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

United States Department of Agriculture
Animal and Plant Health Inspection Service
Wildlife Services

In cooperation with:
United States Department of Agriculture
Forest Service

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I. INTRODUCTION

In 2012, the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Wildlife Services (WS) program prepared an environmental assessment (EA) to evaluate the potential impacts to the quality of the human environment from the implementation of a field trial to determine the safety and immunogenicity of the human adenovirus type 5-rabies glycoprotein (AdRG1.3) (trade name ONRAB; Artemis Technologies Inc., Guelph, Ontario, Canada) rabies vaccine in New Hampshire, New York, Ohio, Vermont, and West Virginia (USDA 2012). The EA evaluates the need for Oral Rabies Vaccination (ORV) field trials and the relative effectiveness of three alternatives to meet that need, while accounting for the potential environmental effects of those activities.

Comments from the 2012 EA public involvement process were reviewed for substantive issues and alternatives and were considered during the development of the Decision for the EA. After consideration of the analysis contained in the EA and review of public comments, a Decision and Finding of No Significant Impact (FONSI) for the EA was issued on August 13, 2012. The Decision and FONSI selected the proposed action alternative to use federal funds to purchase ONRAB oral vaccine baits and to implement expanded ORV field trials involving the distribution of ONRAB oral vaccine baits in select areas of New Hampshire, New York, Ohio, Vermont, and West Virginia and to assist in monitoring and surveillance efforts by capturing and releasing or killing target species for purposes of obtaining biological samples.

II. PURPOSE

The purpose of the EA remains as addressed in section 1.2 of the EA (USDA 2012). The purpose of this supplement to the EA is to 1) examine potential environmental impacts of APHIS-WS' program as it relates to expanding the geographic range of the field trial zone in New York, 2) examine 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 Decision and Finding of No Significant Impact (FONSI) in 2012, 3) clearly communicate to the public the analysis of individual and cumulative impacts of the proposed action since 2012, and 4) document 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.

III. NEED FOR ACTION AND PROPOSED SUPPLEMENT

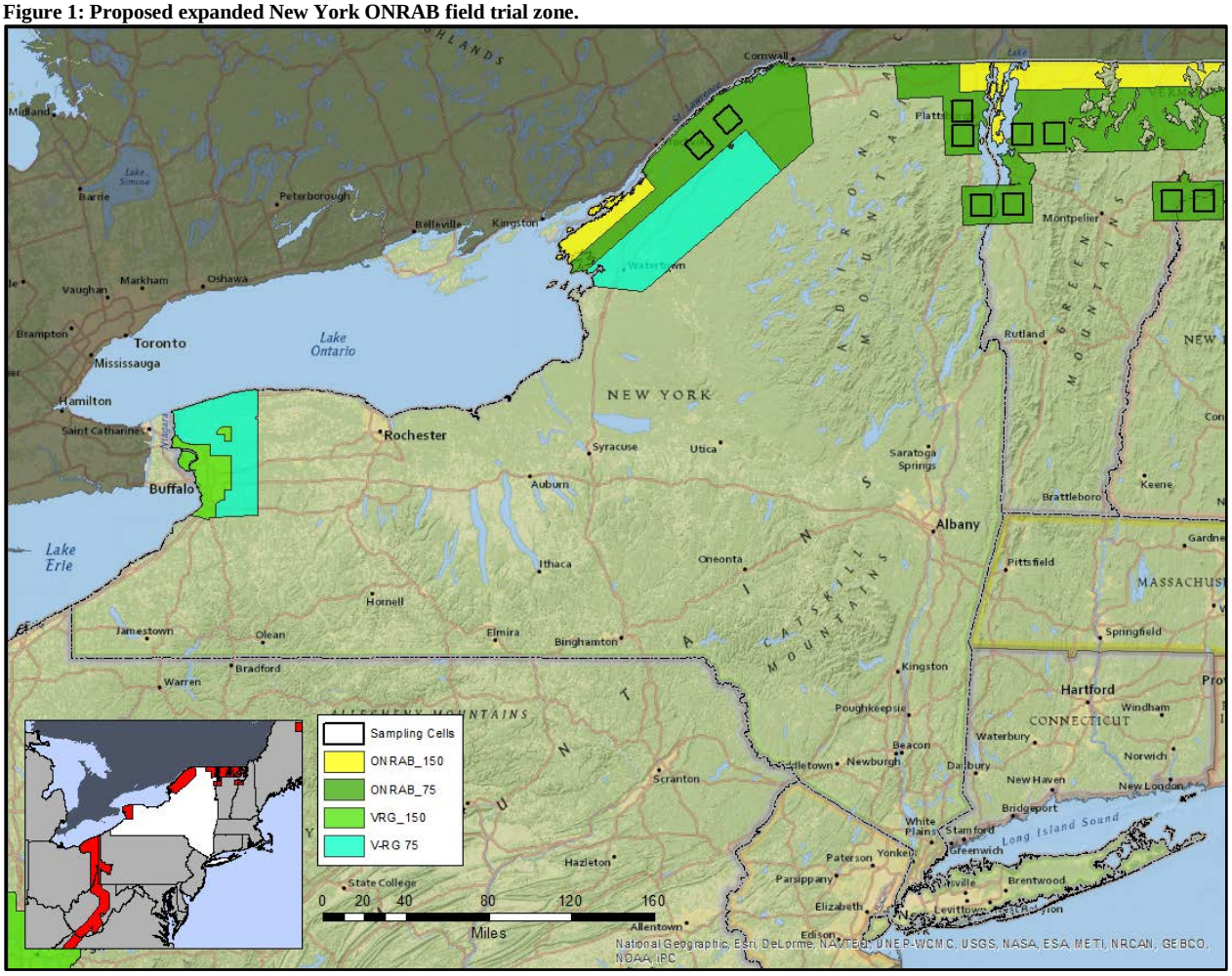
A description of the need for action to control rabies in wildlife populations and to prevent the westward movement of the raccoon rabies virus variant is provided in section 1.3 of the EA (USDA 2012). To further assess the immunogenicity and safety of the vaccine, APHIS-WS' National Rabies Management 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.

