

**DECISION
AND
FINDING OF NO SIGNIFICANT IMPACT
FOR THE 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

In 2012 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 2012) (77 FR 49409-49410) 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 EA documents 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, a Decision/FONSI for the EA was issued on August 13, 2012. The Decision/FONSI selected the proposed action alternative which implemented ORV field trials in portions of New Hampshire, New York, Ohio, Vermont, and West Virginia.

Purpose of the Supplement to the EA

The supplement to the EA analyzes the potential environmental impacts of APHIS-WS' ORV program as it relates to expanding the geographic range of the field trial zone in New York. The EA analyzed APHIS-WS' ORV field trial activities for Clinton and Essex counties in New York. The supplement expands the field trial zone in New York to also include Erie, Franklin, Jefferson, Lewis, Niagara, St. Lawrence, and Wyoming Counties. In addition, it 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 August 13, 2012 Decision/FONSI; 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 activities remain within the impact parameter analyzed in the EA.

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). To further assess the immunogenicity and safety of the vaccine, APHIS-WS' National Rabies Management Program (NRMP) proposes to expand the geographic area of the ONRAB field trial into Erie, Franklin,

Jefferson, Lewis, Niagara, St. Lawrence, and Wyoming counties in New York, as analyzed in this proposed supplement to the EA (USDA 2012).

Currently, APHIS-WS conducts an ORV program using the only licensed oral rabies vaccine in the U.S. [vaccinia-rabies glycoprotein (V-RG)] in the above listed New York counties as part of a national ORV program. APHIS-WS' use of the V-RG vaccine has resulted in several notable accomplishments including the elimination of canine rabies from sources in Mexico which had spread to coyotes in south Texas, the successful control of gray fox rabies virus variant in western Texas, and the prevention of any appreciable spread of raccoon rabies in the eastern U.S. While these represent major accomplishments in rabies management, the inability to eliminate raccoon rabies from high risk spread corridors prompted the need to evaluate vaccine baits capable of producing higher levels of population immunity in raccoons.

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 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 the 2011 and 2012 ONRAB field trials. 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; 77 FR 40322-40323, July 9, 2012) and making the EAs and supplemental EAs available to the public for review and comment prior to an agency decision. Letters were 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 notify the public of 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 June 5, 2013 to July 5, 2013. The document was made available through a Notice of Availability (NOA) for Docket No. APHIS-2013-0046 published in the *Federal Register* on June 5, 2013, 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 2 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 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 supplement to the EA broadens the area affected in New York to include Erie, Franklin, Jefferson, Lewis, Niagara, St. Lawrence, and Wyoming 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, 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.

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 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 (40 CFR 1508.25) 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 aeriually 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 EA were evaluated in the supplement by each issue as those issues related to APHIS-WS' activities conducted since the Decision and FONSI was signed in 2012. Each of those issues was also evaluated as those issues relate to conducting the proposed action alternative as described in the 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 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 EA and has determined that the analysis provided in the EA has not changed and is still appropriate.

ALTERNATIVES

The scope of the supplement to the EA was limited to analysis of potential environmental impacts of a proposal to geographically expand the ONRAB field trial zone in New York. Alternative 1 would

involve no change to APHIS-WS' ONRAB field trial as implemented in 2012. 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 and Finding of No Significant Impact (FONSI) for the EA issued on August 13, 2012.

Alternative 2. Proposed Action (the Preferred Alternative). This alternative would involve the use of federal funds to expand the geographic range of the ONRAB field trials, described in the EA (USDA 2012), to include Erie, Franklin, Jefferson, Lewis, Niagara, St. Lawrence, and Wyoming counties in New York, as proposed in this supplement. Under this alternative, APHIS-WS would use federal funds to purchase ONRAB oral vaccine-baits and to participate in 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 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 New York counties proposed in this supplement.

