UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
WILDLIFE SERVICES

ENVIRONMENTAL ASSESSMENT

FIELD TRIAL OF AN EXPERIMENTAL RABIES VACCINE, HUMAN ADENOVIRUS TYPE 5 VECTOR IN WEST VIRGINIA

In cooperation with:
United States Department of Agriculture
Forest Service

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Acronyms

AdRG1.3	Human Adenovirus Type-5 Rabies Glycoprotein Recombinant Vaccine
AMS	Agricultural Marketing Service
ANG	Air National Guard
AMDUCA	Animal Medical Drug Use Clarification Act
APHIS	Animal and Plant Health Inspection Service
BIA	Bureau of Indian Affairs
BLM	Bureau of Land Management
BO	Biological opinion
CDC	Centers for Disease Control and Prevention
CEQ	Council on Environmental Quality
CFIA	Canadian Food Inspection Agency
CVB	Center for Veterinary Biologics
DEA	Drug Enforcement Agency
DOD	Department of Defense
EA	Environmental Assessment
EO	Executive Order
ERA	Evelyn Rockitinicki Abelseth
ESA	Endangered Species Act
EIS	Environmental Impact Statement
FAR	Federal Aviation Regulation
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FONSI	Finding of no Significant Impact
FR	Federal Register
FY	Fiscal Year
HAd5	Human Adenovirus Type 5
OMNR	Ontario Ministry of Natural Resources
ORV	Oral Rabies Vaccination
MIS	Management Information System

MOU	Memorandum of Understanding
NASA	National Aeronautics and Space Administration
NBDOE	New Brunswick Department of Environment
NBDOH	New Brunswick Department of Health
NEPA	National Environmental Policy Act
NHPA	National Historic Preservation Act
NFS	National Forest System
NOP	National Organic Program
NPS	National Park Service
NRMP	National Rabies Management Program
PEP	Post-Exposure Prophylaxis
RFSS	Regional Forester Sensitive Species
SAD	Street Alabama Dufferin
SAG2	Street Alabama Gif2
SCID	Severed Combined Immunodeficient
SOP	Standard Operating Procedure
T&E	Threatened and Endangered
TDSHS	Texas Department of State Health Services
TVA	Tennessee Valley Authority
TVR	Trap Vaccinate Release
USACE	United States Army Corp of Engineers
USC	United States Code
USCG	United States Coast Guard
USDA	United States Department of Agriculture
USDI	United States Department of the Interior
USFS	United States Forest Service
USFWS	United States Fish and Wildlife Service
VBS	Veterinary Biologics Section
V-RG	Vaccinia-Rabies Glycoprotien
VS	Veterinary Services
VSTA	Virus Serum Toxin Act
WS	Wildlife Services
WVDA	West Virginia Department of Agriculture
WVDHHR	West Virginia Department of Health and Human Resources
WVDNR	West Virginia Department of Natural Resources

CHAPTER 1: PURPOSE AND NEED FOR ACTION

1.1 INTRODUCTION AND BACKGROUND

Rabies is an acute, fatal viral disease of mammals most often transmitted through the bite of a rabid animal. The disease can be effectively prevented in humans and many domestic animal species, but abundant and widely distributed reservoirs among wild mammals complicate rabies control. Within most of the U.S., these reservoirs occur in geographically discrete regions where the virus transmission is primarily between members of the same species (Krebs et al. 2000). These species include but are not limited to raccoons (*Procyon lotor*), coyotes (*Canis latrans*), skunks (primarily striped skunks (*Mephitis mephitis*), gray foxes (*Urocyon cinereoargenteus*), and red fox (*Vulpes vulpes*). Species specific variants of the virus may be transmitted to other animal species. However, these encounters rarely result in sustained virus transmission within that animal species. Once established, virus transmission within a specific animal species can persist at epidemic levels for decades, even perhaps for centuries (Krebs et al. 2000).

The vast majority of rabies cases reported to the Centers for Disease Control and Prevention (CDC) for the United States, including Puerto Rico, each year occur in wildlife (>90% of all cases) as in most developed countries. For example in 2009, wildlife accounted for 92% of positive cases while domestic animals accounted for 8% (Blanton et al. 2010). A total of 6,694 cases were reported in 2009 broken down to 2,327 raccoons (34.8%), 1,625 bats (24.3%), 1,603 skunks (24.0%), 504 foxes (7.5%), 300 cats (4.5%), 126 other wildlife (1.9%)[1], 81 dogs (1.2%), 74 cattle (1.1%), 50 other domestic (0.8%)[2], and 4 humans (0.1%) (Blanton et al. 2010). This is very typical of other years, but the number fluctuates from year to year and can be influenced greatly by epizootics (epidemics in animals). Epizootic outbreaks can occur, increasing the number of reported cases as well as postexposure rabies treatments given to people. Two canine rabies epizootics emerged in Texas in 1988, one involving coyotes and dogs in South Texas and the other in gray foxes in West/Central Texas. The South Texas epizootic alone has resulted in two human deaths and caused over 3,000 people to receive postexposure rabies treatment (TDSHS 2010).

The following document is an Environmental Assessment (EA) that describes and analyzes the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Wildlife Services (APHIS-WS) involvement in field trials of an experimental rabies vaccine, human adenovirus type 5-rabies glycoprotein recombinant vaccine (AdRG1.3), in West Virginia. This EA analyzes a number of environmental issues or concerns with the oral rabies vaccine and with activities associated with Oral Rabies Vaccination (ORV) field trials such as capture and handling animals for monitoring and surveillance purposes. The EA also analyzes alternatives to the proposed action, including no action (no federal funding or participation by APHIS-WS).

1.1.1 Public Health Importance of Rabies

Over the last 100 years, rabies in the United States has changed dramatically. About 90 percent or greater of all animal cases reported annually to the CDC now occur in wildlife (CDC 2010). Before 1960 the

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[1] Includes 34 mongooses (Puerto Rico included in report), 32 groundhogs, 30 bobcats, 12 coyotes, 3 opossums, 3 fishers, 2 deer, 2 squirrels, 2 beaver, 1 ringtail, 1 cougar, 1 otter, 1 muskrat, and 1 rabbit.

[2] Includes 41 horses/mules, 8 sheep/goats, and 1 ferret.

majority of cases were reported in domestic animals. The principal rabies hosts today are wild carnivores and bats. The number of rabies-related human deaths in the U.S. has declined from more than 100 annually at the turn of the century to an average of one or two people/year in the 1990s. Modern day prophylaxis, which is the series of vaccine injections given to people who have been potentially or actually exposed, has proven nearly 100 percent successful in preventing mortality when administered promptly (CDC 2010). In the U.S., human fatalities associated with rabies occur in people who fail to seek timely medical assistance, usually because they were unaware of their exposure to rabies.

Human rabies deaths are rare, but the estimated public health costs associated with disease detection, prevention, and control are high, estimated to exceed $300 to $450 million annually. These costs include the vaccination of companion animals, maintenance of rabies laboratories, medical costs, such as those incurred for exposure case investigations, rabies post-exposure prophylaxis (PEP), and animal control programs (CDC 2010). Accurate estimates of these expenditures are not available. Although the number of PEPs given in the U.S. each year is unknown, it is estimated to be about 40, 000. When rabies becomes epizootic or enzootic (i.e., present in an area over time but with a low case frequency) in a region, the number of PEPs in that area increases. Although the cost varies, a course or rabies immune globulin and four doses of vaccine given over a four-week period typically exceeds $1000 (CDC 2010) and has been reported to be as high as $3,000 or more (Meltzer 1996). The cost per human life saved from rabies ranges from approximately $10,000 to $100 million, depending on the nature of the exposure and the probability of rabies in a region (CDC 2010). In Massachusetts during 1991-95, the median cost for PEP was $2,376 per person (CDC 2010b). Also, as epizootics spread in wildlife populations, the risk of “mass” human exposures requiring treatment of large numbers of people that contact individual rabid animals infected by wild rabid animals increases – one case in Massachusetts involving contact with, or drinking milk from, a single rabid cow required PEPs for a total of 71 persons (CDC 2010b). The total cost of this single incident exceeded $160,000 based on the median cost for PEPs in that state cited above. Perhaps the most expensive single mass exposure case on record in the U.S. occurred in 1994 when a kitten from a pet store in Concord, NH tested positive for rabies after a brief illness. As a result of potential exposure to this kitten or to other potentially rabid animals in the store, at least 665 persons received postexposure rabies vaccinations at a total cost of more than $1.1 million (Noah et al. 1995).

1.1.2 Primary Need for Action

If new rabies strains such as those transmitted by raccoons, gray foxes, and coyotes are not prevented from spreading to new areas of the U.S., the health threats and costs associated with rabies are expected to increase substantially as broader geographic areas of the U.S. are affected. In the area that stretches west from the leading edge of the current distribution of raccoon rabies (which stretches from Alabama northeast along the Appalachian Mountains through coastal Maine) to the Rocky Mountains, and north from the distribution of gray fox and coyote rabies in Texas, there are more than 111 million livestock animals, including cattle, horses, mules, swine, goats, and sheep, which are valued at $42 billion (65 FR 76606-76607, December 7, 2000). If raccoon, gray fox, or coyote rabies were to spread into the above described area, many of these livestock would be at risk to these specific rabies variants. More importantly, human health care concerns would be expected to increase substantially as well if raccoon, coyote and gray fox strains of rabies infect a much broader geographic area which would add to the current high costs of living with these strains. Moreover, the proposed AdRG1.3 field trial is necessary

because it will assist in research to identify a new vaccine which will provide safe and efficacious results in a variety of meso-carnivores, including striped skunks (*Mephitis mephitis).* The vaccine used in the current ORV program, vaccinia-rabies glycoprotein (V-RG), does not provide sufficient levels of population immunity in striped skunks.

1.1.3 Development of Oral Rabies Vaccine Programs

Although the concept of ORV to control rabies in free-ranging wildlife populations originated in the U.S. (Baer 1988), it has a longer history of implementation in Europe and Canada. The emergence of raccoon rabies in the U.S. during the 1970s heightened interest in the application of ORV to raccoons. Due to biological and ecological differences among the types of animals that transmit rabies, development of specific vaccine and bait combinations was needed. One of the main difficulties was the development of a safe and effective vaccine for raccoons. In contrast to red foxes, which were the primary subjects of ORV programs in Europe and Canada, raccoons were not readily immunized by the oral route with the modified live rabies virus vaccines that worked well in foxes (Rupprecht et al. 1988). Because modified "live virus" vaccines pose a small risk of causing vaccine-induced rabies, and have resulted in some cases of vaccine-induced rabies in animals (but no cases in humans) during oral baiting programs in Europe and Canada (Wandeler 1991), a recombinant vaccine was first chosen for use in the U.S.. Vaccinia-rabies glycoprotein (RABORAL V-RG®, Merial, Inc., Athens, GA) vaccine has proven to be orally effective in raccoons, coyotes and foxes. This vaccine was extensively evaluated in the laboratory for safety in more than 50 vertebrate species with no adverse effects regardless of route or dose. As a consequence of field safety testing in the early 1990s, V-RG was conditionally licensed in 1995 and fully licensed in 1997 in the U.S. for vaccination of free-ranging raccoons. It remains the only effective vaccine licensed for use in the U.S. and Canada for raccoons. V-RG was also recently fully licensed by the USDA in 2002 for vaccination of coyotes in the U.S. and Canada. It has been approved for experimental use to vaccinate wild gray foxes in Arizona, New Mexico, and Texas.

However, the V-RG vaccine has not produced sufficient levels of population immunity in skunks [primarily striped skunk (*Mephitis mephitis)*] in the wild at the current dose (Slate et al. 2005), and V-RG may be less effective in skunks than other species (Tolson et al. 1987). In the U.S. the total geographic area affected by skunk rabies is at least 1.4 million mi^2 (3.5 million km^2) or nearly 40% of the entire contiguous lower 48 states (Krebs et al. 2000). Unfortunately, the V-RG vaccine is not effective by the oral route in skunks (Charlton et al 1992) and at least one modified live rabies virus vaccine used for oral vaccination of red foxes (*Vulpes* vulpes), with demonstrated potential for immunization of raccoons (Rupprecht et al. 1989), resulted in vaccine-induced rabies in skunks (Rupprecht et al. 1990). Thus, the need for new and efficacious vaccines to address rabies in skunks as well as other wildlife species is apparent.

Human adenovirus type 5 (HAd5) has been used extensively as a vector for vaccine development mainly due to its well-characterized molecular structure, genomic stability, and ability to grow high titers in a wide spectrum of cells (Graham and Prevec 1992 *in* Knowles et al. 2009b).

One of the most promising vaccines has been a human adenovirus type 5-rabies glycoprotein recombinant vaccine (AdRG1.3); AdRG1.3 was modified from the first construct (AdRG1) in the early to mid-1990s at McMaster University, Hamilton, Ontario, Canada (Yarosh et al. 1996 *in* Rosatte et al. 2009). During

1993, Microbix Biosystems Inc. (Toronto, Ontario, Canada), was commissioned by the Ontario Ministry of Natural Resources (OMNR) to prepare a master seed of virus that OMNR acquired from Microbix in 1999. Subsequent laboratory trials were conducted at the Canadian Food Inspection Agency (CFIA), Nepean, Ontario, Canada, and production vaccine was developed by Artemis Technologies Inc. (Guelph, Ontario, Canada), with assistance from the National Research Council, Biotechnology Research Institute. The trade name for this product is ONRAB® (Artemis Technologies Inc., Guelph, Ontario, Canada) (Rosatte et al. 2009). The AdRG1.3 vaccine has been aerially distributed in Ontario, Canada since 2006.

A number of studies have been conducted to determine the best bait formulations and strategies for delivery of ORV vaccines to raccoons (Hanlon et al. 1989a, Hable et al. 1992, Hadidian et al. 1989, Linhart et al. 1991, Linhart et al. 1994), gray fox (Steelman et al. 1998, 2000), and coyotes (Linhart et al. 1997; Farry et al. 1998a, 1998b). When raccoons, foxes or coyotes eat oral rabies baits and puncture a sachet[3] containing the vaccine, the vaccine is swallowed and bathes the lymphatic tissue in the throat area and initiates the immunization process. A positive rabies antibody titer in an animal from a baited area is most likely due to consumption of a bait and adequate contact with vaccine. However, the lack of a detectable antibody response may not be an accurate reflection of immune status. It is possible that the animal was successfully immunized, but that the blood sample was taken earlier or later than when antibodies could be detected (C. Hanlon, CDC, pers. comm. 2003 as cited in USDA 2004). Antibodies induced by a one-time oral vaccination appear to be of relatively short duration. Among a group of animals in a baited area, the best time to collect blood samples for detection of antibodies is 4-8 weeks after baiting. A successfully immunized animal may have antibodies shortly after vaccination, but then the level may decline to undetectable levels. If the animal is then exposed to rabies, it is still likely that the animal's "memory" immunity will become activated by the rabies exposure and more antibodies will be made very quickly. The successfully immunized animal will most likely survive exposure, even though it did not have measurable antibodies at the time of the exposure (C. Hanlon, CDC, pers. comm. 2003 as cited in USDA 2004).

Each bait contains 1.8 $\pm$0.1 ml of ONRAB® vaccine (titer of not $<10^{9.5}$ cell culture infectious dose 50% [$CCID_{50}$]/ml) in an elongated plastic blister pack that is coated with an attractant-bait matrix (Figure 1-1). The attractant on the vaccine-baits is composed of partially hydrogenated vegetable shortening (34%), Microbond® wax (International Wax Ltd., Agincourt, Ontario, Canada) (30%), stearine (12.5%), icing-sugar (20%), vegetable oil (1%), artificial marshmallow flavor (1%), artificial sweet flavor (1%), and a fat-soluble food dye (0.5%) (khaki green) to camouflage the baits. The bait matrix also contains 100 mg of tetracycline hydrochloride as a biomarker to evaluate bait ingestion. Each vaccine-bait weighs approximately 4 g. The body of the blister pack is an elongated oval with dimensions of 1.81x 0.55x 0.39in (30x14x10 mm) and a rectangular lip extending to 1.57x 0.79 in (40x20 mm) (Figure 1-1). The blister pack contains an identifying label as to the contents of the bait and a toll free phone number where people can obtain information about the baits (Rosatte et al. 2009)

[3] A thin plastic packet much like those in which condiments (e.g., catsup, mustard) are provided at fast food restaurants.

Figure 1-1. ONRAB baits utilized during ORV field trials

(photo: http://www.mnr.gov.on.ca)

The tetracycline biomarker in the baits binds to calcium, which can be found in the metabolically active portions of bones and teeth of animals. Tetracycline deposits can be viewed in the teeth or bones with fluorescent light under a microscope. When the tooth or bone sample of an animal is positive for tetracycline, it is likely that the animal has eaten at least one bait and possibly multiple baits (C. Hanlon, CDC, pers. comm. 2003 as cited in USDA 2004). The presence of tetracycline, however, is not an indication of immunity since it is possible in some situations for an animal to eat the outer bait matrix without rupturing the vaccine sachet inside. Other potential sources of "background" tetracycline in a study area may include consumption of medicated feeds such as those sometimes used for production animals, intentional treatment by humans with tetracycline, and non-specific fluorescence from undescribed but similar chemical compounds that may be found naturally (C. Hanlon, CDC, pers. comm. 2003 as cited in USDA 2004).

In field tests conducted in the U.S. using previous vaccine-bait combinations, the majority of ORV baits have been consumed within the first 7 to 14 days after placement, with reports of up to 100 percent of the baits being consumed within a 7 day period (Farry et al. 1998b, Hable et al. 1992, Hadidian et al. 1989, Hanlon et al. 1989a, Linhart et al. 1994, Steelman et al. 2000, USDA 1995). Similar results may be expected using the ONRAB® baits. The likelihood of a bait being consumed is dependent upon several factors including animal population densities (target and non-target species), bait preference, and the availability of alternative food sources. Those baits that are not consumed may remain in the environment for several months after placement, dependent upon environmental conditions (precipitation, temperature, etc.) and the condition of the baits.

Oral wildlife vaccination for raccoon rabies control has been under field evaluation in the U.S. since 1990. A limited field release of the recombinant vaccine occurred on Parramore Island, VA, prior to wider spread use in the U.S. for control of raccoon rabies (Hanlon et al. 1998). A major objective of this field trial was to evaluate the free-ranging raccoon population for adverse effects after the distribution of V-RG vaccine-laden baits. With the development and field testing of the V-RG vaccine, a potential method of rabies control now exists for some rabies variants to complement other methods of control that include public education, domestic animal vaccination, and human PEP. In 2004, APHIS-WS, in cooperation with the CDC, began conducting small mammal vaccinia monitoring at Parramore Island, VA. Because this is the site where vaccinia was first released into the wild in ORV baits and since these baits have not been released at this site since the early 1990s, viruses in hosts can be monitored.

Microtine mammals, especially rodents, are typically the most likely hosts for orthopox viruses, which include vaccinia. Thus, these mammals are good sentinel species for indicators for the environmental presence of viruses, such as vaccinia. Samples were collected and tested at CDC laboratories to determine the presence of vaccinia virus in small mammals collected at this site. Results of this study found no evidence of V-RG circulation based upon the serological survey (C. Rupprecht, CDC, pers. comm. 2009).

Since the first field release of the V-RG vaccine in 1990, the number of vaccine-laden baits distributed annually in the U.S. has risen exponentially. For instance, APHIS-WS' involvement in the national rabies management program between 1995 and 2010 contributed to 120 million ORV baits disbursed in the U.S (USDA 2009, ORV website). Numerous projects have been conducted or are in progress in the eastern U.S., Texas, and Arizona (USDA 2010, 2009b, 2008b).

1.2 PURPOSE OF THE PROPOSED ACTION

The purpose of the proposed action is to research the human adenovirus type 5-rabies glycoprotein recombinant (AdRG1.3) ONRAB® rabies virus vaccine and to evaluate its potential safety and efficacy as an oral rabies virus vaccine for skunks, raccoons, gray foxes, and coyotes. APHIS-WS has prepared this EA to facilitate in planning, interagency coordination, streamline program management, and clearly communicate with the public and regulators the analysis of the potential for impacts resulting from the application of AdRG1.3 in field trials in West Virginia. This EA will assist in determining if the proposed action will have a significant impact on the quality of the human environment

The specific objective of the proposed action is to use federal funds to purchase and distribute baits laden with the oral rabies vaccine AdRG1.3 as well as to participate in subsequent monitoring and surveillance activities in an effort to determine a safe and efficacious oral rabies vaccine that will further serve in maintaining barriers of immunized target species including skunks, raccoons, gray foxes, and coyotes, thus preventing the expansion of rabies epizootics. Although current APHIS-WS ORV programs employ the use of the V-RG vaccine, which is currently licensed for use in raccoons and coyotes in the U.S. and Canada and approved for experimental use in gray fox in Arizona, New Mexico, and Texas; no vaccine is currently licensed in the U.S. for use in skunks.

Additionally, studies indicate that V-RG does not produce sufficient levels of population immunity in skunks in the wild at the current dose (Slate et al. 2005), and V-RG may be less effective in skunks than other species (Tolsen et al. 1987). Skunks are a major contributor to rabies in North America. During 2009, skunks accounted for 24% of reported cases of rabies in wild animals. Of those, 40.9% were from states where the raccoon rabies virus variant is enzootic (Blanton et al. 2009). This trend that has raised concerns about an independent maintenance cycle for raccoon rabies in skunks (Guerra et al. 2003). Rabies virus containment and elimination in the U.S. will likely remain elusive until an oral vaccine is licensed that is immunogenic in all terrestrial rabies reservoir species (Slate et al. 2005). In addition, skunks rabies virus, which has the broadest geographic distribution of all terrestrial rabies variants in the U.S. (Krebs et al 1995), can currently be addressed only through local trap-vaccinate-release (TVR) or population suppression programs. Therefore, it is critical to find a vaccine that is safe and efficacious in skunks. Research has found that after oral instillation of the AdRG1.3 vaccine, skunks will develop rabies neutralizing antibodies, but with no observable adverse effects.

Although not currently licensed for us in the U.S., AdRG1.3 has been used in field trials in Ontario, Canada since 2006. APHIS regulates veterinary biologics (e.g. vaccines) to ensure that the veterinary biologics available for the diagnosis, prevention, and treatment of animal diseases are pure, safe, potent, and effective. This work is done by APHIS, Veterinary Services (VS), Center for Veterinary Biologics (CVB) and is centered around enforcement of the Virus Serum Toxin Act. Accordingly, APHIS-CVB has conducted a risk analysis and has concluded that the safety risks to animals, public health, and the environment are low. A copy of the risk analysis with confidential business information removed is made available to the public, along with this environmental assessment, following the publication of the *Federal Register* Notice regarding proposed field trials. APHIS-CVB has permitted experimental use of the AdRG1.3 vaccine for the proposed field trial. Completion of field safety trials is a required step prior to full licensure of a vaccine by APHIS-CVB.

