COMPATIBILITY DETERMINATION

USE: Oral vaccination by bait stations to control the raccoon variant of the rabies virus

REFUGE NAME: Mashpee National Wildlife Refuge

DATE ESTABLISHED: September 28, 1995

ESTABLISHING AUTHORITY: Fish and Wildlife Act of 1956

PURPOSE FOR WHICH ESTABLISHED:

"…for the development, advancement, management, conservation, and protection of fish and wildlife resources…16 U.S.C. 742f(a)(4)…for the benefit of the United States Fish and Wildlife Service, in performing its activities and services. Such acceptance may be subject to the terms of any restrictive or affirmative covenant, or condition of servitude…16 U.S. C. 742f(b)(1)"

MISSION OF THE NATIONAL WILDLIFE REFUGE SYSTEM

"To administer a national network of lands and waters for the conservation, management, and where appropriate, restoration of the fish, wildlife, and plant resources and their habitats within the United States for the benefit of present and future generations of Americans."

DESCRIPTION OF USE

(a) What is the use? Is it a priority public use?
The U.S. Department of Agriculture Animal and Plant Health Inspection Service, Wildlife Services (APHIS-WS), in cooperation with various state agencies, (e.g., state health departments and state agriculture departments) proposes to shift the current oral rabies vaccination (ORV) zone on Cape Cod, Massachusetts back towards the Cape Cod Canal in hopes to eliminate the raccoon variant, or "strain," of the rabies virus on Cape Cod.

APHIS-WS would use oral vaccination at bait stations to control the raccoon (*Procyon lotor*) variant of the rabies virus and then conduct subsequent surveillance and live release of trapped animals. This is not a priority public use of the National Wildlife Refuge System under the National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd–668ee) as amended by the National Wildlife Refuge System Improvement Act of 1997 (Public Law 105–57).

(b) Where would the use be conducted?
The proposed use would be conducted on the refuge in the towns of Mashpee and Falmouth,Barnstable County, Massachusetts.

(c) When would the use be conducted?
APHIS-WS would conduct the ORV distribution twice annually, most likely during April-May, and October-November. The annual baiting would recur until the program meets its goals, which is expected to be within 5 to 10 years.

(d) How would the use be conducted?
On a 2X-annual basis, ORV bait stations would be used to distribute ORV baits. Bait stations are filled with a set number of baits per station and are checked throughout the baiting period. Bait packets found in areas surrounding the stations will be picked up and removed. Each station will contain bait for as long as three weeks. Each station is affixed has a label with an identifier and contact information.

Currently, the APHIS-WS ORV program employs the use of the recombinant vaccinia-rabies glycoprotein vaccine (RABORAL V-RG®, MERIAL, Inc., Athens, GA). This vaccine is currently licensed by the USDA for use in raccoons and coyotes throughout the United States and for experimental use in gray foxes in Texas. It has been used extensively and has been distributed successfully in Europe to combat fox rabies. Each animal that finds and ingests one bait block receives a single dose of the vaccine.

The ORV baits are small blocks of fishmeal, soy meal, and fish oil held together with a wax polymer binding agent. The baits are rectangular (approximately 32 × 32 × 19 mm, or 1.25 × 1.25 × 0.75 in) with hollow centers. The plastic sachet (approximately 51 mm × 29 mm, or 2 in × 1.125 in) containing the liquid vaccine is folded in half in the hollow center of the bait. Each fishmeal polymer bait weighs 26 grams (0.91 oz) and costs $1.27.

All baits are marked with a warning label that includes a phone number to call for additional information. The baits may contain a non-toxic biomarker (e.g., tetracycline or iophenoxic acid) to aid in determining whether the animals collected for monitoring have eaten one or more ORV baits. The sachet containing the liquid vaccine is plastic, and is not biodegradable. The bait manufacturer, MERIAL Limited, is not aware of any studies done to assess the biodegradability of fishmeal in the environment.

Post-ORV trapping using box traps is conducted after baiting has ended to evaluate population immunity. All target species (raccoons, skunks, foxes, coyotes) are anesthetized, sampled, vaccinated, tagged, and released at the site of capture. Samples include blood to determine rabies antibody titer and a first premolar tooth for aging and tetracycline biomarker determination (which is present in our ORV baits). Additional samples may be taken at the request of the National Wildlife Disease Program (additional blood, Nobuto strip, etc.). Post-ORV trapping occurs 4-12 weeks after baiting has completed.

(e) Why is this use being proposed?
The program would support and be in cooperation with the Massachusetts Department of Public Health, the Massachusetts Division of Fisheries and Wildlife, and the Cape Cod Rabies Task

Force, in an ongoing effort to eliminate the raccoon rabies strain on peninsular Cape Cod. If the raccoon rabies virus variant is not prevented from spreading to new areas, APHIS-WS expects the health threats and costs associated with rabies to increase substantially. Livestock and domestic animals in those areas would be at risk of exposure. More importantly, if the raccoon variant of rabies infects a much broader geographic area, human health concerns are expected to increase substantially as well.

