

**RECORD OF DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT
FOR THE 2015 SUPPLEMENT TO THE ENVIRONMENTAL ASSESSMENT:**

**FIELD TRIAL OF AN EXPERIMENTAL RABIES VACCINE,
HUMAN ADENOVIRUS TYPE 5 VECTOR
IN NEW HAMPSHIRE, NEW YORK, OHIO, VERMONT, AND WEST VIRGINIA**

INTRODUCTION AND PURPOSE

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 2015 Supplemental Environmental Assessment on Field Trial of an Experimental Rabies Vaccine, Human Adenovirus Type 5 Vector in New Hampshire, New York, Ohio, Vermont, and West Virginia. APHIS-WS' decision is to select Alternative 2, the proposed action, to continue with the APHIS-WS Oral Rabies Vaccination field trials and expand the program in Ohio; also, to increase bait densities in West Virginia portion of the field trials.

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 public 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.

Purpose of the Supplement to the EA

The 2015 supplement to the EA analyzes the potential impacts of APHIS-WS' ORV program as it relates to shifting the geographic range of the field trial zone in Ohio and increasing bait distribution density in the West Virginia field trial zone. The 2012 EA analyzed APHIS-WS' ORV field trial activities for Cuyahoga, Geauga, Lake, Portage, and Summit counties in Ohio. The 2015 supplement to the EA allows for a shift in the Ohio field trial zone to include Ashtabula and Trumbull counties. This proposed change in the field trial zone was deemed necessary because there have been no additional raccoon rabies cases in the western edge of that region since 2011 and the eastern movement of the ORV zone would mark an advancement toward the eventual elimination of wildlife rabies. Additionally, the 2015 supplement to the EA analyzed increasing ONRAB bait distribution density from the program standard rate of 75-150 baits/km² (194-388 baits/mi²) to an increased density of 300 baits/km² (776 baits/mi²) over a portion of the West Virginia field trial zone to test different baiting strategies and to further study the immunogenicity of the vaccine in striped skunks. The 2015 supplement to the EA also examines the potential environmental impacts of APHIS-WS' program as it relates to new information that has become available from public comments, research findings, and data gathering since the issuance of the 2012 and 2013 Decision/FONSIs; clearly communicates to the public the analysis of individual and cumulative impacts of the proposed program since 2012; and documents the analysis of WS' ORV field trial activities in New Hampshire, New York, Ohio, Vermont, and West Virginia since the Decision/FONSI was issued in 2012 to ensure that program's environmental impact remains unchanged.

NEED FOR ACTION

A description of the need for action to control rabies in wildlife populations and to prevent the westward movement of the raccoon rabies virus variant is provided in section 1.3 of the EA (USDA 2012). Since 2012, APHIS-WS has been distributing both ONRAB and V-RG vaccine-baits along the western edge of the Ohio ORV zone as part of a contingency¹ response to positive wildlife rabies cases in that area. Since 2011, there have been no additional raccoon rabies cases in that region of the zone, prompting the need to reduce the western edge of the ORV zone in the Ohio contingency area and to move the zone further east. This proposed shift in the ORV zone would allow for two significant benefits. The proposed change would allow APHIS-WS to distribute ONRAB vaccine in a portion of the ORV zone historically baited only with V-RG, but where there continues to be occasional rabies positive wildlife; and the eastern movement of the ORV zone would mark an advancement toward the eventual elimination of wildlife rabies.

Additionally, APHIS- WS proposes to increase the ONRAB ORV bait distribution density from the

¹ ORV contingency plans include actions taken in response to rabies emergencies and are further defined in USDA 2010.

program standard rate of 75 – 150 baits/km² (194-388 baits/mi²) to an increased density of 300 baits/km² (776 baits/mi²) over a portion of the current West Virginia field trial zone to test the effectiveness of different baiting densities in Greenbrier, Mercer, Monroe, Pocahontas, and Summers counties in West Virginia and to further study the immunogenicity of the vaccine in striped skunks. Due to the sedentary nature and relatively small home range of striped skunks, it is suggestive that more vaccine baits are required per unit of baitable habitat so that each skunk will find at least one bait in its home range (Rosatte et al. 2011). Additionally, studies have found that increased bait densities (300 baits/km²) and narrower flight lines (250m) lead to greater bait acceptance and meaningful levels of immunity in striped skunks (Rosatte et al. 2009 and Rosatte et al. 2011).