Given promising immunogenicity levels documented during field trials in federal fiscal year (FY)2011 and FY2012 as well as the need for further field testing, WS proposes to expand future ONRAB trials in New York beyond Clinton and Essex counties to also include Erie, Franklin, Jefferson, Lewis, Niagara, St. Lawrence, and Wyoming counties (see Figure 1). Expanding field trial activities into the proposed additional New York counties would allow APHIS-WS to make critical sero-prevalence comparisons between the currently used V-RG vaccine and ONRAB. As depicted in Figure 1, not all of the above mentioned counties are expected be included in APHIS-WS' 2013 field trial bait distribution activities as some of the proposed counties could continue to be included in the V-RG bait distribution program. However, future ONRAB field trial activities could and are expected to occur in all of the above listed New York counties.

Figure 1: Proposed expanded New York ONRAB field trial zone.



The national rabies management goals of virus variant containment and eventual elimination will likely

remain elusive until an oral vaccine and bait combination is licensed that is immunogenic in all terrestrial rabies reservoir species (Slate et al. 2005). The field trial proposed in the EA (USDA 2012) and this supplement will help further assess the safety and immunogenicity of ONRAB in meso-carnivore target species. Results from these and other studies are often required for licensure of a rabies vaccine for use in these species by the vaccine manufacturer.

Additionally, continuing the current ONRAB field trial would allow APHIS-WS to implement three key recommendations resulting from the initial 2011 ONRAB field trial (USDA 2012b). It would allow APHIS-WS to continue to maintain buffered ONRAB and V-RG zones so that critical comparisons can be made between ONRAB and V-RG responses in target species, focus field trial efforts in areas with an elevated risk of raccoon rabies spreading to naïve areas to genuinely test this vaccine bait in the face of enzootic rabies, and to bolster previous management efforts to prevent raccoon rabies from spreading beyond the northern U.S. border into Quebec.

IV. SCOPE OF THE ANALYSIS

The EA (USDA 2012) and this supplement evaluate ORV field trial activities in New Hampshire, New York, Ohio, Vermont, and West Virginia. The scope of the analysis remains valid as addressed in the EA (see section 1.5 of the EA). This supplement analyzes a proposal to expand the geographic boundary of the New York portion of ONRAB field trial to include Erie, Franklin, Jefferson, Lewis, Niagara, St. Lawrence, and Wyoming Counties. This supplement to the EA analyzes this expansion with regard to the proposed alternative to ensure that continued implementation of the selected alternative would not adversely affect the human environment and presents information and data that has become available since the completion of the 2012 EA.

Actions Analyzed

The EA and this supplement evaluate the need for APHIS-WS funding of and participation in ORV field trials in New Hampshire, New York, Ohio, Vermont, and West Virginia for determining the safety and immunogenicity of ONRAB as an oral rabies vaccine for meso-carnivores including raccoons and skunks in the U.S. Under the proposed action, ORV distribution and monitoring and surveillance activities are conducted on private, federal, state, county, and municipal lands in New Hampshire, New York, Ohio, Vermont, and West Virginia including USDA-Forest Service National Forest System (NFS) lands, but excluding Wilderness Areas. This supplement analyzes the potential environmental impacts of expanding the geographic range of the field trial in New York with regard to the proposed action.

Native American Lands and Tribes

APHIS-WS does not conduct ORV activities on tribal lands without the consent of the Tribes. ORV activities on tribal lands would occur only pursuant to prior written or oral authorization from the Tribe. Because Tribal officials would be responsible for determining what methods would be available during ORV field trial bait distribution and monitoring and surveillance activities, no conflict with traditional cultural properties or beliefs would be anticipated. The activities and methods addressed in this supplement would include those activities that could be employed on Native American lands, when requested and agreed upon by the Tribe and WS.

Period for which this EA is Valid

If the analysis in this supplement indicates that an environmental impact statement (EIS) is not warranted, the EA, as supplemented, would remain valid until APHIS-WS completes the proposed study. If APHIS-WS makes substantial modifications to the study that would be relevant to environmental concerns, or if new circumstances or information relevant to environmental concerns become apparent, a new EA will be completed or this EA will be further supplemented pursuant to NEPA and with the appropriate analyses.