Rabies is an acute, fatal, viral disease of mammals most often transmitted through the bite of a rabid animal. The disease can be prevented in humans and many species of domestic animals.

The placement of ORV bait stations to distribute ORV baits over the refuge is part of a broader program to create zones of vaccinated target species that serve as barriers against the further advance of the variant virus. The vaccination zones would be determined in cooperation with the Cape Cod Rabies Task Force, the previously mentioned state agencies, or other agencies with jurisdiction over the application of vaccine in species of wildlife and domestic animals.

Widely distributed reservoirs of rabies among wild mammals complicate rabies control. In most of the United States, the reservoirs occur in geographically discrete regions where the virus is transmitted primarily between members of the same species (Krebs et al. 2001). Those species include raccoons, coyotes (*Canis latrans*), skunks (primarily, *Mephitis mephitis*), gray foxes (*Urocyon cinereoargenteus*), and red foxes (*Vulpes vulpes*). Species-specific variants of the virus may be transmitted to other animal species. However, those 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 (Krebs et al. 2001).

The majority of rabies cases reported to the Center for Disease Control and Prevention (CDC) each year occur in raccoons, skunks, and bats (Order *Chiroptera*). Red foxes account for less than 10 percent of the reported rabies cases. Cats, dogs and cattle are among the domestic animals that are most often reported (CDC 2001). Two canine rabies epizootics (epidemics in animals) 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 resulted in two human deaths and caused more than 3,000 people to receive post-exposure rabies treatment (TDH 2001).

Public Health Importance of Rabies

Over the last 100 years, rabies in the United States has changed dramatically. About 90 percent or more of all animal cases reported annually to CDC now occur in wildlife (Krebs et al. 2000; CDC 2001). Before 1960, the majority of cases were reported in domestic animals. The principal hosts of rabies today are wild carnivores and bats. The number of rabies-related human deaths in the United States has declined from more than 100 annually at the turn of the century to an average of one or two people per year in the 1990s. When administered properly, modern-day prophylaxis, which is the series of vaccine injections given to people who potentially or actually have been exposed, has proved nearly 100-percent successful in preventing mortality (CDC

2001). In the United States, human fatalities associated with rabies occur in people who fail to seek timely medical assistance, usually because they were unaware of having been exposed.

Although human deaths from rabies are rare, the estimated public health costs associated with detection, prevention, and control have risen, and are estimated to exceed $300 million to $450 million annually. Those costs include the vaccination of companion animals, the maintenance of rabies laboratories, and medical costs, such as those incurred in investigating exposure cases, rabies post-exposure prophylaxis (PEP), and animal control programs (CDC 2001).

Raccoon Rabies in the Eastern United States

Rabies in raccoons was virtually unknown before the 1950s. It was first described in Florida, and spread slowly during the next three decades into Georgia, Alabama, and South Carolina. In 1977, rabid raccoons were first detected in West Virginia. It is believed that rabies was present in raccoons imported from Florida into West Virginia by hunters in the 1970's. The disease then spread to other raccoons after they were released. Once rabies was established in West Virginia and Virginia, it spread at a rate of approximately 25 to 50 miles per year into Maryland, Washington, D.C., Delaware, and Pennsylvania. This rabies epizootic spread into New Jersey through Warren and Hunterdon counties in October 1989. The raccoon rabies epizootic now extends throughout New England, as far west as Ohio, and south into North Carolina. In the past 21 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 30–35 miles per year (48.3 km/yr). It was 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), and the strain has recently been reported in New Brunswick.

Raccoon rabies presents a human health threat directly through potential exposure to rabid raccoons, or indirectly through the exposure of a pet that encountered a rabid raccoon. To date, no known cases of rabies in humans have been attributed to raccoon rabies directly. However, the number of pets and livestock examined and vaccinated for rabies, the number of diagnostic tests requested, and the number of post exposure treatments, are all greater when raccoon rabies is present in an area. The human and financial resources allocated to rabies-related human and animal health needs also increase in these areas, often at the expense of other important activities and services.

If new rabies strains, such as those transmitted by raccoons, gray foxes and coyotes, are not prevented from spreading to new areas of the United States, the associated health threats and health costs are expected to increase substantially. The current distribution area of raccoon rabies stretches from Alabama northeastward along the Appalachian Mountains through coastal Maine. In the area that stretches west from the leading edge of the current distribution to the Rocky Mountains, and north from the distribution of gray fox and coyote rabies in Texas, live more than 111 million livestock, including cattle, horses, mules, swine, goats, and sheep, which are valued at $42 billion (65 FR 76606-76607, December 7, 2000). If raccoon, gray fox, or coyote rabies were to spread into that area, many of the livestock would be at risk of contracting those specific rabies variants. If raccoon, coyote and gray fox strains of rabies infect a broader

geographic area, human health concerns would increase as well, adding to the current high costs of living with those strains.

