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

ENVIRONMENTAL ASSESSMENT

ORAL VACCINATION TO CONTROL SPECIFIC RABIES VIRUS VARIANTS WITH HUMAN ADENOVIRUS TYPE 5 VECTOR IN MAINE, NEW HAMPSHIRE, NEW YORK, OHIO, TENNESSEE, TEXAS, VERMONT, VIRGINIA AND WEST VIRGINIA

In cooperation with:
United States Department of Agriculture
Forest Service

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Prepared by:
United States Department of Agriculture
Animal and Plant Health Inspection Service
Wildlife Services
4700 River Road, Unit 87
Riverdale, MD 20737-1234

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List of Acronyms

AdRG1.3	Human Adenovirus Type-5 Rabies Glycoprotein Recombinant Vaccine
AMS	Agricultural Marketing Service
AMDUCA	Animal Medical Drug Use Clarification Act
ANG	Air National Guard
APHIS	Animal and Plant Health Inspection Service
AVMA	American Veterinary Medical Association
BIA	Bureau of Indian Affairs
BLM	Bureau of Land Management
BO	Biological Opinion
CEQ	Council on Environmental Quality
CDC	Centers for Disease Control and Prevention
CFIA	Canadian Food Inspection Agency
CFR	Code of Federal Regulations
CVB	Center for Veterinary Biologics
CZMA	Coastal Zone Management Act
DEA	Drug Enforcement Agency
DOD	Department of Defense
EA	Environmental Assessment
EIS	Environmental Impact Statement
EO	Executive Order
EPA	Environmental Protection Agency
ERA	Evelyn Rockitinicki Abelseth
ESA	Endangered Species Act
FAR	Federal Aviation Regulation
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FONSI	Finding of no Significant Impact

FR	Federal Register
Had5	Human Adenovirus Type 5
MOU	Memorandum of Understanding
NASA	National Aeronautics and Space Administration
NEPA	National Environmental Policy Act
NFS	National Forest System
NHPA	National Historic Preservation Act
NRMP	National Rabies Management Program
NWRC	National Wildlife Research Center
NOP	National Organic Program
OMNR	Ontario Ministry of Natural Resources
ORV	Oral Rabies Vaccination
PEP	Post-Exposure Prophylaxis
RFSS	Regional Forester Sensitive Species
RVNA	Rabies Virus Neutralizing Antibodies
SCID	Severed Combined Immunodeficient
T&E	Threatened and Endangered
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
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

Chapter 1. Need for Action and Scope of Analysis

1.1 Introduction

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 2017, wildlife accounted for 91% of positive cases while domestic animals accounted for 9% (Ma et al. 2018). A total of 4,454 cases were reported in 2017; broken down to 1,275 raccoons (28.6%), 939 skunks (21.1%), 1,433 bats (32.2%), 314 foxes (7.0%), 276 cats (6.2%),94 other wildlife (2.1%)[1], 36 cattle (0.8%), 62 dogs (1.4%), 25 other domestic (0.6%)[2], and 2 humans (0.04%) (Ma et al. 2018). 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) proposed involvement in a program to distribute the experimental rabies vaccine, human adenovirus type 5-rabies glycoprotein recombinant vaccine (AdRG1.3) in New Hampshire, New York, Ohio, Tennessee, Texas, Vermont, Virginia, and West Virginia; including portions of USDA Forest Service (USFS) National Forest System lands, excluding Wilderness Areas (WA) (Pub. L. 88-577). The trade name for this product is ONRAB (Artemis Technologies Inc., Guelph, Ontario, Canada). AdRG1.3 will be referred to as ONRAB throughout this document.

This EA analyzes a number of environmental issues or concerns with the oral rabies vaccine and with activities associated with Oral Rabies Vaccination (ORV) programs such as capture and handling of animals for monitoring and surveillance purposes. This EA also analyzes alternatives to the proposed action, including the current action (limited field trials in NH, NY, OH, VT, and WV counties only) and the no action alternative (no federal funding or participation by APHIS-WS).

1.1.1 Development of Oral Rabies 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

[1] Includes 22 bobcats, 13 coyotes, 1 javelina, 3 opossums, 3 deer, 1 ringtail, 1 otter, 17 mongooses, and 33 ground hogs.
[2] Includes 13 horses/donkeys, 11 goats/sheep, and 1 pig.

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 but the oral route with the modified live rabies virus vaccine that worked well in foxes (Rupprecht et al. 1988). Because early 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®, Boehringer Ingelheim, Ingelheim, Germany) 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. V-RG was also recently fully licensed by the USDA in 2002 for vaccination of coyotes in the U.S. and Canada. It was been approved for experimental use to vaccinate wild gray foxes in Arizona, New Mexico, and Texas.

However, a higher level of population immunity in raccoons is desired in order to maximize the effectiveness of ORV programs. Further the V-RG vaccine has not produced sufficient levels of population immunity in skunks (primarily striped skunks) 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 vaccine used for oral vaccination of red foxes, 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 raccoons and skunks as well as other wildlife species is apparent.

Human adenovirus type 5 (Had5) had 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), the vaccine that is subject of the proposed project analyzed in this EA. AdRG1.3 was modified from the first construct (AdRG1) in the early to mid-1990sat McMaster University, Hamilton Ontario (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., with assistance from the National Research Council, Biotechnology Research Institute. As describe above the trade name for this product is ONARB and the AdRG1.3 vaccine will be referred to as ONRAB throughout this EA. ONRAB has been aerially distributed in Canada since 2006 and used in U.S. field trials since 2011.

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. 1989, 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

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

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 ± 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 may contain 100 mg of tetracycline hydrochloride as a biomarker to evaluate bait ingestion. Each vaccine-bait weighs approximately 4 grams. The body of the blister pack is an elongated oval with dimensions of 1.81x 0.55x 0.39 in (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).

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. 1989, 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 V-RG vaccine occurred on Parramore Island, VA, prior to wider spread use in the U.S. for control of raccoon rabies (Hanlon et al. 1989). 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 as a complement to 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 ORV programs between 1995 and 2016 resulted in the distribution of more than 170 million ORV baits in the U.S. (USDA 2019). Numerous projects have been conducted or are in progress in the eastern U.S., Texas, and Arizona (USDA 2010).

In 2011, APHIS-WS conducted the first ORV field trial since the V-RG field trials of the 1990's using ONRAB in West Virginia. Results of this field trial were promising and initial results indicate that ONRAB may be used successfully in ORV programs. Raccoons sampled during post-ORV monitoring and surveillance activities displayed a 49% seroconversion rate (i.e., these raccoons received a sufficient dose of ONRAB and are considered to be vaccinated against the rabies virus). While raccoons sampled pre-ORV activities displayed a 9.6% seroconversion, this may be explained by a possible occurrence of naturally acquired immunity from sub-lethal exposures to raccoon rabies or movements of orally vaccinated raccoons into sampling cells from the adjacent V-RG zone (USDA 2012b).

The 49% post-ORV with ONRAB (uncorrected for the 9.6%) seroconversion represents the highest rabies virus neutralizing antibody (RVNA) level that WS has observed after an initial baiting of a naïve area at 75 baits/km^2 where baselines had been measured prior to ORV. Biomarker presence was also significantly higher among seropositive raccoons post-ORV and similar among raccoons during the pre-ORV sampling period (USDA 2012b).

While this field trial was not specifically designed to compare seroconversion between ONRAB and V-RG, a mean seropositivity of 17% has been observed for V-RG using similar vaccine distribution strategies from 2001 to 2009 in AL, FL, GA, ME, NC, PA, TN, and VA (USDA 2012b). These results are similar to those reported by Fehlner-Gardiner et al. (2012) where a two-fold increase in the seroconversion rate was documented (73%) for ONRAB in New Brunswick, Canada compared to 29% for V-RG across the border in Maine.

Studies have not shown a strong RVNA response to ONRAB at 75 baits/km^2 (Mainguy and Canac-Marquis 2010, Rosatte et al. 2011) in rural habitat. It has been suggested that, because of the sedentary nature of skunks, higher densities of baits may be required per unit area of baitable habitat so that each skunk will find at least one bait in its home range (Rosatte et al. 2011). From 2012 through 2015, under current bait protocols, striped skunks have shown RVNA rates of 17% - 26% (USDA 2016a, 2016b, 2017a, 2018). A recent field study in WV has found that aerial

distribution of ONRAB at a rate of 300 baits/km^2 using 250 m flight line spacing resulted in a three year (2014-2016) mean RVNA rate in skunks of 45% (USDA *unpublished data*).

APHIS regulates veterinary biologics (e.g. vaccines) to ensure that all 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 or Veterinary Biologics (CVB) and is centered around the Virus Serum Toxin Act. Accordingly, APHIS-CVB has conducted a risk analysis and has determined that implementation for the proposal would not significantly affect the quality of the human environment. (USDA 2011a). APHIS-CVB has permitted experimental use of ONRAB for the proposed distribution.

1.2 Need for Action

Based on surveillance data, raccoon rabies did not exist outside a focus area in Florida before the 1940s and is, therefore, considered an exotic rabies virus variant in the U.S. outside this area (C. Rupprecht, pers. comm. 2003 as cited in USDA 2004c). After raccoon rabies was described in Florida, it spread slowly during the next three decades into Georgia, Alabama, and South Carolina. It was unintentionally introduced into the mid-Atlantic states, probably by translocation of infected animals (Krebs et al. 2000). The first cases appeared in West Virginia and Virginia in 1977 and 1978. Since then, raccoon rabies in the area expanded to form the most intensive rabies outbreak in the U.S. Raccoon rabies is now enzootic in all eastern coastal states as well as in Alabama, Ohio, Pennsylvania, Tennessee, Vermont, and West Virginia (Ma et al. 2018b). In the past 20 years, all of the mid-Atlantic and New England states have experienced at least one outbreak. The raccoon rabies epizootic front reached Maine in 1994, reflecting a movement rate of about 30 miles per year (48.3 km/yr). It was also first confirmed in northeastern Ohio in 1996 (Krebs et al. 1998). In 1999, the first three cases of raccoon rabies were confirmed in southern Ontario (Rosatte et al. 2001). Subsequently, raccoon rabies was also confirmed in New Brunswick and Quebec in 2000 and 2006 respectively.

Raccoon rabies presents a human health threat through potential direct exposure to rabid raccoons, or indirectly through the exposure of a pet that had an encounter with a rabid raccoon. To date, three cases resulting in the death of humans is attributable to the raccoon variant of the rabies virus. A 25-year-old, previously healthy northern Virginia man died in June 2003. A diagnosis of rabies had not been considered and was only made 3 months after death when brain tissue was examined. Patient history did not reveal contact with animals and no specific exposure experience could be determined (S. Jenkins, Virginia Department of Health, pers. Comm. 2003, L. Orciari, CDC, pers. comm. 2003 all as cited in USDA 2004c). In February 2013, a man who received a deceased-donor kidney transplant in September 2011 presented to an emergency room with hip pain, nausea, weakness, and lower abdominal pain. His symptoms progressed and he died 22 days after admission (Vora et al. 2013). The organ donor was admitted to an emergency department in August 2011 and declared brain dead 17 days after symptom onset with a presumed diagnosis of ciguatera poisoning. Subsequent investigation revealed the donor had extensive contact with wildlife including two sustained raccoon bites, for which he did not seek medical care (Vora et al. 2013. Adding to the threat of the raccoon variant of the rabies virus are the number of: pets and livestock examined and vaccinated for rabies, diagnostic tests, and post-exposure treatments, all of which are greater when raccoon rabies is present in an area. Human and financial resources allocated to rabies-related human and animal health needs also increase, often at the expense of other important activities and services. Rabid raccoons also present a significant threat to humans because this species is well-adapted to life in urban and suburban areas (Uhaa et al. 1992 *in* Anderson et al. 2014).

The westward movement of the raccoon rabies front has slowed, probably in response to both natural geographic and man-made barriers. The Appalachian Mountains and, perhaps, river systems flowing eastward have helped confine the raccoon variant to the eastern U.S. and an extensive collaborative ORV program has prevented appreciable westward spread to date. The most recent forecast of raccoon rabies spread in the absence of ORV

programs estimates that the virus would spread as far west as the Texas border and western Iowa over a 22-year period Figure 1-2). However, over a longer time period, the spread would likely continue to the Rocky Mountains, where it may finally be stopped due to harsh winters and unsuitable habitat (Anderson et al. 2014).

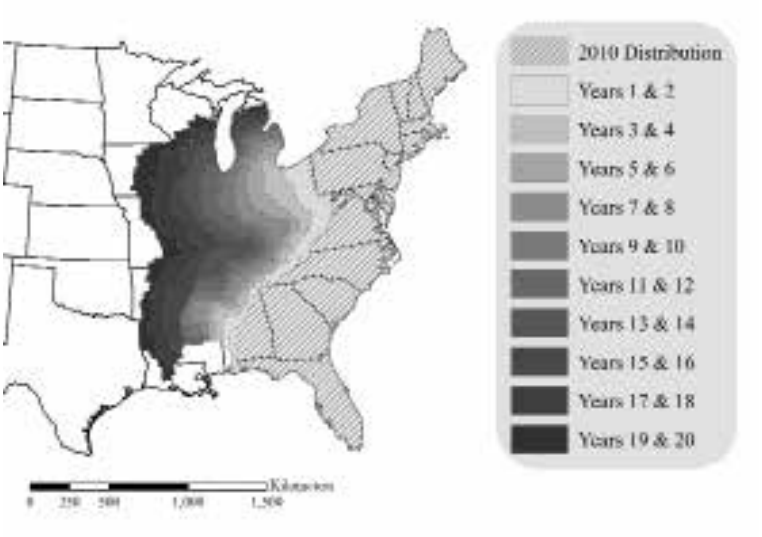


Figure 1-2 Map of the potential spread of raccoon rabies based on the consensus forecast

If rabies virus variant 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 social and economic costs associated with rabies are expected to increase substantially as broader geographic areas of the U.S. are affected. According the Census of Agriculture, there are more than 179 million livestock animals, including cattle, horses, mules, swine, goats, and sheep, which are valued at $70 billion (USDA 2017c). If raccoon, gray fox, or coyote rabies were to spread west beyond 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, increasing numbers of 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 rabies spread to a much broader geographic area than they currently occupy. Allowing these variants of the rabies virus to spread would add to the current high costs of living with rabies. The proposed broadened distribution of ONRAB vaccine is necessary to further determine if it is safe and immunogenic in a variety of meso-carnivores, including raccoons and striped skunks. The vaccine used in the current ORV program, Raboral V-RG®, has not produced sufficient measurable antibody levels in striped skunks where samples in conjunction with raccoon sampling have been evaluated. Throughout the remainder of this document, Raboral V-RG® is referred to as "V-RG". Moreover, higher levels of population immunity are desired in raccoons than have been realized through use of V-RG, to move toward effective raccoon rabies elimination strategies.

Therefore, conducting the proposed projects targeting raccoons and skunks through the distribution of ONRAB vaccine-bait in ME, NH, NY, OH, TN, TX, VT, VA, and WV would allow APHIS-WS to maintain discrete ONRAB and V-RG zones to facilitate critical field effectiveness to bolster efforts to prevent raccoon rabies from spreading beyond established ORV zones, and begin to make appreciable progress towards elimination of the variant.

1.2.1 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 (MA et al. 2018b). Before 1960 the 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 2011). 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 $245 to $510 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 2015). 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 to 50,000. 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 $3000 (CDC 2015). 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 2015). In Massachusetts during 1991-95, the median cost for PEP was $2,376 per person (CDC 1999). 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 1999). 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. 1996).

1.3 National Environmental Policy Act and WS Decision-making

All federal actions are subject to NEPA (Public Law 9-190, 42 USC 4321 et seq.), including the actions of WS[4]. The NEPA sets forth the requirement that all 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. In part, the Council of Environmental Quality (CEQ) regulates federal activities affecting the physical and biological environment through regulations in 40 CFR 1500-1508. The NEPA and the CEQ guidelines generally outline five broad types of activities that a federal agency must accomplish as part of projects they conduct. Those five types of activities are public involvement, analysis, documentation, implementation, and monitoring.

Pursuant to the NEPA and the CEQ regulations, WS is preparing this EA[5] to document the analyses associated with proposed federal actions and to inform decision-makers and the public of reasonable alternatives capable of avoiding or minimizing adverse effects. This EA will serve as a decision-aiding mechanism to ensure that WS infuses the policies and goals of the NEPA and the CEQ into the actions of the WS ORV field trial. This EA will also aid WS with clearly communicating the analysis of individual and cumulative impacts of the proposed activities to the public. In addition, the EA will facilitate planning, promote interagency coordination, and streamline program management analyses between WS and the USFS.

APHIS-WS is preparing this EA pursuant to the NEPA to: 1) facilitate planning, 2) promote interagency coordination, 3) streamline program management, 4) clearly communicate to the public the analysis of individual and cumulative

[4] The WS program follows the CEQ regulations implementing NEPA (40 CFR 1500 et seq.) along with USDA (7 CFR 1b) and APHIS Implementing Guidelines (7 CFR 372) as part of the decision-making process.

[5] The CEQ defines an EA as documentation that "*…(1) briefly provides sufficient evidence and analysis for determining whether to prepare an* [Environmental Impact Statement]; *(2) aids an agency's compliance with NEPA when no environmental impact statement is necessary; and (3) facilitates preparation of an Environmental Impact Statement when one is necessary*" (CEQ 2007).

impacts of proposed activities, and 5) evaluate and determine if there would be any potentially significant or cumulative effects from the alternative approaches developed to meet the need for action. The analyses contained in this EA are based on information derived from WS' Management Information System, published documents (see Appendix A), interagency consultations, and public involvement.

WS-National Rabies Management Program (NRMP) is required to prepare an EA to analyze the effects on the human and natural environment and to document the findings. WS-NRMP will use this EA to determine if the Proposed Action is likely to result in significant impacts to the human and natural environment. If it is determined that there are no significant impacts, WS-NRMP will issue a Finding of No Significant Impact (FONSI). If it is determined that significant adverse impacts might occur, the agency will be required to prepare an Environmental Impact Statement (EIS).

1.4 Decisions to be Made

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

- Should APHIS-WS continue or expand its involvement in ORV programs in the eastern and southwestern United States to include the use of the ONRAB vaccine, including National Forest System lands?
- If not, should APHIS-WS attempt to implement one of the alternatives as describes in this EA?
- Would implementing the proposed action or one of the other alternatives have significant adverse impacts on the quality of the human environment requiring the preparation of an EIS?

1.5 Scope of the Analysis

1.5.1 Actions Analyzed

This EA evaluates environmental effects of the continued and expanded APHIS-WS funding of and participation in ORV programs using the ONRAB wildlife rabies vaccine to eliminate or stop the spread of raccoon variant in the eastern United States and prevent the reintroduction of the dog-coyote rabies variants from Mexico in the southwestern United States, including National Forest System lands. Under the proposed action, ORV and monitoring and surveillance activities would be conducted on private, federal, state, county, and municipal lands in Maine, New Hampshire, New York, Ohio, Tennessee, Texas, Vermont, Virginia, and West Virginia including NFS lands, but excluding Wilderness Areas (Pub. L. 88-577).

The primary goals of this program would involve the continuation and expansion of the national rabies management program, including the continuation and expansion to National Forest System, in attempt to: 1) stop the spread of specific rabies variants to new areas by vaccinating portions of target species population along the leading edges of the rabies fronts; and 2) reduce the incidence of rabies cases involving wild and domestic animals and rabies exposures to humans in areas where the ORV programs are conducted. If the ORV program is successful in stopping the spread of specific rabies virus variants, then the phase two goal would focus on elimination of specific rabies variants. The inclusion of land areas managed by the federal government has become an increasingly important requirement for this program, given the extensive public lands within the targeted ORV zones. If vaccine baiting programs were conducted around these large land masses, reservoirs of the virus would likely persist, creating critical gaps in the program that could make the program less effective at achieving phase one and phase two objectives of stopping the spread and eventually eliminating specific rabies virus variants.

The program would involve the use of APHIS-WS federal funds to purchase and distribute ORV baits to create zones of vaccinated target species that would serve as barriers to cease the further advancement of specific rabies virus

variants in raccoons, gray foxes, and coyotes. Vaccination zones would be determined in cooperation with the various state rabies task forces, state health, agriculture and fish and wildlife departments, and/or other agencies with jurisdiction over vaccine use and application in wildlife and domestic animals. ORV baits could also be used in other areas where raccoon, gray fox, and coyote rabies virus variants are known to occur with the goal of eliminating those variants from these areas. The proposed action would also include APHIS-WS assistance in monitoring and surveillance activities that involve the capture and release or lethal collection of targeted animal species in the above states to take biological samples for testing to determine the effectiveness of the ORV programs. APHIS-WS could also assist the states in implementing contingency plans[6] that include localized population reduction of target species, trap-vaccinate-release (TVR) of target species, increased baiting frequency, or increased baiting density in areas where rabies outbreaks occur beyond ORV barriers. The role of the USFS would involve cooperation with APHIS-WS in facilitating access to National Forest System lands for bait distribution and rabies monitoring and surveillance activities.

Federal funds would be used to: 1) purchase ORV baits and participate in the distribution of ORV baits by air and hand placement; 2) provide other forms of assistance in monitoring rabies and determining the effectiveness of the ORV programs through collection and testing of samples from wild animal specimens, including; and 3) if necessary, participate in implementing contingency plans that may involve a reduction of target species populations through lethal means or trap-vaccinate-release programs to cover an emergency in a local area. The aforementioned actions may also occur on National Forest System lands, however coordination with specific National Forest Offices would occur prior to project implementation.