1.3 NEED FOR ACTION

In North America, specific rabies virus variants are maintained in several meso-carnivore species including raccoons, gray foxes, coyotes, and skunks. Generally, each distinct variant of the virus in mammalian species occurs in geographically discrete areas and is strongly associated with its reservoir species (Krebs et al. 2001). Within each area, a spillover of rabies into other species occurs, especially during epizootics. As a result of spillover, a variant may eventually adapt to a secondary species, which may begin to serve as an alternative reservoir species (Bacon 1985).

Skunks are a major contributor to rabies in North America with 1,603 cases of rabies in skunks reported in 2009. Additionally, states in which the raccoon rabies virus variant is enzootic reported 24% of the cases of rabies in skunks, most of which were presumably the result of spillover infection from raccoons (Blanton et al. 2010). This trend also raises concerns that there may be an independent maintenance cycle for raccoon rabies in skunks (Guerra et al. 2003).

If left unmitigated, this spillover of raccoon rabies into skunks could likely compromise the integrity of the previously established oral rabies vaccination zones. Currently, Raboral V-RG® is the only oral rabies vaccine licensed for use and applied in field settings in the U.S. It is efficacious in meso-carnivores such as raccoons (*Procyon lotor*), coyotes (*Canis latrans*), and gray foxes (*Urocyon cinereoargenteus*), but has not produced sufficient levels of population immunity in skunks (primarily *Mephitis mephitis*) in the wild (Slate et al. 2005), and V-RG may be less effective in skunks than other species (Tolson et al. 1987). The national rabies management goals of virus containment and elimination will likely remain elusive until an oral vaccine is licensed that is immunogenic in all terrestrial rabies reservoir species (Slate et al. 2005). In addition, skunks rabies virus, which has the broadest geographic distribution of all terrestrial rabies variants in the U.S. (Krebs et al. 1995) can currently be addressed only through local trap-vaccinate-release (TVR) or population suppression program. Thusly, development, safety and efficacy testing, and licensure of additional oral vaccines that are effective in all terrestrial rabies reservoir species remain among the highest priorities of the APHIS-WS' National Rabies Management Team (Slate et al. 2005).

1.4 DESCRIPTION OF THE PROPOSED ACTION

In accordance with the provisions of the Act of September 25, 1981, as amended (7 U.S.C. 147b), the Secretary of Agriculture declared that there is an emergency that threatens the agricultural production industry in the U.S., and authorized the transfer and use of funds from the Commodity Credit Corporation of the USDA in FY2001 for the continuation of ORV programs to address rabies problems in several eastern states and Texas (65 FR 76606-76607, December 7, 2000). Additional CCC funds continue to be provided to augment the funding obtained through the appropriations process and support the continuation and expansion of ORV programs to ensure that raccoon and gray fox rabies spread is contained. The APHIS-WS program, in cooperation with the USDA-Forest Service (USFS), is proposing to continue or expand federal cooperation through funding and direct involvement in new vaccine field trials in West Virginia using the AdRG1.3 ONRAB® rabies vaccine.

The field trial area will encompass approximately 559 mi^2 (1,448 km^2) within Greenbrier, Summers, and Monroe Counties, West Virginia, including portions of the USDA Forest Service (USFS) National Forest System lands, excluding Wilderness Areas (WAs). Baits will be distributed at a standard density of 75/km^2. Although animal specimens may be collected throughout the entire study area, targeted monitoring and surveillance will occur within four unique 49 mi^2 (127 km^2) sites within the larger bait drop field trial area. Figures 1-1 and 1-3 illustrate the field trial's anticipated target location. The site was selected for the field trial due to its proximity to the current V-RG ORV zone, availability of suitable habitat and target species, local public support, and because the area is not highly developed thereby reducing the chance for human or domestic animal exposures during the field trial.

The program would involve the use of APHIS-WS federal funds to purchase and distribute ORV baits to vaccinate specific populations of striped skunks and raccoons to determine the efficacy of the AdRG1.3 vaccine in these species. The specific vaccination zone(s) will be determined in cooperation with rabies task forces, WV Departments of Health and Human Resources (WVDHHR) and Agriculture (WVDA), and/or other agencies with jurisdiction over vaccine use and application in wildlife and domestic animals. The proposed action would also include APHIS-WS assistance in monitoring and surveillance activities involving the capture and release or lethal collection of the targeted animal species in and around the field trial vaccination zone to take biological samples for testing to determine the effectiveness of the AdRG1.3 ORV field trials. The role of the USFS would involve cooperation with APHIS-WS in permitting access to National Forest System (NFS) lands for bait dispersal and rabies monitoring and surveillance activities. Coordination with specific National Forest offices will occur prior to project implementation to ensure that the integrity of specially designated areas is maintained (i.e., Research Natural Areas, Wilderness Areas, Wild and Scenic Rivers, etc.).

Pending the verification of legal authorities to do so, ORV baits would be distributed by the state (W.V.) over a variety of classes of land ownership, including private, public, and other state and federal lands. Each bait will have a warning label advising persons not to handle or disturb the bait, along with a toll-free telephone number to call for further information.

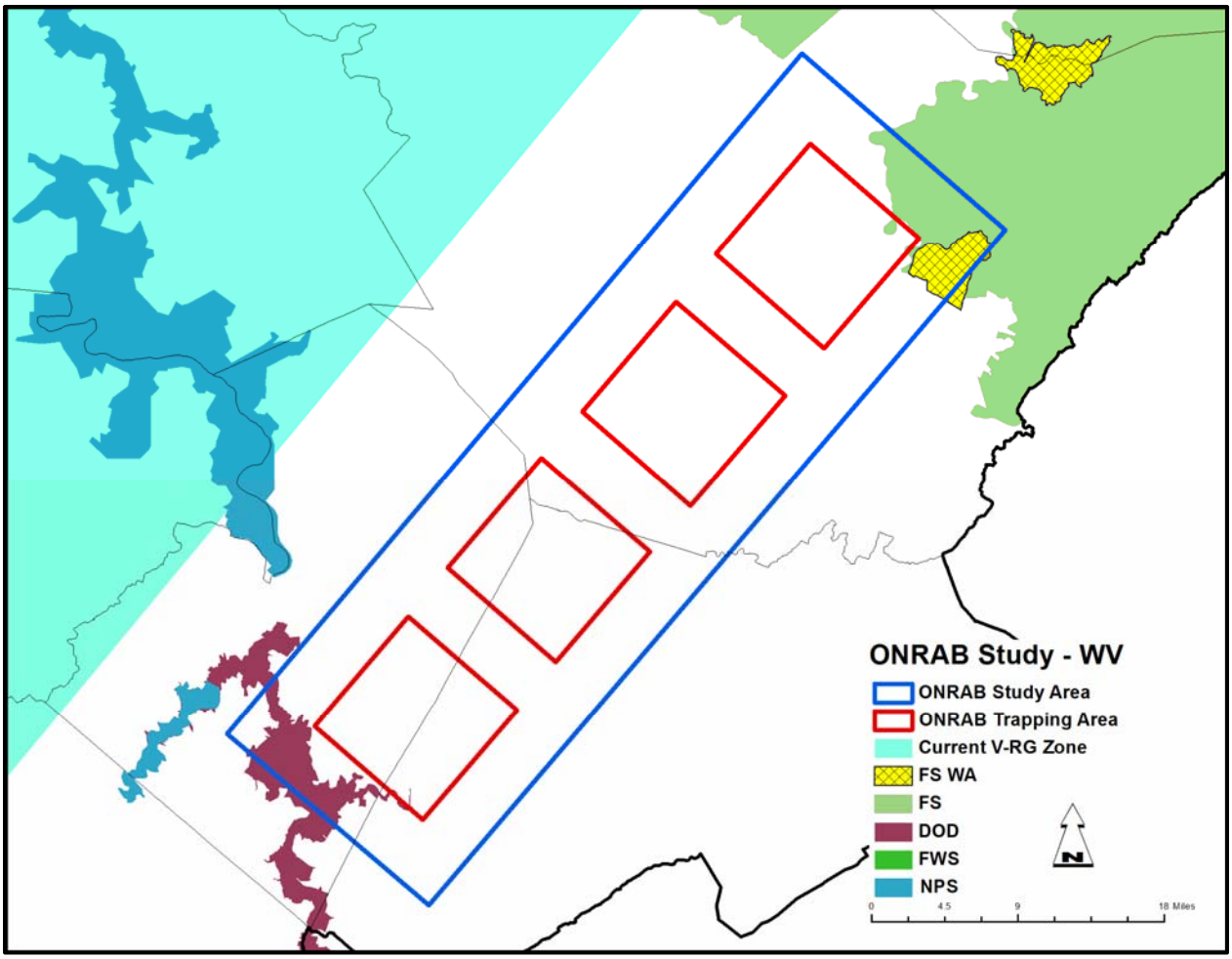

Figure 1-2: Proposed AdRG1.3 field trial zone in Greenbrier, Summers, and Monroe Counties, West Virginia, including portions of United States Forest Service lands. The blue box indicates the area [1,448 km^2 (559 mi^2)] that will be baited at a rate of75 baits/km^2 with AdRG1.3 vaccine baits. The interior red boxes indicate the areas [127 km^2 (49 mi^2)/box] that may be included in monitoring and surveillance activities, excluding Wilderness Areas.

Wild animal collections for purposes of monitoring would be conducted using a variety of live capture or lethal methods. Information from skunks would be predominantly collected from cage-trapped individuals that, if apparently healthy, would normally be released at or near their site of capture. Only legally approved methods would be used in all animal sample collection areas to provide critical data for the evaluation of project effectiveness. Project effectiveness would be based in large part on the percentage of ORV baits consumed in populations of target species, the presence of sufficient levels of serum neutralizing antibodies in a large enough percentage of the population to resist the spread of rabies, and the absence of the rabies strain targeted for control with ORV beyond the vaccination barrier established to prevent spread of the virus. In addition to the primary target species, several other species such as red foxes, gray foxes, and coyotes would be targeted during monitoring and surveillance. Several of these animals would be sampled to help determine efficacy of the treatment. Biological data such as sex, age, and weight would also be collected to determine if baits are consumed differently by various age or sex groups.

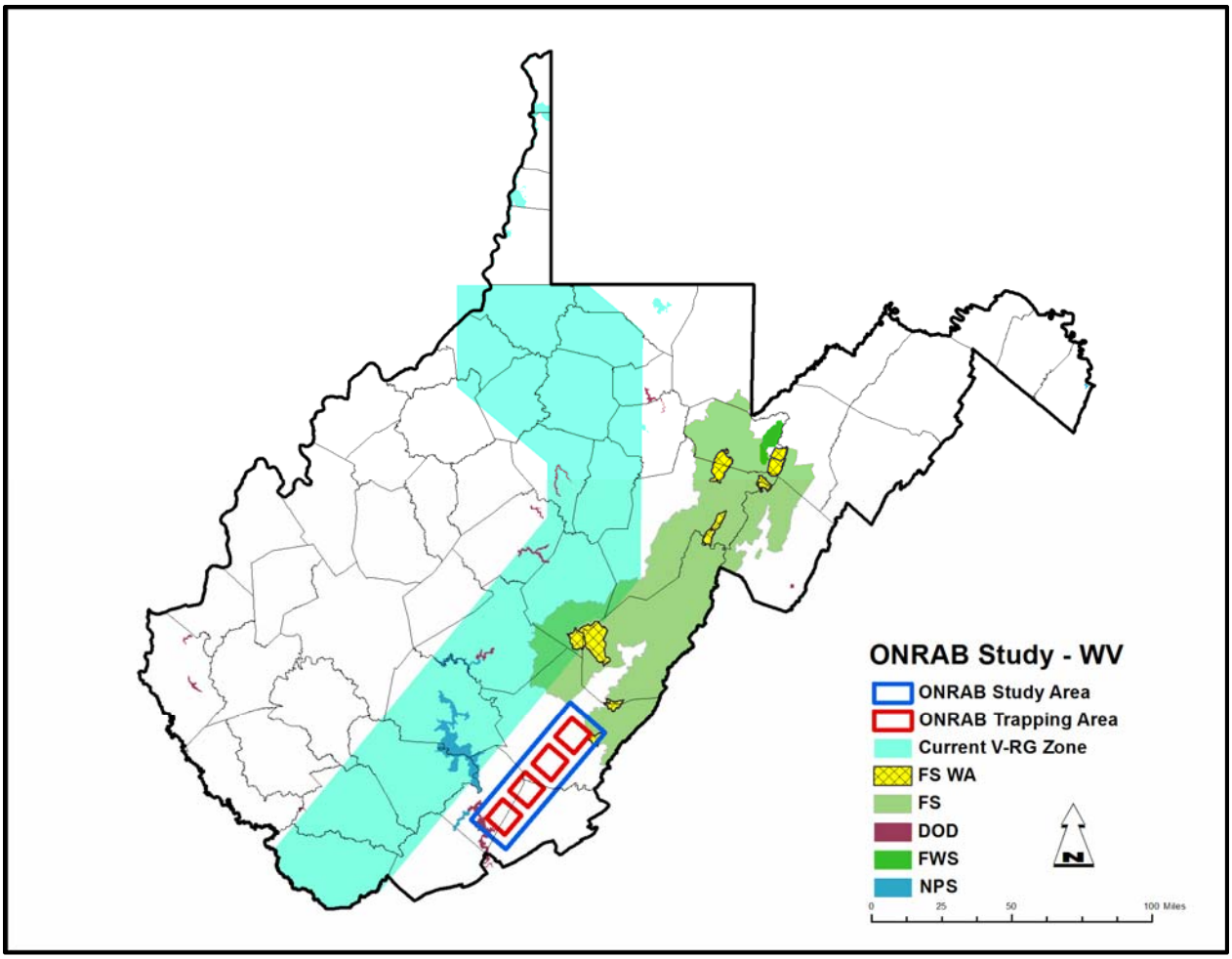

Figure 1-3: Proposed AdRG1.3 field trial zone shown next to APHIS-WS's current V-RG vaccine ORV zone in West Virginia.

The primary goals of this program would be to assess the efficacy of the AdRG1.3 rabies vaccine in the striped skunk population, determine the feasibility of using the AdRG1.3 vaccine to stop the forward advance of specific rabies strains from areas where they occur now by immunizing portions of target species populations along the leading edges of the rabies fronts, and to reduce the incidence of rabies cases involving wild and domestic animals and rabies exposures to humans in areas where the ORV programs are conducted.

1.5 SCOPE OF THIS ENVIRONMENTAL ASSESSMENT ANALYSIS

1.5.1 Actions Analyzed

This EA evaluates the environmental effects of APHIS-WS funding of and participation in ORV field trials in Greenbrier, Summers, and Monroe Counties, West Virginia for determining the efficacy of AdRG1.3 as an oral rabies vaccine for meso-carnivores including skunks, raccoons, gray foxes, and coyotes in the U.S. Under the proposed action, ORV and monitoring and surveillance activities would be conducted on private, federal, state, county, and municipal lands in Greenbrier, Summers, and Monroe Counties, West Virginia including NFS lands, but excluding Wilderness Areas.

1.5.2 Period for which this EA is Valid

This EA will remain valid until APHIS-WS determines the proposed study to be complete. If APHIS-WS modifies the study such that it would have different environmental effects, a new EA will be completed or this EA will be supplemented pursuant to NEPA and with the appropriate analyses.

1.5.3 Site Specificity

This EA analyzes potential impacts of AdRG1.3 as an oral rabies vaccine for managing rabies in skunks, as well as, raccoons, gray foxes, and coyotes. The study will be conducted on lands in Greenbrier, Summers, and Monroe Counties, West Virginia, including NFS lands, but excluding Wilderness Areas. This EA examines the potential for significant environmental effects in the specific areas of the proposed action whenever possible; however, the issues that pertain to AdRG1.3 safety and efficacy are the same, for the most part, whether they would be researched in West Virginia or elsewhere in the U.S.

1.5.4 Coordination

APHIS-WS is the lead agency and decision-maker for this EA. However, to assure that the concerns of other federal land managers have been addressed, the USFS was asked to participate in the development and review of this EA. The agency participated in the review of this EA as per 40 CFR 1501.6 and ensures compliance with their respective Land and Resource Management Plans.

APHIS-WS will coordinate with all applicable federal and state agencies that will be affected by APHIS-WS actions on their lands through the NEPA process or other agency-specific coordination including, but not limited to, entrance into MOUs, establishment of work plans, or issuance of Special Use Permits. All affected agencies will be contacted early and prior to implementation of any APHIS-WS National Rabies Management Program (NRMP) activity to ensure that the agencies are in accordance with APHIS-WS actions and gain their cooperation with any site-specific issues the affected agency might have.

1.6 SUMMARY OF PUBLIC INVOLVEMENT

General issues pertaining to ORV field trials were developed through the scoping process for previous EA prepared to analyze the environmental effects of APHIS-WS' continued and expanded participation with ORV program in the eastern and southwestern United States and were specifically refined for this EA by APHIS-WS. These scoping processes involved numerous federal (i.e., Centers for Disease Control and Prevention), state (i.e., health, agriculture, and natural resource departments), and local government agencies, academic institutions, and Canadian provincial government agencies (i.e., Ontario Ministry of Natural Resources). As a part of the process for this proposed action, and as required by the Council on Environmental Quality (CEQ) and APHIS' NEPA implementing regulations, this document is being noticed to the public through legal notices published in local print media, through direct mailings to parties that have requested to be notified or have been identified to have an interest in ORV programs, and by posting the pre-decisional EA on the APHIS website at http://www.aphis.usda.gov/wildlife_damage/nepa.shtml.

WS will provide a 30-day comment period for the public and interested parties to provide new issues, concerns, and /or alternatives. Through the public involvement process, WS will clearly communicate to

the public and interested parties the analysis of potential environmental impacts on the quality of the human environment. New issues or alternatives identified from the public involvement process will be fully considered.

1.7 DECISIONS TO BE MADE

Based on the scope of this EA, the decisions to be made are:

- Should APHIS-WS undertake field trials in Greenbrier, Summers, Monroe Counties, WV, including portions of National Forest System lands, but excluding Wilderness Areas, to determine the efficacy of AdRG1.3 as an oral rabies vaccine for skunks, raccoons, gray foxes, and coyotes?

- If not, should APHIS-WS implement the other alternative, the "no action" alternative?

- Would implementing the proposed action or the alternative action have significant adverse impacts on the quality of the human environment requiring the preparation of an EIS?

1.8 RELATIONSHIP OF THIS EA TO OTHER ENVIRONMENTAL DOCUMENTS

Work Plan for Oral Vaccination by Ground or Aerial Baiting to Control Specific Rabies Virus Variant in Raccoons on National Forest System Lands in USFS Regions 3, 8 and 9. This Work Plan (March, 2010) was prepared by APHIS-WS in coordination with the USFS to implement ORV program activities on National Forest System lands in USFS Regions 3, 8 and 9.

The USFS has reviewed the proposed action and alternatives described in this EA and has determined the proposed action to be consistent with Land and Resource Management Plan (USDA 2006) for the Monongahela National Forest located within the proposed field trial location, excluding Wilderness Areas.

A number of other NEPA documents have been prepared that analyzed the potential environmental effects of APHIS-WS' ORV programs and the methods used in rabies monitoring and surveillance. Pertinent information from those analyses has been incorporated by reference into this EA.

Wildlife Services Programmatic EIS. APHIS-WS has issued a final Environmental Impact Statement (EIS) (USDA 1997) and Record of Decision on the National APHIS-WS program. Relevant information from the EIS has been incorporated by reference in this document.

EA, FONSI, and Decision – Oral Vaccination to Control Specific Rabies Virus Variants in Raccoons, Gray Foxes, and Coyotes in the United States. This EA and FONSI/Decision (USDA 2010) analyzed the environmental effects of APHIS-WS involvement in the funding of and participation in ORV programs to eliminate or stop the spread of raccoon rabies in a number of eastern states (Alabama, Connecticut, Delaware, Florida, Georgia, Indiana, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, and West Virginia) and gray fox and coyote rabies in Arizona, New Mexico, and Texas. Additionally, the analysis area included

Bureau of Land Management (BLM) and National Forest System lands, excluding Wilderness Areas. APHIS-WS determined the action would not have any significant adverse impact on the quality of the human environment.

EA, FONSI, and Decision – Oral Rabies Vaccination Program for Midwest Region Park Units. APHIS-WS was a cooperating agency in the preparation of this EA and FONSI/Decision (U.S. Department of the Interior (USDI) 2005) which analyzed the environmental effects of NPS participation in ORV programs on nine NPS units in the states of Indiana, Ohio, and Michigan in the effort of stopping the spread of a specific raccoon rabies variant or "strain" of the rabies virus and reducing or eliminating this strain of the virus from the eastern United States. The NPS determined the action would have a negligible impact on the quality of the human environment.

EA, FONSI, and Decision – Oral Rabies Vaccination Program for Northeast Region Eastern Rivers and Mountains Network Park Units. APHIS-WS was a cooperating agency in the preparation of this EA and FONSI/Decision (USDI 2004a) which analyzed the environmental effects of NPS participation in ORV programs on eight NPS units in the states of Pennsylvania and West Virginia in the effort of stopping the spread of a specific raccoon rabies variant or "strain" of the rabies virus and reducing or eliminating this strain of the virus from the eastern United States. The NPS determined the action would have a negligible impact on the quality of the human environment.

EA, FONSI, and Decision - Oral Rabies Vaccination Program for Northeast Region Northern Coastal Barrier Network Park Units. APHIS-WS was a cooperating agency in the preparation of this EA and FONSI/Decision (USDI 2004b) which analyzed the environmental effects of NPS participation in ORV programs on eleven NPS units in the states of Maine, Maryland, Massachusetts, New York, New Jersey, and Virginia in the effort of stopping the spread of a specific raccoon rabies variant or "strain" of the rabies virus and reducing or eliminating this strain of the virus from the eastern United States. The NPS determined the action would have a negligible impact on the quality of the human environment.

EA, FONSI, and Decision – Oral Rabies Vaccination Program for Northeast Region Temperate Network Park Units. APHIS-WS was a cooperating agency in the preparation of this EA and FONSI/Decision (USDI 2004c) which analyzed the environmental effects of NPS participation in ORV programs on six NPS units in the states of New Hampshire, New York, and Vermont in the effort of stopping the spread of a specific raccoon rabies variant or "strain" of the rabies virus and reducing or eliminating this strain of the virus from the eastern United States. The NPS determined the action would have a negligible impact on the quality of the human environment.

