



Project Scoping

March 2011

ORAL RABIES VACCINATION PROGRAM

The U.S. Department of Interior (USDI), National Park Service (NPS), in cooperation with the U.S. Department of Agriculture (USDA), Animal Plant Health Inspection Service, Wildlife Services (APHIS-WS) and various state agencies (i.e., health departments, agriculture departments, and wildlife agencies), is proposing to implement an oral rabies vaccination (ORVAC) program at several park units with lands in Arizona and New Mexico. The program's objective is to stop the spread of a specific gray fox variant or "strain" of the rabies virus which has occurred west of the original gray fox ORVAC zone in Texas toward the New Mexico border and an ongoing outbreak of gray fox variant rabies in western New Mexico and eastern Arizona. Additionally, the program would seek to control the recent spillover of big brown bat variant rabies into gray fox in and around Flagstaff, AZ. Cooperative rabies management programs targeting various wildlife species and variants of the rabies virus are already being conducted on numerous land classes in Arizona, New Mexico, and Texas as well as in 25 states in the eastern U.S. If baiting programs were conducted avoiding large tracts of land such as NPS park units, reservoirs of the virus would likely persist, potentially making the program less effective at stopping or eliminating the advance of the different variants of the rabies virus. By participating, the NPS would aid in enhancing the effectiveness of the national rabies management program.

Park units affected include Canyon de Chelly National Monument (NM), Casa Grande Ruins NM, Chiricahua NM, Coronado NM, Fort Bowie National Historic Site (NHS), Glen Canyon National Recreation Area, Grand Canyon National Park (NP), Hubbell Trading Post NHS, Montezuma Castle NM, Navajo NM, Organ Pipe Cactus NM, Parashant National MM, Petrified Forest NP, Pipe Spring NM, Saguaro NP, Sunset Crater Volcano NM, Tonto NM, Tumacacori National Historic Park (NHP), Tuzigoot NM, Walnut Canyon NM, Wupatki NM, Aztec Ruins NM, Bandelier NM, Capulin Volcano NM, Carlsbad Caverns NP, Chaco Culture NHP, El Malpais NM, El Morro NM, Fort Union NM, Gila Cliff Dwellings NM, Pecos NHP, Petroglyph NM, Salinas Pueblo Mission NM, and White Sands NM.

To evaluate alternatives and determine environmental consequences, we will be preparing an environmen-

tal assessment for the proposed program. We welcome your input in understanding issues and developing alternatives for resolving rabies at these park units.

OVERVIEW OF THE PROCESS

Project milestones include:

- Public scoping period
- Preparation of environmental assessment
- Public review of environmental assessment
- Analysis of public comment
- Preparation of decision document
- Announcement of decision on oral rabies vaccination program

What does the scoping period mean? Scoping is done in the initial phase of a project to seek input from a variety of sources. The input is used to identify issues, areas requiring additional study, and topics that will be analyzed in the EA process. This is an opportunity for you to provide us with your suggestions, comments, and concerns regarding this rabies vaccination project.

Is scoping my only opportunity to comment on the project? No, once the EA is developed, the document will be made available for public review for a 30-day period.

PROJECT BACKGROUND

Rabies is an acute, fatal viral disease of mammals most often transmitted through the bite of a rabid animal. The disease can be effectively prevented in humans and many domestic animal species, but abundant and widely distributed reservoirs among wild mammals complicate rabies control. Within most of the U.S., these reservoirs occur in geographically discrete regions where the virus transmission is primarily between members of the same species. These species include, but are not limited to, raccoons, coyotes, skunks, and foxes. 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, perhaps even for centuries.

Gray Fox Rabies in Arizona/New Mexico

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 Centers for Disease Control and Prevention (CDC) now occur in wildlife. Before 1960 the majority of cases were reported in domestic animals. The principal rabies hosts today are wild carnivores and bats.

Prior to 1988, a gray fox strain of rabies was enzootic (prevalent) in West Texas. From a starting point near Sonora, Texas in Sutton County in 1998, an epizootic (an outbreak of a disease affecting many animals of one kind at the same time in a particular geographic area that can be widely diffused and rapidly spreading) of gray fox rabies cases expanded 80.8 miles (130 km) northward and 158.45 miles (255 km) eastward. This particular strain was readily transmitted to raccoons and to livestock, especially cows and goats. In addition to two human deaths, the south Texas canine rabies epizootic alone has resulted in over 3,000 people receiving post-exposure rabies treatment.

Most recently an outbreak of gray fox variant rabies in coyotes west of the original gray fox ORV zone in Texas toward the New Mexico border was confirmed in 2007 and as a result contingency actions were implemented to halt further spread of this variant. Additionally, an ongoing outbreak of gray fox variant rabies in western New Mexico and eastern Arizona continues to be a cause for concern. The State of Arizona recently released a management plan for invasive species. The rabies virus was included in this list of invasive species that should be controlled and managed. Further, a recent spillover of big brown bat variant rabies to gray foxes, as well as other species including striped skunks and ringtails, has prompted additional need for action.