Site Specificity

The EA and this supplement analyze potential impacts of ONRAB as an oral rabies vaccine-bait for managing rabies in raccoons and skunks in New Hampshire, New York, Ohio, Vermont, and West Virginia, including NFS lands, but excluding Wilderness Areas. The scope of the analysis remains valid as addressed in the EA (see Section 1.5 of the EA). This supplement analyzes potential environmental impacts from expanding the geographic range of the field trial in New York and includes information and data made available since the completion of the 2012 EA to ensure that field trial activities under the proposed alternative are within the parameters evaluated in the EA and to ensure continued implementation of the selected alternative would not adversely affect the human environment.

V. PUBLIC INVOLVEMENT

This supplement to the EA (USDA 2012) will be made available for public review and comment through the publication of a notice of availability in the *Federal Register*, by direct mailing of notices to agencies organizations, and individuals with probable interest in ORV programs, and by posting these documents and a notice of availability on the APHIS website located at http://www.aphis.usda.gov/wildlife_damage/nepa.shtml. Comments received during the public involvement process would be fully considered for new substantive issues and alternatives.

VI. RELATIONSHIP OF THE SUPPLEMENT AND EA TO OTHER ENVIRONMENTAL DOCUMENTS

Section 1.8 of the EA (USDA 2012) provides a detailed description of those documents containing information pertinent to the EA and this supplement.

VII. AUTHORITY AND COMPLIANCE

APHIS-WS' activities with regard to ORV programs are regulated by federal, state, and local laws and regulations. The authority of APHIS-WS is discussed in section 1.9 of the EA (USDA 2012), along with the authorities of other federal, state, and local entities. APHIS-WS' compliance with relevant laws and regulations are also discussed in detail in section 1.9 of the EA (USDA 2012). APHIS-WS' authorities and those of federal, state, and local entities would remain as addressed in the EA, including compliance with all applicable federal, state, and local laws and regulations.

VIII. ISSUES ANALYZED IN DETAIL

Issues are concerns raised regarding potential environmental problems that might occur from a proposed action. The following issues, identified during the scoping process for the EA and discussed in detail in Chapter 2 of the EA (USDA 2012) are analyzed in detail in this supplement with regard to the proposed

geographic expansion of APHIS-WS' ONRAB field trial into Erie, Franklin, Jefferson, Lewis, Niagara, St. Lawrence, and Wyoming counties in New York:

- 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 ONRAB to "revert to virulence" or recombine with other viruses and result in a virus that could cause disease in humans.
- Potential for aerially dropped baits to strike and injure people or domestic animals.
- Humaneness of methods used to collect wild animal species critical for timely program evaluation.

IX. ISSUES ADDRESSED BUT NOT ANALYZED IN DETAIL WITH RATIONALE

In addition to the identified major issues considered in detail, 10 additional issues were considered in section 2.2 of the EA, but were not analyzed in detail with rationale provided 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 analyses provided in the EA are still appropriate regarding those issues.