EA, FONSI, and Decision – Oral Rabies Vaccination Program for Northeast Region Mid-Atlantic Network Park Units. APHIS-WS was a cooperating agency in the preparation of this EA and FONSI/Decision (USDI 2004d) which analyzed the environmental effects of NPS participation in ORV programs on 8 NPS Units in the states of Pennsylvania and Virginia as well as the Appalachian Scenic Trail located in the states of Connecticut, Georgia, Massachusetts, Maryland, Maine, North Carolina, New Hampshire, New Jersey, New York, Pennsylvania, Tennessee, Virginia, Vermont, and West Virginia in the effort of stopping the spread of a specific raccoon rabies variant or "strain" of the rabies

virus and reducing or eliminating this strain of the virus from the eastern United States. The NPS determined the action would have a negligible impact on the quality of the human environment.

EA, FONSI, and Decision – Oral Rabies Vaccination Program for Southeast Region Park Units. APHIS-WS was a cooperating agency in the preparation of this EA and FONSI/Decision (USDI 2004e) which analyzed the environmental effects of NPS participation in ORV programs on fifteen NPS units in the states of Alabama, Florida, Georgia, North Carolina, and Tennessee in the effort of stopping the spread of a specific raccoon rabies variant or "strain" of the rabies virus and reducing or eliminating this strain of the virus from the eastern United States. The NPS determined the action would have a negligible impact on the quality of the human environment.

EA, FONSI, and Decision – Oral Rabies Vaccination Program for Big Bend National Park, Guadalupe Mountains National Park, and Amistad National Recreation Area in Texas. APHIS-WS was a cooperating agency in the preparation of this EA and FONSI/Decision (USDI 2003) which analyzed the environmental effects of NPS participation in ORV programs to eliminate or stop the spread of gray fox rabies on three NPS units in Texas. The NPS determined the action would have a negligible impact on the quality of the human environment.

EA, FONSI, and Decision – Oral Rabies Vaccination Program for Palo Alto Battlefield National Historic Park in Texas. APHIS-WS was a cooperating agency in the preparation of this EA and FONSI/Decision (USDI 2007) which analyzed the environmental effects of NPS participation in ORV programs to eliminate or stop the spread of gray fox rabies on one NPS unit in Texas. The NPS determined the action would have a negligible impact on the quality of the human environment.

1.9 AUTHORITIES

Wildlife disease and damage management are based on interagency relationships, which require close coordination and cooperation because of related or overlapping authorities or legal mandates. The APHIS-WS National Rabies Management Program (NRMP) cooperates and coordinates closely with the United States Forest Service (USFS) and the Bureau of Land Management (BLM). Additionally, the APHIS-WS NRMP consults with the United States Fish and Wildlife Service (USFWS), the Tennessee Valley Authority (TVA), the United States Army Corps of Engineers (USACE), the United States Coast Guard (USCG), the Department of Defense (DoD), the National Aeronautics and Space Administration (NASA), the Federal Bureau of Investigation (FBI), the Bureau of Indian Affairs (BIA), and other agencies when necessary and as appropriate. Finally, the NRMP cooperates closely with state agencies such as the State Health and Wildlife Departments.

1.9.1 Federal Authorities

APHIS – Wildlife Services. USDA is authorized and directed by law to protect American agriculture and other resources from damage associated with wildlife. The primary statutory authorities for the APHIS-WS program are the Act of March 2, 1931 (46 Stat. 1468; 7 United States Code (USC) 426-426c) as amended, and the Act of December 22, 1987 (101 Stat. 1329-331, 7 USC 426c). The Act of March 2, 1931, as amended in the Fiscal Year 2001 Agriculture Appropriations Bill, provides that:

"*The Secretary of Agriculture may conduct a program of wildlife services with respect to injurious animal species and take any action the Secretary considers necessary in conducting the program. The Secretary shall administer the program in a manner consistent with all of the wildlife services authorities in effect on the day before the date of the enactment of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriation Act, 2001*."

In 1988, Congress strengthened the legislative directive and authority of WS with the Rural Development, Agriculture, and Related Agencies Appropriations Act. This Act states, in part:

"*That hereafter, the Secretary of Agriculture is authorized, except for urban rodent control, to conduct activities and to enter into agreements with States, local jurisdictions, individuals, and public and private agencies, organizations, and institutions in the control of nuisance mammals and birds and those mammals and bird species that are reservoirs for zoonotic diseases, and to deposit any money collected under such agreements into the appropriation accounts that incur the costs to be available immediately and to remain available until expended for Animal Damage Control activities.*"

WS recognizes that wildlife is an important public resource greatly valued by the American people. By its very nature, however, wildlife is a highly dynamic and mobile resource that can damage agricultural resources, pose risks to human health and safety, and affect other natural resources. The WS program provides Federal leadership in helping to solve problems that occur when human activity and wildlife are in conflict with one another.

The Act of September 25, 1981, as amended (7 U.S.C. Sec. 147b). This law authorizes the Secretary of Agriculture, in connection with emergencies which threaten any segment of the agricultural production industry of the U.S., to transfer from other appropriations or funds available to the agencies or corporations of USDA such sums as the Secretary may deem necessary, to be available only in such emergencies for the arrest and eradication of contagious or infectious diseases of animals. It is under this authority that funds from the federal Commodity Credit Corporation have been transferred to APHIS-WS to expend for the continuation and expansion of ORV programs in the states identified herein (65 FR 76606-76607, December 7, 2000).

Virus-Serum-Toxin Act (21 U.S.C. 151 et seq.). Vaccines shipped in or from the U.S. must be prepared under and cannot be imported without a USDA license. Federal regulations implementing the Virus-Serum-Toxin Act (VSTA) (9 CFR 103.3) require authorization by APHIS before an experimental biological product can be shipped for the purpose of treating limited numbers of animals as part of an evaluation process.

Public Health Service Act. CDC, located in Atlanta, Georgia, is an agency of the U.S. Department of Health & Human Services. CDC's mission is to promote health and quality of life by preventing and controlling disease, injury, and disability. CDC is authorized under 42 U.S.C. 241 to render assistance to other appropriate public authorities in the conduct of research, investigations, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man. In addition, under 42 U.S.C. 243(a), the Secretary of Health & Human Services may assist states and their political subdivisions in the prevention and suppression of communicable diseases.

National Forest Management Act of 1976 (16 U.S.C. section 2101 [note]). This law amended the Forest and Rangeland Renewable Resources Planning Act of 1974, which called for the management of renewable resources on national forest lands. The National Forest Management Act requires the Secretary of Agriculture to assess forest lands, develop a management program based on multiple-use, sustained-yield principles, and implement a resource management plan for each unit of the National Forest System. This Act is the primary statute governing the administration of national forests.

Cooperative Forestry Assistance Act of 1978 (16 U.S.C. section 2101 [note]). This law authorizes the Secretary of Agriculture to assist in controlling forest insects and diseases directly on National Forest System lands and in cooperation on other federal and non-federal lands of all ownerships.

U.S. Forest Service (USFS). Under the Act of March 2, 1931 (46 Stat. 1468; 7 U.S.C. 426-426b) as amended, and the act of December 22, 1987 (101 Stat. 1329-331, 7 U.S.C 426c), the USFS and the APHIS-WS, along with the states, cooperate to manage wildlife damage on National Forest System lands. Under the framework of an MOU, signed June 4, 2004, between the USFS and APHIS-WS, APHIS-WS is designated as the lead agency concerning animal damage and disease management activities on USFS lands. This includes a responsibility to maintain technical expertise in the science of wildlife damage management, control tools and techniques, conducting management programs, and complying with NEPA for APHIS-WS activities. The MOU directs the USFS to coordinate with APHIS-WS in the development and review of work plans governing APHIS-WS' activities on NFS lands and to cooperate in APHIS-WS' NEPA processes.

1.9.2 State and Local Authorities.

Each of the states involved in APHIS-WS' national ORV program, including West Virginia, the state involved in this proposed action, has a state agency or agencies with authority under state law to approve, conduct or coordinate rabies control programs. APHIS-WS involvement in rabies control in each state has previously occurred and, under the proposed action, would only occur in complete cooperation with the appropriate state agency(ies) and in accordance with state authorities as identified by those agencies.

With regard to ORV programs, it is the cooperating states that exercise their authorities under state law to propose or approve the distribution of ORV baits onto lands owned or managed by a variety of entities including private persons, federal land management agencies [e.g., USDA Forest Service, National Park Service (NPS), and others], state, county, and city governments, and American Indian Tribes. APHIS-WS would not be making the decision to distribute baits on the various land ownerships. In West Virginia, the decision to allow the AdRG1.3 vaccine into the state is made by the West Virginia Department of Agriculture (WVDA). The proposed action assumes that ORV baits would be distributed under West Virginia state authorities, consistent with pertinent property rights laws and regulations and would include acquiring permission from public land managers when appropriate.

1.10 OTHER RELEVANT LAWS AND REGULATIONS

National Environmental Policy Act (NEPA) (42 U.S.C. 4321 et seq.). All federal actions are subject to NEPA (42 U.S.C. §§ 4321 *et seq*.). WS follows CEQ regulations implementing NEPA (40 CFR 1500 *et seq*.) and USDA (7 CFR 1b) and APHIS implementing regulation (7 CFR 372) as part of the decision-making process. These laws and regulations generally outline five broad types of activities to be

accomplished as part of any project: public involvement, analysis, documentation, implementation, and monitoring. NEPA also sets forth the requirement that all major federal actions be evaluated in terms of their potential to significantly affect the quality of the human environment for the purpose of avoiding or, where possible, mitigating and minimizing adverse impacts.

Pursuant to NEPA and CEQ regulations, this EA documents the analysis for potential impacts of a proposed federal action, informs decision-makers and the public of reasonable alternatives capable of avoiding or minimizing adverse impacts, and serves as a decision-aiding mechanism to ensure that the policies and goals of NEPA are infused into federal agency actions. This EA was prepared by integrating as many of the natural and social sciences as warranted, based on the potential effects of the proposed action. The direct, indirect, and cumulative impacts of the proposed action are analyzed.

Endangered Species Act (ESA) (16 U.S.C. 1531 *et seq*.). It is federal policy, under the ESA, that all federal agencies shall seek to conserve threatened and endangered (T&E) species and shall utilize their authorities in furtherance of the purposes of the Act (Sec.2(c)). For actions that "may affect" listed species, APHIS-WS conducts Section 7 consultations with the U.S. Fish & Wildlife Service (USFWS) to ensure that "*any action authorized, funded or carried out by such an agency . . . is not likely to jeopardize the continued existence of any endangered or threatened species . . . Each agency shall use the best scientific and commercial data available*" (Sec.7(a)(2)). WS obtained a Biological opinion (BO) from the USFWS in 1992 describing potential effects on T&E species and prescribing reasonable and prudent measures for avoiding jeopardy (USDA 1997, Appendix F). WS is in the process of initiating formal consultation at the programmatic level to reevaluate the 1992 BO and to fully evaluate potential effects on T&E species listed or proposed for listing since the 1992 USFWS BO (USDA 1997, Appendix F).

National Historic Preservation Act (NHPA) of 1966 as amended (16 U.S.C. § 470). NHPA and its implementing regulations (36 CFR 800) require federal agencies to: 1) determine whether activities they propose constitute "undertakings" that can result in changes in the character or use of historic properties and, 2) if so, evaluate the effects of such undertakings on such historic resources and consult with the State Historic Preservation Office regarding the value and management of specific cultural, archaeological, and historic resources, and 3) consult with appropriate American Indian Tribes to determine whether they have concerns for traditional cultural properties in areas of these federal undertakings.

ORV activities described under the proposed action (Section 1.4) do not cause major ground disturbance, do not cause any physical destruction or damage to property, do not cause any alterations of property, wildlife habitat, or landscapes, and do not involve the sale, lease, or transfer of ownership of any property. In general, such methods also do not have the potential to introduce visual, atmospheric, or audible elements to areas in which they are used that could result in effects on the character or use of historic properties. Therefore, the methods that would be used under the proposed action are not generally the types of activities that would have the potential to affect historic properties. If an individual activity with the potential to affect historic resources is planned under an alternative selected as a result of a decision on this EA, then site-specific consultation as required by Section 106 of the NHPA would be conducted as necessary.

Executive Order on Environmental Justice. Executive Order (EO) 12898, Federal Actions to Address

Environmental Justice in Minority Populations and Low-Income Populations requires federal agencies to analyze disproportionately high and adverse environmental effects of proposed actions on minority and low-income populations. APHIS-WS has analyzed the effects of the proposed action and determined that implementation would not have adverse human health or environmental impacts on low-income or minority populations.

Executive Order on Protection of Children from Environmental Health and Safety Risks. Executive Order 13045 was passed to help protect children who may suffer disproportionately from environmental health and safety risks for many reasons. ORV activities as proposed in this EA would only involve legally available and approved methods that have been subjected to safety evaluations and testing. The analysis in Section 4.1.3 of this EA supports a conclusion of very low to no risk of adverse effects on children from the ORV baiting strategy. Implementation of the proposed action would not increase environmental health or safety risks to children, but would in fact reduce such risks by minimizing the potential for children to contract rabies. Children are particularly at risk from rabies because they are more prone to experiencing "undetected" or "unappreciated" exposures (Huntley et al. unpublished 1996) that do not lead to post-exposure vaccine treatments. Therefore, federal involvement in ORV programs is consistent with and helps to achieve the goals of EO 13045.

Native American Graves Protection and Repatriation Act of 1990. The Native American Graves Protection and Repatriation Act requires federal agencies to notify the Secretary of the Department that manages the federal lands upon the discovery of native American cultural items on federal or tribal lands. Federal projects would discontinue work until a reasonable effort has been made to protect the items and the proper authority has been notified.

Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360). This law places administration of pharmaceutical drugs, including those used in wildlife capture and handling, under the Food and Drug Administration (FDA).

Controlled Substances Act of 1970 (21 U.S.C. 821 et seq.). This law requires an individual or agency to have a special registration number from the federal Drug Enforcement Administration (DEA) to possess controlled substances, including those that are used in wildlife capture and handling.

Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA). The AMDUCA and its implementing regulations (21 CFR Part 530) establish several requirements for the use of animal drugs, including those used to capture and handle wildlife in rabies management programs. Those requirements are: (1) a valid "veterinarian-client-patient" relationship; (2) well defined record keeping; (3) a withdrawal period for animals that have been administered drugs; and (4) identification of animals. A veterinarian, either on staff or on an advisory basis, would be involved in the oversight of the use of animal capture and handling drugs under the proposed action. Veterinary authorities in each state have the discretion under this law to establish withdrawal times (i.e., a period of time after a drug is administered that must lapse before an animal may be used for food) for specific drugs. Animals that might be consumed by a human within the withdrawal period must be identified; the Western Wildlife Health Committee of the Western Association of Fish and Wildlife Agencies has recommended that suitable identification markers include durable ear tags, neck collars, or other external markers that provide unique identification (WAFWA 2010). APHIS-WS establishes procedures in each state for

administering drugs used in wildlife capture and handling that must be approved by state veterinary authorities in order to comply with this law.

Wilderness Act of 1964 – An Act (Public Law 88-577; 88th Congress, S.4; September 3, 1964). The Wilderness Act allows federally owned lands meeting specific criteria to be designated as "wilderness areas." The act prohibits and restricts certain uses of these designated lands. The act provides special provisions to allow certain activities to take place within designated wilderness areas such as the use of aircraft to control fire, insects, and diseases (Sec. 4 (d)). APHIS-WS obtains USFS Forest Supervisor or BLM State Director approval to conduct control activities in Wilderness areas where necessary. However, the proposed action will not occur on any Wilderness Area.

CHAPTER 2: ISSUES AND AFFECTED ENVIRONMENT

2.1 ISSUES

In preparation for previous ORV EAs, APHIS-WS compiled issues from public input received in response to a Federal Register Notice (66 FR 13696-13700, March 7, 2001) and agency concerns discussed during scoping meetings held with state and local departments of health and the CDC. Many issues were discussed in previous EAs and FONSIs (USDA 2001a, 2002, 2003, 2004a, 2007, and 2010), but the following issues were considered to be germane to the proposed action analyzed in this EA and are considered in detail in this EA:

- Potential for adverse effects on target wildlife species populations.
- Potential for adverse effects on nontarget wildlife species, including threatened and endangered species.
- Potential for adverse effects on people, pets, and livestock that are exposed to or consume the vaccine laden baits.
- Potential for the AdRG1.3 virus to "revert to virulence" or recombine with other viruses and result in a virus that could cause disease in humans.
- Potential for aerially dropped baits to strike and injure people or domestic animals.
- Humaneness of methods used to collect wild animal species critical for timely program evaluation.

2.2 OTHER ISSUES CONSIDERED BUT NOT ANALYZED IN DETAIL, WITH RATIONALE

2.2.1 Potential for Drugs Used in Animal Capture and Handling to Cause Adverse Health Effects in Humans that Hunt and Eat the Species Involved

Among the species to be captured and handled under the proposed action, this issue is expected to be the most concern for raccoons and skunks which are hunted and sometimes consumed by people as food. Drugs used in capturing and handling raccoons for surveillance and monitoring purposes in rabies management programs include ketamine hydrochloride, xylazine (Rompun®, Bayer Health Care, Monheim, Germany), and a mixture of tiletamine and zolazepam (Telazol®, Wyeth Pharmaceuticals, Fort Dodge Animal Health, IA). Meeting the requirements of the AMDUCA (see Section 1.9) should prevent any significant adverse impacts on human health with regard to this issue. Standard operating procedures (SOPs) followed in each state include:

- All drugs used in capturing and handling raccoons, coyotes, gray foxes, skunks, and other animals would be under the direction of state or federal veterinary authorities, either directly or through procedures agreed upon between those authorities and APHIS-WS.

- As determined on a federal- or state-level basis by these veterinary authorities (as allowed by AMDUCA), ORV program participants may choose to avoid capture and handling activities that use immobilizing drugs within a specified number of days prior to the hunting or trapping season for the target species to avoid release of animals that may be consumed by hunters prior to the end of established withdrawal periods for the particular drugs used. However, capture and handling activities would likely extend into the hunting season during late summer/fall ORV baiting schedules. Therefore, target species would either be marked or euthanized if immobilizing drugs are used within 30 days of hunting or trapping seasons. These measures would be taken to avoid release of animals that could be consumed by hunters prior to the end of established withdrawal periods for the particular drugs used.

- Animals that have been immobilized and released are ear tagged or marked in some way to alert hunters and trappers that they should contact APHIS-WS personnel before consuming the animal.

By following these procedures in accordance with AMDUCA, rabies management programs would avoid any significant impacts on human health with regard to this issue.

2.2.2 Potential for Drugs Used in Animal Capture and Handling to Cause Adverse Health Effects in Scavengers or Other Nontarget Animals that May Consume the Species Involved

Drugs used in the capturing and handling of raccoons, skunks, gray foxes, or coyotes for surveillance and monitoring purposes in the rabies management program include ketamine hydrochloride, xylazine, and a mixture of tiletamine and zolazepam. These drugs are generally injected intravenously or intramuscularly and, less-often, subcutaneously. Oral delivery of immobilizing drugs may be used to calm animals caught in traps. For example, oral delivery of ketamine can calm the animal enough to allow injection of additional drug via syringe (USDA 2001b). However, oral delivery is not recommended for anesthetizing the animal due to the much higher dosage required to compensate for the slower uptake rate and correct dosages cannot be guaranteed (USDA 2001b).

APHIS-WS personnel would not release an animal until it has returned to full and normal function, thereby reducing its chances of succumbing to potential predators or other dangers. Most immobilizing drugs used, such as ketamine and xylazine, are metabolized and excreted within hours after the animal returns to full function (Dr. L. Bigler, New York State Animal Health Diagnostic Laboratory, pers. comm. 2004 as cited in USDA 2004). In addition, reversal agents, such as yohimbine, may be used to rouse the animal more quickly. Therefore, if a previously immobilized animal dies in the field sometime later, even if a scavenging animal were to ingest an entire animal previously immobilized, they should suffer no adverse effects (Dr. G. Gathright, DVM, APHIS-WS, National Wildlife Research Center, pers. comm. 2004 as cited in USDA 2004). Furthermore, the scavenger would be consuming the animal by oral route, thus requiring a much larger dosage of the drug. Immobilizing drugs would produce carcasses that are not considered toxic to scavengers (USDA 2001b). If an animal must be euthanized, APHIS-WS personnel would remove it from the field immediately, thereby eliminating the chance of scavengers finding the carcass. Due to these factors, immobilizing drugs will have no adverse effect on scavengers or predators that consume previously immobilized animals.

2.2.3 Potential for Adverse Impacts on Wildlife from Aircraft Overflights Conducted in ORV Programs

An issue that has arisen is the potential for low-level flights associated with ORV bait distribution to disturb wildlife, including T&E species, to the point that they are impacted. APHIS-WS uses aircraft in ORV bait distribution, and these aircraft typically fly at about 500 feet above ground level and in straight transects for many miles to distribute baits equally across the landscape. A number of studies have looked at responses of various wildlife species to aircraft overflights. The National Park Service (1995) reviewed studies on the effects of aircraft overflights on wildlife. The report revealed that a number of studies have documented responses by certain wildlife species that suggest adverse impacts could occur. Few, if any studies, have proven that aircraft overflights cause significant adverse impacts on wildlife populations, although the report stated it is possible to draw the conclusion that impacts to populations are occurring. The Air National Guard (ANG) concluded that military training flights which occur frequently and generate much more noise were not expected to cause adverse effects on wildlife after extensive review of numerous studies of this issue (ANG 1997a, 1997b). In general, it appears that the more serious potential impacts occur when overflights are frequent such as hourly and over long periods of time, which represents a chronic exposure. Chronic exposure situations generally involve areas near commercial airports and military flight training facilities. WS ORV bait distribution operations occur over the landscape and occur in any given area only for a short time period.

