority of captive deer and elk are domesticated or farmed; that is, they are raised for profit on private ranches or farms. A smaller number of captive deer and elk are maintained in zoos, other exhibitions, or research facilities.

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Farmed captive deer and elk are raised either for sale for meat, for sale as breeding animals, for harvest of antler velvet, or for hunting on private game facilities. In some States, the regulatory authority over captive deer and elk resides with the State agricultural or animal health agency or the State wildlife management agency, and in some States the authority is shared between agricultural and wildlife management agencies.

We have designed a Federal program to monitor the health of deer and elk herds and eventually certify them as low risk for CWD. The CWD Herd Certification Program relies primarily on animal identification, regular surveillance of herds for evidence of CWD, testing for CWD of animals that die in the monitored herds or are sent for slaughter, and limiting new herd acquisitions to animals from herds that are also enrolled in the program. These activities, along with State-Federal cooperation in tracing the movements of CWD-positive animals and identifying animals and herds that are exposed to them, are the foundation of the CWD Herd Certification Program.

Several States already enroll deer and elk herd owners in programs based on these principles. We believe that it is better to build a Federal program that recognizes State activities than to replace them with a strictly Federal program. Therefore, our proposal would establish certain basic definitions and requirements that we believe are consistent among different State programs to effectively address CWD on a national level. We believe the States that have or are developing CWD programs can readily incorporate our proposed minimum criteria with few or no changes to State programs. Our proposal also includes a process for APHIS to approve State programs that meet these criteria as Approved State CWD Herd Certification Programs, and to ``grandfather'' all herds enrolled in those State programs into the CWD Herd Certification Program. (Note that we do not propose separate Federal and State programs; rather, the CWD Herd Certification Program

includes, as a subset, the Approved State CWD Herd Certification Programs--those herds that did not apply directly to enroll in the CWD Herd Certification Program, but that instead were admitted to it based on their prior enrollment in a State program.)

By this means, State CWD programs would become consistent with Federal minimum criteria and with each other. At the herd level, activities and compliance would be based on State guidelines rather than Federal ones. For herd owners who are involved with Approved State CWD Herd Certification Programs, this means that the owners would continue to work with the State contacts and procedures that are familiar to them.

This proposal represents an attempt to apply current scientific and diagnostic information to the disease control and management practices of deer and elk production units. The science of CWD, like that of other TSE's, is rapidly evolving. As new information becomes available, the CWD Herd Certification Program will be updated. The current proposal is designed to have the necessary flexibility to respond to new developments.

The goal of the program is the eradication of CWD from captive deer and elk herds in the United States. Captive herds are those animals that are privately or publicly owned and held for economic or other purposes within a perimeter fence or confined area. This includes cervids that are ``farmed,'` ``ranched,'` ``game farmed,'` or owned by zoos and other public or private entities. The proposed CWD Herd Certification Program would not apply to animals being held for CWD research purposes by State or Federal agencies or universities.

The CWD Herd Certification Program is designed for captive black-tailed and mule deer (*Odocoileus hemionus*), white-tailed deer (*Odocoileus virginianus*), red deer (*Cervus elaphus*), and captive elk (*Cervus elaphus*) or elk-red deer hybrids. Except for red deer, all these species are known to be susceptible to CWD; red deer are included because of their extreme genetic similarity to elk. These deer and elk belong to the Family Cervidae, along with other types of deer, reindeer, sitka deer, and moose. Aside from research animals and animals in zoological collections, elk and white-tailed deer are the only captive cervid species in which CWD has been reported. However, CWD has been reported in wild mule deer, white-tailed deer, and elk. Should CWD be reported in other cervid species, this program may be used as a model for those industries to follow.

The CWD Herd Certification Program does not apply to free-ranging cervids under the management of Federal, State or Native American Tribal management authorities. Although it is not directly addressed by this proposal, the spread of CWD in free-ranging animals in its endemic area (Colorado, Wyoming and Nebraska) and its appearance elsewhere, such as in Wisconsin and New Mexico, is a major concern. USDA is working as closely as possible with appropriate State and Federal agencies to encourage management actions to address the presence of CWD in all cervids. USDA will continue to support surveillance for CWD in free-ranging cervids across the country.

Under this proposal, States would design and implement Approved State CWD Herd Certification Programs for their own captive deer and elk owners. If a State does not develop a program, cervid owners in that State could directly enroll in the CWD Herd Certification Program. If a State program meets minimum APHIS requirements to ensure that programs are effective and consistent, the Administrator of APHIS would designate the State program to be an Approved State CWD Herd Certification Program. States could make program standards at the herd

level more stringent than the minimum criteria established by APHIS, and could make participation in the CWD Herd Certification Program mandatory if they chose.

Several States have already developed or are developing CWD certification programs. Existing State CWD programs and the deer and elk owners participating in them would be grandfathered into the Federal program if they meet the minimal requirements. The date these herds enrolled in a State program that APHIS subsequently determines qualifies as an Approved State CWD Herd Certification Program would be considered their enrollment date in the CWD Herd Certification Program.

Deer and elk owners in those States that do not have an Approved State CWD Herd Certification Program would be able to join the CWD Herd Certification Program by applying directly to APHIS through their veterinarian in charge \1\ and complying with the minimum program requirements for enrolled herd owners in proposed Sec. 55.23(b).

