DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT
FOR THE ENVIRONMENTAL ASSESSMENT:

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

PURPOSE OF THE EA

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Wildlife Services (APHIS-WS) program has prepared an Environmental Assessment (EA), in cooperation with the U.S. Forest Service, to analyze the potential impacts to the quality of the human environment from conducting a field trial to determine the safety and efficacy of an experimental rabies vaccine, human adenovirus type 5 rabies glycoprotein recombinant vaccine (AdRG1.3) (USDA 2011). The EA documents the need for an AdRG1.3 field trial and assesses the potential impacts on the human environment from the two alternatives to address that need. Under the proposed action, APHIS-WS would use federal funds to purchase AdRG1.3 oral vaccine baits and participate with the West Virginia Departments of Agriculture and Health and Human Resources, the West Virginia Division of Natural Resources, the Greenbrier County Commission, and the Centers for Disease Control and Prevention in field trials involving the distribution of the AdRG1.3 oral vaccine baits under the authorities of the appropriate West Virginia state agencies and to evaluate the efficacy characteristics of the AdRG1.3 vaccine for wildlife rabies control under limited field conditions.

The EA was prepared to: 1) evaluate the potential environmental consequences of the alternatives, 2) facilitate planning and interagency coordination, 3) streamline program management, and 4) clearly communicate to the public the analysis of individual and cumulative impacts, thereby giving the public an opportunity to participate in the decision-making process.

Based on the analysis in the final EA and the Response to Comments, I have determined that there will not be a significant adverse impact, individually or cumulatively, on the quality of the human environment as a result of the proposed action.

AUTHORITIES

Under the Act of March 2, 1931, as amended (7 U.S.C. 426-426b), APHIS-WS is authorized to conduct a program of wildlife services with respect to injurious animal species; and, under the Act of December 22, 1987 (7 U.S.C. 426c), APHIS-WS is authorized to control nuisance mammals and birds and those mammal and bird species that are reservoirs for zoonotic diseases.

NEED FOR ACTION

The vaccine currently in use by APHIS-WS' Oral Rabies Vaccination (ORV) program, vaccinia rabies glycoprotein (V-RG) vaccine does not produce sufficient levels of population immunity in striped skunks (*Mephitis mephitis*). As a result of spill-over rabies infections of skunks from raccoons (*Procyon lotor*), skunks may serve as a source of perpetuating and maintaining the raccoon rabies virus variant and may compromise the effectiveness of APHIS-WS' ORV program. In addition, higher levels of population immunity in raccoons are desired to further APHIS-WS'

goal of eliminating raccoon rabies. Human adenovirus type 5 (Ad5) has been used extensively as a vector for vaccine development mainly due to its well-characterized molecular structure, genomic stability, and ability to grow high titers in a wide spectrum of cells (Graham and Prevec 1992 *in* Knowles et al.). One of the most promising vaccines has been a human adenovirus type 5 rabies glycoprotein recombinant vaccine (AdRG1.3). AdRG1.3 was developed in response to the need for a more efficacious oral wildlife rabies vaccine. These field trials are necessary to test the efficacy of AdRG1.3, because if AdRG1.3 provides both safe and efficacious results it could serve as a successful compliment to APHIS-WS current ORV program and further APHIS-WS goal of eventual elimination of terrestrial strains of rabies.

PUBLIC INVOLVEMENT AND COMMENTS

Following interagency review and discussion, the draft EA was made available to the public for review and comment from August 8, 2011 to September 7, 2011. The document was made available through a Notice of Availability (NOA) for Docket No. APHIS-2011-0089 published in the *Federal Register* on August 8, 2011, the APHIS-WS website http://www.aphis.usda.gov/regulations/ws/ws_nepa_public_notice_WV_rabies.shtml, and through direct mailings of the NOA to interested parties. At the close of the 30-day public comment period, APHIS-WS received 13 comments. A summary of the comments and APHIS-WS responses are attached as Appendix A.