Several examples of wildlife species that have been studied with regard to low-level flights are available in the literature. Colonial waterbirds were reported that low-level overflights of 2-3 minutes in duration by a fixed-wing airplane and a helicopter produced no drastic disturbance of tree-nesting colonial waterbirds, and, in 90% of the observations, the individual birds either showed no reaction or merely looked up (Kushlan 1979). Conomy et al. (1998) quantified behavioral responses of wintering American black ducks (*Anas rubripes*), American wigeon (*A. americana*), gadwall (*A. strepera*), and American green-winged teal (*A. crecca carolinensis*) exposed to low-level flying military aircraft in North Carolina and found that only a small percentage (2%) of the birds reacted to the disturbance. They concluded that such disturbance was not adversely affecting the time-activity budgets of the species. Mexican spotted owls (Delaney et al. 1999) did not flush when chain saws and helicopters were greater than 110 yards away; owls flushed to these disturbances at closer distances and were more prone to flush from chain saws. Owls returned to their predisturbance behavior 10-15 minutes following the event and researchers observed no differences in nest or nestling success (Delaney et al. 1999). Johnson and Reynolds (2002) found that Mexican spotted owls showed only minor behavioral changes to F-16 fly-bys during training runs, but less behavioral changes than to natural occurrences. Andersen et al. (1989) conducted low-level helicopter overflights directly at 35 red-tailed hawk (*Buteo jamaicensis*) nests and concluded their observations supported the hypothesis that red-tailed hawks habituate to low level flights during the nesting period; results showed similar nesting success between hawks subjected to such overflights and those that were not. White and Thurow (1985) did not evaluate the effects of aircraft overflights, but found that ferruginous hawks (*B. regalis*) are sensitive to certain types of ground-based human disturbance to the point that reproductive success may be adversely affected. However, military jets that flew low over the study area during training exercises did not appear to bother the hawks, and nor did the hawks get alarmed when the researchers flew within 100 feet in a small fixed-wing aircraft (White and Thurow 1985). White and Sherrod (1973) suggested that disturbance of raptors by aerial surveys with

helicopters may be less than that caused by approaching nests on foot. Ellis (1981) reported that five species of hawks, two falcons (*Falco spp.*), and golden eagles (*Aquila chrysaetos*) were incredibly tolerant of overflights by military fighter jets, and observed that, although birds frequently exhibited alarm, negative responses were brief and the overflights never limited productivity.

Krausman et al. (1986) reported that only 3 of 70 observed responses of mule deer to small fixed-wing aircraft overflights at 150 to 500 feet above ground resulted in the deer changing habitats. They believed that the deer may have been accustomed to overflights because the study area was near an interstate highway that was frequently followed by aircraft. VerCauteren and Hygnstrom (2002) noted that when studying the efficacy of hunting to manage deer populations, that when deer were flown over during their censuses, they typically just stood up from their beds, but did not flush. In addition, WS aerial hunting personnel frequently observe deer and antelope standing apparently undisturbed beneath or just off to one side of aircraft. Krausman and Hervert (1983) reported that, in 32 observations of the response of bighorn sheep to low-level flights by small fixed-wing aircraft, 60% resulted in no disturbance, 21% in slight disturbance, and 19% in great disturbance. Another study (Krausman et al. 1998) found that 14% of bighorn sheep had elevated heart rates that lasted up to 2 minutes after an F-16 flew over at an elevation of 400 feet, but it did not alter the behavior of penned bighorns. Weisenberger et al. (1996) found that desert bighorn sheep and mule deer had elevated heart rates for 1 to 3 minutes and changed behavior to alerted for up to 6 minutes following exposure to jet aircraft. Fancy (1982) reported that only 2 of 59 bison (*Bison bison*) groups showed any visible reaction to small fixed-wing aircraft flying at 200-500 feet above ground. These studies indicate that ungulates are relatively tolerant of aircraft overflights, even those that involve noise at high decibels.

APHIS-WS has actively used fixed-wing aircraft and some helicopters at low levels for years in areas inhabited by wildlife in operational wildlife damage management. No known problems to date have occurred from APHIS-WS aircraft overflights on wildlife and the effects of these overflights were analyzed in detail in several APHIS-WS predator damage management EAs (e.g., USDA 2005, 2006b). Overflights for the purposes of ORV bait distribution activities for this proposed action would only occur once or twice per year and aircraft would only fly quickly over any one point on the ground. The aircraft do not circle over areas repeatedly, but fly in straight “transect” lines for the purposes of bait distribution. The potential impact would be of short-term (only momentary) duration, on a local scale, with negligible intensity and should not add appreciably to the frequency of overflights. The addition of one more overflight per year for ORV bait distribution should not constitute a substantive increase in any effects that might occur as a result of overflights. Furthermore, the types of aircraft used in bait distribution, the DeHavilland (DHC-6) Twin Otter and Beechcraft King Air B200, meet all Federal Aviation Regulation (FAR) requirements regarding noise limits (FAR Part 36). No evidence has been found to indicate harm to nontarget wildlife, including bald eagles. In addition, the annual overflight is even less likely to adversely impact migratory birds if flights occur in the fall after the birds have dispersed. Thus, the short-term duration, infrequency, and negligible intensity of flights over any given area, in addition to the tolerance of wildlife of such activity, indicates ORV program overflights would have a negligible adverse environmental impact on wildlife. Based on the above information and analysis, it is reasonable to conclude that APHIS-WS the ORV bait distribution program low-level flights should not cause any adverse impacts to nontarget wildlife, including T&E species. Therefore, this issue will not be considered further.

2.2.4 Potential for ORV Bait Distribution to Affect Organic Farming

This issue concerns the potential for ORV baits dropped on crops and livestock operations certified as "organic" under federal regulations to affect the status of the organic certification of such farms. A concern was raised by farmers and livestock producers, as a result of APHIS-WS' national ORV program, that they would not be able to sell, label, or represent their harvested crop or plant as organically produced if it had contact with the prohibited substance, which is the vaccine (V-RG in the case of the national ORV program and AdRG1.3 in the case of the proposed field trial) (7 CFR Part 205.672). The ORV baits to be used in the proposed field trial are comprised of partially hydrogenated vegetable shortening, Microbond® wax, stearine, icing sugar, vegetable oil, artificial marshmallow flavor, artificial sweet flavor, and a fat-soluble dye. The ONRAB® baits vaccine baits are all individually tested for leaks before leaving the manufacturing facility. The vaccine baits should remain intact when dropped out of airplanes, and thus are designed to resist breaking until an animal actually chews on them (G. Gifford, Canadian Food Inspection Agency, pers. comm. to F. Lord, Canadian Food Inspection Agency. 2009)

On April 15, 2003, the USDA-Agricultural Marketing Service (AMS) ruled that the V-RG ORV bait blocks on an organic operation would not have an adverse impact on organic operations (R. Mathews, National Organic Program, pers. comm., 2003). The USDA-AMS considers the ORV program to be an emergency disease treatment for the control of rabies, and as such, is addressed under National Organic Program (NOP) Section 205.672, Emergency Pest or Disease Treatment. The USDA-AMS determined that"…in the unlikely event that a bait block breaks and exposes a plant(s) to the vaccine, the organic producer can remove the affected plant(s) with no adverse effect on the operation's certification. This would comply with NOP Section 205.672(a). The organic status of animals feeding on the ORV bait block and not penetrating that vaccine would not be adversely affected. In the unlikely event that an animal consumes the vaccine within the ORV bait block that animal would lose organic status as provided in NOP Section 205.672(b)". The USDA-AMS believes there to be little chance that an organic animal would consume the vaccine within an ORV bait block; however to reduce the chances of livestock consumption, producers can relocate any bait found within an area containing livestock to a point outside of that area. The USDA-AMS agrees that this previous ruling still stands for the AdRG1.3 field trial (M. Bailey, National Organic Program, pers. comm., 2011)

2.2.5 Potential for ORV to Cause Abortions in Cattle

This issue was raised by a cattle producer in Ohio who reported an increase in abortions of pregnant cows following an ORV bait distribution project involving the V-RG vaccine and was addressed in previous ORV EAs (USDA 2010). It was determined that the increase in cattle abortions was coincidental and not related to V-RG ORV.

The AdRG1.3 vaccine was found to be safe in experimental studies in skunks as well as several nontarget species. A variety of domestic animal species have been included in safety studies on AdRG1.3, including cows, horses, pigs, sheep, chickens, dogs, and cats (Knowles et al. 2009). No adverse reactions in the animals studied were found following oral inoculation with the experimental vaccine, while in most cases antibodies against the rabies viral protein were detected on day 28 post-exposure (CFIA 2008, 2010). Although all the animals were deemed to be clinically normal after AdRG1.3, viral nucleic acids were detected in some tissues or feces of vaccinated animals, suggesting that AdRG1.3 was replicating or

persisting in these hosts for a few weeks post-vaccination. Replication of adenovirus in immunocompromised animals such as nude mice or severe combined immunodeficient (SCID) mice did not appear to result in adverse reactions, but these animals failed to produce neutralizing antibodies against rabies due to their inherent immune deficiency. Collectively, these results indicate that AdRG1.3 may retain some replication capability in both healthy and immunocompromised animals, but does not cause adverse reactions (toxicity) in these animals (CFIA 2008, 2010).

2.2.6 Potential Human Health Impacts in the Event of Human Consumption of Vaccinated Wildlife

The issue expressed here is the potential to develop an adenovirus infection from eating a vaccinated raccoon or some other animal that has eaten one or more ORV baits. Much like vaccinia found in the V-RG vaccine used in current ORV programs, the AdRG1.3 virus is taken up by tissues of the oral cavity and pharynx. The virus will invade these cells and start the expression of the virus genes, including the rabies glycoprotein gene. While the virus is able to penetrate the cells and start the expression of early stage genes, it is unable to utilize the non permissive cells to express the late stage genes necessary for assembly and release of new infectious virus particles. Therefore the animal is able to mount an immune response to the rabies glycoprotein and other early stage proteins, but new infectious particles are not released and further infection of other cells does not take place (A. Beresford, Artemis Technologies, Inc. pers. comm. 2011). Those particular tissues are rarely consumed by humans, but if they were, they would most likely be cooked which would kill the virus.

Adenoviruses are unusually stable to chemical and physical agents and to adverse pH conditions. The stability of the virus is an important factor in its selection as an oral vaccine for wildlife, as baits distributed will remain effective for an extended period of time under adverse environmental conditions (A. Beresford, Artemis Technologies Inc., pers. comm. 2011 and Artemis 2009). Outside of the protective blister pack's protective environment the vaccine virus is likely to be less stable (A. Beresford, Artemis Technologies, Inc., pers. comm. 2011). The work presented by Kalicharran (1992) confirms that virus contained in blister packs was more stable than on an exposed surface. This study also found that virus mixed with feces was less stable than virus mixed with cell culture medium.

As suggested above, even if tissues containing virus were consumed by humans they would likely be cooked to a safe temperature. The literature indicates that exposure of adenovirus to temperatures greater than 56°C (133°F) results in reduction of infectivity. It is reported in Maheshwari et al. (2004) that exposure of Ad5 to temperatures greater than 70°C for longer than 20 minutes result in greater than eight $\log_{10}$ reduction in virus titer.

Studies have been conducted at Artemis Technologies Inc. on the thermal stability of the AdRG1.3 construct at temperatures associated with certain food processing. Exposure of the AdRG1.3 virus to 89°C (192°F) results in a loss of infectivity of more than 3 $\log_{10}$ (1000 fold reduction) in the first 30 seconds of exposure, followed by a linear phase of approximately 0.6 $\log_{10}$ reduction per minute (A. Beresford, Artemis Technologies Inc., pers. comm. 2011).

Therefore, the potential for adverse health effects from consuming animals that have eaten ORV baits should be negligible.

2.2.7 Potential Impacts on Water Resources, including Aquaculture, Fish, Reptiles, and Amphibians

The concern here is for potential impacts of unconsumed AdRG1.3 vaccine and baits adversely impacting ground and surface water resources and aquaculture through direct and indirect exposure. Baits that are not consumed may remain in the environment for several months after placement, which is dependent upon environmental conditions (precipitation, temperature, etc.) and the physical condition of the baits. Potential impacts to water resources are greatly reduced by the limited number of baits dropped in a specific area, the biodegradability of the vaccine liquid and baits, the high consumption rate of ORV baits by animals, the safety and efficacy of the vaccine, and the Standard Operating Procedures (SOPs) that are used when dropping baits near a large water source. This conclusion is based upon:

- The possibility of a large quantity of ORV baits being exposed to a specific water resource is extremely low due to the bait distribution densities used by the program. Under the proposed program, ORV baits would be distributed from aircraft at an average density of 75 baits per km^2.

- The ONRAB® bait matrix contains a mixture of vegetable shortening, Microbond® wax, stearine, icing-sugar, vegetable oil, artificial marshmallow flavor, artificial sweet flavor, and a fat-soluble food dye. Therefore, the unconsumed bait material would biodegrade when exposed to the environment causing little to no effect on water resources.

- Adenoviruses are extremely host specific. Except under certain laboratory conditions, a human adenovirus will not replicate in anything other than human cells (A. Beresford, Artemis Technologies Inc., pers. comm. 2011) Therefore, target and non-target species exposed to the AdRG1.3 vaccine virus will not support active replication of the virus and, as such, AdRG1.3 is not expected to cause any adverse effects on fish, reptiles, amphibians, or any invertebrate species should any members of these species groups consume AdRG1.3 baits or otherwise be exposed to the vaccine.

- Although the vaccine virus is stable at room temperature for days to weeks (Artemis 2010), the ORV baits are readily taken up and consumed by animals, thereby limiting long term exposure to the environment. The likelihood of a bait being consumed is dependent upon several factors including animal population densities (target and non-target species), bait preference, and the availability of alternative food sources. In field tests conducted in the U.S., the majority of ORV baits have been consumed within the first 7 to 14 days after placement, with reports of up to 100 percent of the baits being consumed within a 7 day period (Farry et al. 1998, Hable et al. 1992, Hadidian et al. 1989, Hanlon et al. 1989, Linhart et al. 1994, Steelman et al. 2000, USDA 1995).

In regard to AdRG1.3 bait distribution in New Brunswick, Canada, the New Brunswick Department of Health (NBDOH) requested an exemption to the Wellfield and Watershed Protection Area Designation Orders. In New Brunswick, the Minister of the Environment issues Designation Orders under the *Clean Water Act* (1989) to establish Wellfield and Watershed Protected Areas. Wellfield and Watershed Protected Area Designations are the primary source water protection tool in New Brunswick. In their response granting this exemption, the New Brunswick Department of Environment (NBDOE) found that the health risks associated with the placement of AdRG1.3 vaccine baits is minimal and that the potential for human exposure is low. Further, the NBDOE found that chlorination of municipal water supplies

referenced by the NBDOH is effective at inactivating the adenovirus (R. Haché, New Brunswick Department of Environment, pers. comm. to S. Griffin, 2008).

Program SOPs limit the possibility of ORV baits being directly dropped into large water sources such as rivers, lakes, and reservoirs. When the aircraft approaches a large body of water the bait dropping equipment is shut off approximately 0.25 mile from the water source to reduce the possibility of ORV baits falling into the water. Nevertheless, due to changing environmental conditions and the limited possibility of human error when operating the bait dropping equipment, there is the possibility that baits may inadvertently be dropped into a body of water. Exposure of the AdRG1.3 vaccine into a water source from an intact bait and sachet is highly unlikely. The vaccine is enclosed in a sealed sachet, thereby limiting the possibility of the vaccine liquid being directly released into a water source.

The above information indicates that the risks of AdRG1.3 vaccine and baits pose no more than a negligible threat to groundwater or surface water through direct or indirect means.

2.2.8 Effects on Carnivore Populations in the Absence of Rabies

Concern has been expressed that specific carnivore populations, namely raccoons, may increase in the absence of the rabies virus as a mortality factor, leading to adverse effects on prey populations such as T&E species. The raccoon strain of the rabies virus has only relatively recently spread, and is contiguously distributed from Alabama to Maine, west to the eastern Ohio border with Pennsylvania (Krebs et al. 2000, Kemere et al. 2001). Translocation of rabid raccoons to the mid-Atlantic states has been implicated in establishing a new rabies foci in the mid-1970's (Krebs et al. 1999), from which rabies has spread through the raccoon population at rates averaging about 30 miles/year (48.3 km/year) (Kemere et al. 2001).

Rabies is only one of several diseases that may help regulate carnivore populations. In fact, the article by Guerra et al. (2003) does not support the idea that rabies exists specifically to control raccoon populations. Guerra et al. (2003) state that after an initial peak, populations approach lower 'steady-state' conditions. Based on surveillance data, raccoon rabies did not exist outside a focus areas in Florida before the 1940s. Therefore, elimination of raccoon rabies should merely create the scenario before raccoon rabies spread in the eastern U.S. (Rupprecht and Smith 1994). No evidence exists that the carrying capacity for raccoons could be increased by the implementation of ORV programs compared to population levels before the introduction of rabies (C. Rupprecht, CDC, pers. comm. 2003 as cited in USDA 2004).

Prior to the introduction of raccoon rabies into the mid-Atlantic region in the late 1970's, canine distemper was considered a primary disease mortality factor in raccoons, gray foxes, and skunks (Roscoe 1993, Davidson et al. 1992). The epizootiology of canine distemper in raccoons in New Jersey and Florida has been characterized by outbreaks at the end of the mating season in March and with increased movements of young in September (Roscoe 1993, Hoff et al. 1974). Because of the cyclic nature of canine distemper outbreaks (4 year intervals), the wide distribution of canine distemper cases, and the low incidence of the disease between epizootic peaks in New Jersey, Roscoe (1993) proposed an enzootic status for canine distemper for raccoons that becomes epizootic when raccoon densities reach high levels. Evans (1982) found that 50 to 90 percent of raccoons and gray foxes may be incapable of producing

protective levels of antibodies against the canine distemper virus, implicating it as a potentially important disease mortality factor. Davidson et al. (1992) diagnosed canine distemper in 78 percent of gray foxes studied in the southeastern U.S. and found canine distemper to be more significant as a mortality factor for gray foxes than all other infectious and noninfectious diseases combined. Roscoe (1993) reported that the effects of canine distemper on raccoon populations may diminish if raccoon rabies spreads and that concurrent canine distemper and rabies epizootics may become more common. The dynamics of sympatric rabies and canine distemper are not well understood; however, rabies may compensate for deaths that would have historically occurred due to canine distemper infection. Important attributes of canine distemper include that it is not a zoonotic disease like rabies and, historically, it has been implicated as a virus of importance to carnivore mortality.

2.2.9 Effects of Nontarget Species Consumption of ORV Baits on Program Effectiveness

Consumption of ORV baits by nontarget species is not expected to impact program effectiveness. As described in Section 1.1.3, baits are developed to attract target species. The use of target-preferred baits increases the likelihood of the target species consuming the baits prior to the discovery of baits by nontarget species. Furthermore, bait distribution densities are developed to compensate for the uptake of baits by nontarget species. Baits are distributed at densities that allow raccoons, gray foxes, and coyotes the opportunity to find intact baits. It has been determined, based upon the success of previous ORV bait distribution activities, that baits should be disbursed at an average density of 27 baits per km^2 ($69/mi^{2)}$ in the coyote rabies zone and 39 baits per km^2 ($100/mi^2$) the gray fox rabies zone in Texas. Baiting density averages 75 baits per km^2 ($194/mi^2$) in eastern states where raccoon rabies is targeted. In addition, surveillance activities have been and continue to be conducted to assess aerial or ground ORV baiting efficacy, summer versus fall baiting schedules, and seasonal raccoon movement in a number of states. Numerous density studies also continue to be conducted in the majority of participating states to determine raccoon densities in relation to habitat, elevation, and numbers of baits distributed. In areas where raccoon densities are low, bait distribution numbers may be reduced (USDA 2008a, 2008b).

2.2.10 Effects of Global Warming, Habitat Loss, and Pollution on Wildlife Populations

Program activities likely to result from the proposed APHIS-WS ORV field trials would have a negligible effect on atmospheric conditions including the global climate. Meaningful direct or indirect emissions of greenhouse gasses would not occur as a result of the proposed action. The proposed action would meet the requirements of applicable Federal laws, regulations, and Executive Orders including the Clean Air Act and Executive Order 13514.

2.3 AFFECTED ENVIRONMENT

This section presents some descriptive information on the environment of the area that may be affected by the proposed action. Other descriptive aspects of the affected environment are included in Chapter 4 in the analysis of effects which is based on environmental and other types of issues identified in Section 2.1.

The area of the proposed action includes lands in Greenbrier, Summers, and Monroe Counties, West Virginia, including portions of NFS lands, but excluding Wilderness Areas, where raccoon rabies outbreaks are expected to occur. ORV baiting programs using alternate rabies vaccines are currently or are expected to be conducted in these areas. Currently, cooperative rabies surveillance activities are

conducted in the aforementioned state and would continue under the proposed action.

The potential area involved in the ORV program field trial may cover several land ownership types and diverse land uses, including cultivated agricultural lands, forests, meadows, wetlands and pastures. Aerial distribution of ORV baits would avoid urban and suburban areas that support high human population densities, as well as lakes and rivers. Aerial distribution of baits would primarily target rural areas as well as known areas of suitable target species habitat. When aerial distribution by fixed-wing or helicopter aircraft is not practical, baits would be distributed by careful hand placement to help minimize contact by humans, pets, and other domestic animals.

Figures 1-2 and 1-3 show the area in and around Greenbrier, Summers, and Monroe Counties, West Virginia where APHIS-WS would participate in ORV field trials under the proposed action and the approximate ORV bait drop areas anticipated for the 2011 field trial. In addition, the ORV bait dispersal areas are also the primary expected areas where assistance by APHIS-WS is expected to be requested to collect blood, tooth and other biological samples from target animals for monitoring and surveillance. Figure 1-2 in Chapter 1 shows the National Forest System lands that will be included under the proposed action.

"Major Habitat Types" as described by Ricketts et al. (1999) that are found within the proposed project location are: Temperate Broadleaf and Mixed Forests (WV). Appendix F shows the "ecoregions" (i.e., broadlevel ecosystems) that occur in the potentially affected states (Bailey 1995).

Table 2-1 shows some descriptive statistics for West Virginia (state proposed for ONRAB® field trials).

Table 2-1. Some Descriptive Statistics of West Virginia; the Proposed Area for AdRG1.3 Field Trials by APHIS-WS (data from USDC 2001, 2008, 2010)

State	Resident Population (1000s) from 2008	Population per sq mile from 2008	% popn. in nonmetro-politan areas from 2006	Popn. of nonmetro-politan areas (1000s) from 2000	Total area (1000 acres) from 1997 and 2004	Developed area (1000 acres) from 1997	Rural area (1000 acres) from 1997	% rural area from 1997	Land in farms (mil. acres) from 2008	National Forest Land (1000 acres) from 1999	Total area owned by federal govt. (1000 acres) from 2004	% area owned by federalgovt. from 2004
WV	1,814	75.4	57.4%	1,043	15,411	12,688	13,252	86.6%	4	1,033	1,146	7.4%

The field trial area will be located in south-central West Virginia. The topography is rugged in the west with rolling valleys farther east. Greenbrier County is barricaded on its eastern border by a high range of the Allegheny Mountains, separating the county from neighboring Virginia. Grassy Knob in the northwest has the highest elevation, at 4,360 feet, and the lowest point is near Alderson, at 1,500 feet. Greenbrier Forest and a portion of the Monongahela National Forest occupy parts of the county (e-WV 2011). A leading industry in the area is agriculture and production consists primarily of livestock, dairy products, hay, grain, poultry, and fruit.

