DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT
FOR 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

PURPOSE OF THE EA

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Wildlife Services (APHIS-WS) program completed an environmental assessment (EA) and Decision/Finding of No Significant Impact (FONSI) (USDA 2011) on September 14, 2011 (76 FR 56731) that analyzed the potential environmental effects of a proposal to conduct an experimental oral rabies vaccine field trial in West Virginia using the human adenovirus type 5 rabies glycoprotein recombinant (AdRG1.3; trade name ONRAB®, Artemis Technologies, Inc., Guelph, ON) vaccine. Since that time, APHIS-WS has determined the need to expand ONRAB® safety and immunogenicity field studies to include the states of New Hampshire, New York, Ohio, Vermont, and West Virginia to allow APHIS-WS to further evaluate the immunogenicity of the vaccine in raccoons and striped skunks in the eastern U.S. APHIS-WS, in cooperation with the U.S. Forest Service, prepared an EA to analyze the effects of the proposed expanded ONRAB® field trial. The EA analyzed the proposed action, the no action (current action) alternative, and the no ORV field trial alternative with respect to a number of issues affecting the human environment. Under the proposed action, APHIS-WS would use federal funds to purchase ONRAB® baits and participate with the appropriate New Hampshire, New York, Ohio, Vermont, and West Virginia Departments of Agriculture, Health, and Natural Resources in field trials involving the distribution of ONRAB® baits under the authorities of the appropriate state agencies and to evaluate the immunogenic characteristics of the ONRAB® 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.
COORDINATION

APHIS-WS is the lead agency and decision-maker for this EA. However, to assure that the concerns of other federal land managers have been addressed, the USFS was asked to participate in the development and review of this EA. The USFS participated in the review of this EA as per 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.

NEED FOR ACTION

APHIS-WS currently conducts ORV programs in several Eastern states and Arizona, New Mexico, and Texas utilizing the vaccinia rabies-glycoprotein (V-RG) rabies vaccine (RABORAL V-RG®, Merial Inc., Athens, GA). However, a higher level of population immunity in raccoons than that achieved using V-RG is desired to maximize the effectiveness of ORV programs. Further, the V-RG vaccine has not produced sufficient levels of population immunity in skunks (primarily striped skunks) in the wild at the current dose (Slate et al. 2005).

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. 2009). One of the most promising vaccines has been the AdRG1.3/ORAB® vaccine. ONRAB® was developed in response to the need for a more immunogenic oral wildlife rabies vaccine. The field trials proposed in this EA are necessary to test the immunogenicity of ONRAB®, because if ONRAB® provides both safe and immunogenic results it could serve as a successful compliment to APHIS-WS’ current ORV program and further APHIS-WS’ goal of eventual elimination of targeted terrestrial variants of rabies.

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 and an initial ONRAB® field trial in West Virginia. 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).

For the previous EAs and supplemental EAs, additional efforts to determine further issues that the public might have with the proposed action were made through Federal Register Notices (66 FR 13696-13700, March, 7, 2001; 66 FR 27489, May 17, 2001; 67 FR 44797-44798, July 5, 2002; 68 FR 38669-38670, June 30, 2003; 69 FR 7904-7905, February 20, 2004; 69 FR 56992-56993, September 23, 2004; 70 FR 72997-72978, December 8, 2005; 72 FR 20984-20986, April 27, 2007; 74 FR 61319-61321, November 24, 2009; 76 FR 48119-48120, August 8, 2011) and making the EA available to the public for review and comment prior to an agency decision. A letter was sent to potentially affected or interested American Indian Tribes to assure their opportunity to be involved in the EA process. Comments received were reviewed to identify any substantive new issues or alternatives not already identified for analysis.
To document APHIS-WS’ continued and broadened involvement in an ONRAB® field trial and following interagency review and discussion, the draft EA was made available to the public for review and comment from July 9, 2012 to August 8, 2012. The document was made available through a Notice of Availability (NOA) for Docket No. APHIS-2012-0052 published in the Federal Register on July 9, 2012, the APHIS-WS website http://www.aphis.usda.gov/regulations/ws/ws_nepa_public_notice_US.shtml, and through direct mailings of the NOA to interested parties. At the close of the 30-day comment period, APHIS-WS received nine comment letters. A summary of the comments and APHIS-WS responses are attached as Appendix A.

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 EA. The FONSI and final 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. 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, large bodies of water will be avoided by aerial distribution.

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 the issues identified in that EA 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 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.

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 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

Three 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. Current Action (the No Action Alternative). 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 the other alternatives, and can be defined as the continuation of the current management practices (CEQ 1981).

This alternative would involve the use of federal funds to continue ONRAB® field trial in West Virginia under the authority of the appropriate state agencies and to evaluate the immunogenic characteristic of ONRAB® for wildlife rabies under limited field conditions. 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.

Alternative 2. Proposed Action (the Preferred Alternative). Under this alternative APHIS-WS would use federal funds to purchase ONRAB® oral vaccine baits and to participate in expanded ORV field trials involving the distribution of ONRAB® oral vaccine baits under the authorities of the appropriate New Hampshire, New York, Ohio, Vermont, and West Virginia state agencies and to evaluate the immunogenic characteristic of the ONRAB® vaccine for wildlife rabies under limited field conditions at the 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.
Alternative 3. No ORV Field Trials. This alternative would entail no involvement by APHIS-WS in ORV field trials in the states identified in Section 2.3. Under this alternative, no APHIS-WS funds would be available for purchase of ONRAB® baits and no immunogenicity trials would be conducted.