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\1\ A veterinarian in charge, as defined by current part 55, is ``the veterinary official of Veterinary Services, APHIS, who is assigned by the Administrator to supervise and perform official animal health work for APHIS in the State concerned.'' A list of veterinarians in charge may be obtained from the Animal and Plant Health Inspection Service, National Animal Health Programs Staff, 4700 River Road Unit 43, Riverdale, MD 20737-1235.

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This proposal contains mandatory Federal requirements affecting interstate movement of deer and elk. APHIS would allow interstate movement of captive deer or elk only from herds participating in the program, and participation would have to be documented on the animal health certificate required to move animals interstate. Therefore, owners would

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have to participate in the CWD Herd Certification Program if they wished to move their animals to another State.

#### Section by Section Explanation of Proposal

We are proposing to add a new subpart to 9 CFR part 55 that describes the CWD Herd Certification Program. We also propose to add a new 9 CFR part 81, ``Chronic Wasting Disease in Captive Deer and Elk,'' which would contain the mandatory requirements for moving deer and elk interstate. The next sections describe our proposed changes for parts 55 and 81.

#### Definitions (Sec. 55.1)

The interim indemnity rule established a ``Definitions'' section in part 55 and established several definitions that are used in both the indemnity program and in this proposed herd certification program. The following definitions from the interim indemnity rule are also important for the proposed certification rule.

CWD-positive animal. An animal that has had a diagnosis of CWD

confirmed by means of an official CWD test.

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

CWD-suspect animal. An animal for which an APHIS employee has determined that laboratory evidence or clinical signs suggest a diagnosis of CWD.

We propose to retain these definitions as they are; we are setting them out here only for information.

In addition, we are proposing to modify the definitions in part 55 of CWD-exposed animal, herd, and herd plan, as follows:

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.

The revision would substitute the standard of being ``exposed to a CWD-positive animal'' for language in the earlier definition that based the exposed classification on whether the animal was part of a herd within 5 years prior to that herd's designation as CWD-positive, or had been housed with or been in direct contact with a positive animal, or had been on a contaminated premises.

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

The definition of herd would be revised by changing its current statement that it applies to ``a group of animals'' to read ``one or more animals,'' since in some rare circumstances the owner of a single animal may wish to enroll in the CWD Herd Certification Program.

Herd plan. A written herd management agreement developed by a State representative with input from the herd owner, his or her veterinarian, and other affected parties. The State representative will then submit the herd plan to the Administrator, and the herd plan will not be valid until it has been reviewed and signed by the Administrator. 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 suspect herd, or to prevent introduction of CWD into another 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; cleaning and disinfection requirements; or other requirements. A herd plan may be reviewed and revised 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 must also be submitted to the Administrator for review and signature.

This revision would emphasize that a herd plan is developed primarily not by APHIS, but by a State representative and the herd owner, working in concert with the herd's veterinarian and any other affected parties. Under this definition, APHIS would retain the right to approve or disapprove herd plans. The revision also clarifies that when veterinarians examine animals in accordance with a herd plan they are looking for clinical signs of disease, including signs of chronic wasting conditions, and states that sometimes herd plan requirements may include depopulating the herd.

In addition to the definitions above that are already established, we propose to add the following new definitions to part 55 in support of the CWD Herd Certification program.

Commingled, commingling. Animals are commingled if they have direct contact with each other, have less than 30 feet of physical separation, or share equipment, pasture, or water sources/watershed, except for periods of less than 48 hours at sales or auctions when an APHIS employee or State representative has determined such contact presents minimal risk of CWD transmission. Animals are considered to have commingled if they have had such contact with a positive animal or contaminated premises within the last 5 years.

This definition is needed to address situations where a healthy animal, because it was commingled with a CWD-positive animal, was put at risk of contracting CWD. 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.

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.

This definition is needed because herds exposed to CWD should be restricted and monitored until sufficient evidence is available to confirm whether or not the exposure caused new cases of CWD in the herd. Because current evidence strongly suggests that a cervid would die from CWD no more than 5 years after acquiring the disease, we are not concerned about exposures that took

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place more than 5 years before an animal is diagnosed with CWD.

CWD Herd Certification Program. The Chronic Wasting Disease Herd Certification Program established by this part.

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

This definition is needed to designate herds that are a high risk because they may be determined CWD-positive in the near future, so that appropriate restrictions may be placed on the herd pending final confirmation of the herd's CWD status.

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.

Deer. Mule deer (*Odocoileus hemionus*), black-tailed deer (*Odocoileus hemionus*), white-tailed deer (*Odocoileus virginianus*), red deer (*Cervus elaphus*), and hybrids of these species.

Elk. North American wapiti (*Cervus elaphus*) and wapiti x red deer hybrids.

Herd status. The status of a herd assigned under the CWD Herd Certification Program in accordance with proposed Sec. 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 identification. Identification mark or device approved by APHIS for use in the CWD Herd Certification Program. Examples are listed in proposed Sec. 55.25.

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.

#### Administration (Sec. 55.21)

This proposed section states that the CWD Herd Certification Program is a cooperative effort between APHIS, State animal health agencies, and deer or elk owners. It explains that, under the program, APHIS coordinates with State animal health agencies to encourage deer and elk owners to certify their herds as free of CWD by remaining in continuous compliance with the CWD Herd Certification Program standards.