All letters and comments are maintained at the Wildlife Services Office, 140-C Locust Grove Rd., Pittstown, NJ 07823. This decision document will be made available to the public using the same procedures as for the pre-decision EA. A summary of public comments and our responses are posted on the APHIS-WS website as Appendix A, along with this FONSI and final EA. One minor change was made to the EA as a result of comments received and is shown in the EA as a red line and strikeout text.

AFFECTED ENVIRONMENT

The area of the field trial includes public and private lands within Greenbrier, Summers, and Monroe Counties, West Virginia. Affected public lands include portions of the Monongahela National Forest, but excludes Wilderness Areas. Currently, cooperative rabies surveillance activities are conducted in West Virginia and will continue to occur in conjunction with the AdRG1.3 field trial.

The affected area includes several land ownership types and diverse land uses, including cultivated agricultural lands, forests, meadows, wetlands, and pastures. Aerial distribution of ORV baits will avoid urban and suburban areas that support a higher human population density, as well as large bodies of water.

MONITORING

The APHIS-WS rabies management program annually reviews its ORV program impacts on target and nontarget species to ensure that APHIS-WS activities do not adversely affect the viability of wildlife populations and it will do so for this field trial. APHIS-WS monitors the ORV program impacts using its Management Information System (MIS) database. The MIS database serves as a repository of several types of data including numbers of animals of each species collected, biological information from each animal (e.g., age, sex, weight, and general health conditions), biological samples collected from each animal (e.g., blood, teeth, hair), and the disposition of each animal captured (e.g., released on site, euthanized, etc.). The MIS information will be used to assess the localized and cumulative impacts of the program on wildlife populations. APHIS-WS will provide detailed information on animals to the involved state agencies to assist those agencies with managing species and resources under their jurisdiction.

MAJOR ISSUES

APHIS-WS' ORV program has previously prepared an EA, "Oral Vaccination to Control Specific Rabies Virus Variants in Raccoons, Gray Foxes, and Coyotes in the United States" (USDA 2010), for the current national program and many of those issues were considered to be germane to this field trial EA. Additionally, based on the considerable experience of cooperating agencies and APHIS-WS in addressing concerns expressed by the public in past ORV programs, the following issues were identified for consideration in detail in the EA:

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

ISSUES CONSIDERED BUT NOT IN DETAIL

In addition to the major issues considered in detail, ten other issues were considered but not in detail, with rationale and further analysis.

- Potential for drugs used in animal capture and handling to cause adverse health effects in humans that hunt and eat the species involved.
- 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.
- Potential for adverse impacts from aircraft overflights conducted in ORV programs.
- Potential for ORV bait distribution to affect organic farming.
- Potential for ORV to cause abortions in cattle.
- Potential human health impacts in the event of human consumption of vaccinated wildlife.
- Potential impacts on water resources, including aquaculture, fish, reptiles, and amphibians.
- Effects on carnivore populations in the absence of rabies.
- Effects of nontarget species consumption of the ORV baits on program effectiveness.
- Effects of global warming, habitat loss, and pollution on wildlife populations.

ALTERNATIVES ANALYZED IN DETAIL

Two potential alternatives were developed to address the issues identified above. Three additional alternatives were considered, but not analyzed in detail. A detailed discussion of the anticipated effects of the alternatives on each issue considered in detail can be found in Chapter 4 of the EA. The following summary provides a brief description of each alternative and its anticipated impacts.

Alternative 1. No Action. This alternative would consist of no federal involvement by APHIS-WS in the implementation of field trials in West Virginia field testing the safety and efficacy of the AdRG1.3 oral vaccine. This option would significantly delay control and elimination of raccoon rabies and lead to additional financial costs of coexisting with raccoon rabies over a broader geographic area in the future, increases in wildlife mortality from

rabies and rabies risks to humans. The "No Action" alternative is a procedural NEPA requirement (40 CFR 1502.14 (d)), is a viable and reasonable alternative that could be selected, serves as a basis for comparison with other alternatives, and can be defined as the continuation of current management practices.