ALTERNATIVES CONSIDERED, BUT NOT ANALYZED IN DETAIL

Three additional alternatives were considered, but not analyzed in detail in the EA (see section 3.2). 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 expansion of the ONRAB field trial into Erie, Franklin, Jefferson, Lewis, Niagara, St. Lawrence, and Wyoming 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 EA and, thus, do not require additional analyses in the supplement. 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 supplement as they relate to Alternative 2: the Preferred Alternative, as described in the supplement to the EA:

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%).

Also of concern would be the magnitude of take on a species' population from the use of lethal methods. Expanding the geographic area of ONRAB field trials into Erie, Franklin, Jefferson, Lewis, Niagara, St. Lawrence, and Wyoming counties in New York 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 T&E 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-Jewtougoff 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 10x 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 expansion in New York, 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.

APHIS-WS has determined that the proposed expansion of ONRAB field trials will not result in adverse effects to nontarget species, including T&E species, in the additional counties (Erie, Franklin, Jefferson, Lewis, Niagara, St. Lawrence, and Wyoming) in New York where the trials will be conducted. Further, the proposed program could have an indirect beneficial effect by reducing the chances that nontarget and T&E species are exposed to the rabies virus in the wild.

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.

Although there will be a slight increase in the numbers of humans who may be exposed to ONRAB vaccine-baits, it is unlikely that the effects will vary significantly from those analyzed in section 4.1.3 of the EA. The effects of Ad5 will remain unchanged with APHIS-WS' proposed field trial expansion into the New York counties of Erie, Franklin, Jefferson, Lewis, Niagara, St. Lawrence, and Wyoming. Hazards to public safety are not expected. 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 this 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 transmission and whether the ONRAB 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), under the proposed program, baits will be distributed at common densities of 75 baits/km² (194 baits/mi²) or 150 baits/km² (388 baits/mi²). These densities 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 130 million baits distributed in the U.S. by APHIS-WS during other ORV programs between 1995 and 2012, only 11 incidents have been reported in which a person claimed to have been struck by a falling bait (0.00001% chance of being struck by a bait or 1 strike per 9.1 million baits dropped) (USDA 2011). None of the reports since APHIS-WS' ORV program inception have resulted in injury or harm to the individuals involved.

Although APHIS-WS is proposing to distribute ONRAB over a wider geographic area in the New York State portion of the 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.

FINDING OF NO SIGNIFICANT IMPACT

Based on the analysis provided in the EA, the 2012 Decision/FONSI, the 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 and the 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 130 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 2,050 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. 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 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

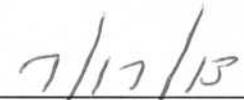
I have carefully reviewed the EA and Supplement prepared for this proposal and the input resulting from the public involvement process. I believe the issues and objectives identified are best addressed through implementation of Alternative 2 (Proposed Action). Alternative 2 is therefore selected because (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 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 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.


for _____
William Clay, Deputy Administrator
APHIS-WS


Date _____

LITERATURE CITED

Artemis Technologies, Inc., 2010. Information for the environmental assessment of rabies vaccine, live adenovirus vector, (AdRG1.3) for the immunization against rabies of striped skunks in Ontario. 51 Watson Road South, Guelph, Ontario, N1L 1E3.

Brown, L.J., R.C. Rosatte, C. Fehlner-Gardiner, J.S. Taylor, J.C. Davies, and D. Donovan. 2012. Immune response and protection in raccoons (*Procyon lotor*) following consumption of baits containing ONRAB, a human adenovirus rabies glycoprotein recombinant vaccine. *J. Wildl. Manage.* 48(4): 1010-1020.

CDC (Centers for Disease Control and Prevention), Lovelace Respiratory Research Institute, Mayo Clinic, and Wildlife Disease Association). 2011. Proposed U.S. field trial of a recombinant human adenovirus – rabies vaccine (ONRAB): recommendations of a national working group to the U.S. Department of Agriculture, August 2011. CDC, 1600 Clifton Road, Atlanta, Georgia, 30333. 14pp.