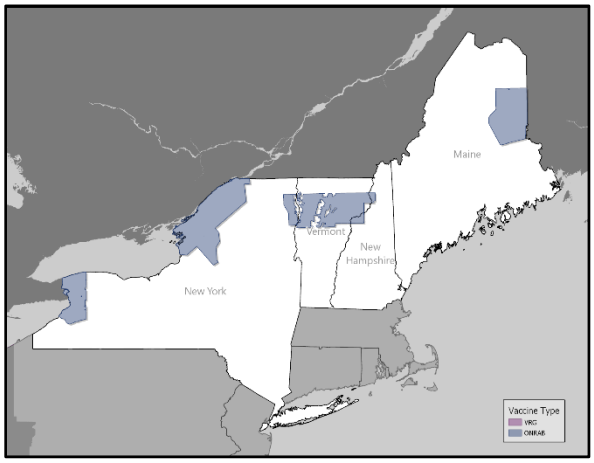
The areas over which the ORV baits would be distributed and from which animal specimens would be collected could be anywhere in ME, NH, NY, OH, TN, TX, VT, VA, and WV, including National Forest System lands, but excluding WAs. National Forest System lands proposed for inclusion in the ORV program are listed in Appendix F. Coordination with specific National Forests lands would occur prior to project implementation to ensure that the integrity of specially designated areas is maintained (i.e., Research Natural Areas, Wild and Scenic Rivers, etc.). APHIS-WS coordinates will all affected Federal land managers, at a minimum, 30-days in advance of any ORV distribution activities. APHIS-WS will coordinate with the USFS to obtain any necessary permits or approvals to conduct ORV activities in specially designated areas. APHIS-WS will abide by the conditions set forth and identified by the USFS for activities in sensitive areas.

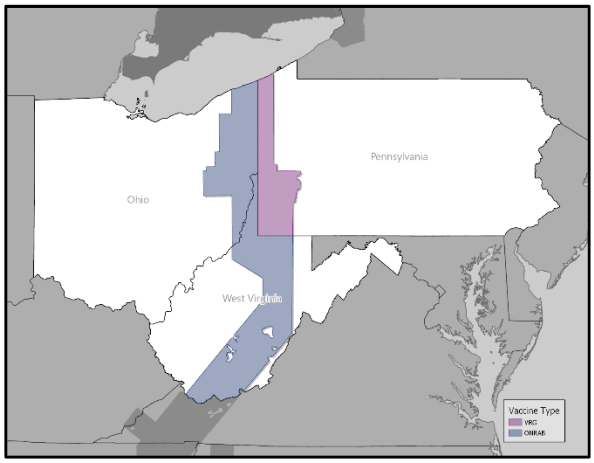
The ORV zones would be delineated based on the most current distribution of rabies cases and the expected direction of disease spread. Vaccination zones would be determined in cooperation with state rabies task forces,

[6] Contingency actions depending on the type(s) of rabies emergency(ies), which were fully analyzed in USDA 2010, may employ one or more of the following practices:

- Enhanced surveillance, which may include capture and release or euthanasia of target and specific nontarget animals for rabies testing.
- Treatment with increased bait density (e.g., 75 baits/km^2 is considered the standard bait density for raccoons) to ensure sufficient baits for high density of target species or to bolster antibody response under "normal" target species densities.
- Increase baiting frequency more than once/year.
- A trap-vaccinate-release (TVR) program could be conducted for specific targets, primarily canids with high populations such as skunks and feral cats that are known to harbor and transmit rabies.
- Localized target species population reduction.

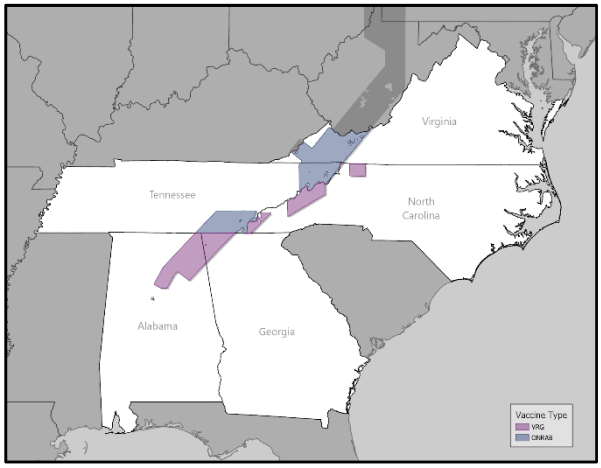
state health departments, or other state agencies with jurisdiction over vaccine use and application in wildlife and domestic animals. Figures 1-1, 1-2, 1-3, and 1-4 show the current areas where APHIS-WS will continue treatment with ORV baits or expand. Pending the verification of legal authorities to do so, ORV baits would be

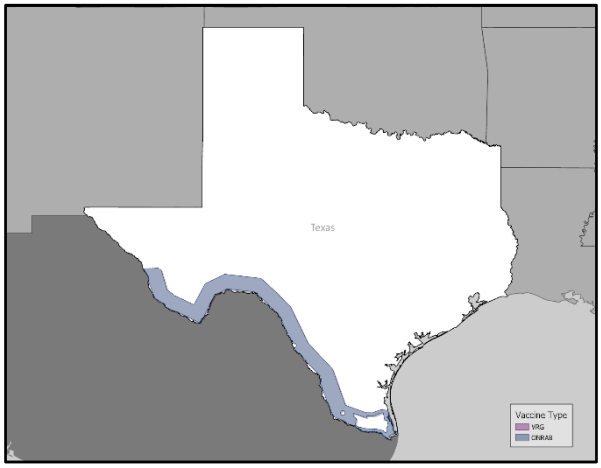




Figures 1-1 and 1-2: Proposed 2019 ORV distribution zones in Maine, New Hampshire, Vermont, New York, Ohio, and West Virginia allowing for expanded use of ONRAB.

distributed by the states over a variety of classes of land ownership, including private, public, tribal, and other state and federal lands. Baits will be distributed at a standard densities of either 75 baits/km^2 or 150 baits/km^2 by fixed-wing, helicopter or hand distribution. Each bait will have a warning label advising persons not to handle or disturb the





Figures 1-3 and 1-4: Proposed 2019 ORV distribution zones in Virginia, Tennessee and Texas allowing for expanded use of ONRAB.

bait along with a toll-free telephone number to call for further information.

Wild animal collections for purposes of monitoring would be conducted using a variety of live capture or lethal methods. Information from raccoons and skunks would be predominantly collected from cage-trapped individuals that, if apparently healthy, would normally be released at or near their site of capture. The requisite sample from coyotes would be obtained primarily by aerial or ground-based shooting from sample areas within the ORV zones. Gray fox samples would be obtained by ground shooting and various capture methods including leghold traps, cage traps, and snares. Only legally approved methods would be used in all animal sample collection areas to provide critical data for the evaluation of project effectiveness. APHIS-WS will abide by any conditions of permits that may be required by the USFS to conduct monitoring and surveiilance activies (e.g trapping and sample collections) on NFS land. 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 variant 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 striped skunks and red foxes will be targeted during monitoring and surveillance, and for disease control in areas where a rabies outbreak has occurred. Several of these animals may be sampled to help determine the effectiveness 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. For example, juvenile male raccoons are the most likely age/sex group to disperse from the home range in which they were born and are, therefore, the cohort which would be most important to vaccinate. Enhanced surveillance (using sick and strange-acting target and nontarget wildlife, nuisance wildlife captured during other WS damage management activities, and road-killed wildlife) would be conducted to track the occurrence of rabies within the ORV bait zones and to determine the epizootic front of the virus, so that ORV and other measures (i.e., trap-vaccinate-release) may be implemented ahead of these cases to maintain the integrity of the barrier.

1.5.2 Site Specificity

This EA analyzes potential impacts of continued or expanded APHIS-WS participation in ORV programs in the states described in Section 1.1 (Figure 1-1, 1-2, 1-3 and 1-4), including National Forest System lands. Because the proposed action is to assist the affected states in accordance with plans, goals, and objectives developed by those states, the proposed action could involve APHIS-WS participation in ORV bait distribution, monitoring and surveillance, or local population reduction of target species anywhere in those states where the need has been identified by the appropriate state agencies. Therefore, all National Forest System lands within the aforementioned states could be affected.

This EA identifies as much as possible the typical habitat and specific areas that are currently known to be in need of ORV program action. However, the location of every wildlife rabies outbreak that would trigger use of ORV cannot be predicted. Implementation of emergency response and contingency action plans that involve localized population suppression of target species could similarly be needed anywhere in the involved states where outbreaks of the targeted rabies variants occur. In addition, changes in funding levels over time could create changes in ORV program activities, such as increasing or decreasing the size of the ORV barrier zone and other areas to be baited and varying the types of monitoring and surveillance and research conducted in an adaptive management mode. Planning for the management of rabies epizootics must be viewed as being conceptually similar to federal or other agency actions whose missions are to stop or prevent adverse consequences from anticipated future events for which the actual sites and locations where they will occur are unknown but could be anywhere in a defined geographic area. Examples of such agencies and programs include fire and police departments, emergency clean-up organizations, and insurance companies.

Although some of the sites where wildlife rabies outbreaks will occur can be predicted, specific locations or times where such outbreaks will occur in any given year cannot be accurately predicted. Thus, this EA addresses the substantive environmental issues that pertain to ORV use and monitoring/surveillance activities, and, if necessary, localized target species population reduction wherever these activities might occur in the states identified herein. The analyses in this EA are intended to apply to any action that may occur *in any locale, except Wilderness Areas (Pub. L. 88-577),* and at *any time* within the analysis area. In this way, APHIS-WS believes it meets the intent of NEPA with regard to site-specific analysis and program planning and that this is the only practical way for WS to comply with NEPA and still be able to accomplish its mission.

1.5.3 Federal, State, County, City, and Private Lands

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 ensured compliance with their Land and Resource Management Plans.

APHIS-WS will coordinate with all applicable federal, state, and local 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 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.

1.5.4 Native American Lands and Tribes

The WS-NRMP would only conduct ORV activities on tribal lands with the consent of the affected tribe(s) and after appropriate authorizing documents were completed. APHIS-WS would only conduct activities after WS and the Tribe signed a Memorandum of Understanding (MOU) or other comparable document. Therefore, the Tribe would determine what activities would be allowed and when WS' assistance was required. Because Tribal officials would be responsible for requesting assistance and determining what methods would be available to conduct ORV projects, no conflict with traditional cultural properties or beliefs would likely occur. Those methods available to conduct ORV projects on federal, commonwealth, municipal, and private lands under the alternative analyzed in this EA would be available to conduct ORV projects of Tribal properties when the Tribe approves those methods. Therefore, the activities and methods addressed under the alternatives would include those activities that WS could employ on Tribal lands, when requested and agreed upon by the Tribe and WS.

1.6 Agencies Involved in this Environmental Assessment and their Roles and 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 NRMP cooperates and coordinates closely with the United States Forest Service (USFS). 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 Bureau of Land Management (BLM), 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 Departments of Health, Agriculture and Fish and Wildlife.

The authorities of WS and other agencies as those authorities related to conducting ORV programs are discussed by agency below:

WS' Legislative Authority

The primary statutory authority for the WS program is the Act of March 2, 1931 (46 Stat. 1468; 7 U.S.C. 8351-8352) as amended, and the Act of December 22, 1987 (101 Stat. 1329-31), 7 U.S.C. 8353).

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.

USDA Forest Service

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 a 2017 MOU 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.

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. Assuring compliance with individual national forest land and resource plans (forest plans) is required.

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.

United States Fish and Wildlife Service (USFWS)

The USFWS is the primary federal agency responsible for conserving, protecting, and enhancing the nation's fish and wildlife resources and their habitat. The USFWS has specific responsibilities for the protection of migratory birds, threatened and endangered species, inter-jurisdictional fish, and certain marine mammals, as well as for land and waters managed by the agency in the National Wildlife Refuge System. The USFWS has statutory authority for enforcing the Fish and Wildlife Improvement Act of 1978 (16 U.S.C. 7.12), the Fish and Wildlife Act of 1956 (16 U.S.C. 742a-j), the Migratory Bird Treaty Act (16 U.S.C. 703-711), and the Bald and Golden Eagle Protection Act (16 U.S.C. 667).

State and Local Authorities

Each of the states involved in APHIS-WS' national ORV program, including ME, NH, NY, TN, TX, OH, VA, VT, and WV, the states 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 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. Those decisions are made by the states. The proposed action assumes that ORV baits would be distributed under state authorities, consistent with pertinent property rights laws and regulations and would include acquiring permission from public land managers and American Indian tribes when appropriate.

1.7 Documents Related to this EA

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 (Pub. L. 88-577). APHIS-WS determined the action would not have any significant adverse impact on the quality of the human environment.

EA, FONSI, and Decision – Field Trial of an Environmental Rabies Vaccine, Human Adenovirus Type 5 Vector in New Hampshire, New York, Ohio, Vermont, and West Virginia. This EA and FONSI/Decision, in cooperation with the USFS, (USDA 2012) analyzed the environmental effects of APHIS-WS involvement in the funding of and participation in an initial field trial to distribute ONRAB oral rabies vaccine baits in New Hampshire, New York, Ohio, Vermont, and West Virginia and to participate in subsequent monitoring and surveillance activities in an effort to determine a safe and immunogenic oral rabies vaccine that will further serve in maintaining barriers or immunized target species, thus preventing the expansion of rabies epizootics.

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 Plans for the National Forests listed in Appendix F and excluding Wilderness Areas (Pub. L. 88-577). The USFS has provided input on additional areas and locations that should be avoided and has recommended protective measures that would reduce or eliminate impacts to NFS visitors as practicable.

1.8 Public Involvement

General issues pertaining to ORV field trials were developed through the scoping process for previous EAs 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 will be made available for public review and comment through the publication of a notice of availability in the *Federal Register,* by posting on the WS stakeholder registry, and by posting these documents and a notice of availability on the APHIS website located 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 to determine whether the EA

should be revisited and, if appropriate, revised prior to the issuance of a final Decision or the publication of a Notice of Intent to prepare an EIS.

1.9 Rationale for Preparing an EA Rather than an EIS

APHIS-WS has the discretion to determine the geographic scope of their analyses under the NEPA. The intent in developing this EA is to determine if the proposed action would potentially have significant individual and/or cumulative impacts on the quality of the human environment that would warrant the preparation of an EIS or a finding of no significant impact (FONSI). In terms of considering cumulative effects, one EA analyzing the impacts for the entire project will provide a more comprehensive and less redundant analysis than multiple EAs covering smaller areas. If a determination is made through this EA that the proposed action or the other alternatives might have a significant impacts on the quality of the human environment, then an EIS would be prepared.

1.11 Laws Related to this EA

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 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 USC 1531 *et seq*.). The ESA recognizes that our natural heritage is of "*esthetic, ecological, educational, recreational, and scientific value to our Nation and its people.*" The purpose of the Act is to protect and recover species that are in danger of becoming extinct. Under the ESA, species may be listed as endangered or threatened. Endangered is defined as a species that is in danger of becoming extinct throughout all or a significant portion of its range while threatened is defined as a species likely to become endangered in the foreseeable future. Under the ESA, "*all federal departments and agencies shall seek to conserve endangered and threatened species and shall utilize their authorities in furtherance of the purposes of the Act*" (sec.2(c)). Additionally,

the Act requires that, "*each Federal agency shall in consultation with and with assistance of the Secretary, insure 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 or result in the destruction or adverse modification of habitat of such species…each agency will use the best scientific and commercial data available*" (Sec.7 (a) (2)). WS consults with the USFWS to ensure that the agency's actions, including the actions proposed in this EA, are not likely to jeopardize the existence of endangered or threatened species or their habitat.

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 1.5.1) do not cause major ground disturbance, do not cause any physical destruction, have only been reported to cause rare negligible property damage (e.g. pool filters, car dent, etc.), 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.

Coastal Zone Management Act of 1972, as amended (CZMA) (16 USC 1451-1464, Chapter 33; P.L. 92-583, October 27, 1972; 86 Stat. 1280). The CZMA established a voluntary national program within the Department of Commerce to encourage coastal states to develop and implement coastal zone management plans. Funds were authorized for cost-sharing grants to states to develop their programs. Subsequent to federal approval of their plans, grants would be awarded for implementation purposes. In order to be eligible for federal approval, each state's plan was required to define boundaries of the coastal zone, identify uses of the area to be regulated by the state, determine the mechanism (criteria, standards or regulations) for controlling such uses, and develop broad guidelines for priorities of uses within the coastal zone. In addition, this law established a system of criteria and standards for requiring that federal actions be conducted in a manner consistent with the federally approved plan. The standard for determining consistency varied depending on whether the federal action involved a permit, license, financial assistance, or a federally authorized activity.

APHIS-WS submitted a National Consistency Determination concerning the potential effects of the national rabies management program on coastal zone resources to all potentially affected states with approved coastal management programs (AL, CT, DE, FL, GA, IN, LA, ME, MD, MA, MI, MS, NH, NJ, NY, NC, OH, PA, RI, SC, and VA). APHIS-WS received concurrence that the national rabies management program would have *de minimus* (15CFR930.33) cumulative or secondary effects on coastal resources. Thus, APHIS-WS has determined the national rabies management program to be consistent with the CZMA and associated coastal zone management programs within the potentially affected coastal zone states and the program is excluded from further state agency consistency review.

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 Alternatives

2.1 Introduction to Issues and Alternatives

Issues are concern of the public and/or professional community raised regarding potential adverse effects that might occur from a proposed action. Such issues must be considered in the NEPA decision-making process. 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 discusses in previous EAs and FONSIs (USDA 2001, 2002, 2003, 2004, 2007, 2010, 2011, 2012), but the following issues were determined to be germane to the proposed action and were considered in detail:

2.1.1 Issues Considered in Detail

The issues as they relate to the possible implementation of the alternatives, including the proposed action, are discussed in Chapter 3. The issues analyzed in detail are the following:

Issue 1 – Potential for adverse effects on target wildlife species populations.

Issue 2 – Potential for adverse effects on nontarget wildlife species, including threatened and endangered species.

Issue 3 – Potential for adverse effects on people, pets, and livestock that are exposed to or consume the vaccine laden baits.

Issue 4 – Potential for ONRAB to "revert to virulence" or recombine with other viruses and result in a virus that could cause disease in humans.

Issue 5 – Potential for aerially dropped baits to strike and inure people or domestic animals.

Issue 6 – Humaneness of methods used to collect wild animal species critical for timely program evaluation.

2.2 Protective Measures

Protective measures are standardized instructions intended to avoid unwanted results. APHIS-WS and WS-NRMP incorporate numerous protective measures when conducting ORV activities in order to prevent, reduce, or compensate for negative impacts that otherwise might result from an action. Relevant protective measures would be incorporated into all Alternatives analyzed herein, except the No Federal ORV Program Alternative (Alternative 5). Most protective measures are instituted to abate specific issues, but some are more general and relate to the overall program. Protective measures 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.

2.2.1 Standard Protective Measures

- The WS Decision Model, which is designed to identify effective wildlife damage management strategies and their impacts, would be consistently used and applied when addressing wildlife disease management.
- Immobilizing and euthanasia drugs would be used in according to the DEA, FDA, and WS' Directives and procedures.
- All controlled substances would be registered with the DEA and FDA.

- WS' employees would follow the approved procedure outlined in the WS' Field Manual for the Operational Use of Immobilizing and Euthanizing Drugs (Johnson et al. 2001).
- WS' employees that use controlled substances would be trained to use each material and are certified to use controlled substances.
- WS' employees who use controlled substances would participate in state-approved continuing education to keep current on developments and maintain their certifications.
- Safety sheet s for controlled substances would be provided to all WS' personnel involved with specific damage management activities.
- All personnel who use firearms would be training according to WS' Directives.

2.2.2 Additional Protective Measures Specific to the Issues

Issue 1 - Potential for adverse effects on target wildlife species populations

- Lethal take of mammals by WS would be reported and monitored by WS and the appropriate state agencies to help evaluate population trends and the magnitude of WS' take of mammals to ensure that activities do not adversely affect mammal populations.
- The take of target mammal species under the alternatives would occur under conditions permitted by the appropriate state agencies, the UFWS, and local ordinances when applicable, and only at levels authorized.
- Methods used to capture 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 would be euthanized in accordance with APHIS-WS policy in a manner as humane as possible under the circumstances.
- Capture devices would be checked on a daily basis in compliance with state law.
- 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.

Issue 2 - Potential for adverse effects on nontarget wildlife species, including threatened and endangered species

- Personnel would be present during the use of live-capture methods or live-traps would be checked at least every 24 hours to ensure nontarget and T&E species are released immediately or are prevented from being captured.
- Nontarget animals captured in traps would be released unless it is determined by WS that the animal would not survive and/or that the animal cannot be released safely.

Issue 3 - Potential for adverse effects on people, pets, and livestock that are exposed to or consume the vaccine laden baits

- Public information, education, and media 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 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 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. Federal land managers will be notified 30-days in advance of scheduled ORV activities to allow sufficient time for appropriate coordination and public notification.

- Toll-free 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 vaccine occur, that person would be referred to their primary care physician or local public health official as appropriate. In the event of an exposure local health officials may engage with the CDC for diagnostic confirmation and consultation.
- APHIS-WS personnel would adhere to air safety standards.
- ORV baits would not be distributed by aircraft within 0.25 miles of larger water bodies (e.g., rivers, lakes, reservoirs) 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, Chapter 1).
- Field personnel involved trapping and handling animals for monitoring and surveillance purposes would be immunized against rabies and tetanus.
- 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 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.

Issue 5 - Potential for aerially dropped baits to strike and injure people or domestic animals

- Bait distribution navigators would be trained to avoid dropping baits on people or structures. During aerial bait operations, the bait dispensing equipment is temporarily turned off over human dwellings, highly developed cities and towns, greenhouses, certain sensitive domestic animal pens, and when people are observed below.
- Hand placement of baits may be used in densily populated areas or where aerial distribution may be ineffective.

Issue 6 - Humaneness of methods used to collect wild animal species critical for timely program evaluation

- Personnel would be trained in the latest and most humane devices/methods for removing animals.

- WS' use of euthanasia methods would follow those recommended by WS' Directives (WS Directive 2.505, WS Directive 2.430) and AVMA guidelines (Leary et al. 2013).

- WS' use of all traps, cable restraints, and other capture devices would comply with WS Directive 2.450.

2.3 Alternatives Considered in Detail

Alternatives were developed for consideration based on the need for action and issues using the WS Decision model (Slate et al. 1992). The alternatives will receive detailed environmental impact analysis in Chapter 3 (Environmental Consequences). The following alternatives were developed to meet the need for action and address the identified issues associated with the application of the ORV program.