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 applications of immunocontraception strategies (i.e., vaccine 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 target species.

Employ other types of ORV instead of the ONRAB® 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 vaccines involved have the potential to cause rabies (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 raccoons and skunks to meet national rabies management goals. 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. Current Action (the No Action Alternative). Alternative 1 analyzes the environmental effects of continuing an ONRAB® field trial in West Virginia. One of the most promising new wildlife rabies vaccines is a human adenovirus type 5-rabies glycoprotein recombinant vaccine (AdRG1.3; trade name ONRAB®). The ONRAB® vaccine employs a human adenovirus type 5 vector into which has been inserted a DNA copy of a rabies virus glycoprotein. ONRAB® 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 adenovirus 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. 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. (1989) 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 ONRAB® vaccine. In the unlikely event that a human contacts the ONRAB® 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.

**Alternative 2. Proposed Action (the Preferred Alternative).** Expanding the geographic range [from WV (Alternative 1) to NH, NY, OH, VT, and WV (Alternative 2)] of the ONRAB® field trial is not expected to increase the risk for adverse effects to the human environment. Alternative 2 is expected to have similar negligible environmental effects as with Alternative 1.

In 2011, APHIS-WS distributed approximately 80,000 ONRAB® baits in West Virginia during the first field trial to determine the safety and immunogenicity of the ONRAB® vaccine in the U.S. Initial results from this trial are promising, with an observed seroconversion rate of 49% in raccoons sampled. WS, NWRC captive histopathologic studies of species common to the West Virginia field trial area evaluated for 10x dose of ONRAB® showed no effects in comparison to a control group for these species.

There were zero calls or reports of human exposures to either intact baits or liquid vaccine during the initial 2011 ONRAB® field trial. With Alternative 2, APHIS-WS will continue to implement Standard Operating Procedures (SOPs), as described in Section 3.3 of the EA, to minimize the potential for human exposure to the baits.

As with Alternative 1, no adverse effects would be expected with Alternative 2. ONRAB® field trial programs conducted in both the U.S. and Canada, as well as research conducted on the ONRAB® vaccine have demonstrated its safety and effectiveness in target species populations. Expanding the APHIS-WS ONRAB® field trial beyond WV into NH, NY, OH, and VT is not expected to result in any adverse effects to target species.

**Alternative 3. No ORV Field Trials.** Under this alternative, there would be no impact on target striped skunks or raccoon populations in New Hampshire, New York, Ohio, Vermont, or West Virginia from ORV field trials. However, in the absence of a safe and immunogenic rabies virus vaccine for both raccoons and skunks, it is likely that more individuals from these species will die from rabies with potentially greater short-term population impacts. Further, without a safe and immunogenic 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 ORV field trial alternative would also likely result in greater risk of human exposure to rabies than the proposed action. Without field trials to address the immunogenicity of new vaccines, current vaccines may not be successful in stopping or preventing the spread of raccoon, skunk, 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.

**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 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 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 125 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 1,128 people have reported contacting, or potentially contacting a vaccine laden V-RG bait. Of these exposures, there have been two reported cases of human adverse reactions to the vaccinia virus used in the V-RG vaccine. Of the approximately 80,000 ONRAB® baits distributed in West Virginia in 2011, there were zero reports of human exposures. 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 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. **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 environmental protection law.** 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 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.

APHIS-WS will notice the availability of the final EA and decision/FONSI documents through notices published in the *Federal Register*, direct mailings to organizations and persons who have expressed an interest, and 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 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 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 7, Concord, NH 03301-8548;
Phone (603) 223-9623.

William Clay, Deputy Administrator
APHIS-WS
8/13/12
Based on our request for public comments on the predecision Environmental Assessment (EA), APHIS-WS received nine letters from state, national, and international agencies, and individuals. The majority of comments were generated from 6 comment letters received from two individuals. The remaining letters were fully supportive of the proposed field trial or were supportive with suggested corrections to update technical information contained in the EA. All letters were reviewed for substantive new issues and alternatives warranting a revision of the predecision analysis. No new substantive issues were raised; most of the issues raised in the comments were addressed in the EA. This appendix provides further elaboration and clarification on the environmental consequences of the issues and alternatives analyzed in this EA.

Comment 1 – Extend time to comment.

The commenter suggests that the comment period should be extended because many people are on vacation this time of year and unavailable to provide comments.

A Notice of Availability was published in the Federal Register, (Docket No. APHIS-2012-0052) on July 9, 2012, that informed the public of the availability of the draft EA and allowed for a 30-day comment period. Additionally, a notice was placed on the USDA Wildlife Services website announcing the availability of the EA and the 30-day comment period and notices were mailed to interested organizations and individuals. APHIS-WS does not agree that the time of year and potential for vacation time warrants an extension of the comment period. The commenter provided no further justification why the comment period should be extended so this suggestion was not considered further.

Comment 2 – An Environmental Impact Statement is necessary, not an EA.

As per 40 CFR 1508.9, an EA serves three functions: 1) briefly provide sufficient evidence and analysis for determining whether to prepare an EIS; 2) aids an agency’s compliance with NEPA when no EIS is necessary; and 3) facilitates the preparation of an EIS when one is necessary.

Issues that were raised through scoping for previous ORV EAs and interdisciplinary meetings and were considered germane to this EA were considered. The EA and resulting Finding of No Significant Impact provide a thorough analysis which is adequate to determine that the effects of the program are not significant and therefore do not trigger the need to prepare an EIS.