ORVAC Programs

Oral Rabies Vaccination zones are delineated based on the most current distribution of rabies cases and the expected direction of disease spread. Vaccination zones are determined in cooperation with state rabies task forces and other agencies with jurisdiction over vaccine use and application in wildlife and domestic animal species. Baits are distributed over a variety of classes of land ownership, including private, public, tribal, and state and federal lands. As a variety of classes of land ownership are located within the proposed program boundaries, participation by the NPS helps ensure effective coverage and distribution of ORVAC baits and reduces the chance

of foci that could serve as sources of rabies reinfection.

Currently APHIS-WS conducts ORVAC programs in 25 eastern states and Arizona, New Mexico, and Texas. Arizona and New Mexico ORVAC programs do not currently include NPS sites. In 2009 the APHIS-WS ORVAC program distributed a total of 9,488,219 baits over 210,519.3 km². Of those, 96,862 baits were dropped over 1585.1 km² of NPS land in eastern states and Texas.

Oral Rabies Vaccine

The oral rabies vaccine that would be used in this program is the recombinant vaccinia-rabies glycoprotein (RABORAL V-RG® MERIAL, Inc., called "V-RG" throughout remainder of this document) vaccine currently USDA-licensed for use in raccoons and coyotes in the U.S. and Canada and USDA-approved for experimental use in gray fox in Texas. It has been used extensively and successfully in Europe to combat fox rabies and in the U.S. to combat raccoon, fox, and canine strains of the rabies virus. This vaccine is contained in baits which are distributed by aircraft (fixed-wing airplane or helicopter) and by ground placement. When animals find and ingest the bait they receive a single dose of the vaccine. The vaccine has been found to be safe for use in a number of animal species, including coyotes. This vaccine was extensively laboratory-tested for safety in more than 50 animal species with no adverse effects regardless of route or dose. In addition, a domestic animal's annual rabies vaccination can be safely administered even if it recently ingested a dose of oral rabies vaccine.

As a recombinant vaccine, the letter "V" is used to denote vaccinia, the self-replicating pox virus that serves as the vector (i.e., carrier) for the rabies virus gene that is responsible for the production of rabies glycoprotein. The letters "RG" stand for rabies glycoprotein, which is the protective sheath around the bullet-shaped rabies virus core. The glycoprotein by itself is non-infective and cannot cause rabies, but it serves as an "antigen," which means it elicits an immune response to rabies. Therefore, there is no possibility of vaccine induced rabies with V-RG because the vaccine only contains the non-infective surface protein of the rabies virus. The viral nuclear material (i.e., RNA) required for the rabies virus to replicate is not present in the vaccine. The vaccinia virus portion of the V-RG vaccine has been recognized as having the potential to cause infections in persons exposed to the vaccine. Vaccinia virus rarely poses much risk of serious health effects. Even when it was directly applied (via scarification or by scratching the skin) to many hundreds of millions of

people during smallpox eradication campaigns, the number that developed vaccinia virus-related illness was only a few per million. Another highly important characteristic of the V-RG vaccine is that it is weaker (more “attenuated”) than the original parent vaccinia strain used in making it. Over 89 million doses have been distributed in the U.S. since 1995 with only two cases of vaccinia virus infection reported in humans to date.

The ORVAC baits that would be used are small blocks of fishmeal that are held together with a polymer binding agent and are considered to be “food grade” materials. The baits weigh approximately 1 ounce (26 grams) and measure 1 1/4 x 1 1/4 x 3/4 inches. The sachet¹ containing the liquid vaccine is contained in a hollow center in the middle of the bait. Sachets coated with a simple fishmeal attractant (called “coated sachets”) could also be used and have been determined to be equally effective as the fishmeal block baits. When target species eat the ORVAC baits and puncture the sachet containing the vaccine, the vaccine is swallowed which bathes the lymphatic tissue in the throat area and initiates the immunization process. The sachet is composed of a thin plastic material that is not readily digested by the animal ingesting the bait and is subsequently passed through the animal’s digestive tract.

Each individual bait block would have a warning label advising persons not to handle or disturb the bait along with a toll-free telephone number to call for further information (note: the coated sachet does not contain a warning label). Baits may contain a non-toxic tetracycline biomarker to aid in determining whether animals collected for monitoring purposes have eaten one or more ORVAC baits. However, no animals will be collected for monitoring purposes on the NPS units listed above.

Goals of the ORVAC program

The primary goals of the program are to:

- ✓ To cooperate with APHIS-WS and the involved state agencies in stopping the advance of the Texas gray fox variant of rabies into New Mexico, preventing a new terrestrial variant of rabies (caused by a spillover of the big brown bat variant of rabies to gray foxes) from radiating from specific focus areas, and as funds become available, in managing the current outbreak of the gray fox variant of rabies in eastern Arizona and western New Mexico by approving the use of ORVAC to immunize portions of target species popula-

¹ A thin plastic packet much like those in which condiments (e.g., catsup, mustard) are provided at fast food restaurants.

tions along the leading edges of the rabies fronts; and

- ✓ To cooperate with APHIS-WS and the involved state agencies in reducing the incidence of rabies cases involving wild and domestic animals and rabies exposures to humans in the areas where the ORVAC programs are conducted.