X. AFFECTED ENVIRONMENT

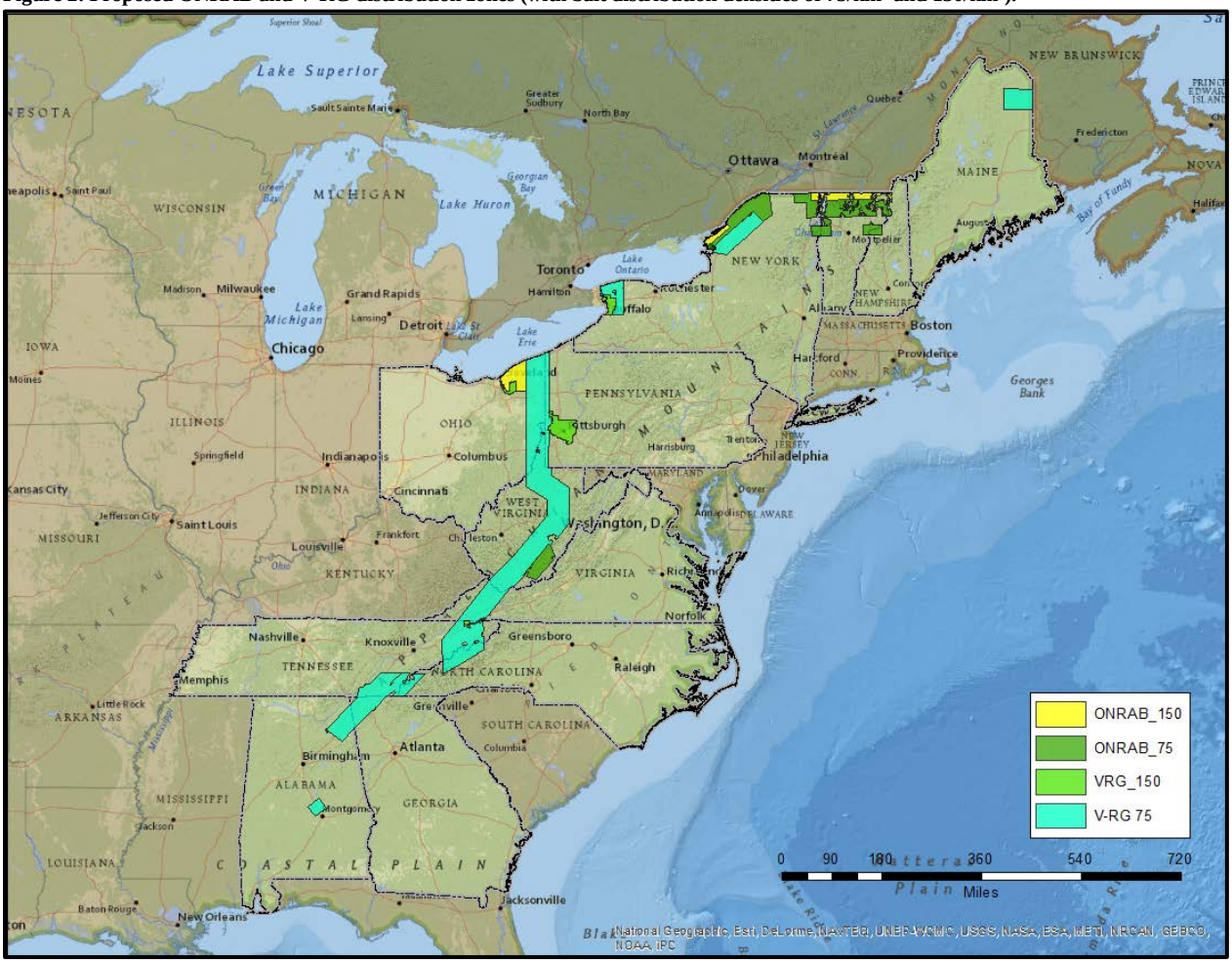
The affected environment was described in section 2.3 of the EA (USDA 2012). APHIS-WS is proposing to expand the geographic boundary of the field trial in New York. Currently, as analyzed in the EA (USDA 2012), the ONRAB field trial zone in New York includes Clinton and Essex Counties. APHIS-WS is proposing to expand the ONRAB field trial zone in New York to include the following counties: Erie, Franklin, Jefferson, Lewis, Niagara, St. Lawrence, and Wyoming (see Figure 1).

The potential area involved in the ORV program field trial may cover several land ownership types and diverse land uses, including cultivated agricultural lands, forests, meadows, wetlands, pastures, and developed lands. Aerial distribution of ORV baits would avoid urban and suburban areas that support high human population densities, as well as lakes and rivers. Aerial distribution of baits would primarily target rural areas as well as known areas of suitable target species habitat. When aerial distribution by fixed-wing or helicopter aircraft is not practical, baits would be distributed by careful hand placement to help minimize contact by humans, pets, and other domestic animals.

Figure 2 shows the areas within the proposed states where APHIS-WS would participate in ORV field trials under the proposed action, as supplemented, and the approximate V-RG ORV bait distribution zones. In addition, the ORV bait dispersal areas are also the primary expected areas where assistance by APHIS-WS is expected to be requested to collect blood, tooth and other biological samples from target

animals for monitoring and surveillance.

Figure 2: Proposed ONRAB and V-RG distribution zones (with bait distribution densities of 75/km^2 and 150/km^2).



XI. ALTERNATIVES

The alternatives considered and evaluated using the identified issues are described and discussed in detail in Chapter 3 of the EA (USDA 2012). In addition, the EA contains a detailed description and discussion of the alternatives and the effects of the alternatives on the issues identified (USDA 2012). The EA also provides a description of the methods that could be used or recommended by APHIS-WS under each of the alternatives. The EA describes three alternatives that were developed to address the issues identified above. The following 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.

XII. 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.

XIII. STANDARD OPERATING PROCEDURES

APHIS-WS has adopted Standard Operating Procedures (SOPs) that serve to prevent, reduce, or compensate for negative impacts that otherwise might result from an action. The current ORV programs, including field trials, use many such SOPs that would be incorporated into the expanded field trial activities. The SOPS discussed in the EA (see section 3.3) remain appropriate for APHIS-WS' ONRAB field trial, including the proposed expansion into Erie, Franklin, Jefferson, Lewis, Niagara, St. Lawrence, and Wyoming counties in New York as analyzed in this supplement.

XIV. ENVIRONMENTAL CONSEQUENCES

The major issues are discussed in detail in Chapter 2 of the EA (USDA 2012). Alternatives developed and identified during the development of the EA to meet the need for action and to address those issues are discussed in Chapter 3 of the EA (USDA 2012). 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 this 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), as described in the EA, addresses the need and implementation of ORV field trials using the ONRAB vaccine by APHIS-WS. The following is an analysis of potential impacts of Alternative 2 (proposed action) for each of the major issues analyzed in the EA since the completion of the EA and includes consideration of seven additional counties (Erie, Franklin, Jefferson, Lewis, Niagara, St. Lawrence, and Wyoming) within the New York State portion of the proposed ONRAB field trial zone:

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

The primary concern is whether the ONRAB vaccine-bait might cause disease in target raccoons and striped skunks, the target species in this ONRAB field trial, if they consume this vaccine-bait. In order for such vaccines to be licensed for use they must be shown to be safe, pure, potent, efficacious, and genetically stable (Agriculture Canada 1989).