Comment 3 – The EA is not available on regulations.gov as stated in the notice published in the Federal Register.

The link provided in the Federal Register notice directing the public to the EA on regulations.gov was found to be operational. Notification of this was sent to the commenter and a hard copy of the EA was mailed as requested.

Comment 4 - Rabies vaccines are delivered too frequently, not taking into account their effective period. Over application of rabies vaccines causes cancer in animals.

The commenter makes the claim that “RABIES VACCINES HAVE MUCH LONGER EXTENSION OF EFFECTIVENESS DATES THAN THIS AGENCY SEEMS TO REGULATE THEM FOR AND MANY SPECIES ARE GETTING CANCER FROM RABIES VACCINES. WE NEED MORE INFORMATION AVAILABLE ON HOW CANCER FOLLOWS VACCINE INJECTIONS” [sic].
While a great deal of research is available regarding the duration of immunity of rabies vaccines for domestic animals, much less is known about the duration of wildlife vaccines. However, there is no evidence to suggest that there are any adverse effects from repeated dosing of wild animals. In fact, studies by Knowles et al. (2009) using ONRAB® and Rupprecht et al. (1992) using V-RG® (as discussed in USDA 2010, 2011, and the current EA) concluded that there were no adverse effects to several target and nontarget species when given a 5-10x dose of the respective vaccine.

Annual distribution of Oral Rabies Vaccination (ORV) baits within APHIS-WS ORV zones is necessary to address the immigration of new adults from beyond the ORV zones, birth of unvaccinated juveniles within the ORV zones, and the translocation of rabies reservoir species to ensure that a sufficient level of population immunity is achieved.

Regarding the potential to cause cancer, adenoviruses are divided into three different subgroups based on their oncogenic potential. As discussed in the EA, subgroup C (types 2, 5, and 6) are non-oncogenic. The adenovirus used in the production of ONRAB® is type 5, considered a non-oncogenic viral species. Further discussed in the EA were histopathological studies conducted on a variety of target and nontarget species following application of ONRAB®. Captive studies conducted at APHIS-WS’ National Wildlife Research Center (NWRC) selected species to represent common fauna to southeastern WV and serve to compliment the spectrum of species that have already been evaluated for histopathologic effects relating to ONRAB® exposure in Canada (Knowles et al., 2009). Similar histopathologic results in vaccinates and control animals were observed for the four species in which the analysis was completed, suggesting no untoward effects from ONRAB® consumption at a 10x dose above exposure to a single bait. Based on current research and field trial results, there is no evidence to suggest that ONRAB® has the potential to cause cancer in wildlife species.

The commenter also expressed the concern that more information is needed regarding the prevalence of cancer after rabies vaccine injections. APHIS-WS believes the commenter may be referring to parenteral vaccination of domestic dogs and cats; therefore this comment is outside of the scope of this EA. The ONRAB® field trial analyzed in this EA uses an orally delivered vaccine rather than an injectable, therefore the comment is not relevant to this EA. However, other ORV programs make limited use of IMRAB® 3 (Merial, Inc.) (an injectable vaccine) during trap-vaccinate-release (TVR) contingency action responses which are analyzed in USDA 2010. Contingency actions, such as TVR, may be implemented when a targeted rabies strain advances beyond the barriers created by ORV zones. As discussed in USDA 2009, IMRAB® 3 is licensed for the vaccination of pets and other domestic animals (e.g., cats, dogs, horses, sheep, cattle, and ferrets) and may be used “off-label” for wildlife under the direction of a veterinarian. IMRAB® 3 uses the same virus strain that is used in the Pasteur Merieux Connaught human vaccine.

Comment 5 – APHIS-WS conducts wildlife damage management based on one request and kills millions of animals.

The commenter claims “APHIS HAS NO REGARD FOR ANIMAL LIFE. ITS IN THE BUSINESS OF KILLING ANIMALS BASED ON ONE TELEPHONE CALL FROM ONE WACKO. WHEN THEY PROCEED TO SNEAK INTO AN ARE AND KILL MILLIONS OF ANIMALS.” [sic]

Each of the states involved in APHIS-WS’ national ORV program, including NH, NY, OH, VT, and WV, the states involved in this proposed action, has a state agency or agencies with authority under state law to approve, conduct or coordinate rabies control programs. APHIS-WS involvement in rabies control in each state has previously occurred and, under the proposed action, would only occur in complete cooperation with the appropriate state agency (ies) and in accordance with state authorities as identified by those agencies.

With regard to ORV programs, it is the cooperating states that exercise their authorities under state law to propose or approve the distribution of ORV baits onto lands owned or managed by a variety of entities including private
persons, federal land management agencies [e.g., USDA Forest Service and others], state, county, and city governments, and American Indian Tribes. APHIS-WS would not be making the decision to distribute baits on the various land ownerships. Those decisions are made by the states. The proposed action assumes that ORV baits would be distributed under state authorities, consistent with pertinent property rights laws and regulations and would include acquiring permission from public land managers and American Indian tribes when appropriate.

Any other inferences derived from this comment are outside the scope of this EA.