This region is primarily characterized by stony, loam soils. Within the field trial area can be found vast tracts of forest, pin oak (*Quercus palustris*) and alder shrub (*Alnus tenuifolia*) swamps, agricultural lands, and residential sites. Climate of the region is humid continental with hot summers and cool to cold winters. Characteristic vegetation of the area includes oak (*Quercus* spp.), maple (*Acer* spp.), poplar (*Liriodendron tulipifera*), walnut (*Juglans nigra*), hickory (*Carya* spp.), birch (*Betula* spp.), and softwoods such as hemlock (*Tsuga Canadensis*), pine (*Pinus* spp.), and spruce (*Picea* spp.).

Rhododendron (*Rhododendron maximum*), laurel (*Kalmia latifolia*), dogwood (*Cornus* spp.), redbud (*Cercis canadensis*), and pussy willow (*Salix discolor*) are among the flowering trees and shrubs.

Human population density in the field trial areas is relatively low, with approximately 34 people per square mile (Census 2011). The distribution of this population is uneven, however, with larger population concentrations occupying major towns and along highways, while other areas, including public and private forest, remain largely uninhabited.

CHAPTER 3: ALTERNATIVES

3.1 ALTERNATIVES CONSIDERED, INCLUDING THE PROPOSED ACTION

Alternative 1. No Action. This action would consist of no federal involvement by APHIS-WS in the implementation of field trials in West Virginia testing the efficacy of the AdRG1.3 oral vaccine. This option would significantly delay the eventual control and elimination of the current raccoon rabies epizootic and lead to additional costs in wildlife mortality and human endangerment. The "No Action" alternative is a procedural NEPA requirement (40 CFR 1502.14 (d)), is a viable and reasonable alternative that could be selected, serves as a basis for comparison with other alternatives, and can be defined as the continuation of current management practices (CEQ 1981).

Alternative 2. Proposed Action (the preferred alternative). Under this alternative APHIS-WS would use federal funds to purchase AdRG1.3 oral vaccine baits and to participate in ORV field trials involving the distribution of the AdRG1.3 oral vaccine baits under the authorities of the appropriate West Virginia state agencies and to evaluate the efficacy characteristic of the AdRG1.3 vaccine for wildlife rabies under limited field conditions at specific sites listed in section 2.3. Under this alternative APHIS-WS would also assist in monitoring and surveillance efforts by capturing and releasing or killing target species for purposes of obtaining biological samples.

3.2 ALTERNATIVES CONSIDERED BUT NOT ANALYZED IN DETAIL, WITH RATIONALE

3.2.1 Depopulation of Target Species

This alternative would result in the lethal removal of raccoons, skunks, gray foxes and coyotes throughout the zones where outbreaks of the targeted strains of rabies are occurring or are expected to occur. The goal would be to achieve elimination of the rabies strains by severely suppressing populations of the target animal species over broad areas so that the specific strain~~s~~ of rabies could not be transmitted to susceptible members of the same species. This could theoretically stop the forward advance of the disease and potentially result in elimination of the particular rabies variants as infected animals die from rabies before they could transmit it to other members of the same species.

Localized population reduction has been proposed as part of local programs to address raccoon rabies outbreaks as they are just beginning (Rosatte et al. 1997). This has been deemed necessary because by the time a suspected rabies case is confirmed through animal testing, other raccoons in the area have invariably been infected and are incubating the disease, at which point vaccination would not be effective for those individuals (Rosatte et al. 1997).

Population reduction is often suggested as a method to control rabies in wildlife populations since the disease is density dependent (Debbie 1991). Bounty incentives, regulated hunting and trapping, ingestible poisons, and fumigation of dens have all been employed to control populations with varying levels of success. MacInnes (1998) reviewed some of the past efforts to control rabies with population reduction of carrier species and concluded that, with a couple of exceptions, most such efforts have failed. In some of the situations, it could not be determined whether an observed decline or disappearance of rabies cases was attributable to population control or to the disease simply reaching some unexplainable

geographical limitation or just dying out on its own (MacInnes 1998). Also, population control as a strategy can be questionable because the leading edges of rabies outbreaks do not necessarily coincide with the edge of the range of the principal "vectors" (e.g., raccoons, gray foxes, and coyotes), nor are they always related to the population density of such vectors (MacInnes 1998).

Hanlon et al. (1999) reviewed historical efforts to control rabies through population reduction and evaluated the potential for success with this strategy. Information and conclusions they presented are summarized as follows:

Skunk rabies was successfully controlled in Alberta, Canada by population reduction (Pybus 1988). Success was attributed to a high level of effort during several years, the well-defined behavior of skunks in prairie habitats, and access to an effective method (Pybus 1988). Compensatory changes in carnivore reproduction (i.e., the tendency for larger litters and larger percentages of adult females to have litters) and dispersal (i.e., immigration of animals from surrounding uncontrolled populations) can limit the effectiveness of controlling population numbers of other species in different conditions (Clark and Fritzell 1992, Thompson and Fleming 1994).

Population reduction with toxicants as a broad scale control alternative for rabies is impractical. The only approved toxicants currently registered are sodium cyanide in the M-44 device (registered for zoonotic disease control involving wild canids), and carbon monoxide-producing gas cartridges that can be used to kill skunks, coyotes, and red foxes in dens. Currently, these methods are primarily used in limited areas of the western U.S. for livestock protection. Presently, population reduction is most likely to be publicly accepted and effective in localized or site-specific scenarios in the U.S. (e.g., reducing the density of raccoon populations in parks where visitors could potentially come into contact with rabid animals).

Population reduction using strychnine baits was successful in stopping the spread of rabies in foxes in Denmark (Gaede 1992). However, carcass recovery statistics indicated nontarget species [498 martens (*Martes* sp.), twelve European badgers (*Meles meles*), and four domestic dogs] were killed in slightly greater numbers than the targeted red foxes (n=482). The number of rabies cases declined sharply and the country has reportedly remained free of terrestrial rabies since 1982 (Gaede 1992). Broad scale population control with toxicants is most likely politically infeasible in the U.S. due to opposition by the public and state wildlife agencies.

This alternative was not considered in detail because it would be impractical to obtain approval from the many landowners on whose properties the lethal control methods would have to be conducted. The greatest difficulty with population reduction as a strategy for reducing or eliminating rabies is that the high level of effort must be maintained almost indefinitely and would also undoubtedly be opposed by most members of the public (MacInnes 1998). Population suppression can be a challenge to maintain in many situations due to immigration (of other members of the same species from surrounding populations) and possibly compensatory reproduction (i.e., larger litters and greater percentages of females breeding following population reduction) (Clark and Fritzell 1992, Connolly and Longhurst 1975). These factors can mean local populations can recover to their previous levels within a year, thus requiring annual or more frequent suppression efforts to maintain such populations at low levels. Nevertheless, temporary localized population suppression activities could be conducted in an integrated program of ORV use as part of the proposed action, but such activities, if conducted at all, would be expected to occur as a part of

contingency actions in response to a breach in a vaccination barrier. APHIS-WS has covered predator removal including to control disease, but mostly to resolve damage associated with them to resources such as livestock, in other EAs for Texas, New Mexico, and Arizona (Predator Damage Management EAs) and some eastern states for raccoons (APHIS-WS EAs can be found at http://www.aphis.usda.gov/wildlife_damage/ nepa.shtml).

3.2.2 Population Control through Birth Control

Under this alternative, APHIS-WS would provide funds or operational assistance to implement one or more methods to control populations of the target species by reducing reproduction. Such methods could involve live capture and surgical sterilization [reviewed by Kennelly and Converse (1997)], the use of chemical reproductive inhibitors placed out in baits or delivery devices (Balser 1964, Linhart et al. 1968), or the application of *immunocontraception* strategies (i.e., vaccines that can cause infertility in treated animals).

The suppression of reproduction over time would eventually reduce the size of target species populations and lead to a reduction in the potential for the spread of rabies by reducing the chances of contact between infected and healthy animals. However, this approach would do nothing in the short term to reduce the risk of rabies spread in the existing populations, since those animals would continue to be present and capable of contracting and passing on the disease. Therefore, this type of strategy would be viewed as a long-term remedy for stopping rabies spread. It would probably not be useful in meeting the immediate needs for stopping a localized outbreak of rabies that occurs beyond designated ORV baiting zones.

Live capture and surgical sterilization of whole local populations of animals would be extremely expensive, time-consuming, and difficult to achieve. Considerable expense would be involved in employing experienced and qualified veterinarians to perform large numbers of surgical procedures on captured animals. From a rabies control standpoint, if all or nearly all of a local population could be live captured, it would be more effective and less costly to administer rabies vaccinations by injection, which is already considered as Alternative 3 in USDA 2010.

Immunocontraception is a potentially useful concept for mammalian population suppression but is still in the early stages of research and development (Bradley 1995, Miller 1997). Genetically engineered vaccines that cause a target species to produce antibodies against its own sperm or eggs or that affect reproductive hormone functions have been produced (Miller 1997). Several logistical concerns still would need to be addressed before this method could be applied successfully in the field. These concerns include: 1) durability of the contraceptive vaccines in baits after distribution in the field; and 2) the limitation of some current vaccine designs that require baiting an animal population twice, about one month apart, to successfully treat individual wild animals (Miller 1997). Furthermore, it is likely that a greater proportion of the population would have to be treated with contraceptive vaccines than with rabies vaccines in order to achieve effective rabies control. Thus, achieving effective control would be more costly and difficult under this alternative than under ORV programs (C. MacInnes, Ontario Ministry of Natural Resources, pers. comm. 2001 as cited in USDA 2001a). In addition, several environmental concerns regarding this strategy still need to be addressed, including safety of the proposed genetically engineered vaccines to humans, other wildlife species, and even nontarget members of the target species (e.g., juveniles) that might consume baits (Miller 1997, Guynn 1997, Hanlon and Rupprecht 1997).

No contraceptive agents are currently registered for use on raccoons, gray foxes, or coyotes and, thus, are not legal for use. For all of the above reasons, birth control strategies to control rabies will not be considered further.

3.2.3 Employ Other Types of ORV Instead of the AdRG1.3 Vaccine

Under this alternative, APHIS-WS would provide funds to purchase and use "modified-live-virus" (i.e., "attenuated" or weakened strains that have been shown to have little chance of causing rabies in treated animals), "killed-virus" (i.e., "inactivated" virus) oral vaccines, or recombinant vaccines such as the V-RG vaccine in ORV baits. Modified-live-virus vaccines include those that have been used in the past in the U.S. to vaccinate domestic animals by injection. Oral baits that employed several strains of these types of virus vaccines have been investigated and used in Europe to stop the spread of rabies in red foxes (Flamand et al. 1993, Artois et al. 1993, Artois et al. 1997). They have also been tested in red foxes in Canada (Lawson et al. 1989, Lawson et al. 1997), and in red foxes and raccoons in the U.S. (Rupprecht et al. 1989, Rupprecht et al. 1992c).

The primary concern with attenuated or "live" virus vaccines (e.g., SAD and ERA) is that they can sometimes cause rabies (Flamand et al. 1993, Pastoret et al. 1992). Flamand et al. (1993) reported that one strain used widely in oral baits in Europe to vaccinate wild red foxes in the 1970s could cause rabies in rodents when injected and that the ability to cause rabies in nontarget animals by other modes (i.e., oral administration) could not be ruled out. Previously used attenuated strains are also "heat sensitive" which can limit their use in warmer seasons or climates (Pastoret et al. 1992). These types of safety concerns with attenuated rabies virus vaccines have been sufficient to prevent their approval for use in the U.S. (Rupprecht et al. 1992c).

The Street Alabama Gif 2 (Rabigen® SAG2, Virbac S.A., Carros, France) vaccine, itself a live "attenuated" rabies vaccine, shows great promise both in terms of safety and efficacy in multiple species. Unlike its predecessors, SAD and Era, SAG2 is a more highly attenuated virus strain and has been found to be completely safe for mice, wild rodents, and in more than 35 other nontarget species (Masson et al. 1996, Follman et al. 1996, Bingham et al. 1997, Aubert. *Unpublished*, Bingham et al. 1999, Rupprecht et al. 1998, Fekadu et al. 1996, Garniere. *Unpublished*). In contrast to traditional modified-live rabies virus vaccines, the SAG2 virus does not cause rabies when inoculated intramuscularly and intracerebrally in adult laboratory mice (Hanlon et al. 2002). SAG2 is a double mutant and remains avirulent after three successive passages in suckling mouse brain or after ten successive cycles of multiplication in cell culture (Lafay et al. 1994). However, SAG2 is also not licensed for use in North America.

"Inactivated" virus or "killed-virus" rabies vaccines are safer than "live" vaccines in that they cannot cause rabies. This type of vaccine was found to be less effective in causing immunity when delivered into the intestinal tract in foxes (only 30 percent effective in test animals) and took two doses to cause immunity in the foxes that were successfully immunized (Lawson et al. 1989). Also, the amounts of virus particles that would have to be ingested in oral baits by wild carnivores to effectively vaccinate them would be 100 to 1000 times the amount of the live-attenuated virus particles required (Rupprecht et al. 1992c). To manufacture vaccines with these amounts would likely be cost-prohibitive (Rupprecht et al. 1992c).

The recombinant V-RG vaccine has been used throughout the U.S. since 1990 and is currently the only licensed oral rabies vaccine in the U.S. The nature of the recombinant virus used in the V-RG vaccine is such that it cannot cause rabies, although the vaccinia virus portion of the V-RG vaccine has been recognized as having the potential to cause infections to persons exposed to the vaccine. However, of the nearly 89 million baits distributed since the inception of APHIS-WS' ORV program only 2 known adverse reactions have been reported (USDA 2010).

Despite the increased safety of the V-RG vaccine, it remains limited in its efficacy among multiple species, including skunks and mongoose. The V-RG vaccine does not produce significant detectable virus neutralizing antibodies in skunks, a major terrestrial reservoir for rabies (based on seroconversion from field samples) (USDA 2010b). The majority of spillover infections from raccoons are into skunks (predominantly *Mephitis mephitis*) and this species may have a role in maintaining the raccoon rabies variant within ORV zones (Blanton et al. 2007).

The AdRG1.3 vaccine has been used in field trials in Canada since 2006 (Rosaette et al. 2009), producing both efficacious and safe results. For these and the above reasons, AdRG1.3 has been chosen for use in APHIS-WS's ORV field trials.

3.3 SOPs TO MINIMIZE POTENTIAL IMPACTS OF THE RABIES ORV FIELD TRIAL

APHIS-WS has adopted Standard Operating Procedures (SOPs) that serve to prevent, reduce, or compensate for negative impacts that otherwise might result from an action. The current ORV program uses many such SOPs that would be incorporated into the field trial activities in West Virginia. Many APHIS-WS SOPs are discussed in depth in USDA (1997, Chapt. 5). The key SOPs are incorporated into both alternatives as applicable, except the no action alternative (Alternative 1). Most SOPs are instituted to abate specific issues while some are more general and relate to the overall program. SOPs include those recommended or required by regulatory agencies such as EPA and these are listed where appropriate. Additionally, specific measures to protect resources such as T&E species that are managed by other agencies (USFWS and State Departments of Wildlife) are included in the lists below.

- Public information, education, and media announcements would be made available to inform the public about ORV bait distribution activities in each county before they occur. APHIS-WS would coordinate with the appropriate state agency involved in the ORV program on preparing leaflets, posters, press releases, or other media to distribute to the public. Leaflets and posters would be posted in schools, hospitals, campgrounds, visitor centers, and state and county public agency offices. Notification of ORV bait drops would be sent to the state police, state emergency management associations, county hazardous materials coordinators, county cooperative extension agents, state and federal correctional facilities, wildlife rehabilitators, and medical and veterinary facilities within the ORV area informing them of the program and providing information about the ORV bait and vaccine and potential exposure issues.

- Toll-free telephone numbers would be advertised in the media and on web sites for people to call for answers to questions.

- Should a human exposure to the AdRG1.3 vaccine occur, that person would be referred to their primary care physician or local public health official as appropriate. In the unlikely event of an adverse reaction to the Ad5 virus, local health officials may engage with the CDC for diagnostic confirmation and consultation (C. Rupprecht, CDC, pers. comm., 2011).

- Bait distribution navigators would be trained to avoid dropping baits on people or structures. During aerial bait drop operations, the bait dispensing equipment is temporarily turned off over human dwellings, cities, towns, greenhouses, certain sensitive domestic animal pens, and when people are observed below.

- APHIS-WS personnel would adhere to air safety standards.

- ORV baits would not be distributed by aircraft within 0.25 miles of large water bodies to reduce the potential of baits entering the water source.

- APHIS-WS personnel would be trained in hand distribution of baits to avoid properties with greater risk of human or pet encounters with baits.

- Labels would be placed on each ORV bait, instructing persons not to disturb or handle them. Labels would contain a toll-free telephone number to call for further information and guidance in the event of accidental exposure to the vaccine (see Figure 1-1 in Chapter 1).

- Methods used to capture raccoons, skunks, and other target species would mainly involve the use of cage traps; however, other methods such as snap traps may be used for small mammal surveys. Animals caught in cage traps that are killed for monitoring and testing purposes, local depopulation, or per cooperating landowner's request would be euthanized in accordance with APHIS-WS policy in a manner as humane as allowable under the circumstances.

- Capture devices would be checked on a daily basis.

- Field personnel involved in trapping and handling animals for monitoring and surveillance purposes would be immunized against rabies and tetanus.

- All drugs designated for capturing and handling raccoons and other animals would be used under the direction of state or federal veterinary authorities, either directly or through procedures agreed upon between those authorities and APHIS-WS.

- Monitoring and surveillance activities may extend into the hunting season during late summer/fall ORV field trial baiting schedules. Therefore, target species would either be ear tagged, marked in some other way, or euthanized if capture and handling activities that utilize immobilizing drugs are used within 30 days of hunting or trapping seasons. These measures would be taken to avoid release of animals that may be consumed by hunters prior to the end of established withdrawal periods for the particular drugs used. Most animals administered immobilizing drugs, however, would be released

well before state controlled hunting/trapping seasons, which would give the drug time to completely metabolize out of the animals' systems before they might be taken and consumed by humans.

3.3.1 Monitoring

APHIS-WS, in coordination with the appropriate agencies, will monitor the program that results from this EA. The impacts discussed in this EA would be monitored and used in two ways:

1) APHIS-WS would determine if any additional information that arises subsequent to a NEPA decision from this EA would trigger the need for additional NEPA compliance. APHIS-WS would review program results and related NEPA documents annually, or as needed, to ensure that the need for action, issues identified, alternatives, regulatory framework, and environmental consequences are consistent with those identified in the final NEPA documents.

2) APHIS-WS would monitor impacts on target and nontarget wildlife populations through its Management Information System (MIS) database. The MIS information would be used to assess the localized and cumulative impacts of the program on wildlife populations. APHIS-WS provides detailed information on animals removed to the involved state agencies to assist those agencies with managing species and resources under their jurisdiction.

4.0 CHAPTER 4: ENVIRONMENTAL CONSEQUENCES

This chapter analyzes potential environmental consequences using Alternative 2 (proposed action) as the baseline for comparison with Alternative 1 (no action) to determine if the real or potential impacts are greater, lesser or the same. Table 4-1 at the end of this chapter summarizes a comparison of the issues and impacts to each alternative.

The following resource values within the state are not expected to be negatively impacted by any of the alternatives analyzed: soils, geology, minerals, floodplains, wetlands, visual resources, air quality, aquatic resources and range. These resources will not be analyzed further.

Other than minor uses of fuels for motor vehicles and other materials, there are no irreversible or irretrievable commitments of resources. The contribution of the proposed action to the emission of gases that potentially contribute to global warming will be similar to the other alternatives and is expected to be minimal. Thus, these will not be analyzed further.

The proposed action does not involve construction, major ground disturbance, or habitat modification. Therefore the following resource values are not expected to be affected by the proposed action: soils, geology, minerals, water quality/quantity, flood plains, wetlands, visual resources, air quality, prime and unique farmlands, aquatic resources, vegetation, timber, and range. These resources will not be analyzed further.

4.1 ENVIRONMENTAL CONSEQUENCES FOR ISSUES ANALYZED IN DETIAL

4.1.1 Potential for Adverse Effects on Target Wildlife

4.1.1.1 Alternative 1: No Action

<u>Effects of the ORV AdRG1.3 Vaccine on Target Species (Striped Skunks and Raccoons)</u>

Under this alternative, there would be no impact on target striped skunk or raccoon populations in West Virginia from ORV field trails. However, in the absence of a safe and efficacious rabies virus vaccine for skunks, it is likely that more skunks will die from rabies with potentially greater short-term population impacts. Further, without a safe and efficacious rabies virus vaccine for wildlife rabies epizootics may be expected to occur that would likely result in short-term die-offs of target species over broader geographic areas.

ORV programs utilizing the V-RG vaccine would be expected to continue, however, as discussed in section 1.2, studies have indicated that V-RG does not produce sufficient levels of population immunity in skunks in the wild at the current dose (Slate et al. 2005) and V-RG may be less effective in skunks than other species (Tolsen at al. 1987). Rabies virus containment and elimination in the U.S. will likely remain elusive until an oral vaccine is licensed that is immunogenic in all terrestrial rabies reservoir species (Slate et al. 2005).

<u>Effects of Monitoring and Surveillance on Target Species (Striped Skunks and Raccoons)</u>

Under this alternative there would be no monitoring and surveillance activities to support an ORV

AdRG1.3 field trial distribution, therefore there would be no effect to the West Virginia striped skunk or raccoon populations. However, as stated above, it is likely that striped skunks will continue to die as a result of rabies virus infection.

4.1.1.2 Alternative 2: Proposed Action (the preferred alternative)

Effects of the AdRG1.3 Vaccine on Target Species (Striped Skunks and Raccoons)

The primary concern here is whether the AdRG1.3 vaccine might cause disease in target animals that consume the ORV baits. In order for such vaccines to be licensed for use they must be shown to be safe, pure, potent, efficacious, and genetically stable (Agriculture Canada 1989). Striped skunks and raccoons are the target species for purposes of the AdRG1.3 field trial.