- CFIA (Canadian Food Inspection Agency), Canadian Centre for Veterinary Biologics (CCVB). 2010. Environmental Assessment – Rabies vaccine, live adenovirus vector (AdRG1.3 baits) For field use in vaccination campaigns by the Ontario Ministry of Natural Resources. CCVB File No. 900VV/R5.0/A22., 59 Camelot Drive, Ottawa, Ontario, K1A 0Y9.
- CFIA (Canadian Food Inspection Agency), Canadian Centre for Veterinary Biologics (CCVB). 2008. Environmental Assessment – Rabies vaccine, live adenovirus vector (AdRG1.3 baits) For field use in field trials by le Ministère des ressources naturelles et de la faune du Québec. CCVB File No. 900VV/R5.0/A22, 2 Contellation Crescent, Ottawa, Ontario, K1A 0Y9.
- Charleton, K.M., M. Artois, L. Prevec, J.B. Campbell, G.A. Casey, A.I. Wandeler, and J. Armstrong. 1992. Oral rabies vaccination of skunks and foxes with a recombinant human adenovirus vaccine. *Arch. Virol.*; 123:169-179.
- Fehlner-Gardiner, C., R. Rudd, D. Donovan, D. Slate, L. Kempf, and J. Badcock. 2012. Comparison of ONRAB and Raboral V-RG® oral rabies vaccine field performance in raccoons and striped skunks in New Brunswick, Canada, and Maine, U.S.A. *Journal of Wildlife Diseases* 48: 157-167.
- Fry, T.L., K.K. VanDalen, C. Duncan, K. Vercauteren. 2013. The safety of ONRAB in select non-target wildlife. Manuscript submitted for publication.
- Knowles, M.K., S.A. Nadin-Davis, M. Sheen, R. Rosatte, R. Mueller, and A. Beresford. 2009. Safety studies on an adenovirus recombinant vaccine for rabies (AdRG1.3 ONRAB) in target and non-target species. *Vaccine*; 27: 6619-6626.
- Lutze-Wallace, C., T. Sapp, M. Sidhu, A. Wandler. 1995a. In vitro assessments of the genetic stability of a live recombinant human adenovirus vaccine against rabies. *Can. J. Vet. Res.* 59:157-160.
- Lutze-Wallace, C., A. Wandler, L. Prevec, M. Sidhu, T. Sapp, and J. Armstrong. 1995b. Characterization of a human adenovirus 5: rabies glycoprotein recombinant vaccine reisolated from orally vaccinated skunks. *Biologics.* 23:271-277.
- Mainguy, J., C. Fehlner-Gardiner, D. Slate, and R. Rudd. 2013. Oral rabies vaccination in raccoons: comparison of ONRAB and RABORAL V-RG® vaccine-bait performance in Quebec, Canada and Vermont, USA. *J. Wildl. Dis.* 49(1): 190-193.
- Prevec, L., J.B. Campbell, B.S. Chrisite, L. Belbeck, and F.L. Graham. 1990. A recombinant human adenovirus vaccine against rabies. *J. Infect. Dis.*; 161:27-30.
- Ranriarison-Jewtoukoff, V. and M. Perricaudet. 1995. Recombinant adenoviruses as vaccine. *Biologicals*; 23:145-157.
- USDA (U.S. Department of Agriculture), Animal and Plant health Inspection Service (APHIS), Wildlife Services. 2012. Environmental Assessment (EA) and decision/finding of no significant impact (FONSI) – Field trial of an experimental rabies vaccine, human adenovirus type 5 vector in New Hampshire, New York, Ohio, Vermont, and West Virginia. USDA, APHIS, Wildlife Services. 4700 River Road, Unit 87, Riverdale, MD 20737-1234.