**Comment 6 – The vaccine will have negative effects on nontarget species.**

One commenter suggested that the vaccine will have adverse effects on nontarget species and that APHIS-WS failed to review sufficient research in making this determination. The commenter states “THIS VACCINE HAS NEGATIVBE ADVERSE EFFECTS ON ANIMALS. DEATH WILL RESULT. NONTARGET ANIMALSCAN BE NEGATIVELY AFFECTED. I DON’T BELIEVE THE AGENCY LOOKED VERY HARD TO FIND NONTARGET ANIMALS NEGATIVELY AFFECTED SINCE YOU DIDN’T WANT TO FIND SUCH EVIDENCE, SO YOU JUST DIDN’T LOOK. THEN YOU SAY THERE IS NONE BECAUSE YOU FOUND NONE.” [sic]

Section 4.1.2 of the EA provides analysis of anticipated effects on the ONRAB field trial to nontarget animals. Effects to nontarget species are a primary concern to APHIS-WS. Knowles et al. (2009) reported on the result of safety studies on 17 species including red fox (Vulpes vulpes), domestic dog (Canis familiaris), domestic cat (Felis domesticus), striped skunk (Mephitis mephitis), raccoon (Procyon lotor), grey squirrel (Sciurus carolinensis), groundhog (Marmota monax), cotton rat (Sigmodon hispidus), meadow vole (Microtus pennsylvanicus), nude mouse (Mus musculus), deer mouse (Peromyscus leucopus), European rabbit (Oryctolagus cuniculus), cow (Bos taurus), sheep (Ovis aries), and pig (Sus domesticus). Kowles et al. concluded at the end of this study that a wide range of species and methodologies were employed to examine the gross pathological consequences of ONRAB® administration, to explore the long-term presence of virus in these species, and the possibility of environmental contamination as a result of vaccine excretion. All data indicated a very low recovery of ONRAB® from tissues, feces, and oral samples of animals that were given a relatively high dose of vaccine, thus making the horizontal transmission in wildlife species unlikely. Additionally, the Canadian Food Inspection Agency, Centre for Veterinary Biologics (2008, 2010) confirms that ONRAB® vaccine was found to be safe in several nontarget species and that no adverse reaction in the animals studied were found following oral inoculation of the vaccine, while in most cases antibodies against the rabies viral protein were detected on day 28 post-exposure. ONRAB® may retain some replication capability in both healthy and immunocompromised animals, but does not cause adverse reactions (toxicity) in these animals.

In 2011, the USDA-APHIS-NWRC, which is the research arm of the APHIS-WS program, conducted histopathologic studies of species common in the original West Virginia field trial area including: cottontail rabbit (Sylvilagus floridanus), opossum (Didelphis virginiana), fox squirrel (Sciurus niger), and Eastern wild turkey (Meleagris gallopavo silvestri). These species were evaluated for a 10x dose of ONRAB® and showed no effects in comparison to control groups for these species. The eastern wood rat (Neotoma floridana) is also in the process of being evaluated. A 10x dose was evaluated given that animals could consume more than one bait (USDA 2012).

**Comment 7 – The expense of this program is too great and not justified.**

The commenter suggests that aerial distribution of ORV baits is expensive, that taxpayers cannot afford the expense, and requests cost proposals. The commenter also makes the claim that “2 PEOPLE DYING IN A YEAR DOES NOT MANDATE SO MUCH SPENDING. THE PRIORITY FOR THIS SPENDING IS LOW” [sic]. The commenter also states that “CITING MASSACHUSETTS AS BEING REPRESENTATIVE FOR COST OF RABIES SHOTS IS PICKING THE HIGHEST COST STATE AROUND. WHAT IS THE COST OF RABIES
SHOTS IN ALABAMA OR MISSISSIPPI? NOT $2,376. EVERYONE KNOWS MASSACHUSETTS IS A VERY HIGH COST STATE.” [sic] The commenter further adds that “LIVESOCK RISK ARE THE RISKF OF FARMERS WHO SHOULD PAY TO PROTECT THEIR OWN LIVESTOCK. IT IS NOT GENERAL TAXPAYERS OBLIGATION TO PAY TO PROTECT AGribUSINESS LIVESTOCK. IN FACT, WE WANT A DIMINUTION OF RANCHING LIVESTOCK, WHICH IS DESTROYHING THE ENVIRONMENT.” [sic]

The public health costs associated with disease detection, prevention, and control are estimated to exceed $300 to $400 million annually. These costs include the vaccination of companion animals, maintenance of rabies laboratories, medical costs, rabies post-exposure prophylaxis (PEP), and animal control programs (CDC 2011). Accurate estimates of these expenditures are not available. Although the number of PEPs given in the U.S. each year is unknown, it is estimated to be about 40,000. When rabies becomes epizootic or enzootic (i.e. present in an area over time but with a low case frequency) in a region, the number of PEPs in that area increases. The cost per human life saved from rabies ranges from approximately $10,000 to $100 million, depending on the nature of the exposure and the probability of rabies in a region (CDC 2011).

Although the EA does provide a median cost estimate for PEP in MA from 1991-1995 of $2,376 (CDC 1999), it provides reference for cost estimates ranging from $1000 (CDC 2011) to $3,000 (Meltzer 1996). The EA provides further evidence of PEP costs in reference to a single incident involving a kitten from a pet store in Concord, NH in 1994. As a result of potential exposure to this kitten or to other potentially rabid animals in the store, at least 665 persons received post-exposure rabies vaccination at a total cost of more than $1.1 million (Noah et al. 1995).

WS provides assistance with managing damage associated with wildlife, including rabies management that occurs to a variety of resources that have been categorized as agricultural resources, natural resources, property, and threats to human safety. WS does not discriminate based on the economic status of any individual person, entity, or segment of society requesting assistance with managing damage to those resources. The effects of livestock on the environment are outside of the scope of this EA.