The V-RG construct was the first recombinant rabies vaccine distributed in the field (Pastoret et al. 1988) and several safety studies evaluated the generation of pathological lesions, explored the short-term persistence of the virus in foxes, raccoons, a variety of European non-target wildlife, and immunodeficient animals (Blancou et al. 1986, Brochier, et al. 1989, Thomas et al. 1990, Rupprecht et al. 1988, and Hanlon et al. 1997 *in* Knowles et al. 2009). Based on these prior studies, Knowles et al. (2009) designed studies to investigate the safety of AdRG1.3. These studies concluded that in regard to gross pathological consequences and the possible long-term presence of virus in species tested, all data indicate very low recovery of AdRG1.3 from tissues, feces, and oral samples of animals given a relatively high dose of vaccine, thus making the likelihood of AdRG1.3 spread by horizontal transmission in wildlife species unlikely (Knowles et al. 2009).

Adenovirus infections occur worldwide in humans as well as in a variety of animals. Adenoviruses are extremely host specific. Except under exceptional laboratory conditions, a human adenovirus will not replicate in anything other than human cells (A. Beresford, Artemis Technologies Inc., pers. comm., 2011). With few exceptions, the human adenovirus serotypes are generally not pathogenic to animals, and animal adenoviruses are only pathogenic within the species of origin (Taylor 1977). Therefore target species exposed to the AdRG1.3 vaccine virus would not be expected to support active replication of the virus.

Additionally, both Charlton et al. (1992) and Prevec et al (1989a) confirmed that, after oral immunization of skunks and foxes with AdRG1, no pathogenic effect related to AdRG1 was observed. These results indicate that recombinant adenoviruses (rAd) such as AdRG1 may be an attractive candidate for a wildlife oral rabies vaccine (Randrianarison-Jewtoukoff and Perricaudet 1995). Also, experiments have shown that when skunks and raccoons receive four to five times the anticipated dose of AdRG1.3 to be used in baits, no adverse reactions occurred (Artemis 2010).

Knowles et al. (2009) conducted safety studies on several species including striped skunks and raccoons. Vaccine was administered by direct instillation into the oral cavity with a syringe and polyethylene tubing while the skunks and raccoons were recovering from sedation. Tissues were collected post vaccination and analyzed for the presence of AdRG1.3. Among skunks and raccoons, only lung tissue tested positive for vaccine virus. Oral swabs taken from rabies vector species did not show any recovery of virus at 7 days post vaccination. The duration of fecal contamination by vaccine was short lived, being 3-4 days in most of the species tested. Skunks given the vaccine dose to be used in the field excreted virus in feces

over 3 days only. Possible aspiration of vaccine during oral instillation was associated with finding of acute bronchopneumia and necrosis in one skunk tested.

AdRG1.3 has been used in field trials in Ontario, CA since 2006. Before approval to field test AdRG1.3 vaccine-baits in Ontario was granted by the Canadian Food Inspection Agency (CFIA), Veterinary Biologics Section (VBS), extensive laboratory testing of the experimental vaccine had to be completed (Rosatte et al. 2009). The limited host range of human adenovirus reduces the risk of spread in target and non target wildlife or domestic animals. The risk of release of this vaccine is expected not to be greater than that for other licensed vaccines (ERA, V-RG), and is actually considered to have less potential adverse consequences (CFIA 2008, 2010).

Effects of Monitoring and Surveillance on Striped Skunks in Greenbrier, Summers, and Monroe Counties, West Virginia

Although easily recognized by their black and white fur, the striped skunk may be most readily recognized by the odiferous smell of its musk. They are common throughout the U.S. and Canada (Rosette 1987). Striped skunks are primarily nocturnal and do not have a true hibernation period, although during extremely cold weather they may become temporarily dormant. The striped skunk is an omnivore, feeding heavily on insects such as grasshoppers, crickets, beetles, bees, and wasps (Godin 1982). The striped skunk's diet also includes small mammals, the eggs of ground-nesting birds, and amphibians. Striped skunks are typically non-aggressive, and will attempt to flee when approached by humans (Rosatte 1987). However, when provoked, skunks will give a warning and assume a defensive posture prior to discharging their foul-smelling musk. This musk consists of sulfur-alcohol compounds known as butylmercaptan (Godin 1982).

The striped skunk may use abandoned burrows of other animals as a home. They may also dig their own burrow, or use a protected place, such as a hollow log, crevice, or the space beneath a building.

Adult skunks begin breeding in late February. Yearling females (born in the preceding year) mate in late March. Gestation usually lasts 7-10 weeks, and there is usually only 1 litter annually. Litters commonly consist of 4-6 young. The home range of the striped skunk is usually not consistent. It appears to be in relation to life history requirements such as winter denning, feeding activities, dispersal and parturition (Rosatte 1987). Reported home ranges of striped skunks average between 2.2 and 4.9 km^2 (0.85-1.9 mi^2) in rural areas of Minnesota and Illinois (Rosatte 1987). During the breeding season, males may travel larger areas in search of females. Skunk densities vary widely according to season, food sources, and geographic area. Densities have been reported to range from 1 skunk per 77acres to 1 per 10 acres (Rosatte 1987).

No population estimates are available for striped skunks in West Virginia. Striped skunks can be found in a variety of habitats across West Virginia. To analyze impacts of ORV field trial activities on striped skunk populations in West Virginia, the best available information will be used. There are over 13 million acres of rural land in WV (USDC 2001), with approximately 4 million acres in farmland (USDC 2008). Using the assumption that 50% of the rural lands throughout the state have sufficient habitat to support striped skunks, skunks are found only in rural habitat, and skunk densities average 1 skunk per 77 acres (lowest estimate available), a conservative statewide striped skunk population could be estimated at

approximately 84,400 skunks. Considering skunks inhabit urban areas as well as rural, an estimate of 84,400 is likely very low (R. Rogers, WV Dept. of Natural Resources, pers. comm. 2011). Using the same assumptions, there are approximately 4,646 skunks in the field trial zone.

Striped skunks are classified as a furbearer in West Virginia with regulated trapping and no take limit (WVDNR 2010a). Based on tag checks and fur dealer transactions, the yearly estimate for striped skunks harvested by trappers in West Virginia averaged over 125 per year during 1999-2009 (WNDNR 2010b).

During FY2010 the West Virginia WS program killed 28 striped skunks and captured and released 6. APHIS-WS and cooperating state or local agencies expect to live-trap or lethally remove less than 1 percent of the lowest estimated number of striped skunks for monitoring and surveillance purposes for the ORV AdRG1.3 field trial. The majority of striped skunks captured for monitoring and surveillance purposes would be released at the site of capture once they have fully recovered from anesthesia. Individual skunks may be lethally removed and tested for rabies if they are demonstrating strange behavior symptomatic of the rabies virus or if they are injured. An exception may be when the animals are captured and drugged for handling purposes close to or during the trapping season, at which time they may be euthanized to avoid concerns about hunters or trappers consuming skunks that contain drug residues (see Section 2.2.1).

Based upon the above information, WS' limited lethal take (less than 460) of striped skunks would have no adverse impacts on overall populations of the species in West Virginia.

Effects of Monitoring and Surveillance on Raccoons in Greenbrier, Summers, and Monroe Counties, West Virginia

The estimated cumulative size of the proposed field trial area to be treated with AdRG1.3 ORV baits is approximately about 1,448 km^2 (or about 559 mi^2). Raccoon densities range from 0.9 to as high as 250 per km^2 (about 2 to 650 per mi^2) with most reported densities ranging from 4 to 30 per km^2 (about 10 to 80 per mi^2.) in rural areas (Riley et al. 1998). Assuming that this range of raccoon densities occurs in the treatment area, it is reasonable to assume that the raccoon population for the field trial area would be between 5,792 – 43,440. Statewide raccoon density estimates range between 251,032 – 1.8 million individuals.

Raccoon populations can generally be expected to withstand harvest rates of about 49 percent or more annually (Sanderson 1987, USDA 1997j). APHIS-WS and cooperating state or local agencies expect to continue to live-trap or lethally remove less than one percent of the lowest estimated number of raccoons in West Virginia combined for monitoring and surveillance purposes or implementation of localized contingency plans involving lethal population reduction in all ORV programs, including AdRG1.3 field trials.

The APHIS-WS EA – Oral Vaccination to Control Specific Rabies Virus Variants in Raccoons, Gray Foxes, and Coyotes in the U.S. (2010) indicates the lowest estimated size of the raccoon population totaled from those states participating in the current ORV program was 2,225,031 raccoons in 2006. The APHIS-WS program killed 1,036 raccoons for enhanced rabies surveillance as a part of cooperative ORV efforts, or 0.05 percent of the total lowest estimated population in 2007. The report summarizes that the

ORV program continues to have no adverse impacts to raccoon densities and that, in the absence of the ORV program, it is highly likely that far more raccoons would die from rabies than are killed for surveillance and monitoring purposes to critically evaluate the integrity of ORV campaigns. In comparison, during 2005-2006, sportsmen in Pennsylvania and Ohio harvested 106,082 and 46,886 raccoons respectively (or 11.4% and 5.5% of the total raccoon populations in those states) (ODNR 2009, PGC 2009a, USDA 2009). During FY2010 the West Virginia Wildlife Services program lethally removed 179 raccoons and captured and released 490 raccoons.

The majority of raccoons captured for monitoring or surveillance purposes would be released at their site of live capture once they have fully recovered from anesthesia. Individual raccoons may be lethally removed and tested for rabies if they are demonstrating strange behavior symptomatic of the rabies virus or if they are injured. An exception may be when the animals are captured and drugged for handling purposes close to or during hunting/trapping seasons, at which times they may be euthanized to avoid concerns about hunters or trappers consuming raccoons that contain drug residues (see Section 2.2.1).

APHIS-WS will conduct post-field trial ORV monitoring to evaluate program efficacy by collecting blood and tooth samples for determining rabies VNA levels and bait uptake (when appropriate) in raccoons and striped skunks. Serum samples are collected from unique (previously uncaptured and unsampled) raccoons and striped skunks captured.

Effects on other species not targets for purposes of ORV field trials, but which may be considered targets for monitoring and surveillance

Although the ORV AdRG1.3 field trials specifically targets striped skunks and raccoons, several other species may be treated as targets for monitoring and surveillance. These species will be referred to as non-ORV targets for purposes of this EA. The methods proposed for use in skunk rabies monitoring and surveillance areas would have no significant adverse effects on non-ORV target species. Species that are considered targets for monitoring and surveillance, but are not targets for the ORV AdRG1.3 field trial will include all known rabies reservoir species including red foxes, grey foxes, coyotes, spotted skunks (*Spilogale putoris*), bobcats (*Lynx rufus*), groundhogs (*Marmota monax*), feral dogs (*Canis familiaris*), and feral cats (*Felis domesticus*). Additionally, several small mammal species may targets for monitoring and surveillance including Eastern chipmunk (*Tamias* striatus), Eastern gray squirrel (*Sciurus carolinensis*), red squirrel (*Tamiasciurus hudsonicus*), Southern flying squirrel (*Galucomys volans*), short-tailed shrew (*Blarina brevicauda*), deer mouse (*Peromyscus maniculatus*), white-footed mouse (Peromyscus leucopus), Southern red-backed vole (*Clethrionomys gapperi*), meadow vole (*Microtus pennsylvanicus*), and pine vole (*Microtus pinetorum*). Occasionally samples may be collected for serology from some mammal species that are incidentally captured during ORV monitoring and surveillance activities, but not specifically targeted by the ORV AdRG1.3 field trials. They may be opportunistically sampled to determine the potential effectiveness of the AdRG1.3 as many of these species have a propensity for contracting, harboring, and spreading the rabies virus. Non-ORV target animals captured in cage traps would normally be released unharmed unless the animal appears sick or injured. Therefore, monitoring and surveillance should have little or no effect on non-ORV target populations.

4.1.2 Potential for Adverse Effects on Nontarget Wildlife Species, Including Threatened or Endangered Species

4.1.2.1 Alternative 1: No Action

Effects of the AdRG1.3 Vaccine on Nontarget Wildlife including Threatened or Endangered Species

Under the no action alternative, there would be no potential for APHIS-WS assistance to result in adverse impacts on nontarget wildlife because of ORV field trials.

Effects of capture/removal methods (used in monitoring and surveillance activities) on nontarget species, including threatened or endangered species

Under the no action alternative, the potential for APHIS-WS assistance to result in adverse impacts on nontarget wildlife would be zero.

4.1.2.2 Alternative 2: Proposed Action (the preferred alternative)

Effects of the AdRG1.3 Vaccine on Nontarget Wildlife including Threatened or Endangered Species

A primary concern of the AdRG1.3 vaccine is that it might cause disease in nontarget animals that consume or contact vaccine in the baits.

At least 17 species have been included in the safety studies on AdRG1.3 (Knowles et al. 2009) from the following taxonomic groups:

- Order *Carnivora*

  Family *Canidae* [red fox (*Vulpes vuples*), domestic dog (*Canis familiaris*)]

  Family *Felidae* [domestic cat (*Felis domesticus*)]

  Family *Mustelidae* [striped skunk (*Mephitis mephitis*)]

  Family *Procyonidae* [raccoon (*Procyon lotor*)]

- Order *Rodentia*

  Family *Sciuridae* [grey squirrel (*Sciurus carolinensis*), groundhog (*Marmota monax*)]

  Family *Muridae* [cotton rat (*Sigmodon hispidus*), meadow vole (*Mictrotus pennsylvanicus*), nude mouse (*Mus Musculus*), deer mouse (*Peromyscus leucopus*)]

- Order *Lagomorpha*

  Family *Leporidae* [European rabbit (*Oryctologus cuniculus*)]

- Order *Artiodactyla*

Family *Bovidae* [cow (*Bos Taurus*), sheep (*Ovis aries*)]

- Order *Suina*

  Family *Suidae* [pig (*Sus domesticus*)]

- Order *Perissodactyla*

  Family *Equidae* [horse (*Equus ferus*)]

- Order *Galliformes*

  Family *Phasianidae* [chicken (*Gallus domesticus*)]

No adverse reactions in the animals studied were found following oral inoculation of the experimental vaccine, while in most cases antibodies against the rabies viral protein were detected on day 28 post-exposure (CFIA 2008, 2010). Test animals were found to be clinically healthy after vaccination with AdRG1.3, however viral nucleic acids were detected in some tissues or feces of some vaccinated animals, suggesting that AdRG1.3 was replicating or persisting in these hosts for a few days to a couple of weeks post-vaccination. Replication of adenovirus in immunocompromised animals such as nude mice and SCID mice did not appear to result in adverse reactions (CFIA 2008, 2010).

Overdosage of AdRG1.3 in amounts four to five times greater than the dose found in the vaccine baits resulted in no adverse effects in experiments involving skunks and raccoons (Artemis 2010). Therefore, even if domestic animals or other nontarget wildlife receive multiple doses of vaccine by consuming multiple baits, no adverse effects would be expected to occur.

Knowles et al. (2009) confirmed in studies involving meadow voles, deer mice, grey squirrels, rabbits, and groundhogs that lung was the only tissue that tested positive four days post-vaccination (in one groundhog and one squirrel), while the remaining tissues sampled tested negative for vaccine virus. The distribution and consumption of baits is expected to have no adverse effect on any species. The distribution and consumption by mammals is more likely to have a positive effect on mammals because a successful program will reduce the risk of mammals contracting and dying from rabies.

As stated in section 4.1.1.2, adenoviruses are extremely host specific. Except under exceptional laboratory conditions a human adenovirus will not replicate in anything other than human cells (A. Beresford, Artemis Technologies Inc., pers. comm., 2011). With few exceptions, the human adenovirus serotypes, are generally not pathogenic to animals, and animal adenoviruses are only pathogenic within the species of origin (Taylor 1977). The limited host range of human adenovirus reduces the risk of spread in target and nontarget wildlife or domestic animals. The risk of release of this experimental rabies vaccine is expected not to be greater than that for other licensed rabies vaccines (e.g. ERA, V-RG), and this vaccine is actually considered to have less potential for adverse consequences (CFIA 2008, 2010). Therefore non-target species exposed to the AdRG1.3 vaccine virus would not be expected to support active replication of the virus.

T&E Species Effects

Although no T&E species were specifically tested for safety of AdRG1.3 baits, safety studies involving AdRG1.3 on other species representing 11 unique taxonomic families listed above indicate that no species will be affected by the baits (Knowles et al. 2009b, Randrianarison-Jewtoukoff and Perricaudet 1995, Artemis 2010).

Reports of rabies among carnivores other than primary reservoir host species are rare but, other carnivorous mammals, including T&E species or closely related species, can be a source of rabies exposure to humans and domestic animals. A total of 2,851 cases of rabies among other carnivorous mammals of at least 17 different species were reported from 1960 through 2000. This total represents 1.5% of the 185,014 wildlife cases reported during the same time period. A total of 45 otters (*Lontra canadensis*), 40 badgers (*Taxidea taxus*), 31 wolves (*Canis lupus*), 29 ringtails (*Bassariscus astutus*), 23 domestic ferrets (*Mustela putoris*), 12 coatis (*Nasua narica*), 11 mink (*Mustela vison*), 11 weasels (*Mustella* spp.), 8 fisher (*Martes pennanti*), 4 puma (*Puma concolor*), 4 bears (*Ursus* spp.), and 1 ocelot (*Leopardus pardalis*) tested positive for the rabies virus (Krebs et al., 2003). Rabies among some other carnivorous mammals has been regarded as a threat to the survival of certain rare or endangered species (MacDonald, 1993). An epizootic of rabies in Alaska was credited with decimating an entire pack of wolves in one instance (Chapman 1978), and on several occasions a substantial number of wolves wearing radio-collars as part of long-term ecological studies have died of rabies (Ritter 1991; Theberge et al., 1994; Kat et al., 1995). Therefore, control of rabies in raccoons, foxes, and coyotes may have a potential indirect beneficial effect of preventing unnecessary die-offs of T&E and other sensitive species from rabies.

As discussed, the distribution of ORV baits will not have an adverse effect on these species. It is expected that the vaccination of animals, the primary target species, and potentially the T&E species, could have a beneficial effect on T&E mammals, especially the carnivores and ungulates that are more apt to be in contact with infected animals, but not be killed by them. Mammals succumb to the rabies virus if exposed, unless they are vaccinated. The chance of a T&E mammal species being exposed in ORV treatment areas is much less. No federally listed species occurring in West Virginia would be expected to consume or contact the AdRG1.3 vaccine; therefore the ORV field trials will have no effect on any listed species (see Appendix C for species list). Additionally, APHIS-WS has obtained and reviewed the list of West Virginia State listed T&E species and Special Concern species, as well as the USDA-Forest Service Regional Forester Sensitive Species (see Appendices D and E for species information) and has determined, for the reasons described above, that the proposed program will not adversely affect any of the species listed in West Virginia.

<u>Effects of capture/removal methods (used in monitoring and surveillance activities) on nontarget species, including threatened or endangered species</u>

The methods proposed for use in AdRG1.3 field trial monitoring and surveillance areas would have no significant adverse effects on nontarget species. Nontarget animals captured in cage traps would normally be released unharmed unless the animal appeared injured or sick. Therefore, monitoring and surveillance should have no effect on nontarget species populations. Analysis of nontarget take resulting from other APHIS-WS ORV programs can be found in USDA 2010.

T&E Species Effects

Special efforts are made to avoid jeopardizing T&E species through biological evaluations of the potential effects and the establishment of special restrictions or mitigation measures. Mitigation measures and SOPs to avoid T&E effects are described in section 3.3 of this EA.

APHIS-WS reviewed lists of federal and state T& E species (Appendices C and D), as well as Regional Forester Sensitive Species (Appendix E) to determine if any species might be affected. ORV programs or the methods used in capture/removal of target species in monitoring activities or contingency plan implementation would have no effect on any listed fish, invertebrate, or plant species, as described below.

***Federally Listed T&E Species* (USFWS 2011):**

The current list of species designated as threatened and endangered in West Virginia as determined by the USFWS was obtained and reviewed during the development of this EA. Consultation with the USFWS under Section 7 of the ESA concerning potential impacts of APHIS WS' programmatic activities on T&E species was conducted as part of the development of APHIS WS' programmatic FEIS (USDA 1997). Methods that will be used in this proposed action were considered as a part of this consultation. WS obtained a BO from the USFWS addressing WS' programmatic activities. For full context of the BO, see Appendix F of WS' programmatic FEIS (USDA 1997).

Striped skunks and raccoons are the primary targeted species in surveillance and monitoring with other species such as red foxes, gray foxes, coyotes, spotted skunks, bobcats, groundhogs, feral dogs, and feral cats being secondarily targeted to determine the prevalence of rabies in these species and the effectiveness of the ORV Program. Additionally, several small mammal species may targets for monitoring and surveillance including Eastern chipmunk (*Tamias* striatus), Eastern gray squirrel (*Sciurus carolinensis*), red squirrel (*Tamiasciurus hudsonicus*), Southern flying squirrel (*Galucomys volans*), short-tailed shrew (*Blarina brevicauda*), deer mouse (*Peromyscus maniculatus*), white-footed mouse (Peromyscus leucopus), Southern red-backed vole (*Clethrionomys gapperi*), meadow vole (*Microtus pennsylvanicus*), and pine vole (*Microtus pinetorum*). Cage traps are used to capture/take these species and have the potential to take T&E species. Species on the federal T&E list that could be taken under the proposed action with cage traps are mammals, birds, reptiles, and amphibians, mostly similar in size and weight to the target species. These are discussed below. The use of firearms is highly target-specific and would have no effect on T&E species.

After review of program activities and methods used during monitoring and surveillance activities associated with the proposed ORV field trials, APHIS WS has determined that the proposed field trial activities in West Virginia would not adversely affect the gray bat (*Myotis grisescens*), Indiana bat (*Myotis sodalist*), Virginia big-eared bat (*Plecotus townsendii virginianus*), eastern cougar (*felis concolor cougar*), pink mucket (*Lampsilis abrupt*), tubercled blossom (*Epioblasma torulosa torulosa*), running buffalo clover (*Trifolium stoloniferum*), and small whorled pogonia (*Isotria medeoloides*). This determination is based on the conclusions made by the USFWS during the 1992 consultation on APHIS WS' programmatic activities and subsequent BO (USDA 1997). The gray wolf (*Canus lupus*) was addressed in the 1992 BO issued by the USFWS and is listed in West Virginia but is not currently known

to occur in the State. APHIS WS would abide by all reasonable and prudent measures identified in the BO for the gray wolf when conducting ORV activities.