Goals of the ORV program

The primary goals of the program in Massachusetts are to: (1) reduce the incidence of rabies cases involving wild and domestic animals, and the rabies exposures to humans, in areas where the ORV program is conducted (Cape Cod). If the ORV program is successful in stopping the forward advance of the raccoon strain, then the ultimate goal could include the elimination of this rabies variant; and (2) use what is learned on Cape Cod about the management of rabies elsewhere in the country.

AVAILABILITY OF RESOURCES:

The program would involve the use of APHIS-WS federal funds to purchase and distribute ORV baits. Bait distribution and ORV monitoring and surveillance are the responsibility of the APHIS-WS (the permit holder). Refuge staff time associated with the administration of this use includes the issuance of the Special Use Permit, answering questions of the permit holder or the public concerning the use and the conditions of the permit, monitoring compliance with those conditions, and monitoring the potential impacts of the use on refuge resources and visitors. The refuge manager will administer the program. The refuge visitor services manager will monitor visitor impacts. The refuge wildlife biologist will monitor resource impacts. Administering this use requires no special equipment, facilities, or resources. We estimate the salaries, equipment, fuel and other costs associated with refuge involvement in this use at less than $1000 annually.

ANTICIPATED IMPACTS OF THE USE:

This use is part of a larger, national program to identify and reduce the spread of various strains of rabies across the United States and into Canada. The Service will be assisting the effectiveness of that national program by participating in it. Combating these rabies virus variants would likely have beneficial impacts on both humans and wildlife.

Oral Rabies Baits and Vaccine
V-RG

This vaccine was laboratory-tested extensively for safety in more than 50 animal species with no adverse effects, regardless of route or dose. Rupprecht et al. (1992) report there has been no mortality or morbidity (i.e., signs or symptoms of disease) and no lesions typical of pox virus infections caused by V-RG vaccine in more than 350 individual animals representing 20 taxonomic families of animals. They concluded that the extensive laboratory safety experiments showed V-RG to be safe in all species tested to date, including raccoons, coyotes, and gray foxes. In addition, a domestic animal's annual rabies vaccination can be safely administered even if it recently ingested a dose of oral rabies vaccine. There is no possibility of vaccine-

induced rabies with V-RG because the vaccine contains only the non-infective surface protein of the rabies virus. The vaccine contains none of the viral nuclear material (i.e., RNA), which would be required for the rabies virus to replicate.

Since 1990, more than 100 million doses have been distributed in the United States (USDA 2011a); to date, only two cases of vaccinia virus infection have been reported in humans. These cases are described further in USDA 2010. The ORV program would reduce the likelihood of wildlife being exposed to the rabies virus. If threatened or endangered species were to find and consume an ORV bait block, we expect they would experience no effect other than possibly becoming immunized against rabies. Therefore, the Raboral V-RG® vaccine distributed in baits would have no adverse effects on any state- or federal-listed threatened or endangered species or their critical habitats.

The newest APHIS-WS national programmatic Environmental Assessment (EA) and Decision/Finding of No Significant Impact, final in January 2010, analyzes the potential environmental effects of a proposal to continue and expand the involvement of APHIS-WS in cooperative ORV programs in a number of Eastern States and Arizona, New Mexico, and Texas. That document is available for inspection at: http://www.aphis.usda.gov/regulations/ws/ws_environmental_us.shtml.

The following conclusions concern the issues that the 2010 V-RG EA analyzes in detail.

- We expect negligible adverse impacts on the environment from the limited number of baits placed in a specific area, the biodegradability of the baits and vaccine liquid, their high consumption rate by animal species, the safety and efficacy of the vaccine, and the standard operating procedures for dropping baits near a large source of water.

- We expect negligible adverse impacts on humans exposed to baits or vaccine, and expect beneficial impacts from reducing the threat of human exposure to the rabies virus.

- We expect no adverse impacts on target species, and expect beneficial impacts from immunizing target species against rabies.

- We expect no adverse impacts on non-target, threatened, or endangered species, and expect minor, beneficial impacts from immunizing non-target wildlife species against rabies.

- We expect no adverse impacts on domestic animals, and expect minor beneficial impacts from immunizing domestic animals against rabies.

- We expect negligible impacts on visitor use or experience from distributing ORV baits, and expect beneficial impacts from reducing the threat of visitors encountering a rabid animal.

- We expect negligible risk of the recombined V-RG virus reverting to virulence, resulting in a virus that could cause disease in humans or animals.