USDA (U.S. Department of Agriculture), Animal and Plant Health Inspection Service (APHIS), Wildlife Services. 2011. Monitoring Report-Calendar Year 2008-for Environmental Assessment – Oral vaccination to control specific rabies virus variants in raccoons, gray foxes, and coyotes in the United States. USDA, APHIS, Wildlife Services, 140-C Locust Grove Rd, Pittstown, NJ, 08867. 26p.

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

APPENDIX A

Based on our request for public comments on the predecision supplement to the Environmental Assessment (EA), WS received 2 letters from one individual. The letters were reviewed for substantive new issues and alternatives warranting a revision of the predecision analysis. The letters did not raise any issues warranting a revision of the predecision analysis; most of the issues raised in the comments were addressed in the EA and the supplement to the EA. Comments received during the public involvement process are summarized below along with WS' response to those comments.

Comment 1 – Rabies vaccines cause cancer.

The commenter asks “*WE ALL NOW THAT DOGS AND CATS WITH VACCINATIONS ARE GETTING CANCER WITHIN A FEW YEARS. SO HAVE YOU DONE LONG TERM TO SEE IF YOU ARE KILLING RACCOONS WITH THIS RABIES VACCINE AND ARE THEY GETTING CANCER AND DYING?*”? [sic]

Regarding the potential to cause cancer, adenoviruses are divided into three different subgroups based on their oncogenic potential. As discussed in the EA (USDA 2012), 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 (USDA 2012) were histopathological studies conducted on a variety of target and nontarget species following application of ONRAB. As discussed in the supplement to the EA, 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 10x 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.*). Post-mortem examination did not reveal gross or histopathological changes that could be linked to the vaccine (Fry et al. 2013). This study serves to compliment the spectrum of species that have already been evaluated for histopathologic effects relating to ONRAB exposure in Canada (Knowles et al. 2009). 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 concern regarding the parenteral vaccination of domestic dogs and cats, however this comment is outside of the scope of the supplement to the EA. The ONRAB field trial analyzed in this supplement to the EA uses an orally delivered vaccine rather than an injectable, therefore the comment is not relevant to this EA. However, WS does 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 variant advances beyond the barriers created by ORV zones. As discussed in USDA 2010, 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 2 – The number of rabies cases does not justify the cost of the program.

The commenter states “*I see ohio had only 3 cases of rabies so why are American taxpayers asked to come up with millions upon millions of dolalrs for this program...*” [sic] The commenter also asks “*where*

is the report for the public on how many rabies cases are being found in the states you are ‘experimenting in’”. [sic]

The commenter refers to the number of reported rabies cases in Ohio, but does not specify a time period for reporting. As reported by the Ohio Department of Health (ODH), there were a total of 41 rabies cases (39 bats, 2 raccoons) confirmed in 2012 (ODH 2013). WS’ current Oral Rabies Vaccination (ORV) zone includes the eastern Ohio/ western Pennsylvania boundary, thus preventing the westward spread of rabies further into Ohio and beyond. We would expect, and are pleased, that Ohio reports a low number of confirmed wildlife rabies cases. APHIS-WS believes this is indicative of the success of the ORV program in the targeted vaccination zone.

The Centers for Disease Control and Prevention (CDC) collects information about cases of animal and human rabies from state health departments and publishes the information annually in a summary report. This report, which can be found here: <http://avmajournals.avma.org/doi/pdf/10.2460/javma.241.6.712>, indicates that wildlife have accounted for > than 90% of rabid animals reported in the U.S. since 1980 (Blanton et al. 2012). Additionally, wild animals accounted for 6,031 (91.8%) of the rabid animals reported in 2011. Of these, 1,981 were raccoons and 1,627 were skunks.

The public health costs associated with disease detection, prevention, and control are estimated to exceed \$300 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). Detailed 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).

Comment 3 – Because nontargets could consume the vaccine, it may negatively impact other species.