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.

In 2011, raccoons sampled by APHIS-WS during post-ONRAB ORV monitoring and surveillance activities displayed a 49.2% seroconversion rate (n=262) (i.e., these raccoons received a sufficient dose of ONRAB and are considered to be vaccinated against the rabies virus). While raccoons sampled pre-ONRAB ORV activities displayed a 9.6% (n=395) seroconversion, this may be explained by a possible occurrence of naturally acquired immunity from sub-lethal exposures to raccoon rabies or movements of orally vaccinated raccoons into sampling cells from the adjacent V-RG zone (USDA 2012b).

The 49% post-ORV with ONRAB (uncorrected for the 9.6%) seroconversion represents the highest rabies virus neutralizing antibody (RVNA) level that WS has observed after an initial baiting of a naïve area at 75 baits/km^2 where baselines had been measured prior to ORV. Biomarker presence was also significantly higher among seropositive raccoons post-ORV and similar among raccoons during the pre-ORV sampling period (USDA 2012b).

Recently, a study focusing on immune response in raccoons following treatment with ONRAB (Brown et al. 2012) found similar, promising results. In this study, forty two wild-caught, captive raccoons were offered an ONRAB vaccine bait. Results of this study concluded that ONRAB effectively stimulated the production of RVNA in a high proportion of raccoons (67%) within the first two months after vaccination. Twenty of these ONRAB treated raccoons were later challenged with rabies virus infection. Of these raccoons, fifteen (75%) survived rabies virus challenge. Throughout the study, no vaccine-induced morbidity or mortality was observed among raccoons (Brown et al. 2012).

Field studies using ONRAB in Ontario, Canada have reported vaccine efficacy in raccoons in the wild ranging from 79% to 81% using baiting densities similar to APHIS-WS' ORV programs (i.e., 75-150 baits/km^2) (Rosatte 2009). Further studies have compared field performance between ONRAB and V-RG. In 2008, ORV programs in Maine, distributing V-RG baits, and New Brunswick, Canada, distributing ONRAB baits, provided an opportunity to carry out a comparative analysis of the field performance of these two vaccine-baits in skunks and raccoons (Fehlner-Gardiner et al. 2012). While antibody prevalence in skunks was low in both Maine and New Brunswick, Fehlner-Gardiner et al. (2012) concluded that this may be attributed to bait densities and flight line spacing. Samples collected from raccoons receiving ONRAB baits in New Brunswick showed antibody response rates ranging from 67% to 78%, depending on the test used for analysis. Conversely, samples from raccoons receiving V-RG baits in Maine showed lower antibody response rates of 25% to 32%. Although a number of factors, as described by Fehlner-Gardiner et al. (2012), could have impacted the interpretation of antibody data,

many of these factors would have favored the V-RG results in Maine. The antibody prevalence in raccoons achieved in this study using ONRAB suggests that this vaccine may prove effective not only for the prevention of raccoon rabies in enzootic areas, but also for rabies elimination (Fehlner-Gardiner et al. 2012). Mainguy et al. (2013) conducted a similar cross-border comparison between ONRAB and V-RG. This study examined antibody response rates between raccoon receiving ONRAB baits in Quebec, Canada versus raccoons receiving V-RG in neighboring Vermont. This study found that the percentage of antibody-positive raccoons was greater with ONRAB in Quebec (51%) than with V-RG in Vermont (38%) although field conditions, similar to those in the above mentioned New Brunswick-Maine study, should have favored a higher antibody prevalence in Vermont.

APHIS-WS expanded the ONRAB field trials in 2012 to portions of New Hampshire, New York, Ohio, Vermont, and replicated the 2011 trial in West Virginia. While serology results are currently pending, it is expected that results will be similar to those experienced in 2011.

As discussed in section 4.1.1 of the EA (USDA 2012), post-field trial ORV monitoring and surveillance activities conducted to evaluate the safety and effectiveness of the ONRAB vaccine-bait are expected to have negligible adverse risks or impacts to target species populations. 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. The current V-RG ORV program conducts raccoon monitoring and surveillance activities in 17 eastern states. To date, lethal removal has accounted for less than 0.03% - 0.19% of the lowest estimated raccoon population annually (USDA 2011c, 2009, 2008, 2007, 2005, 2004, 2004b, 2003) for all ORV programs. APHIS-WS rabies management program's lethal removal of far less than 1% of raccoons did not reduce statewide or regional densities of raccoons. A review of monitoring and surveillance data (USDA 2011c, 2009, 2008, 2007, 2005, 2004, 2004b, 2003) indicates that the potential for cumulative impacts to raccoon populations continues to be negligible. Additionally, based on the conservative state-wide striped skunk population estimates for NH, NY, OH, VT, and WV described in section 4.1.1 of the EA, APHIS-WS and cooperating state and local agencies continue to expect to lethally remove less than 1% of the total striped skunk population in any of the involved states.