Alternative 1 – Continue the Current ORV Program (No Action Alternative)

The no action alternative would involve the continued limited use of ONRAB in New Hampshire, New York, Ohio, Vermont, and West Virginia as described in USDA 2012, as supplemented (2013, 2015, 2017, and 2018.)

Alternative 2 – Expand the use of the ONRAB Vaccine (Proposed Action)

The proposed action involves the expanded use of ONRAB throughout the ORV zone in Maine, New Hampshire, New York, Tennessee, Texas, Vermont, Virginia, and West Virginia. This alternative would involve the continued or expanded use of federal funds by APHIS-WS to purchase ONRAB oral vaccine baits and to participate in their distribution under the authorities of the appropriate state agencies in selected areas of the states listed above to stop or prevent raccoon, gray fox, and coyote rabies, and to assist with monitoring and surveillance efforts by capturing and releasing or killing target species for purposes of obtaining biological samples. APHIS-WS assistance could also include participation in implementing state contingency plans that involve target species population reduction or concentrated ORV baiting in localized areas if rabies outbreaks occur beyond designated ORV vaccination barriers to stop such outbreaks from spreading.

Alternative 3 – Live-Capture Vaccinate and Release Alternative

This alternative would involve the live capture of species being targeted (e.g., raccoon, gray fox, coyotes) followed by administration of rabies vaccines by injection and release back into the wild. This strategy has been used in certain localized areas for reducing the incidence and spread of rabies in raccoons (Brown and Rupprecht 1990, Rosatte et al. 1990, Rosatte et al. 1992, Rosatte et al. 1993) and skunks (Rosatte et al. 1990, Rosatte et al. 1992, Rosatte et al. 1993). This method has not been attempted for vaccination of foxes and coyotes because they are much more difficult to capture in cage traps (Baker and Timm 1998). In addition, the use of other traps such as leghold traps and snares, for foxes and coyotes has shown to be problematic in capturing and releasing a large enough population (Rosatte et al. 1993; C. MacInnes, Ontario Ministry of Natural Resources pers. comm. 2001 as cited in USDA 2001; personal observation of APHIS-WS personnel). Currently, no vaccine is specifically licensed for this type of use (CDC 2000). However, certain injectable vaccines may be used "off-label" under the direction of veterinarians to vaccinate wild animal species in certain situations (J. Mitzel, APHIS-Veterinary Services, pers. comm. 2001 as cited in USDA 2001). This method generally results in a higher percentage of a raccoon population being vaccinated than ORV, but takes much longer to accomplish in a given area. For example, in Ontario, 7 trappers working from July to October were required to trap and vaccinate 50-85 percent of the raccoons in an area less than 700 $km.^2$ (270.3 mi^2), whereas the same area could have been treated with aerially dropped ORV baits in half a day (C. MacInnes, Ontario Ministry of Natural Resources, pers. comm. 2001, as cited in USDA 2001).

Alterative 4 – No Animal Surveillance or Monitoring or Lethal Removal Program Alternative

Under this alternative, APHIS-WS would provide resources for and assistance in ORV bait distribution only and would not engage in or provide funds for the collection of wild animal specimens by APHIS-WS for monitoring and project evaluation purposes or for implementation of localized lethal removal actions under state contingency plans. The states could still conduct these activities without APHIS-WS assistance.

Alternative 5 – No Federal ORV Program

This alternative would imply no involvement by APHIS-WS in rabies prevention or control in the states identified in Section 1.1. Under this alternative, no APHIS-WS funds would be available for purchasing ORV baits. Some states may still fund ORV programs to some degree without APHIS-WS' assistance.

2.4 Alternatives Considered but not Analyzed in Detail

2.4.1 Population Reduction 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 variants of rabies are occurring or are expected to occur. The goal would be to achieve elimination of the rabies variants by severely suppressing populations of the target animal species over broad areas so that the specific variants 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).

2.4.2 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 (1993)], the use of chemical reproductive inhibitors placed out in baits or deliver devices, 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 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 view as a long-term remedy for controlling rabies spread. It would likely not be useful in meeting the immediate needs for stopping a localized outbreak of rabies that occurs beyond the ORV baiting zones.

Live capture and surgical sterilization of whole populations of animals would be extremely expensive, time-consuming, and difficult to achieve. Considerable expense would be involved in employing experience 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.

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 and eggs or 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 great proportion of the population would have to be treated with contraceptive vaccines that with rabies vaccines in order to achieve rabies control. Thus, achieving effective control would be more costly and difficult under this alternative than under ORV programs. 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 1993, Hanlon and Rupprecht 1993).

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.

2.4.3 Employ Other Types of ORV Instead of the ONRAB 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. 1992).

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. Another experimental live virus, Rabitech-M (IDT Biologika, Dessau Rosslau, Germany), is a highly attenuated third

generation live modified oral rabies virus vaccine that has been shown to be safe and efficacious in the laboratory setting (Ortmann et al. 2018, Blanton et al. 2006, EMA 2017).

"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. 1992). To manufacture vaccines with these amounts would likely be cost-prohibitive (Rupprecht et al. 1992).

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 more than 170 million baits distributed by ORV programs in the U.S., only 2 known adverse reactions have been reported (USDA 2019).

Despite the increased safety of the V-RG vaccine, it remains limited in its field effectiveness 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). 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. 2011).

ONRAB has been used in field trial in Canada since 2006 (Rosatte et al. 2009) and in the U.S. since 2011, producing both safe and efficacious results. For these and the above reasons, ONRAB has been chosen for use in APHIS-WS's ORV program.

Chapter 3. Environmental Effects

Chapter 3 provides information needed for making informed decisions in selecting the appropriate alternative to address the need for action described in Chapter 1 and issues in Chapter 2. This chapter analyzes the environmental consequences of each alternative in relation to the issues identified. Additionally, this chapter compares the environmental consequences of the proposed action to the environmental consequences of the other alternatives.

3.1 Issues Considered in Detail and Their Associated Impacts by Alternative

The no action alternative (Alternative 1) serves as the baseline for the analysis and the comparison of expected impacts among alternatives. The environmental consequences of the alternatives are discussed below with emphasis on the issues described in Chapter 2.

3.1.1 Potential for Adverse Effects on Target Species

Alternative 1 – Continue the Current ORV Program (No Action)

Effects of the ONRAB Vaccine on Target Species

The primary concern here is whether the ONRAB 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 2012). Raccoons, striped skunks, coyotes, and grey foxes are the target species for purposes of the ONRAB 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 ONRAB. 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 ONRAB from tissues, feces, and oral samples of animals given a relatively high dose of vaccine, thus making the likelihood of ONRAB 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 ONRAB vaccine virus would not be expected to support active replication of the virus.

Additionally, both Charlton et al. (1992) and Prevec et al. (1990) 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 ONRAB to be used in baits, no adverse reactions occurred (Artemis 2010).

Knowles et al. (2009) conducted safety studies on several species including raccoons and striped skunks. 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 ONRAB. 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.

ONRAB has been used in field trials in Ontario, Canada since 2006. Before approval to field test ONRAB 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). In 2010, the OMNR distributed 870,000 ONRAB baits in ON and 1,052,402 ONRAB baits were used in Quebec. Post-baiting serology data indicate a positive antibody response (seroprevalance) rate of as high as 44.5% in striped skunks during 2010 in ON (OMNR RRDU 2010-2011). Data from 2009 and 2010 indicate seroprevalance rates ranging from a low of 19.6% to a high of 61.6% of skunks samples during post-baiting activities in ON. Post-bait surveillance in QC indicated seroprevalance rates of 20.7 to 60.3% in raccoon populations and 8.3 to 17.7% in skunk populations (Mainguy and Canac-Marquis 2010). These values were affected by a variety of factors including bait densities and flight line spacing.

Following the initial ONRAB field trial study in West Virginia, raccoons sampled by APHIS-WS during the post-ONRAB ORV monitoring and surveillance activities displayed a 49.2% seroconversion rate (n=262) (i.e., these raccoons received a sufficient dose of ONRAB and are considered to be vaccinated against the rabies virus). While raccoons sampled pre-ONRAB ORV activities displayed a 9.6% (n=395) seroconversion, this may be explained by a possible occurrence of naturally acquired immunity from sub-lethal exposures to raccoon rabies or movements of orally vaccinated raccoons into sampling cells from the adjacent V-RG zone (Slate et al. 2014).

A study focusing on immune response in raccoons following treatment with ONRAB (Brown et al. 2012) found similar, promising results. In this study, forty two wild-caught, captive raccoons were offered an ONRAB vaccine bait. Results of this study concluded that ONRAB effectively stimulated the production of RVNA in a high proportion of raccoons (67%) within the first two months after vaccination. Twenty of these ONRAB treated raccoons were later challenged with rabies virus infection. Of these raccoons, fifteen (75%) survived rabies virus challenge. Throughout the study, no vaccine- induced morbidity or mortality was observed among raccoons (Brown et al. 2012).

Field studies using ONRAB in Ontario, Canada have reported vaccine efficacy in raccoons in the wild ranging from 79% to 81% using baiting densities similar to APHIS-WS' ORV programs (i.e., 75-150 baits/km^2) (Rosatte 2009). Further studies have compared field performance between ONRAB and V-RG. In 2008, ORV programs in Maine, distributing V-RG baits, and New Brunswick, Canada, distributing ONRAB baits, provided an opportunity to carry out a comparative analysis of the field performance of these two vaccine-baits in skunks and raccoons (Fehlner-Gardiner et al. 2012). While antibody prevalence in skunks was low in both Maine and New Brunswick, Fehlner-Gardiner et al. (2012) concluded that this may be attributed to bait densities and flight line spacing. Samples collected from raccoons receiving ONRAB baits in New Brunswick showed antibody response rates ranging from 67% to 78%, depending on the test used for analysis. Conversely, samples from raccoons receiving V-RG baits in Maine showed lower antibody response rates of 25% to 32%. Although a number of factors, as described by Fehlner-Gardiner et al. (2012), could have impacted the interpretation of antibody data, many of these factors would have favored the V-RG results in Maine. The antibody prevalence in raccoons achieved in this study using ONRAB suggests that this vaccine may prove effective not only for the prevention of raccoon rabies in enzootic areas, but also for rabies elimination (Fehlner-Gardiner et al. 2012). Mainguy et al. (2013) conducted a similar cross-border comparison between ONRAB and V-RG. This study examined antibody response rates between raccoons receiving ONRAB baits in Quebec, Canada versus raccoons receiving V-RG in neighboring Vermont. This study found that the percentage of antibody-positive raccoons was greater with ONRAB in Quebec (51%) than with V-RG in Vermont

(38%) although field conditions, similar to those in the above mentioned New Brunswick-Maine study, should have favored a higher antibody prevalence in Vermont.

Serology results for the 2016 post-ONRAB distribution raccoon sampling from New Hampshire, New York, Ohio, Vermont, and West Virginia are presented in Table 3.1. During raccoon sampling efforts, APHIS-WS also collected and sampled 190 striped skunks, 3 fishers, 3 gray foxes, and 1 red fox. Of those 55 striped skunks (29%), 1 fisher (33%), 1 gray fox (33%), and 0 red foxes had RVNA.

Table 3.1. APHIS-WS Post-ONRAB Sampling Efforts – Serology Results 2016

State	All post-ONRAB serum samples	Positive rabies antibody response (≥0.05IU) (% Positive)	Post-ONRAB tooth samples	Presence of tetracycline	RVNA due to IMRAB[1]
NY	213	161 (75.6%)	294	146 (49.7%)	
OH	407	325 (79.9%)	355	94 (26.5%)	
VT	588	293 (49.8%)	721	259 (35.9%)	1
WV	563	494 (87.7%)	433	340 (78.5%)	
Total	**1,771**	**1,273 (71.9%)**	**1,803**	**839 (46.5%)**	**1**
Mean ± Standard Deviation		**73.3±16.4%**		**47.6±22.7%**	

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 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 Target Species

Raccoons

The estimated cumulative size of the current experimental ONRAB ORV zone that may be treated with ONRAB is 41,938 km^2 (16,193mi^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 NH, NY, OH, VT, and WV the state-wide raccoon density estimates ranges between 506,923 – 2.7million individuals.

Raccoon populations can generally be expected to withstand harvest rates of about 49 percent or more annually (Sanderson 1987). 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 the aforementioned states combined for monitoring and surveillance purposes or implementation of localized contingency plans involving lethal population reduction in all ORV programs, including ONRAB field trials.

The 2016 Monitoring Report (USDA 2019) for ORV EAs indicates the lowest estimated size of the raccoon population totaled from those states participating in the current ORV program was 3,994,987 raccoons in 2016. The monitoring report and previous ORV EAs (USDA 2010 and USDA 2012, as supplemented) summarize 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.

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 were demonstrating strange behavior symptomatic of the rabies virus or were injured. An exception may be when the animals were 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).

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. Post ONRAB bait distribution monitoring and surveillance activities would not contribute further to any adverse impacts to the raccoon population. As discussed above, total lethal removal of raccoons (for all ORV programs, including the ONRAB field trial) will remain at less than 1% of the total population in the aforementioned states.

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 NH, NY, OH, VT, and WV combined for monitoring and surveillance purposes or implementation of localized contingency plans involving lethal population reduction in all ORV programs, including ONRAB field trials. The current V-RG ORV program conducts raccoon monitoring and surveillance activities in 17 eastern states. To date lethal removal has accounted for less than 0.006% - 0.2% of the lowest estimated raccoon population annually (USDA 2019, 2018, 2017a, 2016a, 2016b, 2014) indicating that the potential for cumulative impacts to raccoon populations continues to be negligible.

Striped Skunks

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 vary 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 skunk population estimates are available for NH, NY, OH, VT, or WV. Striped skunks can be found in a variety of habitats across these states. To analyze impacts of ORV field trial activities on striped skunk populations in the aforementioned states, the best available information will be used.

Although striped skunk population estimates were not available for the states involved at the time of this publication, the best available information was used to estimate statewide populations. There are approximately 4 million, 26 million, 22 million, 5 million, and 13 million rural acres in NH, NY, OH, VT, and WV respectively (USDA 2019c). Using the assumption that 50% of rural lands throughout the states have sufficient habitat to support striped skunks, skunks are found only in rural habitat, and skunk densities average 1 skunk per 77 acres, conservative statewide striped skunk populations can be estimated at over 25,900 for NH, 169,200 for NY, 139,700 for OH, 32,900 for VT, and 84,400 for WV. Considering skunks inhabit urban areas as well as rural, these estimates are likely very low.

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 ONRAB 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 signs of strange behavior that could indicate a rabies infection or if they are injured.

Based upon the above information, WS' limited lethal take or striped skunks would have no adverse impacts on overall populations of this species in NH, NY, OH, VT, and WV.

Non-ORV target species

Although the ORV ONRAB field trials specifically targets raccoons and striped skunks, 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 monitoring and surveillance activities 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 ONRAB field trial will include all known rabies reservoir species including 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 be 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 ONRAB field trials. They may be opportunistically sampled to determine the potential effectiveness of ONRAB 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.

Alternative 2 – Expand the Use of the ONRAB Vaccine (Proposed Action)

Under this alternative, APHIS-WS could distribute ONRAB vaccine-baits throughout the ORV zones in ME, NH, NY, OH, TN, TX, VT, VA, and WV. As with Alternative 1, no adverse effects would be expected with Alternative 2. Previous ONRAB field trial programs conducted in both the U.S. and Canada, as well as research conducted on the ONRAB vaccine, have demonstrated its safety and effectiveness in target species populations. Expanding the APHIS-WS ORV program to include the use of ONRAB throughout the ORV zone in ME, NH, NY, OH, TN, TX, VT, VA, VW is not expect to result in any additional adverse effects to target species.

Effects of Monitoring and Surveillance on Target Species Populations

Raccoons

As with the effects of monitoring and surveillance described above for Alternative 1, Alternative 2 is also expected to have negligible adverse risks or impacts to raccoon populations. As discussed above, APHIS-WS and cooperating state and local agencies expect to lethally remove less than 1% of the lowest number of raccoons in all ORV program states, including any raccoons that may be lethally removed during ONRAB monitoring and surveillance. Raccoon populations can generally be expected to withstand harvest rates of about 49 percent or more annually (Sanderson 1987). 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 ME, NH, NY, TN, TX OH, VA, VT, and WV combined for

monitoring and surveillance purposes or implementation of localized contingency plans involving lethal population reduction in all ORV programs.

The estimated cumulative size (over all involved states) of the proposed action that may be treated with ONRAB ORV baits would be 127,992 km^2 (49,418 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 cumulative state-wide raccoon population for the proposed treatment area would be between 2 million and 10.4 million (USDA 2018).

The current APHIS-WS ORV program conducts raccoon monitoring and surveillance activities in 17 eastern states. To date lethal removal has accounted for less than 0.006% - 0.2% of the lowest estimated raccoon population annually (USDA 2019, 2018, 2017a, 2016a, 2016b, 2014) indicating that the potential for cumulative impacts to raccoon populations continues to be negligible.

APHIS-WS rabies management program's lethal removal of far less than 1% of raccoons did not reduce statewide or regional densities of raccoons. As a result of the review of possible impacts to raccoons, the potential for cumulative impacts continues to be negligible.

Striped Skunks

The effects of the proposed alternative on striped skunk populations would be similar to those with the current program. Although striped skunk population estimates were not available for the states involved in the proposed expanded ORV program at the time of this publication, the best available information was used to estimate statewide populations. There are approximately 19 million, 5 million, 30 million, 26 million, 25 million, 164 million, 22 million, 5 million, and 14 million rural acres in ME, NH, NY, OH, TN, TX, VT, VA, and WV, respectively (USDA 2009b). Using the assumption that 50% of rural lands throughout the states have sufficient habitat to support striped skunks, skunks are found only in rural habitat, and skunk densities average 1 skunk per 77 acres, conservative statewide striped skunk populations can be estimated at over 123, 400 for ME, 25,900 for NH, 194,800 for NY, 168,800 for OH, 162,300 for TN, 6,300,000 for TX, 142,800 for VA, 32,500 for VT, and 90,900 for WV. 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 program in each state. 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 signs of strange behavior, a potential indication of rabies infection, 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 for hunters or trappers consuming skunks that contain drug residues (see Section 2.2).

Gray foxes and Coyotes

The APHIS-WS program in Texas has analyzed the impacts of program activities on gray fox and coyotes populations including activities that involve assistance with rabies monitoring and surveillance in several previous EAs (USDA 2013, 2014a, 2014b, 2014c, 2014d, 2014e, 2015a, 2015b). Those EAs covered such activities in the area of the state affected by the ORV program as well as the entire state, and include analysis of the effects of all lethal removal of gray foxes and coyotes by APHIS-WS. The analyses in, and subsequent monitoring reviews of, the EAs showed that APHIS-WS' total take of gray fox and coyotes combined with other known take (e.g. annual trapper and hunter harvest), has been far below any level that would begin to adversely impact overall populations of gray foxes and coyotes (USDA 2013, 2014a, 2014b, 2014c, 2014d, 2014e, 2015a, 2015b). Thus, the cumulative impact on gray fox and coyote populations in Texas would be insignificant.

These EAs state that gray fox populations can generally be expected to withstand annual harvest rates of about 25 percent or more (Fritzell 1987). Table 3-2 shows the number of gray foxes removed by the Texas WS program equates to 1.1% - 1.2% of the estimated population. These levels are far below the sustainable harvest level of 25%.

Table 3.2 APHIS-WS Operations and Private Harvest Impacts to Gray Fox Populations in Texas 2014-2016.

Year	WS Kill[7] All WS Programs/ (ORV Specimens)	Other Harvest[8]	Total	Estimated Population	Cummulative Take as a % of Population
2014	1,308 (82)	7,846	9,154	810,000	1.1%
2015	1,259 (71)	7,846	9,105	810,000	1.1%
2016	1,474 (46)	7,846	9,320	810,000	1.2%

Impacts on coyote populations from APHIS-WS depredation management and rabies monitoring activities in Texas were also analyzed in prior EAs (USDA 2013, 2014a, 2014b, 2014c, 2014d, 2014e, 2015a, 2015b). Those EAs covered such activities in the area of the state affected by the coyote rabies ORV program and include analysis of the effects of all lethal removal of coyotes in those areas by APHIS-WS.

Analyses show that APHIS-WS' take in combination with other known harvest (e.g., sportsman harvest) has been less than 12% of the estimated population in Texas [approximately 5.5% harvested by sportsman, 6.5% by WS] in any one year since 2014 (USDA 2016, 2018, 2019) which is far below the 70% harvest level that can be sustained by coyotes (Pitt et al. 2001, Connolly and Longhurst 1975, and Connolly 1995). Thus, the cumulative impact on coyote populations in Texas would be insignificant. Combining APHIS-WS lethal removal during ORV activities with all other APHIS-WS lethal take and sportsman harvest continues to result in take that is well below sustainable harvest levels. Therefore, cumulative impacts (monitoring and surveillance, localized population reduction, annual trapper and hunter harvest, and other mortality) to coyote populations have been and are expected to continue to be negligible.

Table 3.3 APHIS-WS Operations and Private Harvest Impacts to Coyote Populations in Texas.

Year	WS Kill [7] All WS programs/ (ORV specimens)	Other Harvest[8]	Total	Estimate Population	Cummulative Take as a % of Population
2014	17,539 (113)	17,132	34,671	318,000	10.9%
2015	16,922 (75)	17,132	34,054	318,000	10.7%
2016	18,090 (107)	17,132	35,222	318,000	11.1%

Non ORV Target Species

As discussed above, non-ORV target animals captured in cage traps would normally be released unharmed unless the animal appears sick or injured. Therefore, monitoring and surveillance activities that would occur with the implementation of Alternative 2 should have little or no effect on non-ORV target populations.

Alternative 3 - Live-Capture Vaccinate and Release Alternative

Effects of the ORV ONRAB Vaccine on Raccoons, Gray Foxes, and Coyotes

Under this alternative, APHIS-WS would not provide funds for ORV purchase and distribution but would assist in monitoring and surveillance programs involving the capture or lethal collection and testing of wild raccoons, gray foxes, and coyotes following live-capture-vaccinate and release activities. Under a live-capture-vaccinate-release alternative, it is expected that little or no ORV use by the states would occur. Thus, there would be little or no potential for the ONRAB oral vaccine to affect these species.