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

ALTERNATIVES CONSIDERED, BUT NOT ANALYZED IN DETAIL

Depopulation of target species. This alternative would result in the lethal removal of raccoons, skunks, gray foxes, and coyotes throughout the zones where outbreaks of targeted rabies virus variants occur or are expected to occur. The goal would be to achieve elimination of the rabies virus by severely suppressing populations of target animal species over broad areas so that specific variants of rabies virus could not be transmitted. This could theoretically stop the forward advance of the disease and potentially result in local elimination of the particular rabies variants as infected animals die from rabies before they could transmit it to other animals. The alternative was not considered in detail because of the cost and effort that would be involved and because it would undoubtedly be opposed by most members of the public.

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 would involve live capture and surgical sterilization, the use of chemical reproductive inhibitors placed out in baits or delivery devices, or the application of immunocontraception strategies (i.e., vaccines that can cause infertility in treated animals). This alternative was not considered in detail because of the extreme expense and difficulty involved, the greater effectiveness of vaccination alternatives, and because no contraceptive agents are currently registered for use in the target species.

Employ other types of ORV instead of the AdRG1.3 vaccine. Under this alternative, APHIS-WS would provide funds to purchase and use "modified-live-virus" (i.e., "attenuated" or weakened strains that have been shown to have little chance of causing rabies in treated animals), "killed-virus" (i.e., "inactivated" virus) oral vaccines, or other recombinant vaccines such as the V-RG vaccine in ORV baits. This alternative was not considered in detail because some of the vaccines involved have the potential to cause rabies (e.g., 'live' virus vaccines), others would be cost-prohibitive or ineffective through oral vaccination route (e.g., "killed" virus vaccines), and V-RG (which is currently used in APHIS-WS' national ORV program) has not produced sufficient levels of population immunity in skunks. In addition, models and empirical evidence suggest that higher levels of immunity in raccoon populations are required at the same bait density to achieve elimination than have been observed with use of V-RG.

SUMMARY OF ENVIRONMENTAL EFFECTS OF THE ALTERNATIVES

Alternative 1. No Action. Under this alternative, there would be no impact on target striped skunks or raccoon populations in West Virginia from ORV field trials. However, in the absence of a safe and efficacious rabies virus vaccine for skunks, it is likely that more skunks will die from rabies with potentially greater short-term population impacts. Further, without a safe and efficacious rabies virus vaccine for wildlife, rabies epizootics may be expected to occur that would likely result in short-term die-offs of target species over broader geographic areas.

The no action alternative would also likely result in greater risk of human exposure to rabies than the proposed action. Without field trials to address the efficacy of new vaccines, current vaccines may not be successful in stopping or preventing the spread of raccoon, grey fox, and coyote rabies virus variants. Therefore, an absence of new field trials could be expected to result in increased risk of human rabies cases because of expanding epizootics.

Alternative 2. Proposed Action (the preferred alternative). One of the most promising new wildlife rabies vaccines is a human adenovirus type 5-rabies glycoprotein recombinant vaccine (AdRG1.3). The AdRG1.3 vaccine employs a human adenovirus type 5 vector into which has been inserted a DNA copy of a rabies virus glycoprotein. AdRG1.3 cannot cause rabies in humans because the vaccine only carries the gene for producing the outer coating of the rabies virus (i.e., rabies virus glycoprotein). 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 occur worldwide in humans as well as in a variety of animals. Adenoviruses are extremely host specific. A human adenovirus will not replicate in anything other than human cells, except under laboratory conditions. With few exceptions, the human adenovirus serotypes are generally not pathogenic to animals (Taylor 1977). Additionally, both Charleton et al. (1992) and Prevec et al. (1989a) confirmed that, after oral immunization of skunks and foxes with AdRG1, no pathogenic effect related to AdRG1 was observed.

