RECORD OF DECISION

AND

FINDING OF NO SIGNIFICANT IMPACT

FOR THE ENVIRONEMTNAL ASSESSMENT:

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

INTRODUCTION

This Record of Decision has been developed by the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Wildlife Services (APHIS-WS) in compliance with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, the Council on Environmental Quality's (CEQ) regulations implementing NEPA, as amended, and the USDA and APHIS NEPA implementing regulations and procedures.

This Record of Decision documents USDA APHIS' decision for its Final 2019 Environmental Assessment on Oral Vaccination to Control Specific Rabies Virus Variants with Human Adenovirus Type 5 Vector in Maine, New Hampshire, New York, Ohio, Tennessee, Vermont, Virginia, and West Virginia. APHIS-WS' decision is to select Alternative 2, the proposed action, to expand the use of ONRAB in the aforementioned states.

This Record of Decision (a) states APHIS-WS' decision, (b) identifies the alternatives and issues considered in reaching the decision and specifies the environmentally preferable alternative, (c) identifies and discusses the factors APHIS-WS balanced in making its decision; and (d) states whether all practical means to minimize environmental harm from implementation of the selected alternative have been adopted.

In 2012 the USDA, APHIS-WS program completed an environmental assessment (EA) and that analyzed the potential environmental effects of a proposal to conduct an experimental oral rabies vaccine (ORV) field trial in New Hampshire, New York, Ohio, Vermont, and West Virginia using the human adenovirus type 5 rabies glycoprotein recombinant (AdRG1.3; trade name ONRAB, Artemis Technologies, Inc., Guelph, ON) vaccine. The 2012 EA documented the need for ORV field trials and the relative effectiveness of three alternatives to meet that need, while accounting for the potential environmental effects for those activities. After consideration of the analysis contained in the EA and review of public comments, APHIS-WS issued a Decision/Finding of No Significant Impact (FONSI) (USDA 2012) (77 FR 49409-49410). The Decision/FONSI selected the proposed action alternative which implemented ORV field trials with the ONRAB vaccine in portions of New Hampshire, New York, Ohio, Vermont, and West Virginia.

In 2013, APHIS-WS determined there was a need to expand the ONRAB field trials into additional counties in New York that were not previously included in the EA (USDA 2012). A 2013 supplement to the EA was completed and, after consideration of the new analysis and all comments submitted during the 30-day comment period, APHIS-WS issued a Decision/FONSI for the supplement to the EA on July 17, 2013. The 2013 Decision/FONSI selected the proposed action alternative which implemented the continuation of ONRAB field trials in New Hampshire, New York, Ohio, Vermont, and West Virginia; while adding additional counties in New York into the field trial zone.

In 2015, APHIS-WS further determined there was a need to shift the ONRAB field trial zone into additional counties in Ohio and increase the vaccine-bait distribution density in West Virginia. A 2015 supplement to the EA was

completed and, after consideration of the new analysis and all comments submitted during the 30-day public comment period, APHIS-WS issued a Decision/FONSI for the supplement to the EA on August 18, 2015. The 2015 Decision/FONSI selected the proposed action alternative which implemented the continuation of ONRAB field trials in New Hampshire, New York, Ohio, Vermont, and West Virginia; while adding additional counties in Ohio into the field trial zone and increasing vaccine-bait density distribution in West Virginia.

In 2017, APHIS-WS determined the need to expand the geographic range of the ONRAB field trial zone into additional counties in Ohio, West Virginia, and New York. A 2017 supplement to the EA was completed and, after consideration of the new analysis and all comments submitted during the 30-day public comment period, APHIS-WS issued a Decision/FONSI for the supplement to the EA on August 17, 2017. The 2017 Decision/FONSI selected the proposed action alternative which implemented the continuation of ONRAB field trial in New Hampshire, New York, Ohio, Vermont, and West Virginia; while expanding the geographic area of the field trial in Ohio, New York, and West Virginia.