The issue of potential for adverse effects on nontarget wildlife species has been adequately analyzed in Section 4.1.2 of the EA (USDA 2012) and the supplement to the EA, and will not be discussed further.

Comment 4 – Because the vaccine is intended for raccoons and skunks, it could negatively impact smaller animals that consume too much vaccine.

As discussed in Section 4.1.2 of the EA (USDA 2012) and the supplement to the EA, Knowles et al. (2009) included 17 species in ONRAB safety studies. Many of the species in this study, including grey squirrel (*Sciurus carolinensis*), cotton rat (*Sigmodon hispidus*), nude mouse (*Mus musculus*), meadow vole (*Microtus pennsylvanicus*), and deer mouse (*Peromyscus maniculatus*), are smaller than raccoons (*Procyon lotor*) and skunks (*Mephitis mephitis*). 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). Knowles et al. (2009) confirmed in studies involving meadow voles, deer mice, grey squirrels, rabbits (*Oryctolagus cuniculus*), and groundhogs (*Marmota monax*) that lung was the only tissue that tested positive four days post-vaccination

(in one groundhog and one squirrel), while the remaining tissues sampled tested negative for vaccine virus. The distribution and consumption of baits is expected to have no adverse effect on any species. The distribution and consumption by mammals is more likely to have a positive effect on mammals because a successful program will reduce the risk of mammals contracting and dying from rabies.

Additionally, the 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 10x dose of ONRAB was administered to Eastern wild turkeys, opossums, cottontail rabbits, fox squirrels, and woodrats. The limited viral recovery through both oral and fecal routes is of minimal concern regarding potential persistence of ONRAB in nontarget species (Fry et al. 2013). Post-mortem examination did not reveal histopathological changes that could be linked to the vaccine. These study results suggest a low likelihood or persistence of ONRAB in the environment or in individual animals that contact the vaccine even at ten times the desired dose (Fry et al. 2013). 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.

Comment 5 - There is no need for this program.

The commenter asks “*are taxpayers being soaked and gouged for a non existent problem so that workers in the field keep making big money and don’t lose their jobs through a program that is non essential*”? [sic]

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 (Blanton et al. 2012) reports 6,031 rabid wild animals and 6 human cases in 2011. Additionally, over the past five years, U.S. laboratories have tested an average of 112,837 animals for rabies each year (Blanton et al. 2012). Human and animal rabies are nationally notifiable conditions in the U.S. (CDC 2012). In 2011 a total of 303 rabid cats and 70 rabid dogs were reported. Samples from 41 human patients in the U.S. were submitted to the CDC for rabies testing in 2011. Six cases of human rabies were reported. Since 2002, a total of 33 human rabies cases have been reported in the U.S. (Blanton et al. 2012).

Comment 6 – The public should have access to information on laboratory tested animals.

“...*why cant the public find out specific information on what happened to the animals you tested on IN THE LABORATORY? WHERE IS THAT INFORMATION AND WHY CANT WE FIND OUT HOW MANY ANIMALS DIED FROM TESTING IN THE LABS? WE WANT INFO ON THE TESTING IN LABS*”. [sic]

The ONRAB vaccine is a new technology and safety testing in laboratory environments has been limited to the studies referred to in the EA and supplement to the EA which includes Knowles et al. 2009 and Fry et al. 2013. These studies included the humane euthanasia of 42 striped skunks, 21 wild turkeys, 17 opossums, 14 Eastern cottontails, 12 red foxes, 12 raccoons, 16 meadow voles, 16 deer mice, 10 grey squirrels, 10 rabbits, 10 groundhogs, 4 cows (*Bos taurus*), 4 horses (*Equus ferus*), 4 pigs (*Sus domesticus*), 4 sheep (*Ovis aries*), 10 chickens (*Gallus domesticus*), 4 cats (*Felis domesticus*), 16 cotton rats, 16 SCID mice, and 16 nude mice, 21 fox squirrels, and 15 wood rats. All of these animals were

humanely euthanized for tissue collection and post-mortem examination. Laboratory studies are a critical component of safety testing prior to field application

WS understands that some people will remain opposed to the death of any animal for any reason, however, the numbers of animals euthanized for safety studies is negligible compared to the numbers of animals that could die from rabies if it is not contained.