#### Participation (Sec. 55.22)

This proposed section describes the eligibility of captive deer or elk herd owners and State animal health agencies to participate in the CWD Herd Certification Program. Herds of any size, even a single animal, may participate in the program. This section states that any owner of a captive deer or elk herd (except for a CWD-positive herd, a CWD-exposed herd, and a CWD-suspect herd) may apply to enroll, and any State may apply to have its CWD program approved, by contacting the appropriate APHIS or State offices. Before determining that the herd is eligible to join, APHIS or the State may contact the herd owner to obtain more information about the herd and its operations, if needed. APHIS or the State animal health agency will send each approved herd owner a notice of enrollment that includes the herd's enrollment date (in the case of 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). This proposed section also states that APHIS intends to maintain a list of herds participating in the CWD Herd Certification Program, and the certification status of each herd, available on an Internet Web site and by written request.

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\2\ A list of these offices may be obtained from the Animal and Plant Health Inspection Service, National Animal Health Programs Staff, 4700 River Road Unit 43, Riverdale, MD 20737-1235.  
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With regard to States applying to have a State program approved, this section states that the Administrator will approve or disapprove a State program in accordance with proposed Sec. 55.23(a), discussed below. This section also says that in States with an Approved State CWD Herd Certification Program, program activities would be conducted in accordance with the guidelines of that program, as long as the State program meets certain minimum requirements of the subpart.

#### Responsibilities of States and Enrolled Herd Owners (Sec. 55.23)

This proposed section describes the minimum requirements State programs must meet in order to be approved by the Administrator. It also describes the responsibilities of herd owners who enroll in the CWD Herd Certification Program.

The Administrator would review a letter from the State describing its CWD control and deer and elk herd certification activities, and would also review relevant State statutes, regulations, and directives pertaining to animal health activities, and reports and publications of the State animal health agency. The Administrator would determine whether the State had sufficient authority and active programs to conduct traceback, surveillance, and testing activities needed to identify herds exposed to CWD, and to restrict the movement of all CWD-positive, CWD-suspect, and CWD-exposed animals. The Administrator would also look for effective State programs to require individual animal identification in participating deer or elk herds, and to require prompt reporting of suspected cases of CWD and test results for CWD to State or Federal authorities.

We also propose that the State program must have placed all known CWD-positive and CWD-exposed herds under movement restrictions, with movement of animals only for destruction or for research. States must remove herd movement restrictions placed on CWD-positive or CWD-exposed herds only after the herds complete a herd plan. States must also have programs to educate those engaged in the interstate movement of deer and elk regarding requirements of the State program. States would also have to sign a memorandum of understanding with APHIS that delineates the respective roles of each in the CWD Herd Certification Program implementation.

States would also have to designate at least one State animal health official to coordinate CWD Herd Certification Program activities in the State, and would have to agree to update the National CWD Database administered by APHIS with information about the CWD status of herds in the State and information about animals being traced across State lines.

Regarding the responsibilities of deer or elk herd owners who enroll in the CWD Herd Certification Program, proposed Sec. 55.23(b) states that they must agree to maintain their herds in accordance with certain program conditions. These proposed conditions are:

[sbull] Each cervid on the premises in the herd must be officially

identified using means of identification allowed by proposed Sec. 55.25;

[sbull] The herd premises must have perimeter fencing adequate to prevent ingress or egress of cervids. This fencing must comply with any applicable State regulations;

[sbull] The owner must immediately report to an APHIS employee or State representative all deaths of deer or elk

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aged 16 months or older, and must make the carcasses of such animals available for tissue sampling and testing. This includes animals killed on premises maintained for hunting. The owner also must allow test samples to be collected from any animals sent to slaughter that APHIS desires to test;

[sbull] 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 animal 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 a physical herd inventory with verification reconciling animals and identifications with the records maintained by the owner;

[sbull] 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. No commingling of animals may occur. Movement of animals between herds must be recorded as if they were separately owned herds; and

[sbull] New animals may be introduced into the herd only from other herds enrolled in the CWD Herd Certification Program (including herds in Approved State CWD Herd Certification Programs). 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.

Herd Status and Movement of Animals Between Enrolled Herds (Sec. 55.24)

In this proposed section, the progress of a herd through the various stages of the program are described. When a herd is first enrolled in the CWD Herd Certification Program, it would be placed in First Year status. If the herd continues to meet the requirements of the program, each year, on the anniversary of the enrollment date the herd status would 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 would be changed to Certified, and the herd would remain in Certified status as long as it remained enrolled in the program (and provided no signs of CWD are detected). Once the herd has received Certified status, the requirements the herd must meet to remain in the program would be slightly reduced. Testing of all animals sent to slaughter and all animals killed on hunting premises would no longer be required, because 5 years of program participation would have documented a minimal herd risk that does not justify such expensive comprehensive

testing, but other requirements of the program would remain in force.

This proposed section also describes how a herd could lose its herd status or have it temporarily suspended. If a herd is designated a CWD-positive herd or a CWD-exposed herd, it would immediately lose its program status, and the owner could only re-enroll after completing a herd plan. Owners of CWD-positive herds must make a business decision on whether it is worthwhile to complete a herd plan, which usually would require depopulation of the herd. If an owner completes a herd plan, he or she can at least use the same premises and equipment to raise elk in the future, even if the herd animals are depopulated. If the owner elects not to complete a herd plan, animals from the herd may not move interstate, and the owner may find it difficult to sell animals even within the State, due to buyer reluctance and State restrictions. If a herd is designated a CWD-suspect herd, a trace back herd, or a trace forward herd, it would immediately be placed in Suspended status pending an epidemiologic investigation by APHIS or a State animal health agency. This epidemiologic investigation could have three possible outcomes: It could determine that the investigated herd was not commingled with a CWD-positive animal; it could determine that the herd was commingled with a CWD-positive animal; or it could be unable to make a definite determination of exposure.