West Virginia Northern Flying Squirrel (*Glaucomys sabrinus fuscus*). The West Virginia northern flying squirrel was recently re-listed on March 25, 2011. This squirrel could potentially be taken in cage traps, mostly being attracted to the different baits used or from curiosity. If APHIS-WS needed to conduct surveillance in an area where this species was present, APHIS-WS Specialists would implement measures to minimize the potential for take. Cage traps would be baited with unattractive baits. If a squirrel was inadvertently captured in a cage trap, it would be immediately released unharmed to avoid lethal take and reported to the appropriate wildlife agency. The USFWS issued a BO (USDA 1997, Appendix F) stating that the above mentioned species is not likely to be adversely affected by the APHIS-WS program. Additionally, ORV monitoring and surveillance activities would not occur in northern flying squirrel suitable or occupied habitat, typically high elevation hardwood forests, therefore WS will have no effect on this species.

Additional T&E species in West Virginia include the clubshell (*Pleurobema clava*), fanshell (*Cyprogenia stegaria*), northern riffleshell (*Eppioblasma torulosa rangiana*), flat-spired three-toothed snail (*Triodopsis platysayoides*), James spinymussel (*Pleurobema collina*), American burying beetle (*Nicrophorus americanus*), pink ring (*Obovaria retusa*), Madison Cave isopod (*Antrolana lira*), Northeastern bulrush (*Scripus ancistrochaetus*), harperella (*Ptilimnium nodosum*), shale barren rock-cress (*Arabis serotina*), and Virginia spirea (*Spiraea virginiana*). After review of the proposed activities under this alternative, APHIS WS has determined that the APHIS WS' ORV field trial activities in West Virginia would have no effect on these T&E species and critical habitat not included in the 1992 BO as none of these have the potential to be captured in cage traps used during monitoring and surveillance activities, nor will there be any ground disturbance which could affect plant species.

Currently no federally listed T&E birds or reptiles occur in West Virginia. APHIS-WS has taken a few larger amphibians, mainly bullfrogs. It is possible that APHIS –WS could take toads and larger frogs as nontarget species during ORV operations in cage traps. Only 1 amphibian, the Cheat Mountain salamander (*Plethodon nettinig*), is federally listed as T&E species. APHIS-WS believes that it will have no effect on this species, because no cheat mountain salamanders are known or believed to occur within the field trial area (USFWS 2011).

Recently, APHIS-WS initiated formal consultation with the USFWS for those species where a "may affect" situation exists within the national program. Any new findings that result from this most recent consultation will supersede previous findings. Additionally, for those findings which are more stringent, all reasonable and prudent alternatives and measures required by the USFWS will be incorporated into the proposed program.

As discussed, the distribution of ORV baits will not have an adverse effect on amphibians, even though some could potentially be eaten by a few species. Rabies is a mammalian disease. Amphibians cannot be infected with rabies nor can they be vaccinated against the disease, even if they consume ORV baits.

***State Listed Species* (WVDNR 2010c) *and Regional Forester Sensitive Species* (USDA 2011):**

APHIS-WS is also concerned with the take of state-listed sensitive species (includes only species in the

S1 (critically imperiled), S2 (imperiled), and S3 (vulnerable)) and Regional Forester Sensitive Species (RFSS) (Appendices D and E). On average, APHIS-WS lethally takes approximately 13 nontarget animals during all ORV program monitoring and surveillance activities annually (USDA 2010). This includes take from 18 states that participate in ORV monitoring and surveillance. It is therefore expected that the take resulting from the proposed field trials in WV would be much less. The majority of nontarget captures will be released at the site of capture unharmed. Additionally APHIS-WS will consult with WVDNR and the USFS and provide them information on any listed species taken during ORV monitoring and surveillance, but believes that the proposed program is not likely to adversely impact any state-listed sensitive species or RFSS. As discussed above for federal T&E species impacts, APHIS-WS believes that the consumption of ORV baits would have no effect on state listed species or RFSS, but the overall effect of the program would be beneficial if the prevalence of rabies is reduced.

The majority of the state listed sensitive species and RFSS (Appendices D and E) will be unaffected by the APHIS-WS Program. This includes species too small to be held by cage traps including the southern bog lemming (*Synaptomys cooperi*), golden mouse (*Ochrotomys nuttalli*), and eastern harvest mouse (*Reithrodontomys humulis*). Conversely, three species, in addition to the West Virginia northern flying squirrel discussed above, have the potential to be taken during ORV monitoring and surveillance activities and are discussed below.

Eastern Spotted Skunk *(Spilogale putoris)*. This species is state-listed as a sensitive species in Alabama, Maryland, and West Virginia. This species is taken as a target or nontarget infrequently (2 from 2001-2007) due to its rarity in most areas where APHIS-WS has been conducting ORV surveillance. However, it is attracted to baits often used in cage traps. APHIS-WS personnel will check cage traps frequently and keep them in areas where animals captured are not exposed to the elements. This species, along with the other skunks, frequently contract rabies and, therefore, are monitored and taken as targets. However, APHIS-WS will not have a negative effect on their populations in West Virginia. Also, an indirect beneficial effect would be a reduced risk of the species suffering further declines because of a rabies epizootic.

Allegheny Woodrat (*Neotoma magister*). This rat is large enough to be captured in cage traps, however they have only a slight chance of being taken even in cage traps because they could exit the traps through gaps in the door or wire-mesh. The primary concern with this species is exposure to the elements such as excessive heat/sun as this could result in a lethal take. However, APHIS-WS would check traps frequently in this species' occupied habitat so that any individuals captured could be release unharmed.

Appalachian Cottontail (*Sylvilagus obscurus*). Cottontails would not likely be attracted to or consume ORV baits. Although unlikely, this species could conceivably be captured in cage traps. If cage traps are used in their ranges, they will be located such to minimize exposure and checked frequently enough to release them alive. Therefore, WS will have minimal potential to take these species and will have virtually no impacts on their populations.

4.1.3 Potential for Adverse Effects on People, Pets, and Livestock that are Exposed to or Consume the Vaccine Laden Baits

4.1.3.1 Alternative 1: No Action

Potential to Cause Rabies in Humans

The no action alternative would likely result in greater risk of human exposure to rabies than the proposed action. Without field trials to address the efficacy of new vaccines, current vaccines may not be successful in stopping or preventing the spread of the raccoon, grey fox, and coyote rabies virus variants. As discussed in Section 1.1.3, the current vaccines available do not produce sufficient levels of population immunity in all species. Therefore, an absence of new field trials could be expected to result in increased risk of human rabies cases because of expanding epizootics.

Potential for Adverse Effects on Pet Dogs or Other Domestic Animals that Might Consume the Baits

Under the no action alternative, the potential for APHIS-WS activities to result in adverse impacts on domestic pets or other domestic animals would be zero. However, in the absence of field trials to determine new efficacious vaccines, failure to stop or prevent the spread of rabies would result in adverse effects on domestic animals by increasing their likelihood of exposure to rabid wild animals.

4.1.3.2 Alternative 2: Proposed Action (the preferred alternative)

Potential to Cause Rabies in Humans

The nature of the recombinant virus used as the AdRG1.3 vaccine is such that it cannot cause rabies. This is because the AdRG1.3 vaccine only carries the gene for producing the outer coating of the rabies virus (i.e., rabies virus *glycoprotein*) and not those portions of the virus that could result in replication of the rabies virus which would have to happen for the disease to occur. Implementation of ORV programs would reduce the risk of humans contracting rabies by reducing the chance of encountering rabid animals that have been infected by rabid raccoons, striped skunks, foxes, or coyotes.

Potential for the Human Adenovirus Type 5 (Ad5) to Cause Disease in Humans

The AdRG1.3 vaccine employs a human adenovirus type 5 vector into which has been inserted a DNA copy of the ERA® virus glycoprotein gene. Adenoviruses belonging to the family *Adneviridae* are nonenveloped DNA viruses, and are commonly found in mammals, including humans (Randrianarison-Jewtoukoff and Perricaudet 1995). This live human adenovirus-vectored rabies vaccine virus could cause infection in humans accidentally breaking open the bait packages, if the person is not already immune (CFIA 2008, 2010). In man, adenovirus infections are ubiquitous and are normally without significant or severe clinical symptoms. Usually, only the appearance of specific antibodies and seroconversion are indicative of an infection (Horowitz 1990 *in* Ranrianarison-Jewtoukoff and Perricaudet 1995). Nevertheless, some adenovirus serotypes can be the causative agents of mild or severe respiratory disease (Ranrianarison-Jewtoukoff and Perricaudet 1995). Specifically, Ad5 is a virus normally associated with mild respiratory symptoms endemic among preschool children (Orstavik and Wiger 1989 *in* Knowles et al. 2009). Vectors based on Ad5 have been extensively investigated for use in human gene therapy

(Douglas 2007 *in* Knowles et al 2009) and thus, from a human health perspective, Ad5 is relatively innocuous although a single death has been documented in a clinical trial (Raper et al. 2003 *in* Knowles et al. 2009).

Adenovirses are distributed worldwide and infections with human adenovirus type 5 do not result in serious disease (Rowe et al. 1995, Andiman and Miller 1982, Charlton et al. 1992, Russell 1998 *in* Rosatte et al. 2009). Ad5 is endemic in those parts of the world that have been studied and is associated with mild respiratory symptoms. By age one, 80% of children in the New Orleans area had acquired antibodies to adenovirus, with the percentage slightly lower in New York and Seattle. Antibodies against Ad5 was the third most common antibody detected (Foy 1997). Pre-existing antibodies to Ad5 or previous exposure to Ad5 will enable a rapid response to any subsequent exposure.

In studies conducted on sera collected from adults, virus neutralizing antibody to Ad5 was detected in 37% to 85% of the samples tested (Nwanegbo et al. 2004). This study reported 37% of sampled adults in the U.S. had neutralizing antibody to Ad5 virus. The percentage in the samples tested from Gambia and South Africa was much higher with approximately 85% to 80% detection rates respectively. The 37% seropositivity in the U.S. samples is lower than expected based on the information presented by Evans and Kaslow (1997). Other studies conducted in Europe indicated that 55% to 70% of samples from children >12 years old were seropositive for Ad5 antibody (Potter and Shedden 1963 and D'Aambrosio et. al. 1982). A study conducted in 2005 reported Ad5 seropositivity rates of 50% in the U.S., 82% in Haiti, 93% in Botswana, 93% in Zambia, and 88% in South Africa (Sumida et al. 2005). Most recently Cheng et al. (2005) reported the rate of Ad5 antibody occurrence in their North American test subjects as 37.5%. Results from a previous study confirmed 55% of subjects had Ad5 antibody indicative of previous natural Ad5 infection. It is generally accepted that the majority of adults in North America will have been exposed to Ad5 during childhood.

Human adenoviruses are currently being utilized in vaccine development due to their genetic stability and ability to be grown to high titers in a variety of cell types (Prevec et al. 1990 *in* Rosatte et al. 2009), and they are being considered to serve as vectors for human vaccination and gene therapy (Bonnekoh et al. 1998, Molinier-Frenkel et al. 2000, Flotte 2004 *in* Rosatte et al. 2009). The prevalence of Ad5 antibody in the population has been suggested as one of the factors in the lack of efficacy of an Ad5 based human immunodeficiency virus (HIV) vaccine in clinical studies and has stimulated research into the use of less common adenovirus serotypes as a more suitable vector for use in human vaccine and gene therapy (A. Beresford, Artemis Technologies, Inc., pers.comm. 2011).

While infection of people with human adenovirus type 5, more frequently children under five years old, is not generally associated with serious illness, it is noted, that adenoviruses are among the many pathogens and opportunistic agents that cause serious infection in congenitally immunocompromised persons, in patients undergoing immunosuppressive treatment for organ and tissue transplants and for cancers, and in HIV infected patients. In addition, adenovirus infection is observed to be more severe in children than adults. Therefore the AdRG1.3 could present health hazards to humans, especially children or adults with immunocomprised status, given that AdRG1.3 is a live virus with replication potential (CFIA 2008, 2010). Although infection with Ad5 is more frequent than other adenovirus types in children up to 5 years of age, it is not generally associated with serious illness. In most cases, infection is limited to the upper respiratory tract with or without fever (Artemis 2010). Retrospective sampling studies of antibody

titers to Ad5 show that, depending on the geographic region, from 50% to almost 100% of the population over the age of 5 years have been infected with Ad5 (Fox et al. 1969, van der Veen 1963, Vihma 1969 *in* Artemis 2010). The widespread immunity in humans over the age of 5 for related human type 5 adenoviruses would make person-to-person spread of infection unlikely, even if significant contact with a bait's blister pack contents was to occur (CFIA 2008, 2010).

Human adenovirus 5 is widespread in the human population (Foy and Grayson 1976 in Charlton et al. 1992), suggesting that few, if any, unforeseen consequences of human exposures to AdRG1 would occur (Charlton et al. 1992). Rosatte et al. (2009) discussed that there are no perceived environmental or public health impacts of distributing ONRAB® in Ontario, or elsewhere, because the vaccine has been extensively safety tested and it has been shown that there are very few human or companion animal contacts with the vaccine and no adverse reactions noted. Furthermore, adenovirus replication is highly species specific to the extent that developing an animal model of human infection has proven difficult. These properties suggest the Ad5 should be a safe viral vector for applications where widespread environmental release is conducted but experimental data are required to substantiate this position (Knowles et al. 2009).

Out of approximately 89 million V-RG baits disbursed since APHIS-WS ORV program inception in 1995, only 1,341 people reported contacting or potentially contacting a bait (i.e., picking up bait, finding a bait in yard, or removing bait or sachet from pet's mouth, feces, or vomit - any type of contact with a bait is also defined throughout the document as an "exposure"). This equates to one human exposure per 66,359 baits distributed (0.0015% contact cases) (USDA 2009). In addition, exposure cases were generally insignificant as most involved finding an intact bait. Very few cases involved touching a broken bait, sachet, or liquid vaccine. Furthermore, of the 0.0015% of contact cases reported since APHIS-WS ORV program inception in 1995, only two known adverse reactions have occurred (USDA 2010, 2009; CDC 2009).

Recent V-RG bait exposure information collected during an ORV project completed in western Pennsylvania (August-September, 2003) revealed that out of 1,710,399 baits distributed over approximately 25,189 km^2, 190 humans or pets were exposed to a bait. This equates to one exposure per 9,002 baits disbursed or 0.011% of distributed baits being found by pets or people. In at least 69 of the 190 potential contact cases, the household pet (dog or cat) found the bait; however, the bait and sachet or sachet alone was normally still intact (at least 91% of cases). Of the six cases in which the sachet was ruptured, no reports were submitted regarding the development of an adverse reaction (i.e., lesions) (USDA 2004c). This ORV project involved hand baiting in several urban areas such as Allegheny County, and aerial baiting of the rural areas. Therefore, pets and other domestic animals were more likely to find the baits and are the primary source for potential and human exposure to ORV baits. Most ORV baiting locations occur over rural or undeveloped lands where human exposure cases can be expected to be much lower.

Hazards to public safety are not expected. The above information shows there is a minute potential for unusual circumstances to result in short-term adverse health effects from exposure to the human adenovirus type 5 in the AdRG1.3 vaccine. However, the overall risk of such effects appears to be minimal based on the extremely low rate of reported occurrences in ORV programs.

Potential to Cause Cancer (Oncogenicity)

Adenoviruses are divided into three different subgroups based on their oncogenic potential. Subgroup A (adenovirus types 12, 18, and 31) is highly oncogenic, subgroup B (types 3, 3, and 16) are weakly oncogenic, and subgroup C (types 2, 5, and 6) are non-oncogenic (Fujinaga et al. 1979). The adenovirus used in the production of AdRG1.3 is type 5.

Adenoviruses, like many DNA viruses, are known as tumor viruses because of their ability to induce tumors in experimental animals or transform cells in culture (Graham 1984 *in* Artemis 2010). There are a number of reasons for believing that adenoviruses are unlikely to be oncogenic in humans. First, no naturally occurring tumors in any animal have been shown to be caused by members of the adenovirus family in spite of the fact that adenoviruses are ubiquitous. In particular, an extensive survey of human tumors failed to find any evidence for virus specific sequences related to any of the three major groups of human adenoviruses (Green et al. 1979 *in* Artemis 2010). Second, even under the best experimental conditions, human adenoviruses are not highly effective at inducing tumors or transforming cells in culture. Third, in cell culture assays, adenoviruses generally replicate in, and lyse, cells from their normal host. Although human cells transformed by human adenoviruses exist, they have been generated only with considerable difficulty by DNA-mediated transformation techniques, using noninfectious viral DNA fragments (Graham et al. 1977 and Byrd et al. 1982 *in* Artemis 2010).

Some Ad viruses (Ad 4, 7, 11, 21, 37) have a potential to be oncogenic or pathogenic, especially in infants and immunodeficient subjects. Because some Ad (e.g. Ad 12) can induce tumors in experimental animals, a search for human cancers induced by Ad was conducted. No convincing evidence of Ad involvement in human tumors has ever been reported (Randrianarison-Jeewtoukoff and Perricaudet (1995).

Potential for Adverse Effects on Pet Dogs or Other Domestic Animals that Might Consume the Baits

Knowles at al. (2009) discussed results from AdRG1.3 in a variety of target and nontarget species. Several nontarget species included the following domestic livestock and companion animals: cows, horses, pigs, sheep, chickens, dogs, and cats. Although, histopathological findings included conditions related primarily to pulmonary congestion in 11 of the test subjects, no such results were found in the livestock and companion animals tested. This study concluded that upon examination of any gross pathological consequences of AdRG1.3, the possible long-term consequences of virus in these species, and the possibility of environmental contamination as a result of vaccine excretion, all data indicate very low recovery of AdRG1.3 from tissues, feces, and oral samples of animals given a relatively high dose of vaccine.

Overdosage of AdRG1.3 in amounts four to five times greater than the dose found in the vaccine baits resulted in no adverse effects in experiments involving skunks and raccoons (Artemis 2010). Therefore, even if domestic animals or other nontarget wildlife receive multiple doses of vaccine by consuming multiple baits, no adverse effects would be expected to occur.

In APHIS-WS' previously established ORV programs involving the V-RG vaccine, incidents involving dogs or cats finding and ingesting baits have been relatively limited. USDA (2009) documented that of

the 89 million baits distributed during the APHIS-WS program between 1995 and 2007 only 1,068 instances have been reported where a pet or other domestic animal had contact with a bait. This equates to 1 domestic exposure per 83,321 baits disbursed or 0.001 % contact cases. In addition, USDA (2009) documented that 203 incidents were reported in which pets came into contact with a bait in 2007; however, there were no reports of pets or other domestic animals experiencing any type of adverse reaction, other than 16 dogs who experienced vomiting or upset stomachs after ingesting a number of baits. The dogs involved in the adverse reactions have reportedly not experienced any substantive or long term adverse effects. Domestic animals that bite into and ingest a bait of either V-RG or AdRG1.3 are most likely to be immunized against rabies or receive a boost from a previous vaccination. USDA (2009) also documented the number of baits distributed in those states conducting ORV programs and the number of people who reported contact or potential contact with a bait by their pet or other domestic animal (i.e., carrying bait in mouth, chewing bait, vomiting sachet). In 2007, 203 incidents were reported in which pets came into contact with a bait. The number of documented exposures equates to 0.002% of the 12.4 million baits distributed in 2007 or one domestic animal exposure per 61,569 baits distributed (USDA 2009).

Rosatte et al. (2009) documented that after the 2007 AdRG1.3 baiting program in Ontario, one person contacted a bait and one dog chewed a bait. No adverse reactions were noted in either case.

4.1.4 Potential for the Recombined AdRG1.3 Virus to "Revert to Virulence" or Recombine with Other Viruses and Result in a Virus that Could Cause Disease in Humans or Animals

4.1.4.1 Alternative 1: No Action

Under the no action alternative AdRG1.3 ORV baits would not be distributed, therefore the potential of the vaccine to revert to virulence or recombine would not be a concern here.

4.1.4.2 Alternative 2: Proposed Action (the preferred alternative)

Potential for the Recombined V-RG Virus to "Revert to Virulence" and Result in a Virus that could Cause Disease in Humans or Animals

The concern here is whether the AdRG1.3 recombinant virus is genetically stable so that it would not become virulent (i.e., capable of causing disease) after it replicates (or reproduces) in animals that eat ORV baits containing the AdRG1.3 vaccine and perhaps be transmitted to other animals.

An important concern from the standpoint of safety is that of genetic stability, since predictions of the vaccine behavior rely heavily on the knowledge of the genetic makeup of the recombinant. In order for a recombinant vaccine to be useful it should not undergo substantive mutation during production of the vaccine by passage or upon administration to the target species (Lutze-Wallace et al. 1995a). Lutze-Wallace et al. (1995a) examined AdRG1 (the precursor to AdRG1.3) for genetic stability upon 20

passages[4] in a permissive[5] human cell line. The results from this study indicated that the product obtained after 20 passages expressed authentic rabies glycoprotein. Since there is little evidence in the literature for the replication of Ad5 in animal species, the primary concern with AdRG1.3 is the maintenance of the rabies glycoprotein gene (Knowles et al. 2009). The data obtained from the Lutze-Wallace et al. study suggests that the AdRG1 recombinant live viral vaccine underwent no major mutations and indicate that the genetically engineered vaccine virus is highly genetically stable.

In another study, Lutze-Wallace et al. (1995b) examined the genetic stability of AdRG1 upon passage through orally vaccinated skunks. Vaccine virus, recovered from vaccinated skunks, was propagated on permissive cells. Passage of oral swab, rectal swab, and fecal suspensions produced 111 samples which were positive for AdRG1. Of these 111 isolates examined, three mutants comprising two forms of the vaccine virus were found, an insertion mutant (one case) and a deletion mutant (two cases). All three mutants were isolated from animals receiving the same lot of vaccine. The exact origin of these two mutant forms of the vaccine virus AdRG1 is not known. It may be possible that these mutants were present in the vaccine lot administered to the animals; however passages of 99 isolated plaques of the vaccine virus lot in question yielded no detectable mutants. Mutants were also not detected when vaccine virus was diluted to 20 plaque forming units (pfu) (150 samples) and subsequently passaged on permissive cells. Another possible explanation for the appearance of these mutants is through limited replication of the virus in the recipient animal (Lutze-Wallace et al. 1995b)

Most recently, Knowles et al. (2009b) conducted both *in vitro*[6] and *in vivo*[7] passages with AdRG1.3. The results from this study indicated that the titer of the AdRG1.3 virus, harvested from 20 *in vitro* passages, was maintained at a fairly constant level. From the 20th passage, 67 virus clones were recovered for molecular characterization and in all cases the size of the resulting amplicon[8] matched what was expected, indicating no substantial alteration in sequence over this region. The *in vitro* genetic stability of the AdRG1.3 construct was established by demonstrating that 67 independent viral clones, recovered after 20 passages in cell culture, exhibited no sequence variation over the transgene region. This is in accord with the high genetic stability reported previously for the AdRG1 recombinant (Lutze-Wallace et al. 1995 a). If mutations within the transgene region had emerged in even a small proportion of viruses of the stock population, the approach used by Knowles et al. (2009b) would have allowed for their identification. For the *in vivo* passages a total of five sequential passages were performed using 5 groups of 5 cotton rats. During the *in vivo* passages, none of the animals exhibited any clinical symptoms throughout the course of the experiment. For each series of cotton rats, lung homogenates yielded virus titers between 10^4 and

[4] This means the AdRG1 was inoculated into one group of cells from which material containing the virus was obtained later and injected into a second group of cells, and then material obtained from the second group was injected into a third group, etc., until twenty such passages had been conducted.