Comment 7 – How does tetracycline affect the health of animals that consume it?

Tetracycline is a physical marker which has been used extensively in wildlife research. When used for ORV applications, tetracycline leaves rings in the teeth of the animals that consume it. These rings, which are visible under ultraviolet light, allow information to be gathered related to the number and time between exposures, and serve as an index of the number of baits consumed during a single vaccination period (Fry and Dunbar 2007). The tetracycline deposits may last for the life of the animal when incorporated into the cementum and dentin of permanent teeth (Johnston et al., 1987)

Tetracycline has been used as a biomarker and incorporated into baits intended for free-ranging animals for a variety of purposes, including baits designed to carry antifertility agents to coyotes (*Canis latrans*) (Linhart and Kennelly, 1967), those designed to orally vaccinate feral pigs (*Sus scrofa*) against diseases like brucellosis and pseudorabies (Fletcher et al., 1990); and placebo baits designed to vaccinate mongooses (*Herpestes javanicus*) and coyotes against rabies (Creekmore et al., 1994; Farry et al., 1998). Tetracycline has been incorporated into rabies vaccine-laden baits since 1978 for red fox (*Vulpes vulpes*) vaccination field trials (Bachmann et al., 1990), since 1990 in the U.S. for raccoon rabies vaccination (Hanlon et al. 1993), and since 1995 during coyote rabies vaccination in Texas (Fearneyhough et al., 1998).

APHIS-WS is not aware of any reported negative effects from the use of tetracycline as a biomarker in wildlife. APHIS-WS recognizes that some people have expressed concern regarding tetracycline in the environment. However, the majority of baits distributed by APHIS-WS do not contain tetracycline. The ONRAB baits contain tetracycline to facilitate a science-based evaluation of this new vaccine.

Comment 8 – There are no studies in Rhodamine B, yet it is still being used.

Rhodamine B is not currently used as a biomarker in either of the vaccine-bait combinations (V-RG and ONRAB) currently used during WS' ORV distribution. The use of Rhodamine B is not addressed in the EA or the supplement to the EA, thus its consideration is outside the scope of analysis.

Literature Cited

Bachmann, P., R.N. Bramwell, S.J. Fraser, D. A. Gilmore, D. H. Johnston, K.F. Lawson, C.D. MacInnes, F.O. Matejka, H.E. Miles, M.A. Pedde, and D.R. Voigt. 1990. Wild Carnivore acceptance of baits for delivery of liquid rabies vaccine. *J. of Wildl. Dis.* 26: 486-501.

Blanton, J.D., J. Dyer, J. McBrayer, and C.E. Rupprecht. 2012. Rabies surveillance in the United States during 2011. *J Am Vet Med Assoc* 241:712-722.