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.

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.

The proposed field trial is a collaborative effort among APHIS-WS; the Centers for Disease Control and Prevention (CDC); the vaccine manufacturer (Artemis Technologies Inc.); the NH Departments of: Agriculture, Markets, and Food; Health and Human Services; and Fish and Game; the NY Departments of: Agriculture and Markets; Health; and Environmental Conservation; the OH Departments of: Agriculture; Health; and Natural Resources; the VT Departments of: Agriculture, Food, and Markets; Health; and Fish and Wildlife; and the WV Departments of: Agriculture; Health and Human Resources; the WV Division of Natural Resources; the Ontario Ministry of Natural Resources; and the Quebec Ministry of Natural Resources and Wildlife.

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 as well as for APHIS-WS' ONRAB field trial. Issues were identified through public involvement and planning/scoping meetings with numerous federal (i.e. CDC), state (i.e. health, agriculture, and natural resources departments) and local government agencies, academic institutions, and Canadian provincial government agencies (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 an ONRAB field trial and following interagency review and discussion, the draft supplement to the EA was made available to

the public for review and comment from July 17, 2015 to August 17, 2015. The document was made available through a Notice of Availability (NOA) for Docket No. APHIS-2015-0047 published in the *Federal Register* on July 17, 2015 and sent to interested parties through the APHIS Stakeholder Registry. APHIS-WS also published the document on the program website at <http://www.aphis.usda.gov/wildlifedamage/nepa>. At the close of the 30-day comment period, APHIS-WS received one comment letter in support of the program.

All of the letters and comments are maintained at the Wildlife Services Office, 140-C Locust Grove Rd., Pittstown, NJ 08867. This decision document will be made available to the public using the procedures as for the pre-decision supplement to the EA. The FONSI and final supplement to the EA are posted on the Wildlife Services website.

AFFECTED ENVIRONMENT

The area of the field trial includes public and private lands in New Hampshire, New York, Ohio, Vermont, and West Virginia. The 2015 supplement to the EA broadens the area potentially affected in Ohio to include Ashtabula and Trumbull counties. Affected public lands include portions of the Monongahela National Forest, but excludes Wilderness Areas. Currently, cooperative rabies surveillance activities are conducted in all of the above mentioned states and will continue to occur in conjunction with the ONRAB 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. These areas will be treated by a more specific ground distribution of ORV baits. Additionally, aerial distribution of ORV baits will be conducted in a way to avoid 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.

ISSUES ANALYZED IN DETAIL

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 the issues identified in that EA were considered to be germane to the field trial EA (USDA 2012).

Chapter 2 of the 2012 EA describes in detail the issues considered and evaluated in the EA (USDA 2012). The following issues were identified as important to the scope of the analysis with each alternative evaluated in the EA relative to the impacts on the major issues:

- 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 ONRAB virus to ‘revert to virulence’ or recombine with other viruses and result in a virus that could cause disease in humans.
- Potential for the 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.

Those issues identified during the development of the 2012 EA were again evaluated in the 2015 supplement to the EA by each issue as those issues related to APHIS-WS’ activities conducted since the signing of the 2012 and 2013 Decision/FONSI. Each of those issues was also evaluated as those issues relate to conducting the proposed action alternative as described in the 2015 supplement to the EA.

ISSUES CONSIDERED BUT NOT IN DETAIL

In addition to those issues analyzed in detail, several additional issues were identified during the development of the 2012 EA, but were not considered in detail. The rationale for the decision not to analyze those issues in detail is discussed in the EA (USDA 2012). APHIS-WS has reviewed the issues not considered in detail as described in the 2012 EA and has determined that the analysis provided in the EA has not changed and is still appropriate for the 2015 Supplement to the EA.