If the epidemiologic investigation determined that the herd was not commingled with a CWD-positive animal, the herd would be reinstated to its former program status, and the time spent in Suspended status would count toward its promotion to the next herd status level.

If the epidemiologic investigation determines that the herd was commingled with a CWD-positive animal, the herd would lose its program status and would be designated a CWD-exposed herd. The herd would not be eligible to reenroll in the CWD Herd Certification Program until it completed a herd plan.

If the epidemiological investigation was unable to make a determination regarding the exposure of the herd, because the necessary animal or animals were 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 would continue as Suspended unless and until a herd plan was developed for the herd. If a herd plan was developed, the herd would 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. Treatment of these indeterminate status herds differs from treatment of Exposed herds in that indeterminate status herds can re-enter the program as soon as a herd plan is developed, while Exposed herds cannot re-enter until they have completed a herd plan and are no longer classified Exposed. The indeterminate herd would have to comply with the requirements of the herd plan as well as the requirements of the CWD Herd Certification Program, and the herd plan would require testing of all animals that die in the herd for any reason, regardless of the age of the animal, and could require movement restrictions for animals in the herd based on epidemiologic evidence regarding the risk posed by the animals in question.

Herds could also lose their program status if the Administrator determined that the herd owner failed to comply with the requirements of the program.

We propose to allow an appeals process for herd owners subject to cancellation of enrollment or loss or suspension of herd status. Herd owners could appeal any of these actions by writing to the Administrator within 10 days after being informed of the reasons for

the proposed action. The appeal would have to 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 would 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 would be held to resolve the conflict. Rules of practice concerning the hearing would be adopted by the Administrator. However, cancellation of enrollment or loss or suspension of herd status would become effective pending final determination in the proceeding if the Administrator determines that such action is necessary to prevent the possible spread of CWD. This cancellation of enrollment or loss or suspension of herd status would continue in effect pending the completion of the proceeding, and any

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judicial review thereof, unless otherwise ordered by the Administrator.

This proposed section also describes restrictions of the source of animals that could be added to an enrolled herd. A herd could add animals from herds with the same or an earlier enrollment date in the CWD Herd Certification Program with no negative impact on the certification status of the receiving herd.\3\ If animals were acquired from a herd with a later date of enrollment, the receiving herd would revert to the program status of the sending herd. If a herd participating in the program acquired animals from a nonparticipating herd, the receiving herd would revert to First Year status with a new enrollment date of the date of acquisition of the animal.

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\3\ Note that in addition to this requirement, proposed Sec. 81.3 contains restriction on the interstate movement of captive deer and elk.

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#### Official Identification (Sec. 55.25)

This section proposes that each animal required to be identified under the CWD Herd Certification Program must have at least two forms of APHIS-approved identification, because a single form of identification can sometimes become detached or obscured (e.g., eartags are sometimes torn loose on brush, or lost due to frostbite damage; tattoo inks sometimes fade, or are obliterated by scarring). Even though not required by most regulations, the use of two forms of animal ID has become common in animal industries, and we believe its program benefits outweigh the additional expense. The official identification would have to be an ear tattoo, tamper-resistant ear tag, electronic implant, or flank tattoo approved for this use by APHIS. The official identification would have to provide a unique identification number that is applied by the owner of the herd or his or her agent and is linked to that herd in the National CWD Database.

This concludes discussion of the changes proposed for part 55. The contents of proposed new part 81 are discussed below.

Definitions (Sec. 81.1) and Identification of Deer and Elk in Interstate Commerce (Sec. 81.2)

These proposed sections would be essentially the same as the definitions and identification requirements discussed above with regard to proposed Sec. Sec. 55.1 and 55.25. The definition of captive proposed for part 81 differs slightly from the definition employed in part 55, because under part 81 it is necessary to restrict the interstate movement of animals that were captured from a free-ranging population for interstate movement and release. Such animals are not covered under the indemnity and certification programs of part 55. The definition of chronic wasting disease (CWD) proposed for part 81 also describes some clinical signs of CWD that are not needed in the similar definition in part 55, because part 81 requires issuance of certificates stating that animals do not exhibit clinical signs of CWD.

#### General Restrictions (Sec. 81.3)

This proposed section would institute the mandatory requirement that no captive deer or elk may move interstate unless it originated in a herd enrolled in the CWD Herd Certification Program and the herd remained in the program long enough to reach a specified status. To encourage early enrollment in the CWD Herd Certification Program and to support its goal of eventually eradicating CWD from captive deer and elk herds in the United States, we are proposing to establish a timetable that gradually increases the time a herd must be in the program in order to move animals interstate. Eventually, only animals from herds that have been enrolled in the program for over 5 years would be allowed to move interstate. If this proposed rule is adopted, immediately after it takes effect, a herd would need to achieve Second Year status before animals from the herd could be moved interstate. (Some herds would have this or greater program status immediately upon enrollment, due to the provisions to "grandfather" herds enrolled in existing State programs that was discussed above.) As of 27 months after the rule takes effect, a herd would need to achieve Third Year status before animals from the herd could be moved interstate. Twelve months later the herd would have to achieve Fourth Year status, then after 12 more months, Fifth Year status, for animals to be moved interstate. Finally, after 12 more months (approximately 5 $\frac{1}{4}$  years after the rule takes effect), the herd would have to achieve Certified status. Under this schedule, the longer a herd owner waits before enrolling in the CWD Herd Certification Program, the longer he or she would have to wait before moving animals interstate. This gradually increasing requirement also means that as time goes on, animals allowed to move interstate will have spent more and more time in the CWD Herd Certification Program, with a corresponding decrease in the risk that such animals could spread CWD.