[5] A permissive cell is a cell that supports replication of a virus.
[6] Meaning outside of a living body.
[7] Meaning within a living body.
[8] A piece of DNA formed as the product of natural or artificial amplification events.

10^5 $TCID_{50}$/ml after the first and second passages. Following the third passage (in four of the series) and the second passage (in one series), virus titers dropped to levels insufficient for continued passaging.

The experiments demonstrated that the ability of the AdRG1.3 virus to cause disease does not increase by repeated animal passage, thus "reversion to virulence" is unlikely. Further alleviating the concern about this issue is the evidence that virus does not transmit readily to other animals from animals that have consumed ORV baits as evidenced by Charelton et al. (1992). This noted that foxes that had been vaccinated with AdRG1 shed adenovirus from oral fluids and feces for a very brief period (2 days) after vaccination and most skunks only excreted virus 1-3 days post-vaccination; however, 1 out of 8 skunks may have virus in oral fluids at 10 days post-vaccination (Charelton et al. 1992). The short period of fecal excretion after oral vaccination suggests that there is little or no replication of AdRG1 in the intestine, and that there would be minimal or no interanimal transmission when AdRg1 is used in the field.

Potential for the AdRG1.3 Vaccine to Recombine with Other Viruses in the Wild to Form New Viruses that could Cause Disease in Humans or Animals

The concern here is whether the AdRG1.3 vaccine in the ORV baits might encounter other viruses in animals, exchange genetic material with them during replication, and result in new viruses that could cause serious diseases in humans or animals.

According to Artemis (2010), regarding the potential for AdRG1.3 to recombine with naturally occurring adenoviruses, the end product of AdRG1.3 recombining with wild human adenovirus type 5 would be human adenovirus type 5. Thus this vaccine is extremely safe in terms of recombination potential.

The potential for *in vivo* recombination of the adenovirus-vectored recombinant vaccine with field and other viruses is unknown, but is considered small (CFIA 2008, 2010). For intergenic recombination to occur, two related viruses would have to infect the same cell. The likelihood of co-infection of individual cells would be predicted to be a rare event because the proposed vaccine has a single viral component and the vaccine virus does not lead to infection in the target species or other wildlife species that are likely to consume the baits. Therefore, occurrence of recombination *in vivo* is not expected (CFIA 2008, 2010).

A concern regarding the release of recombinant vaccines is their ability to remain viable in the environment for prolonged periods; however, a recombinant vaccine must also have a suitable shelf-life and retain its infectivity long enough in the field to successfully immunize target species (Kalicharran et al. 1992). Persistence and stability of the AdRG1.3 virus outside of an organism is highly dependent on ambient temperatures and local environmental conditions. Kalicharran et al. found that at ambient temperatures up to 24-25°C (75-77°F), the half-life of Ad5RG1 (the predecessor of AdRG1.3) would be several weeks. Additionally, several feces samples from experimentally-vaccinated foxes and skunks were screened but none had a reasonably high titer of infectious virus. Of note, bacteria and fungi were removed from the tested feces samples by filtration, whereas whole feces would contain large numbers of viable microorganisms which could inactivate the viruses contained therein (Kalicharran et al. 1992). Once a virus is outside of the blister pack and exposed to microbiological and/or enzymatic activity in the environment, it will degrade more rapidly than it would inside the protective blister pack (A. Beresford, Artemis Technologies Inc., 2011, pers. comm.).

4.1.5 Potential for Aerially Dropped Baits to Strike and Injure People or Domestic Animals

4.1.5.1 Alternative 1: No Action

Under the no action alternative, the potential for APHIS-WS actions to result in this risk would be zero.

4.1.5.2 Alternative 2: Proposed Action (the preferred alternative)

ORV baits would be distributed from aircraft at an average density of 75 baits per km^2 (194 baits per mi^2). This density is sparse enough to predict that the chance of a person being struck and harmed by a falling bait is extremely remote. For example, if 100 persons were standing outdoors in a square mile of area in which ORV baits were being dropped, and each person occupies about 2 square feet of space at the time that baits were dropped, the chance of being struck would be 1 in 139,000 (200 ft^2 total space occupied by persons divided by 27.8 million ft^2 per mi^2). The negligible risk of being struck is further supported by the fact that out of more than 89 million baits distributed in the U.S. by APHIS-WS during other ORV programs between 1995 and 2007, only 11 incidents have been reported in which a person claimed to have been struck by a falling bait (0.00001% chance of being struck by a bait or 1 strike per 8.1 million baits dropped) (USDA 2009). None of the incidents repored since APHIS-WS' national ORV program inception have resulted in any injury or harm to the individuals involved. Eight of these incidents occurred in Pennsylvania, Texas, Ohio, and Ontario and did not result in any significant injury or harm to the individuals involved (G. Moore, TX Dept. of Health, pers. comm. 2001; R. Hale, OH Dept. of Health, pers. comm. 2001; C. MacInnes, Ontario Ministry of Natural Resources, pers. comm. 2001 all as cited in USDA 2001a).

Of the 12.4 million V-RG baits that were distributed by APHIS-WS in other ORV programs in 2007, only one report was received in which a person claimed to have been struck by a falling bait. No reports of injury were received during the 2007 APHIS-WS ORV program (USDA 2009). In 2007, no cases were documented involving falling baits striking or injuring domestic animals. Additionally, in 2007, no reports were received regarding baits striking property (USDA 2009). The potential for falling baits to strike or injure people or domestic animals continues to be insignificant. Impacts of the program on this issue are expected to remain negligible. The potential for baits to strike people or animals is further mitigated by the fact that bait disbursal crews avoid dropping baits into cities, towns, and other areas with human dwellings, or if humans are observed below. Hand placement or dropping of baits from slower moving helicopters to allow for more precise control over the areas on which the baits are dropped would primarily be used in urban parks or suburban situations, which would further reduce the risk of being struck.

4.1.6 Humaneness of Methods Used to Collect Wild Animal Specimens Critical for Timely Program Evaluation.

4.1.6.1 Alternative 1: No Action

Under the no action alternative, APHIS-WS would not assist in collecting wild animal specimens for ORV monitoring programs. Failure of a successful ORV field trial would likely result in an increased, but varying, proportion of the skunk and other wild mammal species populations succumbing to rabies

when exposed to the various specific strains. The symptoms of rabies include insomnia, anxiety, confusion, slight or partial paralysis, excitation, hallucinations, agitation, hypersalivation, difficulty swallowing, and hydrophobia (fear of water) (CDC 2001). Some persons might argue that dying from rabies, which can take several days once symptoms appear, results in more animal suffering than being captured or killed through monitoring and surveillance activities. In any event, it is almost certain that much larger numbers of animals would succumb to rabies without effective ORV programs than would experience stress and suffering from being captured or killed by monitoring activities. The number of animals dying of rabies could increase dramatically as epizootics of specific strains spread across larger areas of the U.S. With this in mind, it would appear that, on balance, the implementation of successful ORV programs that include animal collections for monitoring results in less animal suffering than taking no action.

4.1.6.2 Alternative 2: Proposed Action (the preferred alternative)

Some people would view methods employed to capture and/or kill skunks and other wild animals for monitoring and surveillance or local depopulation purposes as inhumane. Humaneness, as it relates to the killing or capturing of wildlife, is an important but complex concept that can be interpreted in a variety of ways. Humaneness is a person's perception of harm or pain inflicted on an animal, and people may perceive the humaneness of an action differently.

However, humaneness as it relates to the natural world through natural mortality versus man-induced mortality must be brought into perspective. DeVos and Smith (1995) explain the characteristics of natural mortality in wildlife populations. There seems to be an increasing public perception that, left alone by humans, animal populations will experience few premature deaths and live to an old age without harm, pain or suffering. It should be recognized that wildlife populations reproduce at far greater rates than would be necessary to replace deaths if all lived to old age. To counterbalance this high reproduction, it is natural for most individuals of most species to die young, often before reaching breeding age. Natural mortality in wildlife populations includes predation, malnutrition, disease, inclement weather, and accidents. These “natural” deaths are often greater in frequency than human-caused deaths through regulated hunting, trapping, and wildlife damage management operations. From the standpoint of the animal, these natural mortality factors also may cause more suffering by wildlife, as perceived by humans, than human-induced mortality. Under given habitat conditions, most wildlife populations fluctuate around a rather specific density, sometimes called the carrying capacity. Populations that overshoot this density via reproduction become very sensitive to various sources of mortality, and death rates increase. Conversely, as populations drop, mortality rates decline (DeVos and Smith 1995). Thus, human-induced mortality, which often involves much less suffering of individual animals, invariably lessens mortality from other sources. For example, it would seem that an animal taken in a leg-hold trap or by a snare, would certainly suffer less than if it died from rabies.

APHIS-WS has made modifications to management devices through research and development which have increased selectivity toward the species being targeted. Research is continuing with the goal of bringing new findings and products into practical use. Until such time as new findings and products are found to be practical, some animal suffering will occur during lethal collection of animal specimens if monitoring and program effectiveness objectives are to be met.

4.2 CUMULATIVE IMPACTS

No significant cumulative environmental impacts are expected from any alternative, with the possible exception of Alternative 1 - No Action, which might lead to increased human exposures and domestic and wild animal rabies cases across much of the U.S. Although some persons will likely remain opposed to the use of recombinant vaccines or the use of human adenovirus type 5 as a component of ORV, and some will remain opposed to the lethal removal of skunks and other wild animals for monitoring purposes, the analysis in this EA indicates that ORV use and such lethal removals will not result in significant risk of cumulative adverse impacts on the quality of the human environment.

4.3 SUMMARY OF IMPACTS OF ALTERNATIVES FOR EACH ISSUE

Table 4-1 presents a comparison of the alternatives and environmental consequences (impacts) on each of the issues identified for detailed analysis:

Table 4-1. Issues/Impacts/Alternatives - Comparison

	Alternative 1: No action	**Alternative 2: Proposed Action (conduct ONRAB® field trials)**
Potential for adverse effects on target wildlife species populations.		
• Effects of the AdRG1.3 vaccine on target species.	No risk.	No probable risk of adverse effects.
• Effects of monitoring and surveillance on target species.	No impact.	Very low impact.
• Effects of monitoring and surveillance on other species not targets for purposes of ORV, but which may be considered targets for monitoring and surveillance	No impact	Low impact
Potential for adverse effects on nontarget wildlife species, including threatened or endangered species.		
• Effects of the AdRG1.3 vaccine on nontarget wildlife including threatened and endangered species.	No effect.	No adverse effect on T&E species. No probable risk of adverse effects on other nontarget species.
• Effects of capture/removal methods (used in monitoring and surveillance activities) on nontarget species, including threatened and endangered species.	No effect.	No effect on T&E species; Very low risk of adverse effects on other nontarget species.
Potential for adverse effects on people, pets, and livestock that are exposed to or consume the vaccine laden baits.		
• Potential to cause rabies in humans.	No risk.	No probable risk.
• Potential for the human adenovirus type 5 (Ad5) to cause disease in humans.	No risk.	Possible but risk is low; risk of significant adverse effects on individuals that experience Ad5 infections is also low.
• Potential to cause cancer (oncogenicity)	No risk.	No probable risk.
• Potential for adverse effects on pet dogs or other domestic animals that might consume the bait.	No risk	Low risk; Possible benefit from improving immunity to rabies.
Potential for the recombined AdRG1.3 virus to “revert to virulence” or recombine with other viruses and result in a virus that could cause disease in humans or animals.		

• Potential for the recombined AdRG1.3 virus to "revert to virulence" and result in a virus that could cause disease in humans or animals	No risk.	Very low risk.
• Potential for the V-RG virus to recombine with other viruses in the wild to form new viruses that could cause disease	No risk.	Very low risk
Potential for aerially dropped baits to strike and injure people or domestic animals.	.No risk.	Low risk.
Humaneness of methods used to collect wild animal specimens critical for timely program evaluation.	Probably less impact on this issue than Alt. 2; more animals likely to die of rabies if lack of federal action reduces effectiveness of ORV programs.	Capture and handling of skunks would be viewed by some persons as inhumane, but many animals saved from suffering and death due to rabies.

APPENDIX A

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APPENDIX B

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APPENDIX C

SPECIES LISTED AS THREATENED OR ENDANGERED UNDER THE ENDANGERED SPECIES ACT

Information obtained from http://ecos.fws.gov/tess_public/StateListing.do?state=all on May 2011.

West Virginia – 22 listings

Animals – 17

Status	Listing
E	Bat, Indiana (*Myotis sodalist*)
E	Bat, gray (*Myotis grisescens*)
E	Bat, Virginia big-eared (*Plecotus townsendii virginianus*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Blossum, tubercled (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Epioblasma torulosa torulosa*)
E	Clubshell Entire Range; except where listed as Experimental Populations (*Pleurobema clava*)
E	Fanshell (*Cyprogenia stegaria*)
T	Isopod, Madison Cave (*Antrolana lira*)
E	Mucket, pink (pearlymussel) (*Lampsilis abrupt*)
E	Puma (=cougar) eastern (*Felis concolor cougar*)
E	Riffleshell, northern (*Epioblasma torulosa rangiana*)
E	Ring pink (mussel) (*Obovaria retusa*)
T	Salamander, Cheat Mountain (*Plethodon netting*)
T	Snail, flat-spired three-toothed (*Triodopsis platysayoides*)
E	Spinymussel, James (*Pleurobema collina*)
E	Squirrel, Virginia northern flying (*Glaucomys sabrinus fuscus*)
E	Wolf, gray Lower 48 States, except MN and where EXPN. Mexico (*Canus lupus*)

Plants – 6

Status	**Listing**
E	Bulrush, Northeastern (*Scriptus ancistrochaetus*)
E	Clover, running buffalo (*Trifolium stoloniferum*)
E	Harperella (*Ptilimnium nodosum*)
T	Pogonia, small whorled (*Isotria medeoloides*)
E	Rock-cress, shale barren (*Arabis serotina*)
T	Spirea, Virginia (*Spirea virginiana*)

E=Endangered, T=Threatened

APPENDIX D

SUMMARY OF SPECIES LISTED AS THREATENED, ENDANGERED, OR SPECIAL STATUS UNDER STATE LAW IN WEST VIRGINIA

Number of State Listed Species by Category
(Species for which concerns about ORV programs might be raised are identified and shown in bold)
Information obtained from http://www.wvdnr.gov/Wildlife/documents/Animals2007.pdf on February 2011.

State	Mammals	Birds	Reptiles	Amphibians	Fish	Invertebrates	Plants
West Virginia	6S1, 11S2, 5S3 **West Virginia northern flying squirrel, eastern spotted skunk, Appalachian cottontail**	28S1, 15S2, 15S3	3S1, 9S2, 6S3	6S1, 7S2, 5S3	26S1, 26S2, 20S3	173S1, 80S2, 26S3	267S1, 136S2, 27S3

WV designations for levels of concern: S1= 5 or fewer documented occurrences, S2= 6 to 20 documented occurrences, S3= 21 to 100 documented occurrences

State	T&E Protections under State Law
West Virginia	only lists federal T&E species as having protections; "Species of Concern" are listed, but have no legal status other than those that are already federally listed

APPENDIX E

REGIONAL FORESTER SENSITIVE SPECIES for the MONONGAHELA NATIONAL FOREST (USDA 2011)

Mammals

Virginia Northern Flying Squirrel	*Glaucomys sabrinus fuscus*
Southern Rock Vole	*Microtus chrotorrhinus carolinensis*
Eastern Small-footed Myotis	*Myotis leibii*
Little Brown Myotis	*Myotis lucifugus*
Northern Myotis	*Myotis septentrionalis*
Allegheny Woodrat	*Neotoma magister*
Tri-colored bat	*Perimyotis subflavus*
Long-tailed or Rock Shrew	*Sorex dispar*
Southern Water Shrew	*Sorex palustris punctulatus*
Eastern Spotted Skunk	*Spilogale putoris*
Southern Bog Lemming	*Synaptomys cooperi*

Birds

Northern Goshawk	*Accipiter gentilis*
Henslow's Sparrow	*Ammodramus henslowii*
Long-eared Owl	*Asio otus*
Olive-sided Flycatcher	*Contopus cooperi*
American Peregrine Falcon	*Flaco peregrines anatum*
Bald Eagle	*Haliaeetus leucocephalus*
Migrant Loggerhead Shrike	*Lanius ludovicianus migrans*
Red-headed Woodpecker	*Melanerpes erythrocephalus*
Vesper Sparrow	*Pooecetes gramineus*
Golden-winged Warbler	*Vermivora chrysoptera*

Reptiles

Wood Turtle	*Glyptemys insculpta*
Timber Rattlesnake	*Crotalus horridus*

Amphibians

Green Salamander	*Aneides aeneus*
Eastern Hellbender	*Cryptobrachus alleghaniensis*
Mud Salamander	*Pseudotriton montanus*

Arachnids

Dry Fork Valley Cave Pseudoscorpion	*Apochthonius paucispinosus*

Bivalves

Elktoe	*Alasmindonta marginata*
Green Floater	*Lasmigona subviridis*

Crustaceans

An Isopod	*Caecidotea cannula*
Holsiger's Cave Isopod	*Caecidotea holsingeri*
An Isopod	*Caecidotea simonini*
An Isopod	*Caecidotea sinuncus*
Elk River Crayfish	*Cambarus elkensis*
Greenbrier Cave Fish	*Cambarus nerterius*
Culver's Cave Amphipod	*Stygobromus culveri*
Greenbrier Cave Amphipod	*Stygobromus emarginatus*
Pocahontus Cave Amphipod	*Stygobromus nanus*
Minute Cave Amphipod	*Stygobromus parvus*

Gastropods

Organ Cavesnail	*Fontigens tartarea*

Insects

A Geometrid Moth	*Euchlaena milnei*
Rapids Clubtail	*Gomphus quadricolor*
Green-faced Clubtail	*Gomphus viridifrons*
A Noctuid Moth	*Hadena ectypa*
Cobweb Skipper	*Hesperia metea*
Bronze Copper	*Lycaena hyllus*
West Virginia White	*Pieris virginiensis*
A Cave Beetle	*Pseudanophthalmus fuscus*
Timber Ridge Cave Beetle	*Pseudanophthalmus hadenoecus*
A Cave Beetle	*Pseudanophthalmus hypertrichosis*
Dry Fork valley Cave Beetle	*Pseudanophthalmus montanus*
Gandy Creek Cave Springtail	*Pseudosinella certa*
A Springtail	*Pseudosinella gisini*
Southern Grizzled Skipper	*Pyrgus wyandot*

A Springtail	*Sinella agna*
Diana Fritillary	*Speyeria Diana*

Invert-Other

Hoffmaster's Cave Flatworm	*Macrocotyla hoffmasteri*
A Cave Obligate Planarian	*Phagocata angusta*
Greenbrier Valley Cave Millipede	*Pseudotremia fulgida*
Germany Valley Cave Millipede	*Pseudotremia lusciosa*
South Branch Valley Cave Millipede	*Pseudotremia princeps*
Culver's Planarium	*Sphalloplana culveri*
West Virginia Blind Cave Millipede	*Zygonopus krekeleri*
Grand Caverns Blind Cave Millipede	*Zygonopus weyeriensis*
Luray Caverns Blind Cave Millipede	*Zygonopus whitei*

APPENDIX F

ECOREGION DESIGNATIONS WITHIN WEST VIRGINIA

Ecoregions are ecosystems of regional extent as defined by Bailey (1995). An "X" means the state contains the ecosystem/ecoregion described in the key below. The reader is referred to Bailey (1995) for more detailed descriptions of each ecoregion and the climate, soils, vegetation, and animal life that occur there.

	212	M212	221	222	M221	231	232	234	255	313	M313	315	321	322	331	M331	411
West Virginia			X		X												

Key to Ecoregion Designations (adapted from descriptions by Bailey 1995):

Numbers in the 200 series are within the "Humid Temperate Domain":

M221 Central Appalachian Broadleaf Forest-Coniferous Forest-Meadow Province - low mountains at elevations ranging from 300 to 6,700 ft.; distinct summers and winters; average annual precipitation varies from 35 in. in the valleys to up to 80 in. on the highest peaks; native vegetation characterized by mixed oak-pine forest, dominated by the white and black oak groups at lower levels; northeastern hardwood forest at mid elevation levels; and spruce-fir forest and meadows on the highest peaks.

221 Eastern Broadleaf Forest (Oceanic) Province - diverse topography; elevations from 1,000 to 3,000 ft.; cold winters and warm summers; year-round precipitation averaging 35 to 60 in.; native vegetation characterized by temperate deciduous forest dominated by tall broadleaf trees that provide a dense, continuous canopy in summer and shed their leaves in winter; dominant deciduous species include American beech, yellow-poplar, basswoods, sugar maple, buckeye, red oak, white oak, hemlock; includes areas of pine-oak forest ("Pine Barrens").

APPENDIX G

STATUTES REGARDING RABIES MANAGEMENT IN WEST VIRGINIA

West Virginia Department of Agriculture (West Virginia Code of State Regulations: Section §19-9-2A). The West Virginia Department of Agriculture is charged with prevention, suppression, control, and eradication of any communicable disease of animals or poultry.

West Virginia Department of Health and Human Resources (West Virginia Code of State Regulations: Chapter 16, Section §16-2-11 (a)(1)(iii)). Chapter 16 of the West Virginia Department of Health and Human Resources authorizes the creation of a state public health system, including local boards of health, whose duties include "prevention and control of rabies."

West Virginia Division of Natural Resources (West Virginia Code of State Regulations: Section §20-2-1). The West Virginia Division of Natural Resources is charged with protecting the wildlife resources for the use and enjoyment of all the citizens in West Virginia.