In 2018, APHIS-WS again determined the need to expand the geographic area of the field trial zone in Ohio and West Virginia. A 2018 supplement to the EA was completed and, after consideration of the new analysis and all comments submitted during the 30-day public comment period, APHIS-WS issued a Decision/FONSI for the supplement to the EA on August 09, 2018. The 2018 Decision/FONSI selected the proposed action alternative which implemented the continuation of ONRAB field trial in New Hampshire, New York, Ohio, Vermont, and West Virginia; while expanding the geographic zone of the trial in Ohio and West Virginia.

PURPOSE OF THIS EA

This 2019 EA evaluates environmental effects of the continued and expanded APHIS-WS ORV programs using the ONRAB wildlife rabies vaccine to eliminate or stop the spread of raccoon rabies 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. This EA will supersede the 2012 EA, as supplemented.

COORDINATION

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

ISSUES

Issues are concerns regarding potential effects that might occur from a proposed activity (see Section 2.1 of the EA). Federal agencies, such as the WS program, must consider such issues during the decision-making process of the NEPA. WS and the USFS identified several issues during the development of the EA. WS and the USFS analyzed the environmental consequences of implementing the alternative approaches for each of the following issues.

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 injure people or domestic animals.

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

ALTERNATIVES

The following alternatives were developed to respond to the issues identified in Chapter 2 of the EA. A detailed discussion of the effects of the alternatives on the issues is described in the EA under Chapter 3; below is a summary of the alternatives.

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 the distribution of vaccine baits 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 the 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 Fehlner-Gardiner, 2018; Sobey et al., 2010; WHO, 2013; Wohlers et al., 2018). 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; WHO, 2005; Rosatte 2011; C. MacInnes, Ontario Ministry of Natural Resources pers. comm. 2001 as cited in USDA 2001). 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. Parenterally-delivered veterinary vaccines have been shown to produce nearly 100% antibody response in raccoons and skunks after intramuscular injection (R. Rosatte et al. 1990; R. Rosatte et al., 1992; Sobey et al., 2010). 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 mi2), 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).

Alternative 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.

MONITORING

The APHIS-WS National Rabies Management Program annually reviews its ORV program impacts on target and nontarget species to ensure the APHIS-WS activities do not adversely affect the viability of wildlife populations. In addition, the EA will be reviewed each year to ensure that the analyses are sufficient.

PUBLIC INVOLVEMENT AND COMMENTS

Several EAs have been prepared previously to analyze the environmental effects of APHIS-WS' continued and expanded participation with an ORV program in the eastern and southwestern United States. Issues were identified through public involvement and planning/scoping meetings with numerous federal (i.e. CDC), state (i.e. health, agriculture, and natural resource departments) and local government agencies, academic institutions, and Canadian provincial governments (i.e., Ontario Ministry of Natural Resources and Quebec Ministry of Natural Resources and Wildlife).

To document the need for APHIS-WS' continued and broadened involvement in ONRAB ORV distribution and following interagency review and discussion, the draft EA was made available to the public for review and comment from July 9, 2019 to August 8, 2019. The document was made available through a Notice of Availability (NOA) for Docket NO. APHIS-2019-0034 published in the *Federal Register* on July 9, 2019 and sent to interested parties through the APHIS Stakeholder Registry. APHIS_WS also published the document on the program website at https://www.aphis.usda.gov/aphis/ourfocus/wildlifedamage/programs/nepa. At the close of the 30-day comment period APHIS-WS received 6 comment letters. APHIS-WS responses to comments are included in Appendix B. All correspondence on the EA is maintained at the WS National Rabies Management Program (NRMP) Office, 59 Chenell Drive, Suite 2, Concord, NH 03301

CUMMULATIVE IMPACTS OF THE PROPOSED ACTION

No significant cumulative environmental impacts have resulted from implementation of APHIS-WS' ORV program, including ONRAB distribution. It is possible that Alternative 1 (No Action Alternative), Alternative 4 (No Surveillance or Monitoring), and Alternative 5 (No Federal ORV Program) might indirectly lead to increased human exposures and domestic and wild animal rabies cases across the U.S. As discussed in Chapter 3 of the EA, APHIS-WS and cooperating state and local agencies expect to continue to live-trap or humanely kill less than one percent of the lowest estimated number of the target species combined for monitoring and surveillance purposes or implementation of contingency plans involving lethal population reduction in all of APHIS-WS' ORV programs, including the ONRAB distribution.