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).

As discussed in Section 3.3 of the EA, APHIS-WS will employ several measures to mitigate the potential for humans to contact the baits and/or AdRG1.3 vaccine. In the unlikely event that a human contacts the AdRG1.3 vaccine, the risks to human health and safety are expected to be low. Adenoviruses are distributed worldwide and infections with adenovirus type 5 do not typically result in serious disease. In fact, Ad5 is endemic in those parts of the world that have been studied and is associated with mild respiratory symptoms. It is understood that the Ad5 virus can cause more serious infections in immunocompromised people. However, the widespread immunity of Ad5 in human populations over the age of 5 would make person-to-person spread of the virus highly unlikely.

FINDING OF NO SIGNIFICANT IMPACT

Based on the analysis provided in the EA, as well as a review of comments submitted by the public and APHIS-WS' response to those comments, there are no indications that the proposed action (Alternative 2) will have a significant impact, individually or cumulatively, on the quality of the human environment. I agree with this conclusion and therefore, find that an EIS should not be prepared. This determination is based on the following factors:

1. The AdRG1.3 field trial proposed in the EA is limited to the state of West Virginia and is not regional or national in scope.

2. The proposed action poses minimal adverse impact to public health and safety. Of the more than 120 million baits that have been distributed by ORV programs in the U.S., only 11 incidents have been reported in which a person claimed to have been struck by falling bait. Since the inception of APHIS-WS' ORV program in 1995, approximately 1,128 people have reported contacting, or potentially contacting, a vaccine laden bait. Of these exposures, there have been two reported cases of human adverse reactions to the vaccinia virus used in the V-RG vaccine. Adverse health effects from human adenovirus type-5 are expected to be minimal with no significant long-term effects expected.

3. There are no unique characteristics such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas that would be significantly affected. Built in mitigation measures that are part of APHIS-WS' standard operating procedures and adherence to laws and regulations will further ensure that the agencies' activities do not harm the environment.

4. The effects on the quality of the human environment are not highly controversial. Although there is some opposition to wildlife damage management, including disease control programs, this action is not highly controversial in terms of size, nature, or effect.

5. Based on the analysis documented in this EA and the accompanying administrative file, the effects of the proposed field trial on the human environment would not be significant. The effects of the proposed activity are not highly uncertain and do not involve unique or unknown risks.

6. The proposed action would not establish a precedent for any future action with significant effects or represent a decision in principle about future considerations. The EA analyzes a field trial that will occur over a single season only.

7. No significant cumulative effects were identified through this assessment.

8. The proposed activities would not affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would they likely cause any loss or destruction of significant scientific, cultural, or historical resources.

9. APHIS-WS has determined that the proposed action would not adversely affect those threatened or endangered species in the State that were addressed in the Biological Opinion issued by the USFWS on APHIS-WS' programmatic activities (USDA 1997). For those species listed in the State that were not addressed in the Biological opinion or have been listed since the completion of the biological opinion, APHIS-WS has determined the proposed action will have no effect on those species listed in the State.

10. The proposed action would be in compliance with all federal, state, and local laws.

DECISION

I have carefully reviewed the EA prepared for this proposal and the input resulting from the public involvement process. I believe the issues and objectives identified are best addressed through implementation of Alternative 2 (Proposed Action). Alternative 2 is therefore selected because (1) it best enables APHIS-WS' ORV program to maintain the integrity of the previously established ORV zones and best supports the National Rabies Management Program's goal of rabies virus containment and eventual elimination; (2) it offers the greatest chance of maximizing effectiveness and benefits of APHIS-WS' ORV program while minimizing cumulative impacts on the quality of the human environment that might result from the program's effect on target and nontarget species populations, including threatened and endangered species; (3) it presents the greatest chance of maximizing net benefits while minimizing adverse impacts to public health and safety; and (4) it offers a balanced approach to the issues of humaneness and aesthetics when all facets of these issues are considered. The APHIS-WS program will implement the proposed action as described in the EA and in compliance with all applicable mitigation measures listed as components of standard operating procedures in Chapter 3 of the EA.