Comment 8 – Rabies is not a problem.

The commenter states that “THIS PLAN IS PLANNED IN CASE OF. THIS IS A SOLUTION WITHOUT A REAL PROBLEM. THIS IS UNNECESSARY SPENDING.” [sic]

APHIS-WS has interpreted this comment to suggest that the commenter does not believe that rabies presents an actual threat in the U.S. The CDC (CDC 2011) reports 6,154 rabid animals and 4 human cases in 2010. Additionally, since 2006, U.S. laboratories have tested an average of 115,445 animals for rabies each year. Human and animal rabies are nationally notifiable conditions in the U.S. (CDC 2012). In 2010 a total of 303 rabid cats and 69 rabid dogs were reported. Samples from 40 human patients in the U.S. were submitted to the CDC for rabies testing in 2010. Two cases of human rabies were reported. Since 2001, a total of 29 human rabies cases have been reported in the U.S. and 21 of these cases were with domestically acquired rabies (CDC 2011).

Comment 9 - Aerial distribution of ORV baits is highly polluting and scary to birds and animals.

Section 2.2.10 of the EA concludes that program activities likely to result from the proposed APHIS-WS ORV field trials would have a negligible effect on atmospheric conditions including global climate. Meaningful direct or indirect emissions of greenhouse gasses would not occur as a result of the proposed action. The proposed action meets the requirements of applicable Federal laws, regulations, and Executive orders including the Clean Air Act and Executive Order 13514. This is further supported by the fact that APHIS-WS conducts aerial distribution over any area only once or twice per year.

In regards to the potential for adverse impact from overflights on wildlife, this issue is discussed at length in section 2.2.3 of the EA and will not be addressed further.
Comment 10 – APHIS-WS refers to outdated and obsolete literature in the EA.


Although the EA does reference several citations that may be years or decades old, it is our belief that these data were sufficient and conclusive and were not superseded by new specific research in the literature. APHIS-WS makes every attempt to use the most recent and up to date research available when conducting analyses and during decision making processes.

Comment 11 – APHIS-WS cites old information on immunocontraception and is ignorant on GonaCon™.

APHIS-WS believes the analysis on immunocontraception in the EA adequately addresses the issue and concludes that because there is no contraceptive currently registered for use in raccoons, gray foxes, and coyotes the issue will not be considered further. The use of GonaCon™ is not addressed in the EA and is outside the scope of analysis.

Comment 13 – “Personal communications” should not be used as references in the EA.

The personal communications referred to in the EA are used to provide clarification or support on particular subject matters; however at no point does the analysis contained in the EA rely solely on the information contained in these communications.

Comment 14 - Lethal take should not be used as a part of the proposed program.

The commenter states that animals should not be killed because they pose a “potential” danger and that many animals will be killed as a result of testing. The commenter also states that “I NOTE YOU KILL ANIMALS IN CAGE TRAPS BECAUSE OF “LANDOWNER REQUEST.” [sic]

The EA explains that although the majority of animals captured will be release unharmed at the site of capture, individual target species may be lethally removed and tested for rabies if they were demonstrating strange behavior symptomatic of the rabies virus or were injured. APHIS-WS states in the EA that it will remove less than 1% of the total populations of specific target species and, as such, lethal removal will not have an adverse effect on these target species populations. Further detailed information regarding the analysis of lethal take can be found in Section 4.1.1 of the EA.

The reference to lethal removal of animals at landowner request found in section 3.3 of the EA is an error and will be removed from the final EA. Previous ORV EAs do analyze the limited removal of wildlife causing damage during ORV activities; however this type of take is outside of the scope of this EA and will not be addressed further.

Comment 15 - Private take numbers used in the EA may be inaccurate.

The commenter states “HUNTERS ARE NOT HONEST ABOUT THE NUMBERS OF ANIMALS THEY KIL. THEY KILL FAR MORE THAN THEY TELL THE GOVT AGENCY THEY KILL. TO TAKE HARVETS FIGURES FROM HUNTERS IS TO GET INACCUARACY TOLD TO YOU. THEY KILL DOUBLE OR TRIPLE WHAT THEY TELL YOU.” [sic]

The EA uses harvest figures supplied by the appropriate state agencies that manage these species in the states involved in the proposed program. These agencies are in the best position to provide population estimates and to analyze hunter take numbers.
Comment 16 – The reference to the Act of September 25, 1981 is outdated.

The commenter states “TO JUSTIFY THIS EXPENSIVE RABIES BASED ON A 1981 PRONOUNCEMENT OF THE AG SECY WHO IS LONG GONE FROM GOVT AND 32 YEARS LATER, THIS IS NOT AN "EMERGENCY" ANYMORE. IS IT THIS GOVT AGENCY THAT THIS "EMERGENCY" HAS GONE ON FOR 32 YEARS? IF SO, THE GOVT DID NOT REACT PRMOPTLY DID THEY? USING OLD LAWS TO JUSTIFY THIS IS LUDICROUS. THIS LOOKS MORE LIKE A MONEY MAKING FAKE TO GET MORE MONEY TO APHIS.” [sic]

The commenter is referring to Section 1.4 of the EA which references the Act of September 25, 1981, as amended (7 USC 147b); however the commenter has misinterpreted the information provided. The Act of September 25, 1981, as amended provides that the Secretary of Agriculture may, in connection with emergencies which threaten any segment of the agricultural production industry of this country, transfer from other appropriations of funds available to the agencies or corporations of the Department of Agriculture such sums as the Secretary may deem necessary, to be available only in such emergencies for the arrest and eradication of plant pests or contagious or infectious diseases of animals or poultry, and for expenses in accordance with section 147a of this title and section 147b of title 21. As stated in the EA, in FY 2001, using this authority, the Secretary of Agriculture initially authorized the transfer and use of funds from the Commodity Credit Corporation of the USDA for the continuation of ORV programs to address rabies problems in several eastern states and Texas. Additional CCC funds continue to be provided to augment the funding obtained through the appropriations process and support the continuation and expansion of ORV programs to ensure that raccoon and gray fox rabies spread in contained.