[7] https://www.aphis.usda.gov/aphis/ourfocus/wildlifedamage/SA_Reports/SA_PDRs

[8] Gray fox and coyote 5-year average, FY 1998-2002 (TPWD 2005)

Effects of Monitoring and Surveillance on Raccoons, Gray Foxes, Coyotes, and non-ORV Target Species

Under a live-capture-vaccinate-release alternative, it is expected that extent of lethal removal of raccoons in eastern states and gray foxes and coyotes in Texas for monitoring/surveillance activities or localized population reduction under contingency plans to address rabies outbreaks would be similar to the proposed action.

Alternative 4 - No Animal Surveillance or Monitoring or Lethal Removal Program Alternative

Under this alternative, the states would have to fund collection of target species for monitoring and surveillance without APHIS-WS funds or personnel assistance. This would likely mean that less monitoring would be conducted. If insufficient monitoring and surveillance occurs along the leading edge of the advancing rabies variants, rabies managers would not be able to plan the most efficient and effective use of ORV baiting strategies to control the specific variants spread by wild carnivores. One possibility is that, without adequate surveillance, managers would have to resort to distributing ORV baits across more areas than necessary. The ability to stop or prevent the forward advance of specific rabies variants would likely be reduced, perhaps to the point that cooperative efforts fail.

Effects of Monitoring and Surveillance on Raccoon, Gray fox, Coyote, and non-ORV Target Species

Under this alternative, APHIS-WS would not provide assistance in collecting animal specimens for monitoring purposes. The involved states could still conduct such collections; however, it is likely that fewer animals would be collected without APHIS-WS funds and assistance for that activity. Effects on raccoon, gray fox, coyote, and other target species populations would be exceedingly minor as supported by the Alternative 1 analysis in this section.

Alternative 5 - No Federal ORV Program

It is most likely that fewer raccoons, gray foxes and coyotes in the proposed ORV zones would be vaccinated against rabies without APHIS-WS funds to contribute to ORV bait purchases and distribution. Therefore, more animals would likely die from rabies with potentially greater short-term population impacts. Such impacts would be expected to recur as raccoon, gray fox or coyote populations have strong capabilities to recover (Connolly and Longhurst 1975, Fritzell 1987, and Sanderson 1987), which would establish new populations susceptible to rabies mortality. If the state ORV programs failed for lack of APHIS-WS assistance, rabies epizootics may be expected to occur that would likely result in short-term die-offs of target species over broader geographic areas.

Effects of the ORV ONRAB Vaccine on Raccoons, Gray Foxes, and Coyotes

Under the no federal program alternative, states would still be able to employ the ONRAB oral vaccine to combat raccoon rabies, and Texas would still be able to use ONRAB to combat gray fox and coyote rabies. As concluded in the Alternative 1 analysis in this section, baits using the ONRAB vaccine would have no adverse impact on raccoon, gray fox or coyote populations.

Effects of Monitoring and Surveillance on Raccoon, Gray Fox, and Coyote Populations

Under the no federal program alternative, states would still likely implement some level of monitoring, control, and, potentially, implementation of contingency actions in response to breaches in vaccination barriers that result in localized population suppression to attempt to maintain the integrity of vaccination barriers. The numbers of raccoons, gray foxes, and coyotes killed under such programs would probably be less than if APHIS-WS funds and personnel were available. Therefore, as supported by the Alternative 1 analysis in this section, effects on raccoon, gray fox, and coyote populations would be insignificant.

3.1.2 Potential for Adverse Effects on Nontarget Wildlife, Including Threatened and Endangered Species

Alternative 1 – Continue the Current ORV Program (No Action)

Effects of the ONRAB Vaccine on Nontarget Wildlife including Threatened or Endangered Species

A primary concern of the ONRAB 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 ONRAB (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 ONRAB, however viral nucleic acids were detected in some tissues or feces of some vaccinated animals, suggesting that ONRAB 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 ONRAB 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.

APHIS-WS' National Wildlife Research Center (NWRC) conducted research expanding on the species evaluated by Knowles et al. (2009) to investigate the safety of ONRAB in wildlife species likely to come into contact with the vaccine-bait as a result of WS' ORV distribution (Fry et al. 2013). A 10x dose of ONRAB was administered to Eastern wild turkeys (*Meleagris gallopavo silvestri*), opossums (*Didelphis virginiana*), cottontail rabbits (*Sylvilagus floridanus*), fox squirrels (*Sciurus niger*), and woodrats (*Neotoma spp*.). Oral swabs, feces, and blood samples were collected from all species. Following inoculation, no behavior changes were observed in any of the animals. By 7 days post-inoculation (dpi) no viral DNA was detected in the fecal swabs of turkeys, opossums, or cottontails and by 21 dpi no viral DNA from fecal swabs was detected in any of the individuals. At 7 dpi oral shedding was detected in only three of the treated fox squirrels. The limited viral recovery through both oral and fecal routes is of minimal concern regarding potential persistence of ONRAB in nontarget species (Fry et al. 2013). Post-mortem examination did not reveal gross or histopathological pathology that could be linked to the vaccine. These study results suggest low likelihood or persistence of ONRAB in the environment or in individual animals that contact the vaccine even at ten times the desired dose (Fry et al. 2013). Based on the study results, Fry et al. (2013) determined that there was no reason to conclude that ONRAB would have detrimental effects on nontarget wildlife species that incidentally ingest ONRAB during ORV campaigns in the U.S. Similarly, the distribution of ONRAB to control the spread of rabies in Canada has not resulted in any concern regarding nontarget species.

As stated in section 3.1.1, 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 ONRAB vaccine virus would not be expected to support active replication of the virus.

T&E Species ONRAB Effects

Although no T&E species were specifically tested for safety of ONRAB baits, safety studies involving ONRAB on other species representing 11 unique taxonomic families listed above indicate that no species will be affected by the baits (Knowles et al. 2009, 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). Conversely, 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 than in non-treatment areas. No federally listed species occurring in the states affected would be expected to consume or contact the ONRAB vaccine; the ORV program will have no effect on any listed species (see Appendix B for species list). Additionally, APHIS-WS has obtained and reviewed the list of state-listed T&E species and Special Concern species, as well as the USDA-Forest Service Regional Forester Sensitive Species (see Appendices C and D 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 NH, NY, OH, VT, or WV.

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

The methods proposed for use in rabies monitoring and surveillance areas or in implementing localized population reduction under state contingency actions 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.

Annual reporting since preparation of the first ORV-related EA in 2001 and data analyzed for program activities through 2016 (USDA 2013, 2014, 2015, 2016) indicate that nontarget populations have not been adversely affected by APHIS-WS actions. No reports have been received regarding nontarget wildlife experiencing adverse reactions to baits. Nontarget wildlife species have been incidentally captured during ORV monitoring and surveillance efforts. A total of 4,391 nontargets were captured between 2015 and 2016. Most species were captured in cage traps and released unharmed (4,355 nontargets were released out of the total capture of 4,391). The nontargets that were euthanized or died were not considered to be from low density populations and removal was not expected to have any cumulative adverse effects on populations in the area.

Table 3.4 Nontarget Species Taken by WS for the WS for the ORV Program 2015-2016.

Year	2015		2016	
Species	**Freed**	**Killed**	**Freed**	**Killed**
Virginia opossum	1,355		1,720	2
Woodchucks	129	4	135	2
Feral cats	105		143	3
Eastern gray squirrels	99	5	270	11
Cottontail rabbits	70		42	
Fishers	30		40	
Fox squirrels	15	2	16	
Norway rats	10		1	1
American crows	2			
Gray Catbird	2			
Mink	7		3	

Eastern cottontail rabbit			31	2
Red squirrels	6	1	18	2
Wild turkey			1	
Eastern box turtle	1		5	
Muskrats	5		4	
Porcupines	8			
Painted turtle	1			
Brown thrashers			2	
Ruffed grouse			6	
Northern cardinal	1			
Common grackle	10			
Feral dogs	2		4	
Northern mocking bird	1			
River otter	2		1	
Ovenbird	1		2	
Turtles (other)	8		2	
Eastern wood rats	6		9	
Eastern chipmunk	1		1	
Snowshoe hares	8		9	
Common snapping turtle			1	
Gray partridge				1
American robin	1			
Black bear	1		1	
Turkey vulture	1			

From 2001 to 2014, several additional species were captured as nontargets. Most were similar to the nontarget or target species taken in 2014 and 2015. Other than the target and nontarget species taken and listed above, additional mammals were trapped between 2001 and 2010 included a mountain lion, bobcat, domestic ferret, long-tailed and least weasels, spotted skunk, ringtail, field mouse spp., cotton rats, black rats, and marsh rabbits. Additional birds included feral chickens, pheasants, bobwhites, turkey vultures, black vultures, red-winged blackbird, great-horned owl, brown-headed catbird, mallard, American bittern, sharp-shinned hawks, red-tailed hawks, Northern flickers, blue jays, and wood thrush. Finally an alligator, several species of turtles, and bullfrogs have been taken. Most of these species were taken in cage traps and released. Many of these species are likely taken more haphazardly (entering the trap not for the bait, but because it is there) rather than as a result of being attracted to the lure or bait.

Some of the methods proposed for use in collecting target species within ORV zones or other contingency action locations have the potential for accidentally catching or killing nontarget animals (i.e., cage traps, leghold traps, or snares). However, measures such as size or location of traps and types of baits used help to minimize the potential for capturing nontargets. Methods such as ground-based and aerial shooting have no effect on nontarget species as they are essentially 100 percent selective for target species. APHIS-WS has analyzed the effects on nontarget species by such methods in numerous EAs, including this EA, which found no significant adverse effects on populations (USDA 2013, 2013b, 2014, 2014b, 2014c, 2014d, 2014e, 2014f, 2014g, 2015b, 2015c, 2015d, 2016, 2017b, 2018b, 2019b, 2019c).

TVR of targets and specific nontargets, such as skunks and feral cats that are known to harbor and transmit rabies involves the use of a parenteral (injectable) vaccine, such as IMRAB® 3, which can be used “off label” under the direction of veterinarians to vaccinate healthy wildlife. Although targeted species include raccoons in the eastern U.S. and coyotes and gray foxes in Texas, some nontargets have a propensity for contracting, harboring, and spreading the rabies virus which complicates rabies control. Therefore, some nontarget wildlife species, such as skunks, may be vaccinated if incidentally captured during TVR activities. Healthy nontarget animals that are vaccinated should exhibit no effect other than becoming immunized against rabies. The majority of nontargets would be released at the site of capture, whether vaccinated or not. Nontargets would be euthanized for rabies diagnostic testing, if they appear sick, injured, or are demonstrating strange behavior symptomatic of the rabies virus.

Some of the methods proposed for use in collecting target species within ORV zones or other contingency action locations have the potential for accidentally catching or killing free-roaming, domestic animals (i.e., cage traps, leghold traps, or snares). However, measures such as size or location of traps and types of baits used help to minimize the potential for capturing nontargets, including domestic animals. Methods such as ground-based and aerial shooting have no effect on nontarget species as they are essentially 100 percent selective for target species. APHIS-WS has analyzed the effects on nontarget species by such methods in numerous EAs, including this EA, which found no significant adverse effects on populations (cite EAs). Pets and other domestic animals captured incidentally in traps would either be released at the site of capture or brought to the local animal control shelter.

T&E Species Monitoring and Surveillance Effects

No federal T&E species have been adversely affected by APHIS-WS actions during the course of the ORV program between 2001 and 2016. Between 2001 and 2016, a total of 2 federal T&E and one federal candidate species were incidentally captured and all three were released unharmed. One American alligator (*Alligator mississippiensis*) was incidentally captured in Florida during the 2003 ORV program and a second was captured during the 2004 ORV program; however, both were released unharmed. The American alligator was delisted in 1987 and reclassified as "threatened due to similarity of appearance (T-S/A)" [50 CFR 17.42(a)] to the endangered crocodile and is state-listed as a species of concern in Florida. The federal designation regulates commercial sale and trade of alligator skins and other products. Because the animals were released unharmed, APHIS-WS did not violate the spirit of the "similarity of appearance" designation of the Endangered Species Act. During the 2006 ORV program, a gopher tortoise (Gopherus polyphemus) was captured and released unharmed in Florida. In 2006 the gopher tortoise was state-listed in Florida as a Species of Special Concern. Subsequently, in 2011, the gopher tortoise was listed by the USFWS as a candidate species (76 FR 45130-45162).

Additionally, 5 state listed species were also captured during ORV programs from 2001 through 2016. In 2001, one state-endangered river otter (*Lutra canadensis*) was incidentally captured in a cage trap during Ohio ORV surveillance activities, but was released unharmed in accordance with the direction of the Ohio Division of Wildlife. River otters have since been delisted in 2002 due to rapidly increasing numbers of the species throughout Ohio (Ohio 2013). Three eastern box turtles (*Terrapene carolina*) have been captured in MA during ORV activities (two in 2006 and one in 2007). All three were released unharmed. The Eastern box turtle is a state-listed in Massachusetts as a Species of Concern. During 2007 ORV activities, one timber rattlesnake (*Crotalus horridus*) was captured and subsequently euthanized due to injuries it had sustained. The timber rattlesnake is state-listed in West Virginia as a "Vulnerable" species.

Some of the methods proposed for use in collecting target species in ORV areas have the potential for accidentally catching or killing nontarget animals (i.e., leghold traps or snares). Methods such as ground-based and aerial shooting would have no effect on nontarget species because they are essentially 100 percent selective for target species. APHIS-WS has analyzed the effects on nontarget species in NH, NY, OH, VT, and WV by such methods in previous EAs which found no significant adverse effects on populations (USDA 2013b, 2018b, 2014g, 2019c, 2015d).

APHIS-WS reviewed the lists of federal and state T&E species (Appendices B and C) and USDA-Forest Service Regional Forester Sensitive Animals (Regions 8 and 9) 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.

Federally Listed T&E Species (USFWS 2019):

The current lists of species designated as threatened and endangered in New Hampshire, New York, Ohio, Vermont, and West Virginia as determined by the USFWS were obtained and reviewed during the development of this EA. WS has consulted with the USFWS, as appropriate, in the development of several state mammal damage management EAs (USDA 2013b, 2018b, 2014g, 2019c, 2015d) in the affected states. As the methods used in the ORV program (e.g., cage traps) were considered in the development of those EAs, those consultations are appropriate for this EA.

The ORV program has the potential to capture/take T&E species. 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 mammals contracting and dying from rabies. Raccoons, gray foxes, and coyotes are the primary targeted species in surveillance and monitoring with other species such as striped skunks, red foxes, 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.

Canada Lynx (*Lynx canadensis*). This species was recently declared federally threatened in the states of New York, and Vermont (68 FR 40076-40101, July 3, 2003) in the ORV field trial area. The primary habitat for this species is boreal forest with an abundance of snowshoe hare (*Lepus americanus*). No breeding populations are known to exist in New Hampshire or Vermont. Since 1900, lynx in New York and Vermont have always existed solely as dispersers. If APHIS-WS conducts surveillance and monitoring in lynx occupied area, WS will only use cage traps and will check them frequently. Bobcats have been captured in cage traps and the potential exists for a lynx to be taken. Therefore, APHIS-WS determined that the proposed action has the potential to take a lynx if APHIS-WS conducts ORV monitoring in their habitat, but otherwise will have no effect on this species.

WS conducted a formal consultation under Section 7 with the USFWS, and a Programmatic Biological Opinion (PBO) resulted, dated April 27, 2018. The PBO reviewed the potential effects of the WS MDM program on the federally listed Canada lynx and the federally endangered Atlantic salmon (*Salmo salar*) and their respective designated critical habitat. The PBO findings showed a no effect and not likely to adversely affect determinations for these species and their habitats (USFWS 2018). The PBO describes the methods used to avoid disturbance and take of the federally listed Atlantic salmon and Canada lynx (USFWS 2018).

Carolina Northern Flying Squirrel (*Glaucomys sabrinus coloratus*). The Carolina northern flying 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. APHIS-WS has conducted Section 7 consultations in the range of the squirrels and abides by the Reasonable and Prudent Alternatives and Measures, and Terms and Conditions of all Biological Opinions. (USDA 2017b, 2015c)).

For the remainder of the species listed, APHIS-WS concluded a “no effect” determination.

State Listed Species and Regional Forester Species:

APHIS-WS has the potential to take some state-listed T&E and sensitive species. If a state listed species or RFSS were inadvertently captured it would be immediately released to avoid lethal take and reported to the appropriate wildlife agency. APHIS-WS believes, though, that the state-listed species from the following groups will not be impacted, except potentially very minimally, and, therefore, will not be discussed further: bats, insectivores (moles/shrews), birds, reptiles, amphibians, invertebrates, and plants. APHIS-WS believes that if APHIS-WS does have any potential to impact species it would be from the following groups of mammals: rodents, lagamorphs, and carnivores. The woodland jumping mouse (*Napaeozapus insignis*) is likely too small to be held by cage traps or other monitoring methods and will not be discussed further. As discussed, ORV is not expected to cause any adverse effects on any of the sensitive species occurring within the field trial zone (Knowles et al. 2009). It is expected that the vaccination of wild animals, including the primary target species and, potentially T&E species, could have a beneficial effect on T&E mammals, especially carnivores that are more likely to be in contact with infected animals. The chance of a T&E mammal species being exposed in an ORV treatment area is extremely low. However, APHIS-WS does have the potential to incidentally capture certain state-listed T&E and sensitive species during monitoring and surveillance. The following species have the potential to be taken during ORV monitoring and surveillance activities and are discussed in detail below.

New England Cottontail (*Sylvilagus transitionalis*) The New England cottontail is a state-listed species in New Hampshire. This species could be taken in cage traps, leghold traps, or snares. If cage traps are used in their ranges, they will be located such to minimize exposure and checked frequently enough to release them alive. Leghold traps will be equipped with pan-tension devices to preclude capture. Snares will be elevated off the ground high enough to minimize potential exposure especially for cottontails or not set in areas where they would likely be taken. Therefore, proposed activities in Alternative 1 will have minimal potential to take these species and will have virtually no impacts on their populations.

American marten (Martes Americana). This species is state-listed as endangered in Vermont. It is conceivable that this species could consume ORV baits intended for other target species. Although not specifically tested for safety in this species, safety studies on other nontarget species (Knowles et al. 2009) indicate that martens would not be adversely affected if they were to consume ORV baits. If a marten were inadvertently captured in a trap set for the target species, it would be released unharmed to avoid lethal take and reported to the appropriate state agency to complement their population monitoring data for this state-listed species. An indirect beneficial effect of rabies management would be a reduced risk of the species suffering further declines due to a rabies epizootic. Therefore, the proposed action should have no significant impact on this species.

Southern Bog Lemming (*Synaptomys cooperi*) and Southern Rock Vole (*Microtus chrotorrhinus carolinensis*). Lemmings and voles may be large enough to be captured in small-wire mesh or enclosed traps used for monitoring smaller predators. These species only have a slight chance of being taken, even in cage traps, because the small rodents could exit the traps through gaps in the door. The primary concern with these species is exposure to the elements such as excessive sun/heat as this could result in lethal take. However, APHIS-WS would check traps frequently in these species' occupied habitat so that any individuals captured could be released unharmed. APHIS-WS will not likely take these species, but a very slight potential exists.

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 released 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.

Black bear (*Ursus americanus*). Black bears are state-listed in Ohio and Texas. Although unlikely, the potential does exist for cage traps to capture black bear cubs. Traps are checked frequently and if a black bear were captured it would be release unharmed. The APHIS-WS ORV program will not adversely impact this species because take, if it occurs, would be exceedingly minimal. It should be noted that the black bear population in the eastern United States is expanding and growing, with several states now having more frequent damage problems associated with the increase.

West Virginia Northern Flying Squirrel (*Glaucomys sabrinus fuscus*). The West Virginia northern flying squirrel is a state species of concern in West Virginia. 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. Additionally, ORV monitoring and surveillance activities would not occur in northern flying squirrel suitable or occupied habitat, typically high elevation spruce-hardwood forests, therefore proposed activities under Alternative 1 will have no effect on this species.

Alternative 2 – Proposed Action (the Preferred Alternative)

Under this alternative, distribution of ONRAB could occur in Maine, Tennessee, Texas, and Virginia in addition to New Hampshire, New York, Ohio, Vermont, and West Virginia. APHIS-WS has determined that the broadened distribution of ONRAB will not result in any additional effects to nontarget species, including T&E species, in the other states (ME, TN, TX, and VA) where baits would be distributed. Further, the proposed program could have an indirect beneficial effect by reducing the chance that nontarget and T&E species are exposed to the rabies virus in the wild.

As discussed above for Alternative 1, the methods proposed for monitoring and surveillance for the proposed action will have no significant adverse effects on nontarget species. Nontarget animals captured in cage traps would normally be released unharmed unless the animal appeared sick or injured. Therefore, monitoring and surveillance should have no effect on nontarget species populations.

T&E Species Monitoring and Surveillance 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. Protective measures to avoid T&E effects are described in section 2.2 of this EA.

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

Federally Listed T&E Species

The current lists of species designated as threatened and endangered in Maine, Tennessee, Texas, and Virginia were obtained and reviewed during the development of this EA. WS has consulted with the USFWS, as appropriate,

in the development of several state mammal damage management EAs (USDA 2013, 2014, 2014b, 2014c, 2014d, 2014e, 2015b, 2015c, 2016, 2017b 2019b) in the affected states. As the methods used in the ORV program (e.g., cage traps) were considered in the development of those EA, those consultations are appropriate for this EA.