ALTERNATIVES

The scope of the 2015 supplement to the EA was limited to analysis of potential environmental impacts of a proposal to shift the ONRAB field trial zone in Ohio and to increase bait distribution density in West Virginia. Alternative 1 would involve no change to APHIS-WS’ ONRAB field trial as implemented in 2013. Alternatives 2 and 3 are modifications of the current program. The following three alternatives were developed for this supplement to address the issues identified above:

Alternative 1. Maintain Status Quo This alternative would involve the use of federal funds to maintain the status quo of the ONRAB field trials in New Hampshire, New York, Ohio, Vermont, and West Virginia, as described in the 2012 EA and the Decision/FONSI for the EA (USDA 2012), as supplemented (USDA 2013).

Alternative 2. Proposed Action (the Preferred Alternative). This alternative would involve the use of federal funds to shift the geographic range of the ONRAB field trial in Ohio, as described in the EA (USDA 2012) and the 2013 supplement to the EA (USDA 2013), eastward to include Ashtabula and Trumbull counties and to increase ONRAB bait distribution density in Greenbrier, Mercer, Monroe, Pocahontas, and Summers counties in West Virginia, as proposed in this supplement. Under this

alternative, APHIS-WS would use federal funds to purchase ONRAB oral vaccine-baits and to participate in the continuation of ORV field trials involving the distribution of ONRAB oral vaccine-baits under the authorities of the appropriate state agencies in New Hampshire, New York, Ohio, Vermont, and West Virginia to evaluate the immunogenic and safety characteristics of the ONRAB vaccine for wildlife rabies under limited field conditions. Under this alternative, as described in the 2012 EA, the 2013 supplement to the EA, and this supplement, APHIS-WS would also assist in monitoring and surveillance efforts by capturing and releasing or killing target species for purposes of obtaining biological samples.

Alternative 3. No ORV Field Trials. Under this alternative, there would be no involvement by APHIS-WS in ORV field trials in the states identified in Section 1.4 of the EA (USDA 2012) or in any of the additional Ohio counties proposed in this supplement.

ALTERNATIVES CONSIDERED, BUT NOT ANALYZED IN DETAIL

Three additional alternatives were considered, but not analyzed in detail in the 2012 EA [see section 3.2 (USDA 2012)]. These additional alternatives included:

- Depopulation of target species.
- Population control through birth control.
- Employ other types of ORV instead of the ONRAB vaccine.

APHIS-WS has reviewed the alternatives not analyzed in detail in the EA and has determined that the analysis provided in the EA has not changed and is still appropriate with regard to APHIS-WS' proposed geographic shift of the ONRAB field trial into Ashtabula and Trumbull counties in Ohio and the proposed increased bait distribution density in Greenbrier, Mercer, Monroe, Pocahontas, and Summers counties in West Virginia, as analyzed in this supplement to the EA.

SUMMARY OF ENVIRONMENTAL EFFECTS

The potential impacts of Alternative 1 and Alternative 3 on the human environment have not changed from those described and analyzed in the 2012 EA and the 2013 supplement to the EA and, thus, do not require additional analyses in the 2015 supplement to the EA. Chapter 4 of the EA contains a detailed discussion and comparison of the identified alternatives and the major issues (USDA 2012). Alternative 2 (proposed action), described in the EA, addresses the need and implementation of ORV field trials using the ONRAB vaccine by APHIS-WS. The following issues were analyzed in detail in the 2015 Supplement to the EA as they relate to Alternative 2: the Preferred Alternative.

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

Of primary concern is whether the ONRAB vaccine-bait might cause disease in raccoons and striped skunks, the target species in this ONRAB field trial, if they consume this vaccine-bait. The EA (USDA 2012) includes discussion of studies conducted by Charlton et al. (1992), Prevec et al. (1990), and Knowles et al. (2009) documenting the safety of AdRg1 and ONRAB in ORV target species including raccoons, foxes, and skunks. Additionally, the EA presents findings from previous field trial studies conducted in Canada.