In the absence of the ORV program, including the proposed field trial, it is highly likely that substantially greater numbers of raccoons would succumb to the invariably fatal rabies virus with other animal and public health implications than are removed during monitoring and surveillance activities.

Although the ORV ONRAB field trial specifically targets raccoons and striped skunks, several other species may be treated as targets for monitoring and surveillance. These species are referred to as non-ORV targets for purposes of the EA (USDA 2012) and this supplement. The methods proposed for use in monitoring and surveillance activities would have no significant adverse effects on non-ORV target species. Species that are considered targets for monitoring and surveillance, but are not targets for the ORV ONRAB field trial will include all known rabies reservoir or common vector species , including: the red fox, grey fox, coyote, spotted skunk (*Spilogale putoris*), bobcat (*Lynx rufus*), fisher (*Martes*

pennanti), groundhog (*Marmota monax*), feral dog (*Canis familiaris*), and feral cat (*Felis domesticus*). Additionally, several small mammal species may be targets for monitoring and surveillance including Eastern chipmunk (*Tamias* striatus), Eastern gray squirrel (*Sciurus carolinensis*), red squirrel (*Tamiasciurus hudsonicus*), Southern flying squirrel (*Galucomys volans*), short-tailed shrew (*Blarina brevicauda*), deer mouse (*Peromyscus maniculatus*), white-footed mouse (*Peromyscus leucopus*), Southern red-backed vole (*Clethrionomys gapperi*), meadow vole (*Microtus pennsylvanicus*), and pine vole (*Microtus pinetorum*). Occasionally, samples may be collected for serology from some mammal species that are incidentally captured during ORV monitoring and surveillance activities, but not specifically targeted by the ORV ONRAB field trials. They may be opportunistically sampled to determine the potential effectiveness of ONRAB as many of these species have a propensity for contracting, harboring, and spreading the rabies virus. Non-ORV target animals captured in cage traps would normally be released unharmed unless the animal appears sick or injured. Therefore, monitoring and surveillance should have little or no effect on non-ORV target populations as a result of the proposed geographic expansion of field trial activities in New York.

While expanding the geographic area of the field trial in New York should expose higher numbers of target animals to the ONRAB, based on the safety data presented above and in the EA (USDA 2012), as well as APHIS-WS' continued limited lethal removal (i.e., less than 1% of target species populations), no adverse effects to target animals is expected. Beneficial impacts to target species may be expected as previous studies indicate higher levels of rabies antibody response in animals treated with ONRAB versus V-RG.

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). Test animals were found to be clinically healthy after vaccination with ONRAB; however, viral nucleic acids were detected in some tissues or feces of some vaccinated animals, suggesting that ONRAB was replicating or persisting in these hosts for a few days to a couple of weeks post-vaccination. Replication of adenovirus in immunocompromised animals such as nude mice and severe combined immunodeficient (SCID) mice did not appear to result in adverse reactions (CFIA 2008, 2010). Over dosage of ONRAB in amounts four to five times greater than the dose found in the vaccine baits resulted in no adverse effects in experiments involving skunks and raccoons (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*.). Oral swabs, feces, and blood samples were collected from all species. Following inoculation, no behavior changes were observed in any of the animals. By 7 days post-inoculation (dpi) no viral DNA was detected in the fecal swabs of turkeys, opossums, or cottontails and by 21 dpi no viral DNA from fecal swabs was detected in any of the individuals. At 7 dpi oral shedding was detected in only three of the treated fox squirrels. 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 gross or histopathological pathology that could be linked to the vaccine. These study results suggest 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. 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. Analysis of nontarget take resulting from other APHIS-WS ORV programs can be found in USDA 2010.

Special efforts are made to avoid jeopardizing T&E species through biological evaluations of the potential effects and the establishment of special restrictions or mitigation measures. Mitigation measures and SOPs to avoid T&E effects are described in section 3.3 of the EA (USDA 2012).

APHIS-WS reviewed lists of federal and state T& E species (Appendices A and B), as well as Regional Forester Sensitive Species (Appendix C) to determine if any species might be affected due to new listings since the completion of the EA (USDA 2012) or the presence of T&E species in the additional New York counties (Erie, Franklin, Jefferson, Lewis, Niagara, St. Lawrence, and Wyoming). No new listings or presence of T&E species in the expanded New York counties were identified beyond those that have been previously analyzed (USDA 2012). ORV programs or the methods used in capture and removal target species during monitoring and surveillance activities would continue to have no effect on listed fish, invertebrate, or plant species, as described in the EA (USDA 2012).

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-Jewtoukoff and Perricaudet 1995, Artemis 2010).

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.