For additional information regarding this decision, please contact Dennis Slate, National Rabies Management Program Coordinator, APHIS-Wildlife Services, 59 Chenell Dr., Suite 7, Concord, NH 03301-8548; phone (603) 223-9623.

for William Clay, Deputy Administrator
APHIS-WS

9/12/11
Date

LITERATURE CITED:

CFIA (Canadian Food Inspection Agency), Canadian Centre for Veterinary Biologics (CCVB). 2010. Environmental Assessment – rabies vaccine, live adenovirus vector (AdRG1.3 baits) for field use in vaccination campaigns by the Ontario Ministry of Natural Resources. CCVB File No. 900VV/R5.0/A22., 59 Camelot Drive, Ottawa, Ontario, K1A 0Y9.

CFIA (Canadian Food inspection Agency), Canadian Centre for Veterinary Biologics (CCVB). 2008. Environmental Assessment – rabies vaccine, live adenovirus vector (AdRG1.3 baits) for field use in field trials by le Ministére des Resources Naturelles et de la Faune du Québec. CCVB File No. 900VV/R5.0/A22., 2 Constellation Crescent, Ottawa, Ontario, K1A 0Y9.

Charleton, K.M., M. Artois, L. Prevec, J.B. Campbell, G.A. Casey, A.I. Wandeler, and J. Armstrong. 1992. Oral rabies vaccination of skunks and foxes with a recombinant human adenovirus vaccine. Arch. Virol.; 123:169-179.

Graham, F.L. and L. Prevec. 1992. Adenovirus-based expression vectors and recombinant vaccines. *In:* Ellis, R.W., editor. Vaccines: new approaches to immunological problems. Boston: Butterworh-Heinemann. P. 369-390.

Knowles, M.K., S.A. Nadin-Davis, M. Sheen, R. Rosatte, R. Muller, and A. Beresford. 2009. Safety studies on an adenovirus recombinant vaccine for rabies (AdRG1.3 ONRAB®) in target and non-target species. Vaccine; 27: 6619-6626.

Prevec, L., J.B. Campbell, B.S. Christies, L. Belbeck, J.B. Derbyshire, and F.L. Graham. 1989. Use of human adenovirus-based vectors for antigen expression in animals. J. Gen. Virol; 70: 429-434.

Taylor, P.E. 1977. Adenoviruses: Diagnosis of infections. *In:* Kurstak, E. and Kurstak, C., eds. Comaprative diagnosis of viral disease. New York: Academic Press, P. 86-170.

USDA (U.S. Department of Agriculture), Animal and Plant Health Inspection Service (APHIS), Animal Damage Control Program. 1997. Final Environmental Impact Statement – revised October 1997. USDA, APHIS, Wildlife Services Operational Support Staff. 4700 River Road, Unit 87, Riverdale, MD 20737-1234.

USDA (U.S. Department of Agriculture), Animal and Plant Health Inspection Service (APHIS), Wildlife Services. 2011. Environmental Assessment (EA) – Field trial of an experimental rabies vaccine, human adenovirus type 5

vector in West Virginia. USDA, APHIS, Wildlife Services. 4700 River Road, Unit 87, Riverdale, MD 20737-1234.

USDA (U.S. Department of Agriculture), Animal and Plant Health Inspection Service (APHIS), Wildlife Services. 2010. Environmental Assessment (EA) and decision/finding of no significant impact (FONSI) – Oral vaccination to control specific rabies virus variant in raccoons, grey foxes, and coyotes in the United States. USDA, APHIS, Wildlife Services. 4700 River Road, Unit 87, Riverdale, MD 20737-1234.