Recent studies (Brown et al. 2012, Fehlner-Gardiner et al. 2012, and Mainguy et al. 2013) focusing on immune response in raccoons following treatment with ONRAB and comparing vaccine efficacy in U.S.-Canada cross-border studies have shown promising results. Brown et al. (2012) found that of twenty raccoons treated with ONRAB, 15 (75%) survived rabies challenge. Fehlner-Gardiner et al. (2012) and Mainguy et al. (2013) compared field performance between ONRAB and V-RG. The results of these studies showed antibody response rates in raccoons of 67% to 78% following the distribution of ONRAB in New Brunswick, Canada compared to response rates of 25% to 32% following V-RG distribution in Maine during the same time period (Fehlner-Gardiner et al. 2012). Similarly, Mainguy et al. (2013) found that the percentage of antibody-positive raccoons was greater with ONRAB in Quebec (51%) than with V-RG in Vermont (38%).

There will likely be a reduction of ONRAB distribution in Cuyahoga and Summit counties in Ohio as the ORV zone in that region is shifted eastward. Therefore, shifting the geographic area of the field trial in Ohio to include two new counties should not expose a significantly higher number of target animals to the ONRAB vaccine. However, even if all analyzed Ohio counties were baited with ONRAB, based on the safety data presented above and in the EA (USDA 2012), as well as APHIS-WS' continued limited lethal removal (i.e., less than 1% of target species populations), no adverse effects to target animals is expected. Beneficial impacts to target species may be expected as previous studies indicate higher levels of rabies antibody response in animals treated with ONRAB versus V-RG. Additionally, increasing bait density in specific counties in West Virginia is not expected to result in any adverse effects to target species based on the analyses in 2012 EA (USDA 2012).

Also of concern would be the magnitude of take on a species' population from the use of lethal methods. Shifting the geographic area of the ONRAB field trial into Ashtabula and Trumbull counties in Ohio will continue to result in negligible adverse risks to target species populations with regard to monitoring and surveillance activities. APHIS-WS and cooperating state and local agencies continue to expect to humanely kill less than 1% of the lowest number of raccoons in all ORV program states, including any raccoons that may be humanely killed for critical samples during ONRAB field trials.

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

The issue of nontarget species effects, including effects on threatened and endangered species, arises from the potential consumption of wildlife vaccines and the use of monitoring and surveillance methods as described in the EA (USDA 2012). As discussed in section 4.1.2 of the EA (USDA 2012), at least 17 species have been included in the safety studies on ONRAB (Knowles et al. 2009) from several taxonomic groups. No adverse reactions in the animals studied were found following oral inoculation of the experimental vaccine, while, in most cases, antibodies against the rabies viral protein were detected on day 28 post-exposure (CFIA 2008, 2010). Although no threatened and endangered species were specifically tested for safety of ONRAB baits, safety studies involving ONRAB on other species representing 11 unique taxonomic families (see EA Section 4.12) indicate that no species will be affected by the baits (Knowles et al. 2009, Randrianarison-Jewtoukoff and Perricaudet 1995, Artemis 2010).

Subsequent to the completion of the EA (USDA 2012), APHIS-WS' National Wildlife Research Center (NWRC) conducted research expanding on the species evaluated by Knowles et al. (2009) to investigate the safety of ONRAB in wildlife species likely to come into contact with the vaccine-bait as a result of

WS' ORV distribution (Fry et al. 2013). A 10 times dose of ONRAB was administered to Eastern wild turkeys (*Meleagris gallopavo silvestri*), opossums (*Didelphis virginiana*), cottontail rabbits (*Sylvilagus floridanus*), fox squirrels (*Sciurus niger*), and woodrats (*Neotoma spp.*). Based on the study results, Fry et al. (2013) determined that there was no reason to conclude that ONRAB would have detrimental effects on nontarget wildlife species that incidentally ingest ONRAB during ORV campaigns in the U.S. Similarly, the distribution of ONRAB to control the spread of rabies in Canada has not resulted in any concern regarding nontarget species.