Additionally, as discussed in Chapter 3 of the EA, the potential for adverse effects resulting from the recombination of ONRAB with other adenoviruses is negligible. It is unlikely that an exchange of genetic material with wild-type viruses would occur in the field. Even if it did occur, the event would not be expected to generate a more virulent virus than the already present wild-type virus (USDA 2011). Broadening the distribution of ONRAB will not alter this potential.

FINDING OF NO SIGNIFICANT IMPACT

Based on the analysis provided in the EA and 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 Environmental Impact Statement (EIS) should not be prepared. As defined in 40 CFR §1508.27, significance is determined by examining both the context and intensity of an action.

The EA examined the significance of the proposed action in a variety of contexts including the society as a whole, the affected regions, and the affected interests. The proposed action will take place in eight states (Maine, New Hampshire, New York, Ohio, Tennessee, Texas, Vermont, Virginia, and West Virginia). Although the ONRAB ORV zones encompass a broad area, decisions to implement ORV activities are based on local responses to rabies outbreaks. This localized decision making process ensures the ORV program considers the context and location of ORV activities prior to implementing those activities. As described more fully in the EA, if APHIS-WS decides to implement ORV activities, it uses protective measures to minimize local impact.

The following was considered in evaluating the intensity of the proposed program:

1. **Impacts that may be both beneficial and adverse.** The ONRAB vaccine and bait that is used has been found to be safe in more than 20 target and nontarget species; has a low risk of causing adverse effects to humans, is readily consumed by target animal species; and does not cause bioaccumulation in the environment. A limited number of baits will be distributed once per year, thereby minimizing the potential for persons to be exposed to an ONRAB bait or bait distributing equipment. Positive health benefits to the public and target and nontarget animal populations likely to occur through decreased risk of exposure to rabid animals.

2. **Degree of effect on public health or safety.** The proposed action poses minimal adverse impacts to human health and safety. Of more than 170 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 a falling bait. Since the inception of APHIS-WS' ORV program in 1995, approximately 3,600 people have reported contacting, or potentially contacting a vaccine laden V-RG or ONRAB bait. Of these exposures, there have been two reported cases of human adverse reactions to the vaccinia virus used in the V_RG vaccine and zero reported cases of human adverse reactions to the human adenovirus type-5 virus used in the ONRAB vaccine. Adverse health effects from human adenovirus type-5 are expected to be minimal with no significant long-term effects expected.

3. **Unique characteristics of the geographic area such as proximity to historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.** There are no unique characteristics such as parkland, 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' SOPS's and adherence to laws and regulations will further ensure that the agencies' activities do not harm the environment.

4. **Degree to which effects on the quality of the human environment are likely to be highly controversial.** 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. **Degree to which the possible effects on the quality of the human environment are highly uncertain or involve unique or unknown risks.** Based on the analysis documented in the EA and the accompanying administrative file, the effects of the proposed program 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. **Degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.** The proposed action would not establish a precedent for any future action with significant effects or represent a decision in principle about future considerations.

7. **Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.** No significant cumulative impacts were identified through this assessment.

8. **Degree to which the action may adversely affect districts, sites, highways, structures, or objects listed on the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historical resources.** The proposed activities would not affect districts, sites, highways, structures, or objects listed or eligible for listing in the national Register for Historic Places, nor would they likely cause any loss or destruction of significant scientific, cultural, or historic resources.