We also propose that captive deer or elk moved interstate must be accompanied by a certificate that identifies its herd of origin, states that the herd is participating in the CWD Herd Certification Program and gives its program status, and states that it is not a CWD-positive, CWD-exposed, or CWD-suspect animal. One exception to this requirement is that deer or elk that are temporarily captured from free-ranging populations may be moved interstate for release (translocated) without enrollment in the CWD Herd Certification Program. Since the CWD Herd Certification Program is not designed for free-ranging populations, we propose that in such cases the free-ranging population must instead be documented to be free from CWD based on a CWD surveillance program that is approved by the State Government of the receiving State and by

APHIS.

Issuance of Certificates (Sec. 81.4)

This proposed section describes the function and contents of the certificate that would be required by proposed Sec. 81.3. Animal health certificates are used in this section in much the same way they are used in many other APHIS regulations: to document the origin, identity, and disease status of animals moving interstate. The certificate would have to show the herd of origin and official identification numbers of each animal to be moved. (Certificates issued for the translocation of free-ranging animals caught in one State and released in another would not need to record this information, since it does not exist for such cases.) The certificate would also have to 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 would have to include a statement by the issuing accredited, State, or Federal veterinarian that the animals were not exhibiting clinical signs associated with CWD at the time of examination. The certificate would also have to state that the animals are from a herd participating in the CWD Herd Certification Program, and give the herd's program status, or state that the animals are free-ranging animals that are being translocated from a herd that is documented to be free from CWD based on a CWD surveillance program.

This proposed section also includes some administrative details regarding how to attach secondary forms listing animal identification information to an official certificate. We propose that animal identification documents attached to certificates must be a legible copy of State or APHIS forms that requires individual identification of

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animals, and 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. We also propose that 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: the name of the document; and 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. These proposed requirements would help us ensure the authenticity and reliability of animal identification documents, and help us trace the movement of animals when necessary.

Executive Order 12866 and Regulatory Flexibility Act

This proposed 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 proposed 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 proposed rule on small entities, as required under 5

U.S.C. 603. 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 (NADFA). 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.

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 proposed 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 free of CWD and hence 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 and elk altogether, without establishing a voluntary 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 voluntary Federal herd certification program with interstate movement on animals contingent on participation in that program. This alternative substantially reduces the risk of exporting CWD from one state to another--because only deer and elk 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 proposed rule would establish a CWD Herd Certification Program for captive elk and deer, and prohibit the interstate movement of deer and elk that are not enrolled in the program. Herds that participate

would have to follow program requirements for animal identification, testing, herd management, and movement of animals to and from herds. Herd owners would be able to enroll in an Approved State CWD Herd Certification Program that met minimum standards established by APHIS, or enroll directly in the Federal CWD Herd Certification Program if there is no State program in their location.

Currently, there are no Federal requirements for the interstate movement of deer and elk. However, 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 proposed in this rule. The proposed 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 would be able to enroll in the Federal program.

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

The proposed rule would primarily affect deer and elk farms. In the United States there are an estimated 150,000 elk on 2,300 farms, and 550,000 deer on 11,000 farms. It is estimated that, without improved CWD control efforts, the disease could eventually infect almost all U.S. captive elk herds.

The proposed rule should 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 would take advantage of the increased access to out-of-State markets, would benefit immediately. Conversely, some farmers could experience a significant adverse effect, especially any farmers who cannot afford to pay the program's annual costs. However, given the available data, there is no basis to conclude that the proposed rule will have a significant negative economic impact on a substantial number of small entities.

The economic importance of the deer and elk farming industries notwithstanding, the rule's primary benefits would appear to lie in its ability to reduce the potential for the introduction or spread of CWD.

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However, it is difficult to translate that reduced potential into a dollar benefit.

#### The Deer and Elk Industries and the Impact of CWD

The number of deer and elk 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 to-date has been relatively low. It is estimated that fewer than 100 farmed elk and no farmed deer have died as a result of contracting CWD. The number of farmed elk that have died is equivalent to less than one-tenth of 1 percent of the current U.S. farmed elk population, estimated at 150,000. 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 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 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.

NAEBA estimates that there are about 150,000 elk on 2,300 U.S. farms. 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, heifer, calf), market conditions, and other factors. The average value of each elk is roughly estimated at \$2,500, with the typical high end value at about \$8,000. (The more valuable trophy animals hunted on game farms tend to be worth more than this average.) Based on the estimated average of \$2,500 per animal, the value of all 150,000 elk on U.S. farms is estimated at \$375 million (150,000 x \$2,500). In 1999, gross receipts for the elk farming and velvet antler industry in North America totaled an estimated \$150 million.

NADFA estimates that there are about 550,000 deer on U.S. farms. Based on NADFA's estimate of 50 deer per farm, on average, the number of deer farms in the United States would total 11,000. Assuming each farm has 2.1 employees, the average for deer farms in Indiana, employment on all of the estimated 11,000 deer farms would total 23,100. 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 (e.g., wapiti, white-tailed, fallow) and market conditions. An earlier NADFA estimate put the average per animal value of all deer on member farms at \$1,687, which would make the estimated value of all 550,000 deer on U.S. farms \$927.9 million (550,000 x \$1,687). As of January, 2002, capital investment (including land, fencing) in white-tailed deer farms totaled an estimated \$2.5 billion.