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 available for use during monitoring and surveillance activities associated with the proposed expanded ORV field trial, APHIS-WS has determined that the proposed expanded ORV field trial monitoring and surveillance activities in Maine, Tennessee, Texas, and Virginia would not adversely affect the Northern long eared bat (Myotis septentrionalis), Indiana bat (Myotis sodails), gray bat (Myois grisescens), Virginia big-eared bat (Corynorhinus (=Plecotus) townsendii virginianus), Mexican long-nosed bat (Leptonycteris nivalis), and the West Indian manatee (Trichechus manatus). The red wolf (*Canis rufus*) was believed to be extinct in the wild by 1980 with the last remaining known wolves in Texas captured for a captive breeding program. It is still listed in Texas. Two non-essential experimental red wolf populations (NEP) were designated in North Carolina and Tennessee (Parker and Philips 1991). One NEP was established in 1991 in the Great Smokey Mountains National Park of eastern Tennessee and western North Carolina, but was discontinued in 1998 primarily due to poor pup survival caused by domestic dog diseases (Henry 1998). The other NEP began in 1987 on the Albemarle Peninsula of northeastern North Carolina near the Outer Banks region; this population is currently the only population of red wolves known to exist in the wild. Annual counts for the red wolf NEP in North Carolina has been between 100 and 130 (USFWS 2007). The NEPs are not located within current or anticipated ORV zones. Therefore, the ORV bait distribution would have no effect on this species.

In addition to those species described above under Alternative 1, the following species have been further considered.

Carolina Northern flying squirrel (Glaucomys sabrinus coloratus).

This species is federally-listed in TN and VA. These squirrels 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 one of these species was present, APHIS-WS Specialists would implement measures to minimize the potential for take. Cage traps would be baited with unattractive baits. APHIS-WS would monitor the traps frequently and close them when the target species were not likely to be present (e.g., most target species are nocturnal whereas the fox and red squirrels are diurnal, thus, traps could be closed during daylight hours to avoid capture). If APHIS-WS uses leghold traps in any of these squirrels' ranges, pan-tension devices will be used on leghold traps to preclude capture. 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. APHIS-WS has conducted Section 7 consultations (USDA2015c, 2017b) in the range of the squirrels and abides by the Reasonable and Prudent Alternatives and Measures, Terms and Conditions of all BOs, and Incidental Take Permits.

Jaguar (*Panthera onca)*. This species is federally designated as endangered in Arizona, New Mexico, Texas, and Louisiana. The jaguar's historic range included the much of the southern U.S. from California, to Louisiana, south through Texas to central South America. However, the species' current distribution only includes central Mexico to central South America as far south as northern Argentina. There are no known breeding populations in the U.S., although individuals may cross into Texas, New Mexico, and Arizona. Except for occasional wanderers from Mexico, the jaguar is considered extirpated from the U.S. (USFWS 1990, 2007b). McCain and Childs (2008) documented jaguars in Arizona frequently, continuously, and year-round, and videotaped several scent-marking behaviors, indicating the residency of adult jaguars within Arizona. After two sightings of jaguars in 1996, a camera monitoring

program in southeastern Arizona was implemented. From March 2001 to July 2007, 9–44 trail cameras were maintained and opportunistic track surveys were conducted. Two adult males and a possible third unidentified jaguar were observed and recorded with 69 photographs and 28 sets of tracks. One jaguar, originally photographed in 1996, was resighted 64 times between 2004 and 2007 (McCain and Childs 2008). The USFWS (2007) recently concluded in a statement, however, that regular or intermittent use of the borderlands area by wide-ranging males, and no evidence of the presence of females or cubs, indicates that the U.S. does not support a separate breeding population. Therefore, actions taken within the U.S. are likely to benefit a small number of individual jaguars peripheral to the species' range, with little potential to effect recovery of the species as a whole. Thus, the USFWS does not support development of a formal recovery plan at this time.

APHIS-WS does not anticipate take of a jaguar because they are rare in the analysis area with only adult males being documented, are generally not attracted by the baits used, and are too large for most methods that would be used in ORV surveillance and monitoring program. It is conceivable that a jaguar cub could be taken, but highly unlikely. Additionally, the USFWS (1999a and b) issued a BO on the effects of the APHIS-WS program on the jaguar in 1999 and determined that activities by APHIS-WS were not likely to jeopardize the continued existence of this species. The BO contained an incidental take statement with reasonable and prudent measures and terms and conditions that APHIS-WS follows to minimize the risk of incidental take (USFWS 1999a and b). APHIS-WS personnel abide by the requirements of the BO which minimize further the unlikely potential for take.

Gulf Coast jaguarondi (*Herpailurus (=Felis) yagouaroundi cacomitli*) and Ocelot (*Leopardus (=Felis) pardalis*). The Texas Wildlife Services Program (TWSP) initiated consultation with the USFWS for the ocelot and jaguarondi and the USFWS issued a Biological Opinion in 1997. The USFWS issued a "may affect, but not likely to jeopardize" opinion with reasonable and prudent measures to avoid Take. TWSP reinitiated consultation with the USFWS for ocelot. The USFWS issued a new Biological Opinion in 2010 with a "may affect, but not likely to jeopardize" opinion with reasonable and prudent alternatives and measures to avoid take. WS will continue to abide by these measures during the proposed ORV activities described under the preferred alternative to avoid any adverse impacts.

Gray Wolf (*Canis lupus*). This species is not known to currently occur in any of the states where WS conducts ORV. The ORV program would likely only use small cage traps in the range of wolves in the U.S. to preclude capture. However, all use of traps, including padded-jaw leghold traps, would comply with the Reasonable and Prudent Measures and Terms and Conditions of the B.O.s and 10j rules implemented to protect wolves. Any traps used would be checked frequently enough to allow release. WS does not anticipate taking any wolves, but the potential exists. It should be noted that Krebs et al. (2003) documented 31 cases of rabies in gray wolves in the U.S. between 1960 and 2000.

State Listed Species and Regional Forester Species:

In addition to those species described above under Alternative 1, the following species have been further considered.

Louisiana Black Bear. The Louisiana black bear and American black bear are state listed threatened in Louisiana, Mississippi, and Texas. This species could be taken with leghold traps and snares. However, these will not be used in occupied habitat. APHIS-WS has taken a nontarget black bear, a cub, in a cage trap which was released, but not in the listed states. APHIS-WS does not anticipate taking a Louisiana black bear and will take measures to avoid take.

White-nosed Coati. This species is state-listed as an endangered species in Texas. It could be taken as a nontarget with cage traps, leghold traps, and snares during ORV surveillance activities. To minimize take, cage traps will be checked frequently and placed in areas not exposed to harsh elements as possible. Pan-tension devices will be used on traps to exclude capture of larger predators. Neck snares will be used at a minimum in their range.

According to ADHS (2007) eight coatis were found positive for rabies in Arizona between 1968 and 1977 and Krebs et al. (2003) documented 12 cases of rabies in coatis between 1960 and 2000. In March, 2008 a coati tested positive for rabies in Pinal County, Arizona (KVOA NEWS 2008). Thus, an indirect benefit of rabies management programs would be a reduced risk of the species suffering further decline because of a rabies epizootic. Therefore, the proposed action should have no significant impact on this species.

Snowshoe hare. This species is state-listed in Virginia and could be taken in cage traps, leghold traps, or snares. If cage traps are used in their ranges, they will be located such to minimize exposure and checked frequently enough to release them alive. Leghold traps will be equipped with pan-tension devices to preclude capture. Snares will be elevated off the ground high enough to minimize potential exposure especially for cottontails or not set in areas where they would likely be taken. Therefore, proposed activities in Alternative 1 will have minimal potential to take these species and will have virtually no impacts on their populations.

Alternative 3 - Live-Capture Vaccinate and Release Alternative

Under a live-capture-vaccinate-release alternative, it is expected that little or no ORV use by the states would occur. Thus, there would be no potential for the ONRAB oral vaccine to affect nontarget species. Live-capture-vaccinate-release programs would be virtually 100 percent selective for target species and would therefore have little or no potential to affect nontarget wildlife. However, APHIS-WS would continue to assist in monitoring activities and, potentially, in localized contingency plans that involve the use of lethal methods such as those discussed under the proposed action. The potential for effects on nontarget species would be similar to the current and proposed actions. The Alternative 1 and 2 analysis in this section shows that effect on nontarget and T&E species would be negligible.

Alternative 4 - No Animal Surveillance or Monitoring or Lethal Removal Program Alternative

Effects of the ONRAB vaccine on nontarget wildlife would be the same as under the current and proposed actions. The Alternative 1 and 2 analysis in this section showed that adverse effects are unlikely. However, more animals are likely to die of rabies if the lack of federal assistance in monitoring and surveillance results in a reduction in the effectiveness of ORV programs.

Under this alternative, APHIS-WS would not continue to assist in monitoring activities or local depopulation activities that involve the use of lethal methods such as those discussed under the proposed action. Therefore, the potential for adverse effects on nontarget species would be even lower than under the proposed action. States would still likely implement monitoring and localized population reduction actions even without APHIS-WS, but such activities would likely be on a lesser scale without APHIS-WS funds. However, the Alternative 1 and 2 analysis in this section indicates that the effects on nontarget and T&E species would not be significant under the proposed action and would likely also not be significant even without APHIS-WS assistance.

Alternative 5 - No Federal ORV Program

Under the no federal program alternative, there would be no potential for APHIS-WS assistance to result in adverse impacts on nontarget wildlife because of ORV programs. However, states would still be free to conduct ORV programs using the ONRAB vaccine. Such programs would probably be conducted on a reduced scale without APHIS-WS funds. However, based on the Alternative 1 and 2 analysis in this section, there is almost no potential for adverse effects on nontarget wildlife because of ORV bait consumption under any scenario involving the distribution of baits containing the ONRAB vaccine.

Under the no action alternative, the potential for APHIS-WS assistance to result in adverse impacts on nontarget wildlife would be zero. However, states could still conduct ORV programs and monitoring that include the capture and/or killing of wild animals for monitoring purposes or localized depopulation under contingency plans. The

potential effect on nontarget wildlife and T&E species from methods used in monitoring and surveillance programs would be less than the proposed action, but, similar to the proposed action, would be insignificant.

3.1.3 Potential for adverse effects on people, pets, and livestock that are exposed to or consume the vaccine laden baits

Alternative 1 – Continue the Current ORV Program (No Action)

Potential to Cause Rabies in Humans

The nature of the recombinant virus used as the ONRAB vaccine is such that it cannot cause rabies. This is because the ONRAB 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 ONRAB 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 humans, 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. 1955, 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 (Foy 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 ONRAB could present health hazards to humans, especially children or adults with immunocomprised status, given that ONRAB 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).

Over 150 million doses of ORV utilizing V-RG have been distributed in the U.S. since the early 1990s. Human contact with V-RG has been rare, with only two reported human *Vaccinia* infections having occurred from vaccine exposure. However, ONRAB is an alternative that may have a different human safety profile than V-RG given the high prevalence of antibodies in humans to adenovirus type 5 as well as the generally mild illness that may result from infection with this virus (CDC 2013). The ONRAB vaccine employs a human adenovirus type 5 vector into which has been inserted a glycoprotein gene from the ERA rabies vaccine virus. While 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), adenovirus infections are ubiquitous and are normally without significant or severe clinical symptoms. Adenoviruses are distributed worldwide and infections with human adenovirus type 5 do not typically result in serious disease (Rowe et al. 1995, Andiman and Miller 1982, Charlton et al. 1992, Russell 1998 *in* Rosatte et al. 2009).

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 ONRAB 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 ONRAB 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 ONRAB 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 ONRAB, 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 ONRAB from tissues, feces, and oral samples of animals given a relatively high dose of vaccine.

Overdosage of ONRAB 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 (2011c) documented that of the more than 100 million baits distributed during the APHIS-WS program between 1995 and 2008 only 1,327 instances have been reported where a pet or other domestic animal had contact with a bait. This equates to 1 domestic exposure per 75,596 baits disbursed or 0.001 % contact cases.

Following the 2012 ORV bait distribution in Ohio, there were 38 reports involving domestic dogs, resulting in 3 adverse events (CDC 2013). One adverse event involved an ONRAB bait that temporarily obstructed a dog's airway, but the dog survived. The remaining two events involved vomiting or regurgitation following consumption of V-RG baits. There were no other reports of domestic animal exposures. There were fewer reports of domestic animal exposures in Ohio during 2012 than during the preceding three years in the same general area (CDC, unpublished data).

Table 3.5. Comparison of domestic animal to ORV bait contact rates in Ohio verses all U.S. ORV states[9] (CDC unpublished data).

	Ohio		U.S.	
	# Bait Contacts	**# Baits Distributed**	**# Bait Contacts (avg.)**	**# Baits Distributed**
2009	79	874,301	13	9,572,753
2010	74	774,714	22	8,868,939
2011	69	863,215	15	7,920,640
2012	38	776,921	N/A	7,299,174

Table 3.6. Domestic Animal ORV Bait Contacts in Ohio, 2010 – 2014 (USDA unpublished data).

Year/Bait Type	# Pet-Bait Contacts	# Baits Distributed
2010 V-RG	74	774,714
2011 V-RG	69	863,215
2012 ONRAB & V-RG	38	776,921
2013 ONRAB	4	269,100
2013 V-RG	13	511,705
2014 ONRAB	2	224,550
2014 V-RG	11	507,569

In 2014, a caller reported finding an unknown number of V-RG baits on their property and, at some point subsequent to this, the caller's dog died. The caller did not report seeing the dog consume baits, however caller was seeking reimbursement for the pet. The caller was referred to the USDA-APHIS-Financial Management Division; however no claim was filed by caller.

Table 3.7. Domestic Animal ORV Bait Contacts in West Virginia, 2010 – 2014 (USDA unpublished data).

Year/Bait Type	# Pet-Bait Contacts	# Baits Distributed
2010 V-RG	20	1,115,993
2011 V-RG	10	1,019,156
2011 ONRAB	0	79,027
2012 V-RG	11	1,032,457
2012 ONRAB	0	132,678
2013 V-RG	4	1,021,017
2013 ONRAB	1	132,000
2013 Unknown	1	N/A
2014 V-RG	5	1,109,284
2014 ONRAB	2	418,500
2014 Unknown	3	N/A

Pet-vaccine exposures remained low following 2010 through 2014 ORV field seasons (Tables 3.6 and 3.7). Domestic animal contacts with baits are typically low in the remaining states where APHIS-WS distributes ORV baits and is likely due to the factors described above for human contact rates (e.g., human/pet population densities in the baiting area, number of baits distributed in a particular area, and reporting mechanisms). APHIS-WS expects that

[9] U.S. Domestic animal bait contact rates represent an average of the contacts reported for each state involved in ORV distribution as reported by the states to the CDC.

the rate of domestic animal contacts with ORV baits will remain unchanged under the proposed action. Impacts of the program on this issue are expected to remain negligible.

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 ONRAB are most likely to be immunized against rabies or receive a boost from a previous vaccination. APHIS-WS expects that the effects of implementing Alternative 1 would have only a negligible risk of adversely affecting pets or other domestic animals that are exposed to or consume the vaccine laden bait.

Alternative 2 – Proposed Action (the Preferred Alternative)

Potential for Adverse Effects on People that Become Exposed to the Vaccine or the Baits

Implementation of the Proposed Action (expanded use of ONRAB throughout the ORV zone in Maine, New Hampshire, New York, Tennessee, Texas, Vermont, Virginia, and West Virginia) as described in Section 2.3 is not expected to increase the potential the potential for adverse effects on humans. The potential for humans to become exposed to a bait is remote (1 human contact per 42,072 baits distributed under current baiting practices) (USDA 2014f). It is highly unlikely, that the effects of expanding ONRAB bait-vaccine distribution into current V-RG bait-vaccine distribution zones will vary from those analyzed in Alternative 1.

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

A similar impact is expected with regard to implementation of Alternative 2 as with Alternative 1 concerning the potential for adverse effects on pets and other domestic animals that might consume the vaccine-baits.

Domestic animal contacts with baits are typically much lower in the remaining states where APHIS-WS distributes ORV baits and is likely due to the factors described above for human contact rates (e.g., human/pet population densities in the baiting area, number of baits distributed in a particular area, and reporting mechanisms). APHIS-WS expects that the rate of domestic animal contacts with ORV baits will remain unchanged under the proposed action. Impacts of the program on this issue are expected to remain negligible. Under current baiting practices the rate of domestic animal contact with ORV baits is 1 pet contact per 60,185 baits distributed (USDA 2017a)

Alternative 3 - Live-Capture Vaccinate and Release Alternative

Under this alternative, APHIS-WS would not provide funds to purchase or distribute ORV baits but would provide such funds for live-capture-vaccinate-release programs. For purposes of comparison, it is assumed that, with adequate APHIS-WS funding to conduct these types of programs, states would choose not to implement ORV programs.

Potential for Adverse Effects on People that Become Exposed to the Vaccine or the Baits

Live-capture-vaccinate-release programs might be as effective as ORV programs in stopping the spread of the three variants of rabies if conducted throughout all areas where ORV programs would have been conducted under the proposed action. The method itself would not present risk of causing rabies in members of the public. The risk of human rabies cases because of the failure to stop epizootics of raccoon, gray fox, and coyote rabies would be about the same as with ORV programs under the proposed action. Because it is assumed that ORV using the adenovirus vector in ONRAB would not be used by states or by APHIS-WS, there should be no risk of adenovirus infections caused by contact with the vaccine from the ORV bait. No increased risk of cancer would result from this alternative.

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

Live-capture-vaccinate-release programs would pose no risk of inadvertent vaccine exposure to pets or other domestic animals.

Alternative 4 - No Animal Surveillance or Monitoring or Lethal Removal Program Alternative

Under this alternative, the states would have to fund collection of target species for monitoring and surveillance without APHIS-WS funds or personnel assistance. This would likely mean that less monitoring would be conducted. If insufficient monitoring and surveillance occurs along the leading edge of the advancing rabies variants, rabies managers would not be able to plan the most efficient and effective use of ORV baiting strategies to control the specific variants spread by wild carnivores. One possibility is that, without adequate surveillance, managers would have to resort to distributing ORV baits across more areas than necessary. The ability to stop or prevent the forward advance of specific rabies variants would likely be reduced, perhaps to the point that cooperative efforts fail.

Potential for Adverse Effects on People that Become Exposed to the Vaccine or the Baits

This alternative would present the same risk as Alternatives 1 and 2. Since the ONRAB vaccine cannot cause rabies, there would be no potential for the ORV baits to cause rabies in humans under this or any other alternative scenario involving the distribution of ONRAB oral vaccine baits. However, there would be a greater risk of human rabies cases if the lack of federal assistance in monitoring and surveillance results in a reduction in the effectiveness of ORV programs. As shown by the Alternative 1 and 2 analysis in this section, the risk of ONRAB vaccine in ORV baits causing any health problems in humans is exceedingly low. This alternative would result in no probable risk of causing cancer in humans or animals, similar to the proposed action and other alternatives.

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

Under this alternative, the potential for adverse effects on domestic animals from ORV baits would be the same as the proposed action. Based on the Alternative 1 and 2 analyses in this section, there is almost no potential for significant adverse effects on domestic animals because of ORV bait consumption under any scenario involving the distribution of ORV baits containing the ONRAB vaccine. Stopping or preventing the spread of rabies would result in beneficial effects on domestic animals by reducing their likelihood of contracting rabies. However, more domestic animals are likely to die of rabies if the lack of federal assistance in monitoring and surveillance results in a reduction in the effectiveness of ORV programs.

Alternative 5 - No Federal ORV Program

Under this alternative, no APHIS-WS funds would be available for purchasing ORV baits. The states would still likely fund ORV programs to some degree without APHIS-WS' assistance. They may seek other sources of federal funds to complement state or other sources of funding. Thus, people would still have the potential to come into contact with baits or the vaccine; however, the potential would be less. Actual risks of adverse effects from exposure to vaccinia virus would still be exceedingly low and insignificant.

It is conceivable that federal coordination of ORV programs would actually result in fewer numbers of ORV baits used over the years or that ORV bait use in many areas would be for shorter time periods. This is because effective federal coordination may have a better chance of stopping or even eliminating one or more of the several rabies variants from large areas than if the individual states are left to themselves to conduct ORV programs.

Based on the following information, risks to humans from contact with the ONRAB vaccine are believed to be minimal with or without APHIS-WS funding or assistance. The risk and potential severity of adverse effects from rabies exposures in humans would probably be greater without ORV programs than would be the risk of serious adverse effects from vaccinia virus infections with ORV programs.

Potential to Cause Rabies in Humans

The no federal program alternative would most likely result in greater risk of human exposure to rabies than the proposed action because state-run ORV programs without APHIS-WS funds would have less chance of being

successful in stopping or preventing the spread of the three rabies variants. Therefore, an absence of APHIS-WS cooperative funding could be expected to result in increased risk of human rabies cases because of expanding epizootics. The ONRAB vaccine would not cause rabies under any expected scenario involving the distribution of ORV baits.

Potential for Vaccinia Virus to Cause Disease in Humans

Under the no federal program alternative, ONRAB oral vaccine containing the vaccinia virus vector would still be available for state-approved use in ORV programs. Such programs would probably be on a lesser scale without APHIS-WS funds. The potential for vaccinia-related disease cases would be lower than under the proposed action. The likelihood that any cases would occur is extremely remote under any expected scenario involving the distribution of ORV baits.

Potential to Cause Cancer (Oncogenicity)

Under the no federal program alternative, ONRAB oral vaccine containing the human adenovirus type 5 vector would still be available for state-approved ORV programs but would probably be used on less total land area without APHIS-WS funds. Because human adenovirus used in the ONRAB vaccine is not a cancer-causing agent, expected scenarios involving the use of ORV baits by the states would not result in increased cancer risks.

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

Under the no federal program alternative, the potential for APHIS-WS assistance to result in adverse impacts on domestic pets or other domestic animals would be zero. However, states could still conduct ORV programs, but such programs would probably be accomplished on a reduced scale without APHIS-WS funds. Based on the Alternative 1 and 2 analyses in this section, there is almost no potential for adverse effects on domestic animals because of ORV bait consumption under any scenario involving the distribution of baits containing the ONRAB vaccine. On the other hand, 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.

3.1.4 Potential for ONRAB to "revert to virulence" or recombine with other viruses and result in a virus that could cause disease in humans

Alternative 1 – Continue the Current ORV Program (No Action)

The concern here is whether the ONRAB 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 ONRAB 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[10] in a permissive[11] human cell line. The results from this study indicated that the product obtained after 20 passages expressed authentic rabies glycoprotein. Since there

[10] 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.

[11] A permissive cell is a cell that supports replication of a virus.

is little evidence in the literature for the replication of Ad5 in animal species, the primary concern with ONRAB 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).