Over 150 million doses of ORV utilizing V-RG have been distributed in the U.S. since the early 1990s. Human contact with V-RG has been rare, with only two reported human *Vaccinia* infections having occurred from vaccine exposure. However, ONRAB is an alternative that may have a different human safety profile than V-RG given the high prevalence of antibodies in humans to adenovirus type 5 as well as the generally mild illness that may result from infection with this virus (CDC 2013). The ONRAB vaccine employs a human adenovirus type 5 vector into which has been inserted a glycoprotein gene from the ERA rabies vaccine virus. While this live human adenovirus-vectored rabies vaccine virus could cause infection in humans accidentally breaking open the bait packages, if the person is not already immune (CFIA 2008, 2010), adenovirus infections are ubiquitous and are normally without significant or severe clinical symptoms. Adenoviruses are distributed worldwide and infections with human adenovirus type 5 do not typically result in serious disease (Rowe et al. 1995, Andiman and Miller 1982, Charlton et al. 1992, Russell 1998 *in* Rosatte et al. 2009). 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 NY counties of Erie, Franklin, Jefferson, Lewis, Niagara, St. Lawrence, and Wyoming.

Exposures[1] to ONRAB baits have remained relatively low, as discussed in section 4.1.3 of the EA (USDA 2012) and since the completion of the EA. Following the distribution of approximately 80,000 ONRAB baits during the 2011 field trial in West Virginia, there were no reports of human or pet related bait contacts (USDA 2012b). The CDC (2013) reported that following the distribution of 272,034 ONRAB and 504,887 V-RG baits over an area of 11,341 km^2 in Ohio during 2012, 89 baits were reported to have been found. Of these, 15 baits found were ONRAB (5.5 baits found per 100,000 ONRAB baits distributed) and 74 were V-RG (14.7 baits found per 100,000 distributed). Also, during this time there were 14 occurrences of human contacts[1] with ONRAB baits versus 41 human contacts resulting from the V-RG baits distributed in Ohio (Table 1). This equates to 5 contacts per 100,000 baits distributed and 8 contacts per 100,000 baits distributed, respectively. There were no reported adverse events related to human-bait contacts.

Table 1. Human Contacts with ORV Baits in Ohio, 2012 (CDC 2013).

	# Bait Contacts	# Baits Distributed	# Bait Contacts/100,000 Baits Distributed
ONRAB	14	272,034	5
V-RG	41	504,887	8

[1] "Exposures" and "contacts" for purposes of this document include all reported calls whether baits were actually touched or not. For instance, callers may have noticed baits in their yards or on roads, but it does not necessarily mean that they touched or moved the baits. In other situations, people may have picked up a bait with gloves and threw it into the woods or garbage.

Among the 55 human contacts in Ohio, 27 involved baits that were not intact and a barrier (e.g., gloves) had not been used to handle the bait, leaving persons at risk for vaccine exposure and vaccine virus infection (CDC 2013). However, no adverse events were reported. Table 2, below, shows the number of human contacts in Ohio and those contacts resulting in potential vaccine exposure by year and bait type as reported by the CDC (2013).

Table 2. Reported Number of Human Contacts with Oral Rabies Vaccine Baits and Number and Percentage of Contacts with Potential Vaccine Exposure, by Year and Bait Type – Ohio, 2010-2012 (CDC 2013).

Year/Bait Type	No. of Human Contacts	No. of Contacts with Potential Vaccine Exposure	(%)
2010 V-RG	83	37	(45)
2011 V-RG	83	29	(35)
2012 (total)	55	27	(49)
2012 ONRAB	14	11	(79)
2012 V-RG	41	16	(39)

During ORV programs between 2009 and 2011 there was an average of 20 bait contacts per 100,000 baits distributed in Ohio compared to an average of 6 bait contacts per 100,000 baits distributed in all U.S. states participating in ORV programs (Table 3) (CDC, unpublished data).

Table 3. Comparison of Human Contacts with ORV Baits in Ohio in Comparison to all U.S. ORV States (CDC 2013 and unpublished data).

	V-RG Bait Contacts		# Baits Distributed		# Bait Contacts/100,000 Baits Distributed	
	OH	**U.S.**	**OH**	**U.S.**	**OH**	**U.S.**
2009	203	583	874,301	9,572,753	23	6
2010	155	744	774,714	8,868,939	20	8
2011	159	319	863,215	7,920,640	18	4

While contact rates for both ONRAB and V-RG are higher in Ohio than the programmatic average for all states involved in ORV programs, this may be explained given the significantly higher number of ORV baits distributed in Ohio, as well as, the human population density in the baiting area and the bait contact reporting mechanisms in place.

As discussed above, there were no reported bait contacts during the 2011 ONRAB field trial in WV. Further, during ORV programs in Ontario, Canada, a total of 432,000 ONRAB baits were distributed resulting in 6 reports of the public finding baits (D. Donovan, pers. comm., 2012) and 700,000 ONRAB baits were distributed in Quebec, Canada, resulting in only 1 report of the public finding a bait (J. Mainguy, pers. comm., 2012).

These minimal numbers of reports, along with the relatively low number of contacts in Ohio during 2012 indicate that public contact rates with ONRAB baits can be expected to remain low throughout the proposed ORV field trial zone. 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.