#### Benefits of Proposed Rule

The proposed rule would 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 proposed interstate movement restrictions that would allow only ``program'' deer and elk to be moved interstate would 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 and elk that have been subject to certain minimum surveillance and other criteria could be moved interstate.

Preventing spread of CWD among deer and elk benefits entities and individuals that rely on those animals for their income, e.g., deer and elk farms, State agencies that sell hunting licenses, employees of motels and restaurants in hunting areas. It 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. At this time, the various States do not follow a standard interstate movement policy, nor are there standards that would ensure equivalency between State CWD programs. This has 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 elk herds. The elk industry is in its early stages, which requires owners to purchase and sell large numbers of animals for breeding stock as they develop superior lines. Such large movements of animals between herds exacerbates risks of disease spread. One herd in Colorado sold approximately 400 animals to many other herds in one year. 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 elk, and could readily become established in most U.S. herds. Adoption of the proposed rule, therefore, could serve to protect substantial elk industry livestock assets, valued at an estimated \$375 million.

For farmers with infected deer and elk, 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.

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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 spongiform encephalopathies of

animals or humans. The precise impact of Korea's suspension is unknown, because data that is compiled on U.S. exports does 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.\4\ To the extent that the proposed Federal certification program would provide the basis for equivalency between State programs, increased international sales are likely.

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\4\ Elk Production: Economic and Production Information for Saskatchewan Producers, Saskatchewan Agriculture and Food, November 2000.

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The rule's primary benefits are to help prevent the spread of and eradicate CWD; assist efficient domestic elk and deer marketing; maintain and enhance export markets of cervid products; 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 they had no certification program and CWD infection in one herd quickly spread to 38 herds, causing 7,400 elk to be destroyed.

The proposed 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 Proposed Rule

The proposed 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 would require that herd owners employ certain minimum disease preventative measures established by APHIS. The cost to comply with these minimum requirements would 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 already in place, if for no other reason than to keep animals from escaping.

The certification program would require that herd owners submit the

carcasses of all dead deer and elk 16 months of age or older (including animals killed on hunting premises) to a lab for tissue sampling and testing. The rules would allow herd owners to collect and submit the animal's entire head themselves, or to 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 would charge herd owners about \$100 to collect each sample.

Participating herd owners would 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 would 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 would 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 themselves cost about \$2 each. By comparison, veterinarians could be expected to charge herd owners at least about \$25 to implant each microchip.

It is estimated that adoption of the program's minimum disease preventative measures would 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. 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 16 months of age die per year. It is expected that the cost of sample collection would 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 points (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. However, APHIS particularly solicits comments on this point, since we do not have detailed knowledge of hunting premises business operations.

Participating herds that are found to have CWD-positive or CWD-exposed animals would immediately lose their program status, and could re-enroll only after completing a herd plan. (A herd plan is a written herd management agreement, developed by APHIS with input from the herd owner, State representatives, and other affected parties, that 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 would agree to depopulate their herds, for which APHIS would 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. Most herd owners would consider these actions as

tantamount to closure. Fortunately for herd owners,

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herd infection is rare. Only 27 farmed elk herds and 2 farmed deer herds have been found positive, representing only 1 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 two years if this rule is adopted (if this rule is not adopted, there will be less herd monitoring and fewer detections).

Finally, the proposed certification program would establish herd status, based on the number of years of enrollment in the program with no evidence of disease. Herd status would affect the movement of animals, since additions from a herd with a later enrollment date would cause the acquiring herd to revert to the status of the herd from which the deer and elk were acquired. Herd status, therefore, would 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 would 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 would be less likely to acquire animals from nonparticipating herds, due to penalties.

#### Cost for States

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

States that do establish a certification program would incur the costs of setting up and administering that program, including costs for: the development of legislative/regulatory authority, surveillance and monitoring, 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 would 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 7 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, surveillance, and other activities that the States

would otherwise have to fund themselves. Through fiscal year 2002, \$17.3 million of CCC funding was transferred to APHIS for CWD eradication activities. In addition, \$0.8 million of APHIS contingency funds were used for CWD eradication efforts over the last 4 fiscal years.

#### Cost for APHIS

The direct costs APHIS would incur from this proposed 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 proposed rule.

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

#### 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 proposed rule would primarily affect 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 2,300 elk farms and 11,000 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 1997, there were 10,045 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 10,045 farms, the per farm average gross receipts in 1997 was \$105,624, well below the SBA's small entity threshold of \$750,000 for farms in that NAICS category.

To the extent that the proposed rule prevents the spread of--and perhaps eliminates altogether--CWD in farmed deer and elk herds in the United States, small herd owners should benefit over the long term. The proposed rule would 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 would 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 would 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 less than 2 percent of the 1997 per farm average gross receipts for all U.S. farms in NAICS 11299 (\$1,600/\$105,624). Those herd owners who have the option and elect not to participate would avoid the program's annual costs but they would see the value of their animals discounted in the marketplace, since ``non-program'' animals would likely carry a stigma of inferiority. As discussed below, the discount is likely to exceed the program's annual cost for

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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, generally in the range of between \$2,500 and \$8,000 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 proposed rule. The number of such herd owners is unknown but it is likely to be small, given that the added costs are equivalent to less than 2 percent of 1997 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 27 farmed elk herds and 2 farmed deer herds have been found positive to-date, representing only 1 percent of all elk farms and much less than 1 percent of all deer farms in the United States at the present time. It is estimated that additional elk herds will be detected over the next 2 years (with the proposed rule in effect), 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 proposed 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 would 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.