Recently, Knowles et al. (2009b) conducted both *in vitro*[12] and *in vivo*[13] passages with ONRAB. The results from this study indicated that the titer of the ONRAB 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[14] matched what was expected, indicating no substantial alteration in sequence over this region. The *in vitro* genetic stability of the ONRAB 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 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 ONRAB® 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 the virus does not transmit readily to other animals from animals that have consumed ORV baits as evidenced by Charleton 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 inter-animal transmission when AdRG1 is used in the field.

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

[12] Meaning outside of a living body.
[13] Meaning within a living body.
[14] A piece of DNA formed as the product of natural or artificial amplification events.

The concern here is whether the ONRAB 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 ONRAB to recombine with naturally occurring adenoviruses, the end product of ONRAB 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).

In practice, opportunities for co-infection between different adenovirus species are already present in large animal veterinary medicine and farming practices, where natural or intentional adenovirus infections may occur simultaneously in both humans and other animals. Under such circumstances, both humans and other animals may have two different natural adenovirus infections with an opportunity for cross-over infections. Recombination between adenoviruses infecting different species is perhaps more likely in existing settings of human/animal co-habitation at high population densities, rather than in the lower population density, wildlife situations. Should recombination occur, it is unlikely that such an event would yield a viable, transmissible virus, with enhanced pathogenicity for wildlife, domestic animals, or humans (CDC 2011b).

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 ONRAB 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.).

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

A similar impact, as with Alternative 1, is expected with regard to expanding APHIS-WS' ONRAB ORV vaccine-bait distribution throughout the ORV zone in ME, NH, NY, OH, TN, TX, VT, VA, and WV. Therefore, APHIS-WS has determined that adverse effects regarding this potential issue would be minimal.

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

A similar impact, as with Alternative 1, is expected with regard to the proposed action. Therefore, APHIS-WS has determined no effect regarding this potential issue.

Alternative 3 - Live-Capture Vaccinate and Release Alternative

Under this alternative, it is assumed that the states would not use ORV baits with the ONRAB vaccine. Thus, there would be no potential for the ONRAB virus to revert to a more virulent variant to recombine with other viruses in the wild.

Alternative 4 - No Animal Surveillance or Monitoring or Lethal Removal Program Alternative

This potential would be the same as under the proposed action. The risk of adverse effects from the ONRAB virus possibly reverting to a more virulent variant or recombining with other viruses in the wild and resulting in significant adverse effects on humans or animal health would be highly remote.

Alternative 5 - No Federal ORV Program

Potential for the recombined V-RG virus to revert to virulence and result in a virus that could cause disease in humans or animals

Under the no federal program alternative, ORV baits with the ONRAB vaccine would probably still be used by the states even without APHIS-WS funds, although such use would likely be on a reduced scale. As shown by the Alternative 1 and 2 analyses in this section, the potential for serious environmental effects with regard to this issue is very low.

Potential for the V-RG virus to recombine with other viruses in the wild to form new viruses that could cause disease in humans or animals

Under the no federal program alternative, ORV baits with the ONRAB vaccine would probably still be used by the states even without APHIS-WS funds, although such use would likely be on a reduced scale. As shown by the Alternative 1 and 2 analysis in this section, the potential for serious environmental effects with regard to this issue is very low.

3.1.5 Potential for aerially dropped baits to strike and inure people or domestic animals

Alternative 1 – Continue the Current ORV Program (No Action)

ORV baits would be distributed from aircraft at an average density of 75 baits per km^2 (194 baits per mi^2) or 150 baits/km2 (388 baits/mi^2). This density is sparse enough to predict that the chance of a person being struck and harmed by 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 170 million baits distributed in the U.S. between 1995 and 2016 only 11 incidents have been reported in which a person claimed to have been struck by a falling bait (0.000006% chance of being struck by a bait or 1 strike per 15.4 million baits dropped) (USDA 2018). None of the reports since APHIS-WS' ORV program inception have resulted in any injury or harm to the individuals involved. In addition, trained aircrews avoid dropping baits into cities, towns, and other areas with human dwellings, or if humans are observed below. In areas with higher human density, ground

placement of baits is normally used. These techniques used by APHIS-WS' current ORV programs would also be employed during the ONRAB field trials.

Of the 11 million ORV baits that were distributed by APHIS-WS in 2016 there were no reports received in which a person claimed to have been struck by falling bait. No reports of injury were received during the 2016 APHIS-WS ORV program (USDA 2018). In 2016, no cases were documented involving falling baits striking or injuring domestic animals. Additionally, in 2016, no reports were received regarding baits striking property (USDA 2018). 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.

Alternative 2 – Proposed Action (the Preferred Alternative)

A similar impact, as with Alternative 1, is expected with regard to implementation of the proposed action. Although, APHIS-WS is proposing to expand the use of ONRAB overall bait distribution will remain the same in the aforementioned states. AHIS-WS is proposing to use V-RG or ONRAB vaccine baits throughout the current ORV zones

Alternative 3 - Live-Capture Vaccinate and Release Alternative

Under this alternative it is assumed there would be few or no ORV baits dropped from aircraft. Thus, there would be no potential for such baits to strike people or animals.

Alternative 4 - No Animal Surveillance or Monitoring or Lethal Removal Program Alternative

This potential would be the same as under Alternatives 1 and 2. The risk of striking and injuring people or domestic animals with baits is highly remote.

Alternative 5 - No Federal ORV Program

Under the no federal program alternative, the potential for APHIS-WS assistance to result in this risk would be zero. States could still implement ORV programs, but such programs would probably be accomplished on a lesser scale without APHIS-WS funds. As discussed in the Alternative 1 and 2 analysis in this section, the risk of persons or animals being struck by ORV baits is extremely remote.

3.1.6 Humaneness of methods used to collect wild animal species critical for timely program evaluation

Alternative 1 – Continue the Current ORV Program (No Action)

Some people would view methods employed to capture and/or kill skunks and raccoons, as well as 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.

Alternative 2 – Proposed Action (the Preferred Alternative)

As with Alternative 1, a similar impact is expected with regard to the implementation of the proposed program.

Alternative 3 - Live-Capture Vaccinate and Release Alternative

Some persons would view live-capture-vaccinate-release programs as less humane than ORV programs, because large numbers of animals would experience the stress of being caught and handled to administer the vaccine. Others would view them as relatively humane compared to other types of rabies control efforts that involve lethal means to suppress target populations over broad geographic areas. Because it is believed this alternative could be as successful in stopping or preventing the spread of rabies as the proposed action, the amount of animal suffering due to contracting and dying from rabies would probably be similar to the proposed action.

Alternative 4 - No Animal Surveillance or Monitoring or Lethal Removal Program Alternative

Under this alternative, no APHIS-WS funds would be used to collect animal specimens or to conduct localized population reduction of target species using live-capture or lethal methods. States could still conduct these activities, but such efforts would probably be accomplished at a lesser scale without APHIS-WS assistance. This alternative would be viewed by some persons as more humane than the proposed action. Animal suffering due to rabies would probably be similar to the proposed action (i.e., greatly reduced). However, more animals are likely to suffer and die of rabies if reduced monitoring/surveillance results in a reduction in the effectiveness of ORV programs.

Alternative 5 - No Federal ORV Program

Under the no federal program alternative, APHIS-WS would not assist in collecting wild animal specimens for ORV monitoring programs or for local population suppression efforts under contingency plans to address local rabies outbreaks beyond ORV barriers. States would still most likely conduct such programs on their own, although to a lesser degree without APHIS-WS funds and personnel. The primary method that would be used by APHIS-WS to capture raccoons (cage traps) would also most likely be the primary method used by state programs, although possibly to a lesser degree. It is probable that the methods that would be used by APHIS-WS to capture or kill gray fox and coyotes in Texas for rabies monitoring would also be used to a lesser degree without APHIS-WS funds and

personnel. Thus, some persons would view this as being a more humane alternative because of the lower intensity of the methods used.

Failure of a successful ORV program would likely result in an increased, but varying, proportion of the raccoon, gray fox, coyote, 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 2001a). 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 by 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 numbers 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.

3.2 Issues Not Considered for Comparative Analysis

The following resource values are not expected to be significantly impacted by any of the alternatives analyzed as none of the alternatives cause any significant ground disturbance: soils, geology, minerals, water quality/quantity, flood plains, critical habitats (areas listed in threatened and endangered species recovery plans or labeled as such by USFWS and/or the states), visual resources, air quality, prime and unique farmlands, aquatic resources, timber, and range. Therefore, these resources were not analyzed.

Additional issues were identified by WS during the scoping process of this EA that were considered but will not receive detailed analyses for the reasons provided. The following issues were considered but will not be analyzed in detail:

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 of 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 1.11) should prevent any significant adverse impacts on human health with regard to this issue. Minimizing Measures 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.

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 2004c). 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 the entire animal previously immobilized, the scavenger should suffer no adverse effects (Dr. G. Gathright, DVM, APHIS-WS, National Wildlife Research Center, pers. comm. 2004 as cited in USDA 2004c). 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.

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 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 , occur in any given area only for a short time period, and typically occur only once or twice per year in any given area.

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 and mammal damage management EAs (e.g., USDA 2018c, 2015c). 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 the APHIS-WS 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.

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 ONRAB 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 V-RG ruling still stands for the ONRAB® field trial (M. Bailey, National Organic Program, pers. comm., 2012).

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. ONRAB 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 ONRAB, 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 ONRAB, viral nucleic acids were detected in some tissues or feces of vaccinated animals, suggesting that ONRAB 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 ONRAB may retain some replication capability in both healthy and immunocompromised animals, but does not cause adverse reactions (toxicity) in these animals (CFIA 2008, 2010).

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, ONRAB 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.

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 ONRAB construct at temperatures associated with certain food processing. Exposure of the ONRAB 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.

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

The concern here is for potential impacts of unconsumed ONRAB 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 Protective Measures (see Section 2.2) 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 densities of 75 and 150 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 ONRAB will not support active replication of the virus and, as such, ONRAB is not expected to cause any adverse effects on fish, reptiles, amphibians, or any invertebrate species should any members of these species groups consume ONRAB 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 ONRAB 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 ONRAB 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).

Protective Measures 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 ONRAB 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 ONRAB vaccine and baits pose no more than a negligible threat to groundwater or surface water through direct or indirect means.

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 variant 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 area 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 2004c).

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.

The Affected Area Described in the EA includes Lands that Have Not Been Identified as Having a Raccoon Rabies Problem

The affected area of the EA includes some lands that have or have the potential for a raccoon, coyote, and gray fox rabies outbreak to occur. ORV baits are distributed based upon vaccination zones. These vaccination zones are determined in cooperation with the involved state rabies task forces, state agencies, or other agencies with jurisdiction over vaccine use and application in wildlife and domestic animal species. Vaccination zones are delineated based on the most current distribution of rabies cases and the expected direction of disease spread.

Therefore, some, all, or none of the lands, including National Forest System and BLM lands, identified in this EA may be involved in an ORV bait distribution program on an annual basis. Figures 1-1, 1-2, 1-3 and 1-4 in Chapter 1 show the current anticipated ORV zone based upon recent outbreaks of the virus. The states and National Forest System and BLM lands included in this EA were chosen since they have the greatest possibility of being involved in the overall efforts of stopping the northward and westward spread of the raccoon rabies virus in the eastern U.S., the northward expansion of coyote and gray fox rabies in Texas.

Effects of Nontarget 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, 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. 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 general be disbursed at an average density of 27 baits per km^2 in the coyote rabies zone and 39 baits per km^2 in the gray fox rabies zone in Texas. Baiting density averages 75 baits per km^2 in eastern states where raccoon rabies is targeted, however baits may also be distributed at higher density rates of 150 – 300 baits per km^2. 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.

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.

3.3 Summary of Environmental Consequences

No significant cumulative environmental impacts are expected from any of the five Alternatives. Under the Proposed Action any reductions in local target mammal numbers as a result of monitoring and surveillance or contingency actions would not significantly affect local or state native populations, but some short-term local reductions may occur. No risk to public safety is expected when WS' ORV programs are conducted under Alternatives 1 or 2. However, under Alternatives 4 and 5 there may be a slightly increased risk of human rabies cases from reduced effectiveness of ORV programs.

Table 3-8 presents a comparison of the alternatives and environmental consequences (impacts) on each of the issues identified for detailed analysis:

Table 3-8 Issues/Impacts/Alternatives – Comparison

	Alternative 1: Current Action	Alternative 2: Proposed Action	Alternative 3: Live Capture-Vaccinate-Release Alterative	Alternative 4: No Animal Surveillance or Monitoring or Lethal Removal Program Alternative	Alternative 5: No Federal ORV Program
Potential for adverse effects on target wildlife species populations.					
Effects of the ONRAB vaccine on target species.	No probable risk of adverse effects.	No probable risk of adverse effects.	No Risk from ONRAB vaccine	No probable risk of adverse impact (same as Alt 1 and 2).	No probable risk; states would likely still conduct ORV programs, but

					probably on a lesser scale without federal assistance
Effects of monitoring and surveillance and localized population reduction on target species in eastern states (raccoons, skunks)	Very low impact	Very low impact (similar to Alt. 1 and 3)	Very low impact (similar to Alt. 1)	Slightly lower impact than Alt. 1; states would still conduct monitoring and surveillance and contingency actions, but these are likely to be on a lesser scale without federal assistance.	Slightly lower impact than Alt. 1 or 2; states would still conduct monitoring and surveillance and contingency actions, but these are likely to be on a lesser scale without federal assistance.
Effects of monitoring and surveillance and localized population reduction on gray fox population in Texas	No impact (ONRAB not applied in TX)	Low impact (similar to Alt. 3)	Low impact (similar to Alt. 2)	Lower impact than Alt. 2; the state would still conduct monitoring and surveillance and contingency actions, but these are likely to be on a lesser scale without federal assistance.	Slightly lower impact than Alt. 2; the state would still conduct monitoring and surveillance and contingency actions, but these are likely to be on a lesser scale without federal assistance.
Effects of monitoring and surveillance and localized population reductions on coyote populations in Texas	No impact (ONRAB not applied in TX)	Low impact (similar to Alt.3)	Low impact (similar to Alt. 2)	Lower impact than Alt. 2; the state would still conduct monitoring and surveillance and contingency actions, but these are likely to be on a lesser scale without federal assistance.	Slightly lower impact than Alt. 2; the state would still conduct monitoring and surveillance and contingency actions, but these are likely to be on a lesser scale without federal assistance.
Effects of monitoring and surveillance on other species not targets for purposes of ORV, but which may be considered targets for monitoring and surveillance	Low impact	Low impact (similar to Alt 1 and 3)	Low impact (similar to Alt. 1)	Lower impact than Alt. 1; the state would still conduct monitoring and surveillance and contingency actions, but these are likely to be on a lesser scale without federal assistance.	Slightly lower impact than Alt. 1 or 2; the state would still conduct monitoring and surveillance and contingency actions, but these are likely to be on a lesser scale without federal assistance
Potential for adverse effects on nontarget wildlife species, including threatened or endangered species					
Effects of the ONRAB vaccine on nontarget wildlife including threatened and endangered species	No adverse effect on T&E species; No probable risk of adverse effects on other nontarget species.	No adverse effect on T&E species; No probable risk of adverse effects on other nontarget species.	No effect on T&E species; no risk of adverse effect on other species from ORV vaccine.	No adverse effect on T&E species; No probable risk of adverse effects on other nontarget species (Same as Alt. 1); but greater risk of adverse effects on these species from rabies if reduced monitoring and surveillance reduces effectiveness of ORV programs.	No probable risk of adverse effects from ORV vaccine; but greater risk of adverse effects on these species from rabies.
Effects of capture/removal methods (used in monitoring, surveillance, and localized population reduction) on	No effect on T&E species; Very low risk of adverse effects on other nontarget species.	No effect on T&E species; Very low risk of adverse effects on other nontarget species.	Less impact than Alt. 1.	Less impact than Alt. 1; states would still conduct monitoring and surveillance and contingency actions, but these are likely to be on a lesser scale	Probably slightly less impact than Alt. 1 or 2.

nontarget species, including threatened or endangered species.				without federal assistance.	
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 probable risk.	No probable risk	No probable risk.	No probable risk from ORV use; higher risk of human rabies cases if reduced monitoring and surveillance reduces effectiveness of ORV programs.	No probable risk from ORV use by states. Higher risk of human rabies cases if states are unable to stop the spread of rabies without federal assistance.
Potential for the human adenovirus type 5 (Ad5) to cause disease in humans.	Possible but risk is low; risk of significant adverse effects on individuals that experience Ad5 infections is also low.	Possible but risk is low; risk of significant adverse effects on individuals that experience Ad5 infections is also low. (similar to Alt. 1)	No risk.	Possible but risk is low; risk of significant adverse effects on individuals that experience Ad5 infections also is low (same as Alt. 1 and 2).	Slightly lower risk than Alt. 1or 2; states would likely still conduct ORV programs, but probably on a lesser scale without federal assistance
Potential to cause cancer (oncogenicity)	No probable risk.	No probable risk.	No risk	No probable risk.	No probable risk.
Potential for adverse effects on pet dogs or other domestic animals that might consume the bait.	Low risk; Possible benefit from improving immunity to rabies.	Low risk; Possible benefit from improving immunity to rabies (similar to Alt. 1)	No risk of adverse effects from consuming ORV baits.	Low risk (similar risk as Alt. 1 and 2); increased risk of rabies for unvaccinated animals if reduced monitoring and surveillance reduces effectiveness of ORV programs.	Low risk; states would likely still conduct ORV programs. Increased risk of rabies for unvaccinated animals without federal assistance.
Potential for the recombined ONRAB 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 ONRAB virus to "revert to virulence" and result in a virus that could cause disease in humans or animals	Very low risk	Very low risk	No risk.	Low risk (similar risk as Alt. 1).	Less risk than Alt. 1 or 2; states would likely still conduct ORV programs.
Potential for the ONRAB virus to recombine with other viruses in the wild to form new viruses that could cause disease	Very low risk	Very low risk	No risk	Low risk (similar risk as Alt. 1).	Less risk than Alt. 1 or 2; states would likely still conduct ORV programs.
Potential for aerially dropped baits to strike and injure people or domestic animals.	Low risk.	Low risk.	No risk	Low risk (similar risk as Alt. 1).	Less risk than Alt. 1or 2; states would likely still conduct ORV programs.
Humaneness of methods used to collect wild animal specimens critical	Capture and handling of skunks would be viewed by some persons as inhumane,	Capture and handling of skunks would be viewed by some persons as inhumane,	Capture and handling of target species would be viewed by some persons as	This Alt. would be viewed as more humane than Alt. 1 or 2; states likely to still	Probably less impact on this issue than Alt. 1 or 2; states likely to still conduct ORV

for timely program evaluation or to reduce local populations of target species under state contingency plans	but many animals saved from suffering and death due to rabies.	but many animals saved from suffering and death due to rabies.	inhumane. Fewer gray fox and coyotes would be taken in Texas using lethal methods, however, so this alternative would be viewed as more humane than Alt. 1 and 2.	conduct monitoring and surveillance and contingency plan implementation, but at a smaller scale without federal assistance; more animals likely to die of rabies if reduced monitoring and surveillance reduces effectiveness of ORV programs.	programs with monitoring and surveillance and contingency plan implementation, but at a smaller scale without federal assistance; more animals likely to die of rabies if lack of federal assistance reduces effectiveness of ORV programs.

Chapter 4: List of Preparers and Persons Consulted

4.1 List of Preparers

Beth Kabert, USDA-WS, Environmnetal Cooridinator, Belvidere, NJ

Richard Chipman, USDA-WS, National Rabies Program Manager, Concord, NH

Robert Hale, USDA-MRPBS, IT Specialist/Rabies Planner, Powell, OH

4.2 List of Persons/Agencies Consulted

Carrie Gilbert, USDA-FS, Environmental Coordinator – Eastern Region, Milwaukee, WI

Paula Cote, USDA-FS, Environmental Coordinator – Southern Region, Atlanta, GA

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APPENDIX B: SPECIES LISTED AS THREATENED OR ENDANDANERED UNDER THE ENDANGERED SPECIES ACT

Information obtained from https://ecos.fws.gov/ipac/ on March 2019

Maine – 10 Listings

Animals – 7

Status	**Listing**
T	Canada lynx (*Lynx canadensis*)
T	Northern long-eared bat (*Myotis septentrioonalis*)
T	Piping plover (*Charadius melodus*)
T	Red knot (*Calidris canutus rufa*)
E	Roseate tern (*Sterna dougallii dougallii*)
E	Atlantic salmon (*Salmo salar*)
E	Rusty patched bumble bee (*Bombus affinis*)

Plants – 3

Status	**Listing**
T	Eastern prairie fringed orchid (*Platanthera leucophaea*)
E	Furbish lousewort (*Pedicularis furbishiae*)
T	Small whorled pogonia (*Isotria medsoloides*)

New Hampshire – 10 Listings

Animals – 7

Status	**Listing**
T	Canada lynx (*Lynx canadensis*)
T	Northern long-eared bat (*Myotis septentrioonalis*)
T	Piping plover (*Charadrius melodus*)
T	Red knot (*Calidris canutus rufa*)
E	Roseate tern (*Sterna dougallii dougallii*)
E	Dwarf wedgemussel (*Alasmidinta heterodon*)
E	Karner blue butterfly *(Lycaeides melissa samuelis*)

Plants - 3

E	Northeastern bulrush (*Scirpus ancistrochaetus*)
E	Jesop's milk-vetch (*Astragalus robbinsii var. jesupi*)
T	Small whorled pogonioa (*Isotria medeoloides*)

New York – 21 Listings

Animals – 13

Status	**Listing**
E	Indiana bat (*Myotis sodalis*)
T	Northern long-eared bat (*Myotis septentrioonalis*)
E	Piping plover Great Lakes watershed (*Charadrius melodus*)
T	Piping plover except Great Lakes watershed (*Charadrius melodus*)
T	Red knot (*Calidris canutus rufa*)
E	Roseate tern (*Sterna dougallii dougallii*)
T	Bog turtle (*Clemmys muhlenbergii*)
T	Eastern massasauga (=rattlesnake) (*Sistrurus catenatus*)
E	Clubshell (*Pleurobema clava*)
E	Dwarf wedgemussel (*Alasmidinta heterodon*)
E	Rayed bean (*Villosa fabalis*)
T	Chittenango ovate amber snail (*Succinea chittenangoensis*)
E	Karner blue butterfly (*Lycaeides melissa samuelis*)

Plants - 8

Status	**Listing**
T	Houghton's goldenrod (*Solidago houghtonii*)
T	Leddy's roseroot (*Rhodiola integrifolia ssp. leedyi*)
E	Northeastern bulrush (Scirpus ancistrochaet*us*)
T	Northern wild monkshood (*Aconitum noveboracense*)
E	Sandplain gerardia (*Agalinis acuta*)

T	Seabeach amaranth (*Amaranthus pumilus*)
T	Small whorled pogonia (*Isotria medeoloides*)
T	American hart's tongue fern (*Asplenium scolopendrium var*.)