- CDC (Centers for Disease Control and Prevention). 2012. Nationally Notifiable Diseases and Conditions and Current Case Definitions. Retrieved on 27 June 2013 from: http://www.cdc.gov/nndss/document/2012_Case%20Definitions.pdf.
- CDC (Center for Disease Control and Prevention). 2011. Cost of rabies prevention. Retrieved on 27 June 2013 from: <http://www.cdc.gov/rabies/location/usa/cost.html>.
- CFIA (Canadian Food Inspection Agency), Canadian Centre for Veterinary Biologics (CCVB). 2010. Environmental Assessment – Rabies vaccine, live adenovirus vector (AdRG1.3 baits) For field use in vaccination campaigns by the Ontario Ministry of Natural Resources. CCVB File No. 900VV/R5.0/A22., 59 Camelot Drive, Ottawa, Ontario, K1A 0Y9.
- CFIA (Canadian Food Inspection Agency), Canadian Centre for Veterinary Biologics (CCVB). 2008. Environmental Assessment – Rabies vaccine, live adenovirus vector (AdRG1.3 baits) For field use in field trials by le Ministère des ressources naturelles et de la faune du Québec. CCVB File No. 900VV/R5.0/A22, 2 Contellation Crescent, Ottawa, Ontario, K1A 0Y9.
- Creekmore, T.E., S.B. Linhart, J.L. Corn, M.D. Whitney, B.D. Snyder, and V.F. Nettles. 1994. Field evaluation of baits and baiting strategies for delivering oral vaccine to mongooses in Antigua, West Indies. *J. of Wildl. Dis.* 30:497-505.
- Farry, S.C., S.E. Henke, S.L. Beasom, and M.G. Fearneyhough. 1998. Efficacy of bait distribution strategies to deliver canine rabies vaccines to coyotes in souther Texas. *J. of Wildl. Dis.* 34: 23-32.
- Fearneyhough, M.G., P.J. Wilson, K.A. Clark, D.R. Smith, D.H. Johnston, B.N. Hicks, and G.M. Moore. 1998. Results of an oral rabies vaccination program for coyotes. *J. of Amr. Vet. Med.* 212:498-502.
- Fletcher, W.O. T.E. Creekmore, M.S. Smith, and V.F. Nettles. 1990. A field trial to determine the feasibility of delivering oral vaccines to wild swine. *J. of Wildl. Dis.* 26: 502-510.
- Fry, T.L., K.K. VanDalen, C. Duncan, K. Vercauteren. 2013. The safety of ONRAB in select non-target wildlife. Manuscript submitted for publication.
- Fry, T.L., and M.R. Dunbar. 2007. A review of biomarkers used for wildlife damage and disease management. *Proceedings of the Wildlife Damage management Conference.* 12: 217-222
- Hanlon, C.A., J.R. Buchanan, E. Nelson, H.S. Niu, D. Diehl, and C.E. Rupprecht. 1993. A vaccinia-vectored rabies vaccine field trial: Ante- and post-mortem biomarkers. *Revue Scientifique et Technique de l'Office International des Epizootics.* 12: 99-107.
- Johnston, D.H., D.G. Joachim, P. Bachmann, K. V. Kardong, R.E.A. Stewart, L.M. Dix, M.A. Strickland, and I.D. Watt. 1987. Aging furbearers using tooth structure and biomarkers. *In* wild furbearer management and conservation in North America, M. Novak, J.A. Baker, M.E. Obbard, and B. Malloch (eds.) Ontario Trappers Association, North Bay, Ontario, Canada, pp. 228-243
- Knowles, M.K., S.A. Nadin-Davis, M. Sheen, R. Rosatte, R. Mueller, and A. Beresford. 2009. Safety studies on an adenovirus recombinant vaccine for rabies (AdRG1.3 ONRAB) in target and non-target species. *Vaccine;* 27: 6619-6626.

Linhart, S.B., and J.J. Kennelly. 1967. Fluorescent bone labeling of coyotes with demethylchlortetracycline. *The Journal of Wildlife Management* 31: 317-321

ODH (Ohio Department of Health). 2013. Confirmed rabies Cases, 2012. Retrieved on 26 June 2013 from: <http://www.odh.ohio.gov/~media/ODH/ASSETS/Files/dis/rabies/rabtable12.ashx>

USDA (U.S. Department of Agriculture), Animal and Plant Health Inspection Service (APHIS), Wildlife Services. 2012. Environmental Assessment (EA) and decision/finding of no significant impact (FONSI) – Field trial of an experimental rabies vaccine, human adenovirus type 5 vector in New Hampshire, New York, Ohio, Vermont, and West Virginia. USDA, APHIS, Wildlife Services. 4700 River Road, Unit 87, Riverdale, MD 20737-1234.

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