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

#### Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 00-108-2. Please send a copy of your comments to: (1) Docket No. 00-108-2, Regulatory Analysis and Development, PPD, APHIS, station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238, and (2) Clearance Officer, OCIO, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

This proposed rule would require several information collection activities, including written requests by State Governments and herd owners to participate in the program, herd owner responses to requests from APHIS or States for information about animals in their herds, the development of written herd plans and the maintenance of herd records, identification of cervids with ear-tags or other devices, issuance and use of certificates to move cervids interstate, and the creation of a memorandum of understanding between APHIS and each participating State.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

- (1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;
- (2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 2.664 hours per response.

Respondents: Herd owners, personnel employed by herd owners, State animal health authorities, accredited veterinarians.

Estimated annual number of respondents: 5,000.

Estimated annual number of responses per respondent: 30.

Estimated annual number of responses: 150,000.

Estimated total annual burden on respondents: 399,602 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

#### 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 proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

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#### List of Subjects

##### 9 CFR Part 55

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

##### 9 CFR Part 81

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

Accordingly, we propose to amend 9 CFR chapter I as follows:

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

1. The authority citation for part 55 would be 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 would be amended as follows:

a. In the definition of herd, by removing the words ``A group of animals'' and adding in their place the words ``One or more animals''.

b. By revising the definitions of CWD-exposed animal and herd plan to read as set forth below.

c. By adding definitions for commingled, commingling, CWD-exposed herd, CWD herd certification program, CWD-suspect herd, CWD-source herd, deer, elk, herd status, official identification, trace back herd, and trace forward herd. in alphabetical order, to read as set forth below.

Sec. 55.1 Definitions.

\* \* \* \* \*

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

\* \* \* \* \*

Commingled, commingling. Animals are commingled if they have direct contact with each other, have less than 30 feet of physical separation, or share equipment, pasture, or water sources/watershed, except for periods of less than 48 hours at sales or auctions when an APHIS employee or State representative has determined such contact presents minimal risk of CWD transmission. 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-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 herd. A herd for which laboratory evidence or clinical signs suggest a diagnosis of CWD, as determined by an APHIS employee or State representative, but for which laboratory results have been inconclusive or not yet conducted.

Deer. Mule deer (*Odocoileus hemionus*), black-tailed deer (*Odocoileus hemionus*), white-tailed deer (*Odocoileus virginianus*), red deer (*Cervus elaphus*), and hybrids of these species.

\* \* \* \* \*

Elk. North American wapiti (*Cervus elaphus*) and wapiti x red deer hybrids.

\* \* \* \* \*

Herd plan. A written herd management agreement developed by a State representative with input from the herd owner, his or her veterinarian, and other affected parties. The State representative will then submit the herd plan to the Administrator, and the herd plan will not be valid until it has been reviewed and signed by the Administrator. 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 suspect herd, or to prevent introduction of CWD into another 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; cleaning and disinfection requirements; or other requirements. A herd plan may be reviewed and revised 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 must also be submitted to the Administrator for review and signature.

Herd status. The status of a herd assigned under the CWD Herd Certification Program in accordance with Sec. 55.24 of this part, 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 identification. Identification mark or device approved by APHIS for use in the CWD Herd Certification Program. Examples are listed in Sec. 55.25.

\* \* \* \* \*

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 would be 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 Official identification.

Sec. 55.21 Administration.

(a) The CWD Herd Certification Program is a cooperative effort between APHIS, State animal health agencies, and deer and elk owners. APHIS coordinates with State animal health agencies to encourage deer and elk

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owners to certify their herds as free of CWD by being in continuous compliance with the CWD Herd Certification Program standards.

Sec. 55.22 Participation and enrollment.

(a) Participation by owners. 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. 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. After determining that the herd is eligible to participate in accordance with this paragraph, APHIS or the State animal health agency will send the herd owner a notice of enrollment that includes the herd's enrollment date. A notice containing a current list of herds participating in the CWD Herd Certification Program and the certification status of each herd may be obtained from the APHIS Internet Web site at <http://www.aphis.usda.gov/vs/nahps/cwd/>, or by writing to the Animal and Plant

Health Inspection Service, National Animal Health Programs Staff, VS, APHIS, 4700 River Road, Unit 43, Riverdale, MD 20737-1235.

(1) Enrollment date. 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. 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 Sec. 55.23(a) of this part.

(2) [Reserved]

(b) Participation by States. Any State that operates a State program to certify the CWD status of deer or elk 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 Sec. 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 notice containing a current list of Approved State CWD Herd Certification Programs may be obtained from the APHIS Internet Web site at <http://www.aphis.usda.gov/vs/nahps/cwd/>, or

by writing to the Animal and Plant Health Inspection Service, National Animal Health Programs Staff, VS, APHIS, 4700 River Road, Unit 43, Riverdale, MD 20737-1235.

#### Sec. 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 animal health agency that describes State CWD control and deer and elk herd certification activities and that cites relevant State statutes, regulations, and directives pertaining to animal health activities and reports and publications of the State animal health agency. 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 and CWD-exposed herds under movement restrictions, with movement of animals only for destruction or for research. CWD-positive and CWD-suspect animals may be moved only for transport to an approved research facility or for purposes of destruction.

(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 both the State representative and APHIS;

(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 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 APHIS or State animal health official to coordinate CWD Herd Certification Program activities in the State.

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

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

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

(i) Premises information and assigned premises numbers;

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

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

(iv) Accurate herd status data.