Ohio – 28 Listings

Animals – 22

Status	**Listing**
E	Indiana bat (*Myotis sodalis*)
T	Northern long-eared bat (*Myotis septentrioonalis*)
E	Kirtland's warbler (*Setophaga kirtlandii (=Denroica kirtnadii)*)
E	Piping plover (*Charadrius melodus*)
T	Red knot (*Calidris canutus rufa*)
T	Copperbelly water snake (*Nerodia erythrogaster neglecta*)
T	Eastern massasauga (=rattlesnake) (*Sistrurus catenatus*)
E	Scioto madtom (*Noturus trautmani*)
E	Clubshell (*Pleurobema clava*)
E	Fanshell (*Cyprogenia stegaria*)
E	Northern riffleshell (*Epioblasma torulosa rangiana*)
E	Pink mucket (pearlymussel) (*Lampsilis abrupta*)
E	Purple cat's paw (=purple cat's paw pearlymussel) (*Epioblasma obliquata obliquata*)
T	Rabbitsfoot (*Quadrula cylindrical cylindica*)
E	Rayed bean (*Villosa fabalis*)
E	Sheepnose mussel (*Plethobasus cyphyus*)
E	Snuffbox mussel (*Epioblasma triquetra*)
E	White catspaw (pearlymussel) (Epioblasma obliquata perobliqua)
E	American burying beetle (*Nicrophorus americanus*)
E	Karner blue butterfly (*Lycaeides melissa samuelis*)
E	Mitchel's satyr butterfly (*Neonympha mitchellii mitchellii*)
E	Rusty patched bumble bee (*Bombus affinis*)

Plants – 6

Status	Listing
T	Eastern prairie fringed orchid (*Platanthera leucophaea*)
T	Lakeside daisy (*Hymenoxys herbacea*)
T	Northern wild monkshood (*Aconitum noveboracense*)
E	Running buffalo clover (*Trifolium stoloniferum*)
T	Small whorled pogonia (*Isotria medeoloides*)
T	Virginia spiraea (*Spirea virginiana*)

Tennessee – 105 Listings

Animals – 84

Status	Listing
E	Carolina northern flying squirrel (*Glaucomys sabrinus coloratus*)
E	Gray bat (*Myotis grisescens*)
E	Indiana bat (*Myotis sodalis*)
T	Northern long-eared bat (*Myotis septentrioonalis*)
E	Virginia big-eared bat (*Corynorhinus (=Plecotus) townsendii virginanus*)
E	Least tern (*Sterna antillarum*)
E	Amber darter (*Percina antesella*)
T	Blackside dace (*Phoxinus cumberlandensis*)
T	Blue shiner (*Cyprinella caerulea*)
E	Bluemask darter (*Etheostoma akatulo*)
Expn	Boulder darter (shoal creek) (*Etheostoma wapiti*)
E	Boulder darter (*Etheostoma wapiti*)
E	Chucky madtom (*Noturus crypticus*)
E	Conasauga logperch (*Percina jenkinsi*)
E	Cumberland darter (*Etheostoma susanae*)
Expn	Duskytail darter (TN-specified portions of the French and Holston Rivers) (*Etheostoma percnurum*)
E	Duskytail darter (*Etheostoma percnnurum*)

T	Goldline darter (*Percina aurolineata*)
E	Laurel dace (*Chrosomus saylori*)
E	Pallid Sturgeon (*Scaphirhynchus albus*)
Expn	Pygmy madtom (TN-specified portion of the French and Holston Rivers) (*Noturus stanauli*)
E	Pygny madtom (*Noturus stanauli*)
T	Snail darter (*Percina tanasi*)
Expn	Spotfin chub (TN-specified portion of the French and Holston Rivers) (*Erimonax monachus*)
Expn	Spotfin chub (TN-specified portions of Shoal Creek) (*Erimonax monachus*)
T	Spotfin chub (*Erimonax monachus*)
E	Alabama lampmussel (*Lapsilis virescens*)
T	Alabama moccasinhell (*Medionidus acutissimus*)
E	Appalachian Elktoe (*Alasmidonta raveneliana*)
Expn	Appalachian monkeyface (pearlymussel) (*Quadrula sparsa*)
E	Clubshell (*Pleurobema clava*)
E	Coosa moccasinshell (*Medionidus parvulus*)
Expn	Cracking pearlymussel (TN-specified portions of the French Broad and Holston Rivers) (*Hemistena lata*)
E	Cracking pearlymussel (*Hemistena lata*)
Expn	Cumberland bean (pearlymussel) (TN-specified portions of the French Broad and Holston Rivers) (*Villosa trabalis*)
E	Cumberland bean (pearlymussel) (*Villosa trabalis*)
E	Cumberland Elktoe (*Alasmidonta atropurpurea*)
E	Cumberland pigtoe (*Pleurobema gibberum*)
Expn	Cumberlandian combshell (TN-specified portions of the French Broad and Holston Rivers) (*Epioblasma brevidens*)
E	Cumberlandian combshell (*Epioblasma brevidens*)
Expn	Dromedary pearlymussel (TN-specified portions of the French Broad and Holston Rivers) (*Dromus dromas*)
E	Dromedary pearlymussel (*Dromus dromas*)
Expn	Fanshell (TN-specified portions of the French Broad and Holston Rivers) (*Cyprogenia stegaria*)

E	Fanshell (*Cyprogenia stegaria*)
T	Finelined pocketbook (*Lampsilis altilis*)
Expn	Finerayed pigtoe (TN-specified portions of the French Broad and Holston Rivers) (*Fusconaia cuneolus*)
E	Finerayed pigtoe (*Fusconaia cuneolus*)
E	Fluted kidneyshell (*Ptychobranchus subtentum*)
E	Georgia pigtoe (*Pleurobema hanleyianum*)
E	Littlewing pearlymussel (*Pegias fabula*)
Expn	Orangefoot pimpleback (pearlymussel) (TN-specified portions of the French Broad and Holston Rivers) (*Plethobasus cooperianus*)
E	Orangefoot pimpleback (pearlymussel) (*Plethobasus cooperianus*)
E	Ovate clubshell *(Pleurobema perovatum*)
Expn	Oyster mussel (TN-specified portions of the French Broad and Holston Rivers) (*Epioblasma capsaeformis*)
E	Oyster mussel (*Epioblasma capsaeformis*)
E	Pale Lilliput (pearlymussel) (*Toxolasma cylindrellus*)
E	Pink mucket (pearlymussel) (*Lampsilis abrupta*)
E	Purple bean (*Villosa perpurpurea*)
E	Purple cat's paw (=purple cat's paw pearlymussel) (*Epioblasma obliquata obliquata*)
E	Rayed bean (*Villosa fabalis*)
Expn	Ring pink (mussel) (TN-specified portions of the French Broad and Holston Rivers) (*Obovaria retusa*)
E	Ring pink (*Obovaria retusa*)
Expn	Rough pigtoe (TN-specified portions of the French Broad and Holston Rivers) (*Pleurobema plenum*)
E	Rough pigtoe (*Pleurobema plenum*)
E	Rough rabbitsfoot (*Quadrula cylindrical strigillata*)
E	Sheepnose mussel (*Plethobasus cyphyus*)
Expn	Shiny pigtoe (TN-specified portions of the French Broad and Holston Rivers) (*Fusconaia cor*)
E	Shiny pigtoe (*Fusconaia cor*)
E	Slabside pearlymussel (*Pleuronaia dolabelloides*)

E	Southern pigtoe (*Pleurobema georgianum*)
E	Spectaclecase (mussel) (*Cumerlandia monodonta*)
E	Tan riffleshell (*Epioblasma florentina walkeri (=E. walkeri)*)
E	Triangula kidneyshell (*Ptychobrachus greenii)*
E	Tubercled blossom (pearlymussel) (*Epioblasma torulosa torulosa*)
E	Turgid blossom (pearlymussel) (*Epioblasma turgidula*)
E	Upland combshell (*Epioblasma metastriata*)
Expn	White wartyback (pearlymussel) (TN-specified portions of the French Broad and Holston Rivers) (*Plethobasus cicatricosus*)
E	White wartyback (pearlymussel) (*Plethobasus cicatricosus*)
Expn	Anthony's riversnail (TN-specified portions of the French Broad and Holston Rivers) (*Atheatnia anthonyi*)
E	Anthony's riversnail (*Atheatnia anthonyi*)
T	Painted snake coiled forest snail (*Anguispira picta*)
E	Royal marstonia (snail) (*Pyrgulopsis ogmorhaphe*)
E	Spruce-fir moss spider (*Microhexura montivaga*)
E	Nashville crayfish (*Orconectes shoupi*)

Plants – 21

Status	**Listing**
T	Blue ridge goldenrod (*Solidago spithamaea*)
E	Braun's rock-cress (*Arabis perstellata*)
T	Cumerland rosemary *(Conradina verticillata*)
E	Cumberland sandwort (*Arenaria cumberlandensis*)
E	Guthrie's (=pyne's) ground-plum (*Astragalus bibullatus*)
T	Large-flowered skullcap (*Scutellaria montana*)
E	Leafy prairie-clover *(Dalea foliosa*)
E	Morefield's leather flower (*Clematis morefieldii*)
T	Price's potato-bean (*Apios priceana*)
E	Roan Mountain bluet (*Hedyotis purpurea var. montana*)
E	Ruth's golden aster (*Pityopsis ruthii*)

E	Short's Bladderpod (*Physaria globosa*)
T	Small whorled pogonia *(Isotria medeoloides*)
E	Spreading avens (*Geum radiatum*)
E	Spring creek bladderpod (*Lesquerella perforate*)
E	Tennessee yellow-eyed grass (*Xyris tennesseensis*)
T	Virginia spiraea (*Spiraea virginiana*)
T	White fringeless orchid (*Platanthera integrilabia*)
E	Whorled sunflower (*Helianthus verticillatus*)
T	American hart's-tongue fern (*Asplenium scolopenrium var. americanum*)
E	Rock gnome lichen (*Gymnoderma lineare*)

Texas – 107 Listings

Animals - 75

Status	**Listing**
E	Gulf Coast jaguarundi (*Herpailurus (=Felis) yagouaroundi cacomitli*)
E	Mexican long-nosed bat (*Leptonycteris nivalis*)
E	Ocelot (*Leopardus (=Felis) pardalis*)
E	West Indian manatee (*Trichechus manatus*)
E	Attwater's greater prairie chicken (*Tympanuchus cupido attwateri*)
E	Golden-cheeked warbler (=wood) Entire (*Dendroica chrysoparia*)
E	Least tern (*Sterna antillarum*)
T	Mexican spotted owl (*Strix occidentalis lucida*)
E	Northern Aplomado falcon (*Falco femoralis septentrionalis*)
T	Piping plover (*Charadrius melodus*)
T	Red knot (*Calidris canutus rufa*)
E	Red-cockaded woodpecker (*Picoides borealis*)
E	Southwestern willow flycatcher (*Empidonax traillii extimus*)
E	Whooping crane (*Grus americana*)
T	Yellow-billed cuckoo (*Coccyzus americanus*)
T	Green sea turtle (*Chelonia mydas*)

E	Hawksbill sea turtle (*Eretmochelys imbricata*)
E	Kemp's ridley sea turtle (*Lepidochelys kempii*)
E	Leatherback sea turtle (*Dermochelys coriacea*)
T	Loggerhead sea turtle (*Caretta caretta*)
T	Louisiana pine snake (Pituophis ruthveni)
E	Austin blind salamander *Eurycea waterlooensis*)
E	Barton Springs salamander Entire (*Eurycea sosorum*)
T	Georgetown salamander (*Eurycea naufragia*)
E	Houston toad (*Bufo houstonensis*)
T	Jollyville Plateau salamander (*Eurycea tonkawae*)
T	Salado salamander (*Eurycea chisholmensis*)
T	San Marcos salamander (*Eurycea nana*)
E	Texas blind salamander (*Typhlomolge rathbuni*)
T	Arkansas River shiner (*Notropis girardi*)
E	Clear Creek gamusia (*Gambusia heterochir*)
E	Comanche Springs pupfish (*Cyprinodon elegans*)
T	Devils River minnow (*Dionda diaboli*)
E	Fountain darter (*Etheostoma fonticola*)
E	Leon Springs pupfish (*Cyprinodon bovinus*)
E	Mexican blindcat (catfish) (Prietella phreatophila)
E	Pecos gambusia (*Gambusia nobilis*)
Expn	Rio Grande silvery minnow (Hybognathus amarus)
E	San Marcos gamusia (Gambusia georgei)
E	Sharpnose shiner (*Notropis oxyrhynchus*)
E	Smalleye shiner (*Notropis buccula*)
C	Golden orb (*Quadrula aurea*)
C	Smooth pimpleback (*Cyclonaias houstonensis*)
C	Texas fatmucket (Lampsilis bracteata)
C	Texas fawnsfoot (Truncilla macrodon)
E	Texas hornshell (Popenaias popeii)

C	Texas pimpleback (Quadrula petrina)
E	Diamond tryonia (*Pseudotryonia adamantina*)
E	Gonzales tryonia (*Tryonia circumstriata (=stocktonensis)*)
E	Pecos assiminea snail (*Assiminea pecos*)
E	Phantom springtail (*Pyrgulopsis texana*)
E	Phantom tryonia (*Tryonia cheatumi*)
E	Beetle, [no common name] (*Rhadine exilis*)
E	Beetle, [no common name] (*Rhadine infernalis*)
E	American burying beetle (*Nicrophorus americanus*)
E	Coffin Cave mold beetle (*Batrisodes texanus*)
E	Comal Springs dryopid beetle (*Stygoparnus comalensis*)
E	Helotes mold beetle (*Batrisodes venyivi*)
E	Kretschmarr Cave mold beetle (*Texamaurops reddelli*)
E	Tooth Cave ground beetle (*Rhadine persephone*)
E	Bee Creek Cave harvestman (*Texella reddelli*)
E	Bone Cave harvestman (*Texella reyesi*)
E	Braken Bat Cave meshweaver (*Cicurina venii*)
E	Cokendolpher Cave harvestman (*Texella cokendolpheri*)
E	Government Canyon Bat Cave meshweaver (*Cicurina vespera*)
E	Government Canyon Bat Cave spider (*Neoleptoneta microps*)
E	Madla Cave meshweaver (*Cicurina madla*)
E	Robber Baron Cave meshweaver (*Cicurina baronia*)
E	Tooth Cave pseudoscorpion (*Tartarocreagris texana*)
E	Tooth Cave spider (*Leptoneta myopica*)
E	Diminutive amphipod (*Gammarus hyalleloides*)
E	Peck's cave amphipod (*Stygobromus (=Stygonectes) pecki*)
E	Pecos amphipod (*Gammarus pecos*)

Plants – 32

Status	**Listing**

E	Ashy dogweed (*Thymophylla tephroleuca*)
E	Black lace cactus (*Echinocereus reichenbachii var. albertii*)
C	Bracted twistflower (*Streptanthus bracteatus*)
T	Bunched cory cactus (*Coryphantha ramillosa*)
T	Chisos Mountain hedgehog cactus (*Echinocereus chisoensis var. chisoensis*)
E	Davis' green pitaya (*Echinocereus viridiflorus var. davisii*)
T	No common name (*Geocarpon minimum*)
E	Guadalupe fescue (Festuca ligulata)
T	Hinckley oak (*Quercus hinckleyi*)
E	Large-fruited sand-verbena (*Abronia macrocarpa*)
E	Little Aguja (=Creek) pondweed (*Potamogeton clystocarpus*)
T	Lloyd's Mariposa cactus (*Echinomastus mariposensis*)
E	Navasota ladies'-tresses (*Spiranthes parksii*)
T	Neches River rose-mallow (*Hibiscus dasycalyx*)
E	Nellie cory cactus (*Coryphantha minima*)
T	Pecos (=puzzle, =paradox) sunflower (*Helianthus paradoxus*)
E	Slender rush-pea (*Hoffmannseggia tenella*)
E	Sneed pincushion cactus (*Coryphantha sneedii var. sneedii*)
E	South Texas ambrosia (*Ambrosia cheiranthifolia*)
E	Star cactus (*Astrophytum asterias*)
E	Terlingua Creek cat's-eye (*Cryptantha crassipes*)
E	Texas ayenia (*Ayenia limitaris*)
E	Texas golden gladecress (*Leavenworthia texana*)
E	Texas poppy-mallow (*Callirhoe scabriuscula*)
E	Texas prairie dawn-flower (*Hymenoxys texana*)
E	Texas snowbells (*Styrax texanus*)
E	Texas trailing phlox (*Phlox nivalis ssp. texensis*)
E	Texas wild-rice (*Zizania texana*)
E	Tobusch fishhook cactus (*Sclerocactus brevihamatus ssp. tobuschii*)
E	Walker's manioc (*Manihot walkerae*)

E	White bladderpod (*Lesquerella pallida*)
E	Zapata bladderpod (*Lesquerella thamnophila*)

Virginia – 74 Listings

Animals – 57

Status	**Listing**
E	Carolina northern flying squirrel (*Glaucomys sabrinus coloratus*)
E	Gray bat (*Myotis grisescens*)
E	Indiana bat (*Myotis sodalis*)
T	Northern long-eared bat (*Myotis septentrionalis*)
E	Virginia big-eared bat (*Corynorhinus (=Plecotus) townsendii virginianus*)
T	Piping plover (*Charadrius melodus*)
T	Red Knot (*Calidris canutus rufa*)
E	Red-cockaded woodpecker Entire (*Picoides borealis*)
E	Roseate tern (*Sterna dougallii dougallii*)
E	Hawksbill sea turtle Entire (*Eretmochelys imbricata*)
E	Kemp's ridley sea turtle (*Lepidochelys kempii*)
E	Leatherback sea turtle (*Dermochelys coriacea*)
T	Loggerhead sea turtle (*Caretta caretta*)
E	Shenandoah salamander (*Plethodon shenandoah*)
T	Blackside dace (*Phoxinus cumberlandensis*)
E	Candy darter (*Etheostoma osburni*)
E	Duskytail darter (*Etheostoma percnurum*)
E	Roanoke logperch (*Percina rex*)
T	Slender chub (*Erimystax cahni*)
T	Spotfin chub (*Erimonax monachus*)
T	Yellowfin madtom (*Noturus flavipinnis*)
Expn	Yellowfin madtom (VA-specified portions of the Holston River and watershed) (*Noturus flavipinnis*)

E	Appalachian monkeyface (pearlymussel) (*Quadrula sparsa*)
PT	Atlantic pigtoe (*Fusconaia masoni*)
E	Birdwing pearlymussel (*Lemiox rimosus*)
E	Cracking pearlymussel (*Hemistena lata*)
E	Cumberland bean (pearlymussel) (*Villosa trabalis*)
E	Cumberlandian combshell (*Epioblasma brevidens*)
E	Dromedary pearlymussel (*Dromus dromas*)
E	Dwarf wedgemussel (*Alasmidonta heterodon*)
E	Fanshell (*Cyprogenia stegaria*)
E	Finerayed pigtoe (*Fusconaia cuneolus*)
E	Fluted kidneyshell *Ptychobranchus subtentum*)
E	Green blossom (pearlymussel) (*Epioblasma torulosa gubernaculum*)
E	James spinymussel (*Pleurobema collina*)
E	Littlewing pearlymussel (*Pegias fabula*)
E	Oyster mussel Entire Range (*Epioblasma capsaeformis*)
E	Pink mucket (pearlymussel) (*Lampsilis abrupta*)
E	Purple bean (*Villosa perpurpurea*)
E	Rough pigtoe (*Pleurobema plenum*)
E	Rough rabbitsfoot (*Quadrula cylindrica strigillata*)
E	Sheepnose mussel (*Plethobasus cyphyus*)
E	Shiny pigtoe (*Fusconaia cor*)
E	Slabside pearlymussel (*Pleuronaia dolabelloides*)
E	Snuffbox mussel (*Epioblasma triquetra*)
E	Spectaclecase (mussel) (*Cumberlandia monodonta*)
E	Tan riffleshell (*Epioblasma florentina walkeri (=E. walkeri)*)
T	Yellow lance (*Elliptio lanceolata)*
E	Virginia fringed mountain snail (*Polygyriscus virginianus*)
E	Mitchell's satyr butterfly (*Neonympha mitchellii mitchellii*)
T	Northeastern beach tiger beetle (*Cicindela dorsalis dorsalis*)
E	Rusty patched bumble bee (*Bombus affinis*)

E	Spruce-fir moss spider (*Microhexura montivaga*)
T	Big Sandy crayfish (*Cambarus callainus*)
E	Lee County cave isopod (*Lirceus usdagalun*)
T	Madison Cave isopod (*Antrolana lira*)

Plants – 17

Status	**Listing**
T	Eastern prairie fringed orchid (*Platanthera leucophaea*)
E	Harperella (*Ptilimnium nodosum*)
E	Michaux's sumac (*Rhus michauxii*)
E	Northeastern bulrush (*Scirpus ancistrochaetus*)
E	Peter's Mountain mallow (*Iliamna corei*)
E	Roan Mountain bluet (*Hedyotis purpurea var. montana*)
T	Seabeach amaranth (*Amaranthus pumilus*)
T	Sensitive joint-vetch (*Aeschynomene virginica*)
E	Shale barren rock cress (*Arabis serotina*)
T	Small whorled pogonia (*Isotria medeoloides*)
E	Small-anthered bittercress (*Cardamine micranthera*)
E	Smooth coneflower (*Echinacea laevigata*)
T	Swamp pink (*Helonias bullata*)
T	Virginia round-leaf birch (*Betula uber*)
T	Virginia sneezeweed (*Helenium virginicum*)
T	Virginia spiraea (*Spiraea virginiana*)
E	Rock gnome lichen (*Gymnoderma lineare*)