9. **Degree to which the action may adversely affect an endangered or threatened species or its critical habitat.** APHIS-WS has determined that the proposed action would not adversely affect and federally listed T&E species currently listed in the States. In addition, APHIS-WS has determined that the proposed activities would not adversely affect any state-listed T&E species.
10. **Whether the action threatens a violation of federal, state, or local law or requirements imposed for environmental protection.** 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 variant 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 issued are considered. The APHIS-WS program will implement the proposed action as described in the EA and in compliance with all applicable protective measures listed in Chapter 2 of the EA.

APHIS-WS will notice the availability of the final EA and decision/FONSI documents through a notice published in the Federal Register, by posting on the WS stakeholder registry, and by posting on the APHIS-WS website. However, this FONSI will become final and the proposed action may be implemented effective on the date of signature of the Decision/FONSI by the decision maker and upon posting of the final EA and Decision/FONSI on the APHIS-WS website. The rationale for making this Decision/FONSI effective upon signature is based on several important considerations: being able to implement the rabies vaccine field trial effective upon signature and posting on the APHIS-WS website will allow APHIS-WS to quickly commence the valuable vaccine distribution while ensuring sufficient time to complete critical monitoring and surveillance activities; in other words, delaying implementation of the program until after the publication of the notice of availability of the final EA and Decision/FONSI documents in the Federal Register would negatively and unnecessarily reduce the limited time available for APHIS-WS to collect biological specimens critical for the program evaluation prior to the onset of winter weather and target species dormancy in some states; this action will further maximize the effectiveness of APHIS-WS' ORV programs and more aggressively meet raccoon rabies management goals by identifying new vaccines which offer both safety and increased immunogenicity; all actions implemented pursuant to the Decision/FONSI are consistent with applicable laws, regulations, policies, and orders; and no adverse impacts to the environment were identified in the analyses in the final EA.

For additional information regarding this decision, please contact Mr. Richard Chipman, National Rabies Management Program Coordinator, APHIS-Wildlife Services, 59 Chenell Dr., Suite 2, Concord, NH 03301-8548; Phone (603) 223-9623.

JANET BUCKNALL

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Janet L. Bucknall, Deputy Administrator
USDA/APHIS/WS
Washington, D.C.

Date

APPENDIX A

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APPENDIX B

RESPONSES TO COMMENTS

The Appendix contains issues raised by the public during the comment period for the 2019 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 EA and APHIS-WS response to each issue. WS received 6 comment letters regarding the EA. Substantive issues raised in the letters are numbered and are written in bold text. The APHIS-WS response follows each comment and is written in standard text.

1. I live in South Carolina and I would like to have access to this program or oral rabies vaccines for the wildlife on my property. South Carolina had several positive cats and other wildlife and I would like to vaccinate the wild coyotes and wildlife on my property.

ONRAB is currently approved for use in state and federal rabies control programs. It is not available for use by private veterinary practioners or the public.

2. Feral cats, or any non-native animal, should not be vaccinated, but permanently removed from the landscape. Feral cats should not be include in WS TVR Contingency Actions. WS' agents should be directed to destroy all trapped feral cats.

The APHIS-WS ORV program targets raccoons and stripped skunks in the eastern U.S. and gray foxes and coyotes in Texas. Nontarget species, including feral cats, may inadvertently contact or consume a vaccine-bait. Invasive species control (e.g. feral cat management) is outside of the scope of the ORV program and this EA.

As analyzed in Chapter 3 of the EA, as necessary, APHIS-WS may implement localized population reduction of target species under state contingency actions. Nontarget animals captured in cage traps would normally be released unharmed unless the animal appeared sick or injured. During localized emergencies, APHIS-WS may implement one or more Contingency Actions. Contingency Actions are defined in Section 1.5.1 of the EA. It is possible that feral cats might be included during a trap-vaccinate-and release Contingency Action if APHIS-WS determined such an action was necessary to maintain the integrity of established ORV rabies-free zones.

3. Commenter questioned if the new vaccine would also kill raccoon and skunks. Remainder of comments in this letter were in opposition of the WS program but out of the scope of this EA.

Chapter 3 of the EA provides analysis of the anticipated effects of the ONRAB vaccine to target animals. Effects to target species are a primary concern to APHIS-WS. 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.