The methods proposed for use in ONRAB field trial monitoring and surveillance areas, including the proposed geographic shift in Ohio, would have no significant adverse effects on nontarget species. Nontarget animals captured in cage traps would normally be released unharmed unless the animal appeared injured or sick. Therefore, monitoring and surveillance should have no effect on nontarget species populations.

Additionally, based on the analyses in USDA 2012, 2013 and the 2015 supplement to the EA, increasing bait distribution density in the West Virginia portion of the field trial is not expected to result in any adverse effects to nontarget species. Monitoring and surveillance in this area will not differ or increase in intensity from those analyzed in the EA (USDA 2012) and supplement to the EA (USDA 2013), therefore effects on nontarget species will remain within the impact parameters established in the EA and 2013 supplement to the EA.

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

The recombinant virus used as the ONRAB vaccine-bait cannot cause rabies. This is because the ONRAB vaccine only carries the gene for producing the outer coating of the rabies virus (i.e., rabies virus *glycoprotein*) and not those portions of the virus that could result in replication of the rabies virus which would be required for the disease to occur. Implementation of ORV programs would reduce the risk of human exposure to rabies by reducing the chance of encountering rabid animals that have been infected by rabid raccoons, striped skunks, foxes, or coyotes.

It is unlikely that there will be any significant increase in the numbers of humans who may be exposed to ONRAB vaccine-baits due to the changes in the field trial as described in the 2015 supplement to the EA. As described in the 2015 supplement to the EA, the effects of human adenovirus type 5 on people, pets, and livestock will remain unchanged with APHIS-WS' proposed field trial shift into the Ohio counties of Ashtabula and Trumbull and proposed increased bait distribution density in Greenbrier, Mercer, Monroe, Pocahontas, and Summers counties in West Virginia. The information discussed in the EA (USDA 2012) indicates a low potential exists for unusual circumstances to result in short-term adverse health effects from exposure to the human adenovirus type 5 in the ONRAB vaccine. The EA (USDA 2012) concluded that the overall risk of such effects appears to be minimal based on the extremely low rate of reported occurrences in ORV programs. The new data presented in the 2015 supplement further supports this conclusion.

Additionally, APHIS-WS expects that the rate of domestic animal contacts with ORV baits will remain unchanged under the proposed action. Impacts of the program on this issue are expected to remain negligible.

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

The concern is whether the ONRAB recombinant virus vaccine is genetically stable so that it would not become virulent (i.e., capable of causing disease) after it replicates (or reproduces) in animals that eat ORV baits containing the vaccine, followed by the possible transmission to other animals; and whether the ONRAB vaccine might come into contact with other viruses within infected cells of animals, exchange genetic material with them during replication, and result in new viruses that could cause more serious diseases in humans or animals.

Based on the analysis in the EA (USDA 2012), ONRAB is highly genetically stable and has not shown evidence of substantial mutation during passage studies (Lutz-Wallace et al. 1995a, 1995b). Additionally, as discussed in section 4.1.4 of the EA (USDA 2012), recombination of the ONRAB vaccine is highly unlikely. However, if it were to occur, it is equally unlikely that the result would yield a viable, transmissible virus (CDC 2011). APHIS-WS believes this issue was adequately addressed in the EA and the effects of this issue will remain unchanged under the proposed program.

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

As discussed in section 4.1.5 of the EA (USDA 2012), baits are generally distributed at common densities of 75 baits/km² (194 baits/mi²) or 150 baits/km² (388 baits/mi²). Additionally, as described in the 2015 supplement to the EA, APHIS-WS has proposed to increase bait distribution density in Greenbrier, Mercer, Monroe, Pocahontas, and Summers counties of the West Virginia portion of the field trial to 300 baits/km² (776 baits/mi²). These densities, including the increased densities in some counties in West Virginia, are sparse enough to predict that the chance of a person being struck and harmed by falling bait is remote. The negligible risk of being struck is further supported by the fact that out of more than 150 million baits distributed in the U.S. by APHIS-WS during other ORV programs between 1995 and 2014, only 11 incidents have been reported in which a person claimed to have been struck by a falling bait (0.000007% chance of being struck by a bait or 1 strike per 13.6 million baits dropped) (USDA unpublished). None of the reports since APHIS-WS’ ORV program inception have resulted in injury or harm to the individuals involved.