- We expect negligible risk of the V-RG virus recombining with other viruses in the wild to form new viruses that could cause disease in humans or animals.

We do not expect this use to result in short- or long-term impacts that would materially interfere with or detract from the fulfillment of the purposes for which the refuge was established or the mission of the National Wildlife Refuge System. In addition, this action will not affect historic resources, and we do not consider it scientifically controversial. The ORV will be localized in areas where humans are not likely to be exposed, and is limited in terms of quantity. It will not cause contaminants to enter water bodies, does not adversely affect any federally protected species or critical habitat, and does not cause bioaccumulation.

PUBLIC REVIEW AND COMMENT:

The draft Compatibility Determination will be announced by press release and posted for public inspection on the Mashpee National Wildlife Refuge website from September 20, 2013 through October 4, 2013.

DETERMINATION (Check one):

THIS USE IS COMPATIBLE ____

THIS USE IS NOT COMPATIBLE ____

STIPULATIONS NECESSARY TO ENSURE COMPATIBILITY:

Mitigation measures are any features of an action that serve to prevent, reduce, or compensate for impacts that otherwise might result. Thanks to extensive public and interagency involvement in the development of ORV programs and strategies, a number of key mitigating measures are now part of the standard operating procedures of state-operated ORV programs.

1 *Public information, education, and media announcements to inform the public in each county about ORV bait distribution activities before they occur*—APHIS-WS will coordinate with the appropriate state agency on preparing leaflets, posters, press releases or other media for posting in schools, hospitals, campgrounds, visitor centers, and state and county public agency offices. Notification of the ORV bait drop also may be sent to the State Police, State Emergency Management Associations, County hazardous materials coordinators, County cooperative extension agents, state and federal correctional facilities, wildlife rehabilitators, and medical and veterinary facilities in the ORV area informing them about the program and providing information on the ORV bait and vaccine and potential exposure issues.

2 *Toll-free telephone numbers advertised in the media and on websites*—for people to call for answers to questions. The toll-free numbers will allow the caller an opportunity to speak in English or Spanish.

3 *An additional level of assurance that a human reaction would be treated successfully*—in the unlikely event that an adverse vaccinia virus exposure occurs in humans. The CDC can make vaccinia immune globulin available to a state on a case-by-case basis.

4) Before distributing ORV baits on federal lands—the refuge manager will be provided with a map and coordinates showing the location of bait stations. No stations may be established without approval from the refuge manager.

5) Training personnel in hand distribution of baits—to avoid properties with greater risk of human or pet encounters with baits.

6) Labels on each ORV bait—instructing persons not to disturb or handle them and containing a toll-free telephone number to call for further information and guidance in the event of accidental exposure to the vaccine.

7) Should surveillance trapping ever occur on the refuge—to monitor program effectiveness, it would be coordinated with the refuge staff. Methods of capturing raccoons would involve mainly the use of cage traps. Animals capture in cage traps that need to be euthanized (e.g. animals with significant wounds or displaying rabies symptoms) will be handled in accordance with recommendations of the American Veterinary Medical Association and will follow IACUC including that traps are checked within 24 hours of being set. Caution must be used during inclement/cold/wet weather. The manager must be provided with a map and coordinates showing the location of traps prior or immediately following the deployment of any traps.

8) Field personnel—involved in trapping, handling, monitoring or surveying animals would be immunized against rabies and tetanus.

9) All drug use—in capturing and handling raccoons and other animals would be under the direction and authority of state veterinary authorities, either directly or through procedures agreed upon between those authorities and APHIS-WS.

10) Ear tagging or other marking of an animal—drugged and released close to hunting/trapping season alerts hunters and trappers that they should contact state officials before consuming the animal. Most animals administered immobilizing drugs would be released well before state-controlled hunting/trapping seasons, which would give the drug time to metabolize completely out of the animals before humans might take or consume them.

11) Rabbits – If a rabbit is captured during post-ORV trapping activities, the refuge would

want a tissue sample if possible. If a rabbit is found dead or needs to be euthanized, the carcass should be put on ice and delivered to the refuge manager in Sudbury, Mass.

12) The permit holder will provide a summary—of all ORV activities involving the refuge to the refuge manager on an annual basis.

13) The refuge manager reserves the right—to review the compatibility of this activity or rescind the permit at any time.

JUSTIFICATION:

This use has been determined to be compatible provided the Permit Special Conditions are implemented. The use will contribute to the purposes of the refuge and mission of the National Wildlife Refuge System and will not materially interfere with or detract from the purposes of the refuge and the mission of the National Wildlife Refuge System. Compatibility will be reevaluated every 10 years.

SIGNATURE:

Refuge Manager:_____ Date:_____

CONCURRENCE:

Regional Chief:_____ Date:_____

MANDATORY 10-YEAR RE-EVALUATION DATE: _____

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