Vermont – 6 Listings

Animals – 4

Status	**Listing**
T	Canada lynx (Lynx canadensis)

E	Indiana bat (*Myotis sodalis*)
T	Northern long-eared bat (*Myotis septentrionalis*)
E	Dwarf wedgemussel (Alasmidinta heterodon)

Plants – 2

Status	**Listing**
E	Jesup's milk-vetch (*Astragalus robbinsii var. jesupi*)
E	Northeastern bulrush (*Scirpus ancistrochaetus*)

West Virginia – 28

Animals – 22

Status	**Listing**
E	Indiana bat (*Myotis sodalis*)
E	Gray bat (*Myotis grisescens*)
T	Northern long-eared bat (*Myotis septentrionalis*)
E	Virginia big-eared bat (Corynorhinus (=*plecotus townsendii virginianus*)
T	Cheat Mountain salamander (Plethodon netting)
E	Candy darter (*Etheostoma osburni*)
E	Diamond darter (*Crystallaria concotta*)
E	Clubshell (*Pleurobema clava*)
E	Fanshell (*Cyprogenia stegaria*)
E	James spinymussel (*Pleurobema collina*)
E	Northern riffleshell (*Epioblasma torulosa rangia*
E	Pink mucket (pearlymussel) (*Lampsilis abrupta*)
E	Rayed bean (*Villosa fabalis*)
E	Sheepnose mussel (*Plethobasus cyphyus*)
E	Snuffbox mussel (*Epioblasma triquetra*)
E	Spectaclecase (mussel) (*Cumberlandia monodonta*)
E	Tubercled blossom (pearlymussel) Entire Range (*Epioblasma torulosa torulosa*)

T	Flat-spired three-toothed snail (*Triodopsis platysayoides*)
E	Rusty patched bumble bee (*Bomus affinis*)
T	Big Sandy crayfish (*Cambarus callainus*)
E	Guyandotte River crayfish (*Cambarus veteranus*)
T	Madison Cave isopod (*Antrolana lira*)

Plants – 6

Status	**Listing**
E	Harperella (*Ptilimnium nodosum*)
E	Northeastern bulrush (*Scriptus ancistrochaetus*)
E	Running buffalo clover (*Trifolium stoloniferum*)
E	Shale barren rock-cress (*Arabis serotina*)
T	Small whorled pogonia (*Isotria medeoloides*)
T	Virginia spiraea (*Spiraea virginiana*)

E=Endangered, T=Threatened

APPENDIX C: SUMMARY OF SPECIES LISTED AS THREATENED, ENDANGERED, OR SPECIAL STATUS UNDER STATE LAW IN STATES PROPOSED FOR APHIS-WS ONRAB ORV

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://fws.gov/office/statelinks.html on							
State	**Mammals**	**Birds**	**Reptiles**	**Amphibians**	**Fish**	**Invertebrates**	**Plants**
Maine	1E New England cottontail	10E, 11T	3E, 1T	0	1E, 1T	7E,10T	88E, 98T, 105SC
New Hampshire	4E, 1T Canada lynx, New England Cottontail, gray wolf	10E, 10T, 19SC	7E, 5T, 6SC	1E	1T	9E, 2T	316E, 81T
New York	10E, 2T, 3SC Canada lynx, gray wolf, Eastern puma, Allegheny woodrat	10E, 10T, 19SC	7E, 5T, 6SC	2E, 7SC	8E, 11T, 5SC	16E, 8T, 18SC	331E, 135T, 11R
Ohio	3E, 2T American black bear, Allegheny woodrat	16E, 11T, 13 SC, 31SI	5E, 3T, 11SC	5E, 1T, 2SC	23E, 13T, 11SC	71E, 28T, 52SC, 11SI	250E, 152T, 130P
Tennessee	4E, 3 T Carolina northern flying squirrel	4E, 4T, 21SM	3T, 4SM	1T, 10SM	20E, 17T, 40SM	51E, 4T, 1SM	196E, 133T, 186S
Texas	9E, 19T ocelot, jaguarondi, jaguar, gray wolf, red wolf, Louisiana black bear, black bear, white-nosed coati	13E, 21T	3E, 21T	3E, 10T	8E, 22T	1E	23E, 5T
Vermont	7E, 1T Canada lynx, Eastern mountain lion, American marten	8E, 1T	3E, 3T	1E	4E, 2T	8E, 6T	64E, 93T
Virginia	12E, 1T, 3SC Eastern puma, gray wolf, snowshoe hare, Carolina northern flying squirrel	6E, 8T, 31SC	6E, 4T, 1SC	2E, 2T, 9SC	7E, 14T, 17SC	43E, 15T, 18SC	56E, 28T, 11SC
West Virginia	6S1, 9S2, 4S3 West Virginia northern flying squirrel, Appalachian cottontail, Least weasel,	28S1, 15S2, 15S3	3S1, 9S2, 6S3	6S1, 7S2, 5S3	26S1, 26S2, 20S3	173S1, 80S2, 26S3	267S1, 136S2, 27S3

E=State Endangered; T=State Threatened; SC=Species of Concern; SI=Species of Interest; R=Rare; P=Potentially Threatened; S1, S2, and S3=WV designations for levels of concern.

State	T&E Protections under State Law
Maine	unlawful to "hunt, take or trap" any endangered or threatened species without a permit issued for specific action by the commissioner or the state of Maine
New Hampshire	With respect to any endangered or threatened species, it is unlawful to: (a) Export any such species from this state; (b) Take any such species within this state; (c) Possess, process, sell or offer for sale, deliver, carry, transport or ship, by any means whatsoever, any such species; (d) Violate any rule adopted under this chapter pertaining to the conservation of such species of wildlife listed pursuant to RSA 212-A:6, IV
New York	endangered and threatened categories have protections against "take"; "special concern" category has no special additional protection
Ohio	unlawful to "take" any endangered species of fish or wildlife; "take" not specifically defined; no exemptions or permits to allow for incidental take; no special protections for "threatened" or "special interest" species; APHIS-WS advised to just release any state listed species if captured or to report accidental mortality
Tennessee	unlawful to take, possess, transport, export or ship any endangered or threatened species without permit; regulations allow provisions for "take" to alleviate damage and to protect human health and safety
Texas	unlawful to "take" any endangered or threatened species without the issuance of a permit; "take" not specifically defined; state law includes all federally listed species as state listed
Vermont	unlawful to "take" any endangered or threatened species without the issuance of a permit; "take" not specifically defined; state law includes all federally listed species as state listed
Virginia	unlawful to "take" any endangered or threatened species of fish or wildlife; "take" defined same as federal ESA; no exemptions or permits to allow for incidental take
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 D: REGIONAL FORESTER SENSITIVE SPECIES

FOREST SERVICE REGION 8 – SOUTHERN REGION

Amphibians

Aneides aeneus	Green salamander
Cryptobranchus alleganiensis	Hellbender
Desmognathus organi	Northern pygmy salamander
Plethodon hubrichti	Peaks of Otter salamander
Plethodon punctatus	Cow Knob salamander
Plethodon sherando	Big Levels salamander
Plethodon virginia	Shenandoah Mountain salamander
Plethodon welleri	Weller's salamander
Lithobates areolatus	Crawfish frog

Birds

Ammodramus henslowii	Henslow's sparrow
Peucaea aestivalis	Bachman's sparrow

Mammals

Corynorhinus rafinesquii	Rafinesque's bat
Glaucomys sabrinus fuscus	Virginia northern flying squirrel
Myotis austroriparius	Southeastern myotis
Myotis leibii	Eastern small-footed myotis
Perimyotis subflavus	Tricolored bat

Reptiles

Glyptemys muhlenbergii	Bog turtle
Pituophis melanoleucus [excluding *P. m. lodingi*]	Northern pinesnake
Glyptemys insculpta	Wood turtle
Pituophis ruthveni	Louisiana pinesnake

FOREST SERVICE REGION 9 – EASTERN REGION

Amphibians

Ambystoma jeffersonianum	Jefferson Salamander
Ambystoma laterale	Blue-spotted Salamander
Hemidactylium scutatum	Four-toed Salamander
Pseudotriton montanus	Mud Salamander

Aneides aeneus	Green Salamander
Cryptobranchus alleganiensis	Eastern Hellbender

Birds

Accipiter gentilis	Northern Goshawk
Ammodramus savannarum	Grasshopper Sparrow
Ammodramus henslowii	Henslow's Sparrow
Asio flammeus	Short-eared Owl
Asio otus	Long-eared Owl
Bartramia longicauda	Upland Sandpiper
Bonasa umbellus	Ruffed Grouse
Catharus bicknelli	Bicknell's Thrush
Circus cyaneus	Northern Harrier
Contopus cooperi	Olive-sided Flycatcher
Euphagus carolinus	Rusty Blackbird
Falco peregrinus anatum	American Peregrine Falcon
Gavia immer	Common Loon
Haliaeetus leucocephalus	Bald Eagle
Lanius ludovicianus migrans	Migrant Loggerhead Shrike
Melanerpes erythrocephalus	Red-headed Woodpecker
Oreothlypis ruficapilla	Nashville Warbler
Pandion haliaetus	Osprey
Parkesia noveboracensis	Northern Waterthrush
Podilymbus podiceps	Pied-billed Grebe
Pooecetes gramineus	Vesper Sparrow
Setophaga cerulean	Cerulean Warbler
Spizella pallida	Clay-colored Sparrow
Vermivora chrysoptera	Golden-winged Warbler

Mammals

Glaucomys sabrinus fuscus	WV Northern Flying Squirrel
Microtus chrotorrhinus carolinensis	Southern Rock Vole
Myotis leibii	Eastern Small-footed Myotis
Myotis lucifugus	Little Brown Myotis
Neotoma magister	Allegheny Woodrat
Perimyotis subflavus	Tri-colored Bat
Sorex dispar	Long-tailed Shrew
Sorex palustris punctulatus	Southern Water Shrew
Spilogale putorius	Eastern Spotted Skunk
Sylvilagus obscurus	Appalachian Cottontail
Synaptomys borealis	Northern Bog Lemming

Reptiles

Clemmys guttata	Spotted Turtle
Crotalus horridus	Timber Rattlesnake
Glyptemys insculpta	Wood Turtle
Virginia valeriae pulchra	Mountain Earth Snake

APPENDIX E: STATUTES REGARDING RABIES MANAGEMENT

Maine

Maine Department of Human Services - Maine State Health and Environmental Testing Laboratory/Epidemiology Program (22 Maine Revised Statutes Annotated: Subtitle 2, Part 2, Chapter 157-A, Section 565). The Maine State Health and Environmental Testing Laboratory/Epidemiology Program are authorized to offer the direct fluorescent antibody for the rapid and accurate diagnosis of rabies in a suspect animal using brain tissue. The diagnosis of the presence or absence of rabies can be used as a guide for medical recommendations for humans or domestic animals who are at risk of exposure.

Maine Department of Inland Fisheries and Wildlife (22 Maine Revised Statutes Annotated: Subtitle 2, Part 3, Chapter 251, Section 1313). The Maine Department of Inland Fisheries and Wildlife is authorized to provide for or pay all necessary costs for transportation and euthanasia of an undomesticated animal suspected of having rabies.

Maine State Department of Agriculture (7 Maine Revised Statutes Annotated: part 1, Chapter 1, Section 1-B). The Maine State Department of Agriculture has the authority to implement the rules and regulations for rabies throughout Maine. State veterinarians dispense the rabies vaccination to livestock, enforce quarantines, and regulate animal transportation in and out of Maine's borders.

New Hampshire

New Hampshire Department of Health and Human Services (New Hampshire Revised Statutes Annotated: Title X, Chapter 125, Section 125:9:II). The New Hampshire Department of Health and Human Services is authorized to make investigations and inquiries concerning the causes of epidemics and other diseases, the sources of morbidity and mortality, and the effects of localities, employments, conditions, circumstances, and the environment on the public health. Investigations also include an extended rabies surveillance effort which shall be conducted with assistance from the New Hampshire Department of Agriculture, Markets, and Food; and New Hampshire Fish and Game Department.

New Hampshire Department of Agriculture, Markets, and Food (New Hampshire Revised Statutes Annotated: Title XL, Chapter 436-A, Section 436-A:1). The state veterinarian within the New Hampshire Department of Agriculture, Markets, and Food may authorize the application of vaccines and treatments for zoonotic diseases to wildlife within the state through baiting or other methods.

New Hampshire Fish and Game Department (New Hampshire Revised Statutes Annotated: Title XVIII, Chapter 206, Section 206:10:I). The New Hampshire Fish and Game Department is charged with protecting, propagating and preserving the fish, game and wildlife resources of New Hampshire and protecting and conserving nongame birds of New Hampshire.

New York

New York State Agriculture and Markets (New York Legislative Authorization Code: Chapter 69, Article 5, Section 73b). The New York State Department of Agriculture and Markets is authorized to establish a New York State Veterinary Diagnostic Laboratory (Cornell University works under this law during ORV program participation) which is authorized to respond to disease outbreaks in animals; establish diagnostic testing capabilities to establish heard health status and evaluation of disease programs; support disease surveillance and monitoring programs of domestic, zoo, and wild animals; support veterinarians by analyzing and interpreting samples obtained from clinical cases; and evaluate, adjust, and improve New York's ability to recognize diseases that impact animal populations. **(New York Legislative Authorization Code: Chapter 69, Article 5, Section 72).** The New York State Department of Agriculture and Markets is authorized to investigate, suppress, or eradicate infectious or communicable disease affecting domestic animals or carried by domestic animals and affecting humans. Measures shall be taken to prevent such disease from being brought into the state or suppress or prevent the disease from spreading within the state.

New York Department of Environmental Conservation (New York Legislative Authorization Code: Chapter 43-B, Article 11, Title 3, Section 11-0325 and 11-0525). The New York Department of Environmental Conservation is authorized to undertake fish or wildlife control measures to eliminate, reduce, or confine a disease which endangers the health and welfare of fish or wildlife populations. The New York Department of Environmental Conservation is directed to undertake through the use of professional trappers or by other means wildlife control measures when rabies is certified to exist in an area of the state in attempt to eliminate, reduce, or confine the disease.

New York State Department of Health (New York Legislative Authorization Code: Chapter 45, Article 2, Section 201). The New York State Department of Health is directed to supervise the reporting and control of disease and promote education in the prevention and control of disease.

Ohio

Ohio Department of Health (Ohio Administrative Code: Chapter 3701 - Zoonotic Diseases and Animal Bites). The Ohio Department of Health Rabies Program conducts rabies prevention activities to protect Ohio residents from the spread of wildlife rabies to people, pets, and other animals. Bat, raccoon, skunk, other wild animal and domestic animal rabies cases are reviewed to determine any necessary control initiatives.

Ohio Department of Natural Resources – Division of Wildlife (Ohio Administrative Code: Chapter 1501:31). The Ohio Department of Natural Resources is "dedicated to conserving and improving the fish and wildlife resources and their habitats, and promoting their use and appreciation by the public so that these resources continue to enhance the quality of life for all Ohioans."

Ohio Department of Agriculture (Ohio Administrative Code: Chapter 901). The Ohio Department of Agriculture's mission is "to provide regulatory protection to producers, agribusinesses and the consuming public; to promote Ohio agricultural products in domestic and international markets; and to educate the citizens of Ohio about our agricultural industry."

Tennessee

Tennessee Wildlife Resources Agency (Tennessee Code Annotated: Title 70, Chapters 1-8). The Tennessee Wildlife Resources Agency is authorized to protect, propagate, increase, preserve, and conserve the wildlife of this state, and enforce by proper action and proceedings, the existing laws.

Tennessee Department of Health (Tennessee Code Annotated: Title 68, Chapter 8). The Tennessee Department of Health works to promote, protect, and improve the heath and well-being of the people of Tennessee. It provides public health services not available from other sources, such as rabies testing. It also conducts environmental surveys in schools and child care facilities and monitors rabies control.

Tennessee Department of Agriculture (Tennessee Code Annotated: Title 44, Chapters 1-20). The Tennessee Department of Agriculture's mission is to serve the citizens of Tennessee by promoting wise uses of Tennessee's agricultural and forest resources, developing economic opportunities, and ensuring safe and dependable food and fiber.

Texas

Texas Department of State Health Services (Texas Administrative Code: Title 25, Part 1, Chapter 169). The Texas Department of State Health Services is authorized to conduct programs to address wildlife caused disease problems, including the suppression of rabies in wildlife.

Texas Parks and Wildlife Department (Texas Administrative Code: Title 31, Part 2, Chapters 51-69). The Texas Parks and Wildlife Department is authorized to manage and regulate the take of native wildlife and fisheries in the state of Texas, including state listed threatened and endangered species.

Vermont

Vermont Department of Health (Vermont Statutes Annotated: Title 18, Chapter 1). The Vermont Department of Health is authorized to promote health and safety, and prevent disease.

Vermont Agency of Agriculture, Food, and Markets (Vermont Statutes Annotated: Title 6, Chapter 102, §1152). The Vermont Agency of Agriculture, Food, and Markets may contract and cooperate with the USDA and other federal agencies or other states for the control and eradication of contagious diseases of animals. (Vermont Statutes Annotated: Title 6; Chapter 102; §1151, "contagious disease" includes rabies).

Vermont Department of Fish and Wildlife (Vermont Statutes Annotated: Title 10, Chapter 103). The Vermont Department of Fish and Wildlife is charged with conservation of fish, wildlife, and plants and their habitats for the people of Vermont.

Virginia

Virginia Department of Health (Code of Virginia: Section 32.1.42). The Virginia Department of Health is authorized to control human disease and diseases in wildlife that threaten public health.

Virginia Department of Game and Inland Fisheries (Code of Virginia: Title 29.1). The Virginia Department of Game and Inland Fisheries is authorized to manage Virginia's wildlife and inland fish to maintain optimum populations of all species to serve the needs of the Commonwealth; to provide opportunity for all to enjoy wildlife, inland fish, boating, and related outdoor recreation; to promote safety for persons and property in connection with boating, hunting, and fishing.

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.

APPENDIX F: NATIONAL FOREST SYSTEM (NFS) LANDS AND ACREAGE[15] WITHIN CURRENT OR POTENTIAL ORV ZONES AND MAPS OF FORESTS

FOREST SERVICE REGION 8 – SOUTHERN REGION

- **TN**

  Cherokee National Forest (636,125 NFS acres)

  Land Between the Lakes National Recreation Area (170,310 NFS acres)

- **TX**

  Angelina National Forest (153,179 NFS acres)

  Davy Crockett National Forest (160,000 NFS acres)

  Sabine National Forest (160,656 NFS acres)

  Sam Houston National Forest (163,037 NFS acres)

  Caddo/LBJ National Grasslands (38,035 NFS acres)

- **VA**

  George Washington National Forest (1,065,232 NFS acres)

  Jefferson National Forest (720,552 NFS acres)

  Mount Rogers National Recreation Area (118,509 NFS acres)

  Mount Pleasant National Scenic Area (7,580 NFS acres)

FOREST SERVICE REGION 9 – EASTERN REGION

- **ME**

  White Mountain National Forest (746,581 NFS acres)

  White Mountain National Forest Purchase Unit (34,251 NFS acres)

- **NH**

[15] Although entire National Forest System acreage is listed, only portions of each National Forest may be baited, depending on the needs of the program over time.

White Mountain National Forest (746,581 NFS acres)

White Mountain National Forest Purchase Unit (34,251 NFS acres)

- **NY**

  Finger Lakes National Forest (16, 439 NFS acres)

- **OH**

  Wayne National Forest (232,610 NFS acres)

  Wayne National Forest Purchase Unit (1,027 NFS acres)

- **VT**

  Green Mountain National Forest (407,500NFS acres)

- **WV**

  George Washington National Forest (1,065,232 NFS acres)

  Jefferson National Forest (720,552 NFS acres)

  Monongahela National Forest (897,892 NFS acres)

  Monongahela National Forest Purchase Unit (5,986 NFS acres)

  Spruce Knob-Seneca Rock National Recreation Area (57,237 NFS acres)

NATIONAL FOREST MAPS

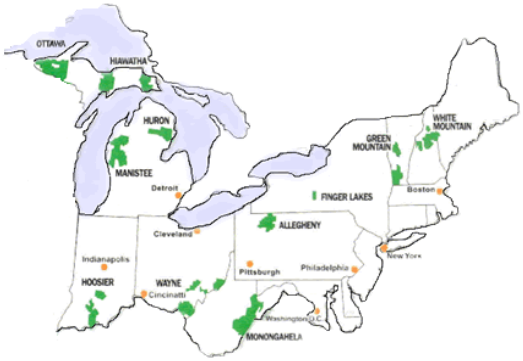
GENERAL

The USFS manages the 193 million acres of the National Forest System in a sustainable manner in collaboration with the American public; interested organizations; private landowners; State, local and tribal governments; federal agencies; and others.

Through the Organic Administration Act of June 4, 1897, (chapter 2, 30 Stat. 34-36) Congress authorized the creation of what is now the National Forest System "to improve and protect" federal forests. To carry out this mission, the USFS has authority "to regulate [the Forests'] occupancy and use and to preserve the forests therein from destruction" (16 U.S.C. 551). The Multiple-Use Sustained-Yield Act of 1960 confirms USFS authority to manage the national forests and grasslands "for outdoor recreation, range, timber, watershed, and wildlife and fish purposes," (16 U.S.C. § 528).

Please see the USFS website, http://www.fs.fed.us/, for detailed descriptions of each National Forest listed in this appendix.

FOREST SERVICE SYSTEM LANDS WITHIN POTENTIAL ORAL RABIES VACCINATION (ORV) ZONES



USFS Region 9 within ORV zone

USFS Region 8 within ORV zone