PURPOSE AND NEED

The proposed program would distribute ORVAC baits on portions of several park units in Arizona and New Mexico as previously listed. Participation by these NPS units is necessary to support and cooperate with the involved state agencies and APHIS-WS in their ongoing efforts of eliminating or stopping the spread of specific rabies virus variants. If baiting programs were conducted avoiding large NPS land masses, reservoirs of the virus would likely persist along the border, potentially making the program less effective at stopping the forward advance or eliminating the canine variant of the rabies virus.

If new rabies virus variants such as those transmitted by gray foxes and coyotes are not prevented from spreading into the U.S., the health threats and costs associated with rabies are expected to increase substantially as broader geographic areas are affected. Livestock and domestic animals in these areas would be at risk to exposure and more importantly, if the canine variant of the rabies virus infects a much broader geographic area, human health concerns would be expected to increase substantially as well.

PROPOSED ACTION

The proposed program would involve the distribution of ORVAC baits at various park units (listed above) in Arizona and New Mexico located within the Intermountain Region of the NPS to create zones of vaccinated target species that would then serve as barriers to cease the further advancement of specific rabies virus variants. Vaccination zones would be determined in cooperation with the various state rabies task forces, state health departments, and/or other agencies with jurisdiction over vaccine use and application in wildlife and domestic animal species. The program would involve use of APHIS-WS federal funds to purchase and distribute ORVAC baits.

On an annual basis, one treatment of ORVAC baits would be distributed by aircraft (fixed-wing airplane or helicopter) and ground placement. The need to distribute baits on each of the park units would be assessed annually and based on the most current distribution of rabies cases and the expected direction of disease spread. The annual treatment would continue on a reoccurring basis until the goals of the

ORVAC program have been met. Baits would be distributed at an average density of 39 per square km during January or late spring and/or early summer months (May 1-July 30). Air drops would be typically conducted at about 500 feet above ground level and would only fly momentarily over any one point on the ground during any given bait distribution flight. The aircraft do not circle over areas repeatedly, but fly in straight "transect" lines for purposes of bait distribution.

ALTERNATIVES

Two preliminary alternatives were developed by an internal scoping process. Those alternatives include:

- the proposed action (described above); and
- a no action alternative. The no action alternative would preclude any involvement by NPS in rabies prevention or control. However, APHIS-WS, involved state agencies, and rabies task forces would continue the ORVAC program on lands not managed by the NPS.

RESOURCE ISSUES/CONCERNS

Preliminary issues identified by an internal scoping process include:

- Potential for adverse effects on people that become exposed to the vaccine or the baits.
- Effects of the ORVAC V-RG vaccine on coyotes and gray foxes
- Potential for adverse effects on nontarget wildlife species, including threatened or endangered species
- Potential for adverse effects on pet dogs or other domestic animals that might consume the baits
- Potential for the recombined V-RG virus to "revert to virulence" and result in a virus that could cause disease in humans or animals
- 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
- Potential for aerially dropped baits to strike and injure people or domestic animals
- Potential effects on NPS wilderness areas
- Potential impacts on visitor use/experience
- Potential for adverse impacts on wildlife from aircraft overflights
- Potential human health impacts resulting from the consumption of a vaccinated wild animal
- Potential for ORVAC bait distribution to affect organic farming
- Potential impacts on water resources

- Effects of nontarget species consumption of ORVAC baits on program effectiveness
- Potential impacts to Indian trust resources
- Potential for adverse impacts on lightscape
- Potential for adverse impacts on soundscape

HOW DO I COMMENT ON THE PROJECT

Your comments would be most helpful if you addressed the following questions:

1. Do you have any ideas to share about issues/concerns, or are there any issues/concerns about the project that you think we should consider?
2. Are there any other alternatives that you think should be considered?
3. Do you have another comments and suggestions for us to consider in the environmental assessment?

Please submit your comments online at the NPS Planning, Environment, and Public Comment website (enter address below and then select Open for Comment):

<http://parkplanning.nps.gov/AZNMORVAC>

Should you prefer to send written comments, please address them to:

Beth Kabert
Environmental Coordinator
USDA-APHIS-Wildlife Services
140-C Locust Grove Road
Pittstown, NJ 08867

Please submit your comments by April 22, 2011 to receive full consideration in the environmental assessment.

If you would like to receive a copy of the environmental assessment when it becomes available for review, please be sure to include your name and mailing address with your comments.

Before including your address, telephone number, electronic mail address, or other personal identifying information in your comments, you should be aware that your entire comment (including your personal identifying information) may be made publicly available at any time. Although you can ask us to withhold your personal identifying information from public review by checking the box "**keep my contact information private,**" we cannot guarantee that we will be able to do so.