Additionally, the West Virginia portion of the field trial proposed for increased bait distribution density is an area of relatively sparse human population (USDC) and where there is significant local support and familiarity with the field trial. Although APHIS-WS is proposing to distribute ONRAB over a new geographic area in the Ohio state portion of the field trial zone and increase baiting density in portions of the West Virginia field trial zone, the analysis in the EA (USDA 2012) as well as the EA for APHIS-WS’ current V-RG ORV program (USDA 2010) indicates that APHIS-WS’ ORV programs, including the proposed field trial, pose minimal potential for adverse effects regarding this issue.

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

The issue of humaneness was also analyzed in detail in relationship to the alternatives in the EA. Since those methods described in the EA (USDA 2012) would continue to be available under the proposed supplement to the EA, the issue of humaneness would be similar despite the frequency of the use of

methods increasing. APHIS-WS' personnel would be experienced and professional in their use of monitoring and surveillance methods. When employing methods to capture target species for monitoring and surveillance purposes, methods would be applied as humanely as possible. Methods used in ORV monitoring and surveillance activities since the completion of the EA and their potential impacts on humanness and animal welfare have not changed from those analyzed in the EA.

CUMMULATIVE IMPACTS OF THE PROPOSED ACTION

No significant cumulative environmental impacts have resulted from implementation of APHIS-WS' ORV program, including ONRAB field trials. It is possible that Alternative 1 (Maintain the Status Quo) and Alternative 3 (No ORV Field Trials, as analyzed in the EA (USDA 2012), might indirectly lead to increased human exposures and domestic and wild animal rabies cases across the U.S. As discussed in Chapter 4 of the EA (USDA 2012) and this supplement, 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 field trial.

Additionally, as discussed in Chapter 4 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, or increasing the baiting density, will not alter this potential.

FINDING OF NO SIGNIFICANT IMPACT

Based on the analysis provided in the EA, the 2013 supplement to the EA, the respective 2012 and 2013 Decision/FONSIs, the 2015 supplement to 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 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, 2013 supplement to the EA, and 2015 supplement to 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 5 states (New Hampshire, New York, Ohio, Vermont, and West Virginia) in the eastern U.S. Although the ONRAB field trial encompasses 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 SOPs and mitigation 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 a variety of 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 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 the more than 150 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 3,500 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 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 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 2015 supplement to the EA, the 2013 supplement to the EA, the 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. **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 those threatened or endangered species in the States within the proposed field trial area that were addressed in the Biological Opinion issued by the USFWS on APHIS-WS' programmatic activities (USDA 1997). For those species listed in the States 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.
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.

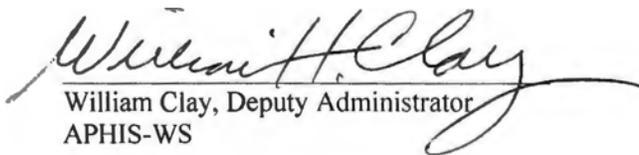
DECISION

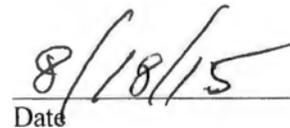
I have carefully reviewed the EA, the 2013 supplement to the EA, and the 2015 supplement to the EA prepared for this proposal and the input resulting from the public involvement process. I believe the issues and objectives identified are best addressed through implementation of Alternative 2 (Proposed 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 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 supplement to the EA and in compliance with all applicable mitigation measures listed as components of standard operating procedures in Chapter 3 of the 2012 EA.

APHIS-WS will notice the availability of the final supplement to the 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 supplement to the 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 field trial 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 supplement to the 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 supplement to the EA.

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


William Clay, Deputy Administrator
APHIS-WS


Date

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