Comment 17 – APHIS-WS uses deceptive language.

The commenter makes the statement “APHIS ALSO USES DECEPTIVE WORDS TO MASK KILLING. IN ONE INSTANCE THEY CALL IT "MANAGEMENT" INSTEAD OF KILLING. IN ANOTHER INSTANCE THEY CALL KILLING "SAMPLING". THE ANIMALS ARE DEAD IN THE END. AND APHIS IS A SNEAK IN THEIR LANGUAGE USE.” [sic]

APHIS-WS is transparent in its use and analysis of lethal take to support the ORV field trial as discussed in section 4.1.1 of the EA. The terms “management” and “sampling” are not veiled references to killing. These terms are used in their traditional sense. When “sampling” of target species referenced in the EA includes lethal removal APHIS-WS makes this clear in the analysis.

Comment 18 - Where is the vaccine produced and what is the method of production?

The commenter asks “DOES THIS VACCINE COME FROM CHINA, HOME OF ALL POISON? PLEASE RESPOND TO WHERE YOUR SOURCEOF VACCINE IS AND METHOD OF PRODUCTION.”[sic]

As stated in section 1.1.3 of the EA, the ONRAB® vaccine is manufactured by Artemis Technologies Inc., Guelph, Ontario, Canada. ONRAB (or AdRG1.3) was modified from the first construct (AdRG1) in the early to mid-1990s at McMaster University, Hamilton, Ontario, Canada (Yarosh et al. 1996 in Rosatte et al. 2009). During 1993, Microbix Biosystems Inc. (Toronto, Ontario, Canada), was commissioned by the Ontario Ministry of Natural Resources (OMNR) to prepare a master seed of the virus that OMNR acquired from Microbix in 1999. Subsequent laboratory trials were conducted at the Canadian Food Inspection Agency (CFIA), Nepean, Ontario, Canada, and production of the vaccine was developed by Artemis Technologies Inc., with assistance from the national Research Council, Biotechnology Research Institute.
Comment 19 – Why isn’t APHIS-WS using the vaccines it already has?

The commenter suggests that effective vaccines already exist and questions why APHIS-WS isn’t using these vaccines. As stated in the EA, vaccinia rabies glycoprotein (RABORAL V-RG®, Merial, Inc., Athens, GA) is the only vaccine licensed for use in the U.S. for raccoons and coyotes, and approved experimentally for grey foxes. APHIS-WS’ ORV program continues to distribute V-RG® annually, however higher levels of population immunity are desired in raccoons than have been realized with V-RG to maximize the effectiveness of the program. Further, V-RG has not produced sufficient measurable antibody levels in striped skunks. In the U.S., the total geographic area affected by skunk rabies is at least 1.4 million mi² (3.5 million km²) or nearly 40% of the entire contiguous lower 48 states (Krebs et al. 2000) which highlights the need for a vaccine that is efficacious in skunks as well as raccoons.

Comment 20 – The vaccines used by APHIS-WS cause rabies.

With regard to why APHIS-WS isn’t using the vaccine available the commenter asks “IS IT BECAUSE YOU CAUSED RABIES WITH IT? YOUR VACCINES SPREAD RABIES. i want to note for the record tha tyour rabies vaccines have in fact cruelly CAUSED RABIES IN ANIMALS, MAKING THEM DEAD BECAUSE OF YOUR FAULTY JUNK SCIENCE. THAT IS COMPLETELY UNACCEPTABLE. YOU HAVE SPREAD RABIES. NOBODY KNOWS THE EXTENT OF THE RABIES PROBLEMS YOU HAVE CAUSED BECAUSE YOU SWEEP THAT UNDER THE RUG AND DONT ADMIT TO IT. ” [sic]

The commenter suggests that the current vaccine used by the APHIS-WS ORV program, V-RG®, may cause rabies. This is incorrect. Although V-RG® is not analyzed in this EA and is, therefore, outside the scope of analysis, we will address this issue for both V-RG® and ONRAB®. As addressed in both this EA and in USDA 2010 neither of these vaccines has the potential to cause rabies. Both vaccines are recombinant vaccines. As a recombinant vaccine, the letter “V” in V-RG® is used to denote vaccinia, the self-replicating pox virus that serves as the vector (i.e., carrier) for the rabies virus gene that is responsible for the production of the rabies glycoprotein. The letters “RG” stand for rabies glycoprotein which is the protective sheath around the rabies virus core. The glycoprotein itself is non-infective and cannot cause rabies, but serves as an antigen which means it elicits an immune response to rabies when the vaccine is swallowed. ONRAB® functions in the same manner, but rather than using a vaccinia virus as the vector, the human adenovirus type 5 (Ad5) is used as the vector.

Comment 21 – Rabies has not spread further west and should be left alone.