(11) Requires that tissues from all CWD-positive or CWD-suspect animals be submitted to a laboratory authorized by the Administrator to conduct official CWD tests and requires complete destruction of the carcasses of CWD-positive 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 officially identified using means of identification allowed by Sec. 55.25 of this subpart;

(2) The herd premises must have perimeter fencing adequate to prevent ingress or egress of cervids. This fencing

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must comply with any applicable State regulations;

(3) The owner must immediately report to an APHIS employee or State representative all deaths of deer and elk in the herd aged 16 months or older, and must make the carcasses of such animals available for tissue sampling and testing. This includes animals killed on premises maintained for hunting. The owner also must allow test samples to be collected from all animals sent to slaughter;

(4) 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 a physical herd inventory with verification reconciling animals and identifications with the records maintained by the owner;

(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. 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.

Sec. 55.24 Herd status.

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

reenrolled, the herd will enter at a First Year status level, with a new enrollment date reflecting the date the herd completed the 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, 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. The herd must comply with the requirements of the herd plan as well as the requirements of the CWD Herd Certification Program, and the herd plan will require testing of all animals that die in the herd for any reason, regardless of the age of the animal, and may require movement restrictions for animals in the herd based on epidemiologic evidence regarding the risk posed by the animals in question.

(c) 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) A herd may add animals from herds with the same or an earlier enrollment date in the CWD Herd Certification Program with no negative impact on the certification status of the receiving herd.\1\ If animals are acquired from a herd with a later date of enrollment, 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 reverts to First Year status with a new enrollment date of the date of acquisition of the animal.

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\1\ Note that in addition to this requirement, Sec. 81.3 of this chapter restricts the interstate movement of captive deer and elk based on their status in the CWD Herd Certification Program.

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Sec. 55.25 Official identification.

(a) Each animal required to be identified by this subpart must have at least two forms of identification. The official identification must be approved for this use by APHIS, and must be an electronic implant, flank tattoo, ear tattoo, or tamper-resistant ear tag. The official identification must provide a unique identification number that is applied by the owner of the herd or his or her agent and must be linked to that herd in the National CWD Database.

4. A new part 81 would be added to read as follows:

PART 81--CHRONIC WASTING DISEASE IN DEER AND ELK

Sec.

81.1 Definitions.

81.2 Identification of deer and elk 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.

Sec. 81.1 Definitions.

Animal. Any captive deer or elk.

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

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.

Captive. Animals that are privately or publicly maintained or held for economic or other purposes within a perimeter fence or confined area, or that were captured from a free-ranging population for interstate movement and release. Animals that are held for research

purposes by State or Federal agencies or universities are not included.

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 an official CWD test.

CWD-suspect animal. An animal for which an APHIS employee has determined that laboratory evidence or clinical signs suggest a diagnosis of CWD.

Deer. Mule deer (*Odocoileus hemionus*), black-tailed deer (*Odocoileus hemionus*), white-tailed deer (*Odocoileus virginianus*), red deer (*Cervus elaphus*), and hybrids of these species.

Elk. North American wapiti (*Cervus elaphus*) and wapiti x red deer hybrids.

## Sec. 81.2 Identification of deer and elk in interstate commerce.

(a) Each animal required to be identified by this part must have at least two forms of identification, except for free-ranging animals captured for interstate movement and release in accordance with Sec. 81.3(a)(2), which must have at least one form of identification. The form of identification must be an electronic implant, flank tattoo, ear tattoo, or tamper-resistant ear tag approved for this use by APHIS. The identification must provide a unique identification number that is applied by the owner of the herd or his or her agent and is linked to that herd in the National CWD Database.

## Sec. 81.3 General restrictions.

(a) No captive deer or captive elk may be moved interstate unless it:

(1) Is moved from a herd that is:

(i) Enrolled in the CWD Herd Certification Program and:

(A) If the movement occurs between [effective date of final rule] and [date 27 months after effective date of final rule], the herd has achieved at least Second Year status in accordance with Sec. 55.24 of this chapter;

(B) If the movement occurs between [date 27 months after effective date of final rule] and [date 39 months after effective date of final rule], the herd has achieved at least Third Year status in accordance with Sec. 55.24 of this chapter;

(C) If the movement occurs between [date 39 months after effective date of final rule] and [date 51 months after effective date of final rule], the herd has achieved at least Fourth Year status in accordance with Sec. 55.24 of this chapter;

(D) If the movement occurs between [date 51 months after effective date of final rule] and [date 63 months after effective date of final rule], the herd has achieved at least Fifth Year status in accordance

with Sec. 55.24 of this chapter;

(E) If the movement occurs after [date 63 months after effective date of final rule], the herd has achieved Certified status in accordance with Sec. 55.24 of this chapter; and,

(ii) The herd is accompanied by a certificate issued in accordance with Sec. 81.4 of this part that identifies its herd of origin and its CWD Herd Certification Program status, and states that it is not a CWD-positive, CWD-exposed, or CWD-suspect animal; or

(2) The captive deer or captive elk has at least one form of official identification and was captured for interstate movement and release from a free-ranging population that a certificate accompanying the animals documents to be free from CWD based on a CWD surveillance program that is approved by the State Government of the receiving State and by APHIS.

#### Sec. 81.4 Issuance of certificates.

(a) A certificate must show the official 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, that the animals are from a herd participating in the CWD Herd Certification Program, and giving the herd's program status.

(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

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the name of the person who issued the document and the date the document was issued.

Done in Washington, DC, this 17th day of December, 2003.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

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