The commenter suggests the “RABIES COULD HAVE SPREAD TO THE WEST ALREADY. IT HAD 200 YEARS TO DO SO. IT HAS NOT. LEAVE IT ALONE SO IT DOESNT. YOU SHOUDL JUST LEAVE NATURE ALONG. IT DOES BETTER WITHOUT YOUR MEDDLING. ” [sic]

As stated in section 1.3 of the EA, raccoon rabies did not exist outside a focus area in Florida before the 1940s and is, therefore, considered an exotic rabies virus variant in the U.S. outside this area (C. Rupprecht, pers. comm. 2003 as cited in USDA 2004). After raccoon rabies was described in Florida, it spread slowly during the next three decades into Georgia, Alabama, and South Carolina. It was unintentionally introduced into the mid-Atlantic states, probably by translocation of infected animals (Krebs et al. 1999). The first cases appeared in West Virginia and Virginia in 1977 and 1978. Since then, raccoon rabies in the area expanded to form the most intensive rabies outbreak in the U.S. Raccoon rabies is now enzootic in all eastern coastal states as well as in Alabama, Ohio, Pennsylvania, Tennessee, Vermont, and West Virginia (Blanton et al. 2008). In the past 21 years, all of the mid-Atlantic and New England states have experienced at least one outbreak. The raccoon rabies epizootic front reached Maine in 1994, reflecting a movement rate of about 30 miles per year (48.3 km/yr). It was also first confirmed in northeastern Ohio in 1996 (Krebs et al. 1998). In 1999, the first three cases of raccoon rabies were confirmed in
southern Ontario (Rosatte et al. 2001). Subsequently, raccoon rabies was also confirmed in New Brunswick and Quebec in 2000 and 2006 respectively.

The westward movement of the raccoon rabies front has slowed, probably in response to both natural geographic and man-made barriers. The Appalachian Mountains and, perhaps, river systems flowing eastward have helped confine the raccoon variant to the eastern U.S. However, a raccoon rabies positive case was confirmed outside of the previously established ORV zone in Ohio in 2004 (Krebs et al. 2005) prompting a closer look at the potential for westward spread of the virus. With no effective physical barrier across the middle of Ohio, rabies would be expected to move more rapidly through this zone than in any previously recorded epizootic (Russell et al. 2005). Live trapping results in Ohio (A. Montoney, APHIS-WS, pers. comm. cited in Kemere et al. 2001) as well as the status of raccoons in the Midwest (Sanderson and Hubert 1982, Glueck et al. 1998, Hasbrouck et al. 1992, Mosillo et al. 1999) suggest that raccoon populations are sufficient for rabies to spread westward along a front at a rate similar to or greater (Rupprecht and Smith 1994) than the rate at which this rabies variant has spread in the eastern U.S. Figure 1-2 in the EA shows the hypothetical spread of this rabies variant across the central portion of the U.S. if it is not stopped. Development of new, more highly efficacious vaccines is critical to maintaining ORV barriers, eliminating the further spread, and eventual containment and elimination of this variant of the rabies virus.

Comment 22 – Animals that consume the bait may not become vaccinated, making the vaccine meaningless.

The commenter states “SINCE THE PACKET YOU HAVE DESIGNED DOES NOT ALWAYS OPEN INSIDE THE ANIMAL, INGESTION OF THE PACKET MAY BE COMPLETELY MEANINGLESS.” [sic]

As discussed in the EA, a number of studies have been conducted to determine the best bait formulations and strategies for delivery of ORV vaccines to raccoons (Hanlon et al. 1989, Hable et al. 1992, Hadidian et al. 1989, Linhart et al. 1991, Linhart et al. 1994), gray fox (Steelman et al. 1998, 2000), and coyotes (Linhart et al. 1997; Farry et al. 1998a, 1998b). When raccoons, foxes or coyotes eat oral rabies baits and puncture a sachet containing the vaccine, the vaccine is swallowed and bathes the lymphatic tissue in the throat area and initiates the immunization process. A positive rabies antibody titer in an animal from a baited area is most likely due to consumption of a bait and adequate contact with vaccine. However, the lack of a detectable antibody response may not be an accurate reflection of immune status. It is possible that the animal was successfully immunized, but that the blood sample was taken earlier or later than when antibodies could be detected (C. Hanlon, CDC, pers. comm. 2003 as cited in USDA 2004). Antibodies induced by a one-time oral vaccination appear to be of relatively short duration. Among a group of animals in a baited area, the best time to collect blood samples for detection of antibodies is 4-8 weeks after baiting. A successfully immunized animal may have antibodies shortly after vaccination, but then the level may decline to undetectable levels.

Results of the initial 2011 ONRAB® field trial are promising. Raccoons sampled during post-ORV monitoring and surveillance activities displayed a 49% seroconversion rate (i.e., these raccoons received a sufficient dose of ONRAB® and are considered to be vaccinated against the rabies virus).

As discussed, the vaccine blister pack is coated with an attractant and is designed to be chewed on and to open upon tooth puncture; not to be swallowed whole as the commenter suggests. APHIS-WS does allow that if an animal were to swallow a bait without puncturing the blister pack it may be possible to pass through the animal without breaking down.

Comment 23 – Capture and handling creates undue stress, injury, and death.

This issue was fully analyzed in section 4.1.6 of the EA and will not be discussed further.

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1 A thin plastic packet much like those in which condiments (e.g., catsup, mustard) are provided at fast food restaurants.
Comment 24 – A few rabid skunks does not justify the cost of this program.

As discussed in the EA, studies indicate that V-RG® does not produce sufficient levels of population immunity in skunks in the wild at the current dose (Slate et al. 2005), and V-RG® may be less effective in skunks than other species (Tolsen et al. 1987). Skunks are a major contributor to rabies in North America. During 2010, skunks accounted for 27.4% of reported cases of rabies in wild animals. Of those, 44.4% were from states where the raccoon rabies virus variant is enzootic (Blanton et al. 2011). This trend has raised concerns about an independent maintenance cycle for raccoon rabies in skunks (Guerra et al. 2003). Rabies virus containment and elimination in the U.S. will likely remain elusive until an oral vaccine is licensed that is immunogenic in all terrestrial rabies reservoir species (Slate et al. 2005). In addition, the skunk rabies virus variant, which has the broadest geographic distribution of all terrestrial rabies variants in the U.S. (Krebs et al. 1995), can currently be addressed only through local trap-vaccinate-release (TVR) or population suppression programs. Therefore, it is critical to find a vaccine that is safe and immunogenic in skunks. Research has found that after oral instillation of the ONRAB® vaccine, skunks will develop rabies neutralizing antibodies, but with no observable adverse effects.

Comment 25 – The scientific name for the Indiana bat is misspelled on pages 49, 53, C-1, C-2, C-3, and C-4. Several species have been recently identified as threatened or endangered for Ohio since March.

Thank you for your comments. Corrections based on the above comments have been made to the final EA. *Myotis sodalis* has been corrected to *Myotis sodalis* where it appears in the text. The following T&E species, which were added to the federal list after March 2012, have been added to the Ohio T&E list in Appendix C of the EA: snuffbox mussel (*Epioblasma triqueta*), rayed bean (*Villosa fabalis*), and sheepnose (*Plethobasus cyphyus*).

Comment 26 – The proposed project lies within the range of the bald eagle in Ohio. Baiting is expected to occur outside of the mid-January through July breeding season. This will prevent disturbances of the eagles from the egg-laying period until the young fledge.

Thank you for your comment. APHIS-WS will consult with the USFWS Ohio Ecological Services office should baiting be expected to occur during the bald eagle breeding season in the future.

Comment 27 – The proposed program involves an apparent indiscriminate distribution of rabies vaccine.

APHIS-WS does not distribute ORV baits indiscriminately. ORV bait distribution zones, including those for the proposed program, are determined by several factors including the locations of the leading edges of the raccoon rabies variant along with existing natural geographic and man-made barriers. Zones for the proposed action were also based upon their relationship to areas previously baited with V-RG baits. ORV zones are positioned strategically to prevent the westward and further northern movement of raccoon rabies while taking into account the natural and man-made barriers mentioned above and focusing on habitat typically occupied by the ORV target species.

Regarding bait distribution densities, Rupprecht et al. (1995) noted that understanding the relationship between animal population density and the minimum density of ORV baits to confer herd immunity is a critical component of an effective immunization program. Several studies (Bachman et al. 1990, Blackwell et al. 2004, Hable et al. 1992, Hadidian et al. 1989, Jojola et al. 2007, Olson and Wermer 1999, Ramey et al. 2008, Sattler et al. 2009, and Tineline et al. 1999) have been conducted to evaluate the necessary bait densities needed to achieve acceptable levels of seroprevalence of rabies neutralizing antibodies (RVNAs) in target species based on factors such as habitat, target species densities, and target species habits. Increases in bait density, particularly in specific suburban habitats, may be made to reach high density raccoon populations. Based on the results of these studies, APHIS-WS distributes baits at densities of 75 baits/km² or 150 baits/km² in the eastern U.S. targeting raccoons and striped skunks.
Comment 28 – A commenter requested to be informed when, where, and how the baits will be distributed. Also, how will the public be notified?

As discussed in the EA and USDA 2010, ORV baits are distributed once or twice per year within the predetermined ORV bait distribution zones. Specifically, it is anticipated the 2012 field trial will occur from mid-August through mid-September 2012. The proposed action will occur over portions of New Hampshire, New York, Ohio, Vermont, and West Virginia as detailed in the EA. Further, as described in the EA, baits will be distributed by fixed-wing aircraft or by helicopter and ground/hand placement in urban and suburban areas for increased bait placement specificity.

As addressed in comment 1 above, a Notice of Availability for the predecision EA evaluating the environmental effects of the proposed action was published in the Federal Register, on the APHIS-WS website, and through direct mailings. A Notice of Availability for the final EA and decision/FONSI will be posted in the same manner. More specifically, as stated in Section 3.3 of the EA, public information, education, and media announcements will be made available to inform the public about ORV bait distribution activities in each county before they occur. APHIS-WS coordinates with the appropriate state agency involved in the ORV program on preparing leaflets, posters, press releases, or other media to distribute to the public. Leaflets and posters would be posted in schools, hospitals, campgrounds, visitor centers, and state and county public agency offices. Notification of ORV bait drops will be sent to the state police, state emergency management association, county hazardous materials coordinators, county cooperative extension agents, state and federal correctional facilities, wildlife rehabilitators, and medical and veterinary facilities within the ORV area informing them of the program and providing information about the ORV bait and vaccine and potential exposure issues.

Comment 29 – How will the health and safety of wildlife, farm animals, domestic pets, and humans be protected from exposure to the vaccine?

These issues have been fully analyzed in sections 3.3, 4.1.1, 4.1.2, and 4.1.3 of the EA and will not be addressed further.
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