Section 4.1.3.1 of the EA (USDA 2012) concluded that ONRAB field trials would have only a negligible risk of adversely affecting pets or other domestic animals that are exposed to or consume the vaccine laden bait. Following the 2012 ORV bait distribution in Ohio, there were 38 reports involving domestic dogs, resulting in 3 adverse events (CDC 2013). One adverse event involved an ONRAB bait that temporarily obstructed a dog's airway, but the dog survived. The remaining two events involved vomiting or regurgitation following consumption of V-RG baits. There were no other reports of domestic animal exposures. There were fewer reports of domestic animal exposures in Ohio during 2012 than during the preceding three years in the same general area (CDC, unpublished data) (see Table 4). Domestic animal contacts with baits are typically much lower in the remaining states where APHIS-WS distributes ORV baits and is likely due to the factors described above for human contact rates (e.g., human/pet population densities in the baiting area, number of baits distributed in a particular area, and reporting mechanisms). 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.

Table 4. Comparison of domestic animal to ORV bait contact rates in Ohio verses all U.S. ORV states[2] (CDC unpublished data).

	Ohio		U.S.	
	# Bait Contacts	# Baits Distributed	# Bait Contacts (avg.)	# Baits Distributed
2009	79	874,301	13	9,572,753
2010	74	774,714	22	8,868,939
2011	69	863,215	15	7,920,640
2012	38	776,921	N/A	7,299,174

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 2011b). 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/km^2 (194 baits/mi^2) or 150 baits/km^2 (388 baits/mi^2). 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 100

[2] U.S. Domestic animal bait contact rates represent an average of the contacts reported for each state involved in ORV distribution as reported by the states to the CDC.

million baits distributed in the U.S. by APHIS-WS during other ORV programs between 1995 and 2011, 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 2011c). None of the reports since APHIS-WS' ORV program inception have resulted in injury or harm to the individuals involved. In addition, trained aircrews avoid baiting in cities, towns, and other areas with human dwellings, or if humans are observed below. In areas with higher human density, ground placement of baits is normally used. These techniques used by APHIS-WS' current ORV programs would also be employed during the ONRAB field trials.

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 2009) 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.

As discussed in the EA (USDA 2012), humaneness, in part, appears to be a person's perception of harm or pain inflicted on an animal. People may perceive the humaneness of an action differently. The challenge in coping with this issue is how to achieve the least amount of animal suffering within the constraints imposed by current technology and funding.

Some individuals believe any use of lethal methods to resolve damage associated with wildlife is inhumane because the resulting fate is the death of the animal. Others believe that specific types of methods can lead to a humane death. Others believe most non-lethal methods of capturing wildlife to be humane because the animal is generally unharmed and alive. Still others believe that any disruption in the behavior of wildlife is inhumane. With the varied attitudes on the meaning of humaneness, the analyses must consider the most effective way to address damage and threats caused by wildlife in a humane manner. The goal of WS is to use methods as humanely as possible to effectively resolve requests for assistance to reduce damage and threats to human safety. WS continues to evaluate methods and activities to minimize the potential for pain and suffering of wildlife when attempting to resolve requests for assistance.

As mentioned previously, some methods have been stereotyped as "humane" or "inhumane". However, many "humane" methods can be inhumane if not used appropriately. For instance, a cage trap is generally considered by most members of the public as "humane". Yet, without proper care, live-captured wildlife in a cage trap can be treated inhumanely if not attended to appropriately.

Therefore, WS' mission is to effectively address requests for assistance using methods in the most humane way possible that minimize the stress and pain of the animal. WS' personnel are experienced and professional in their use of management methods, and methods are applied as humanely as possible.

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. Those methods considered inhumane by certain segments of society would be considered inhumane in spite of the frequency of use. Further, any increase in the use of methods would be exceedingly minimal as APHIS-WS currently conducts operational ORV programs in the area of the proposed field trial and would likely continue to do so even in the absence of field trials. Therefore, the

analyses of the humaneness of methods used by WS to conduct ORV field trial in the interest of eliminating rabies in wildlife has not changed from those analyzed in the EA (USDA 2012).

XV. CUMULATIVE IMPACTS

Cumulative impacts, as defined by CEQ (40 CFR 1508.7), are impacts to the environment that result from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions, regardless of what agency (federal or non-federal) or person undertakes such actions. Cumulative impacts may result from individually minor, but collectively significant, actions taking place over time.

No significant cumulative environmental impacts have resulted from implementation of APHIS-WS' ORV program, including ONRAB field trials. It is possible that Alternative 1 (Maintain the Status Quo) and Alternative 3 (No ORV Field Trials, as analyzed in the EA (USDA 2012), might indirectly lead to increased human exposures and domestic and wild animal rabies cases across the U.S. As discussed in Chapter 4 of the EA (USDA 2012) and this supplement, APHIS-WS and cooperating state and local agencies expect to continue to live-trap or humanely kill less than one percent of the lowest estimated number of the target species combined for monitoring and surveillance purposes or implementation of contingency plans involving lethal population reduction in all of APHIS-WS' ORV programs, including the ONRAB field trial.

Additionally, as discussed in Chapter 4 of the EA and this supplement, the potential for adverse effects resulting from the recombination of ONRAB with other adenoviruses is negligible. It is unlikely that an exchange of genetic material with wild-type viruses would occur in the field. Even if it did occur, the event would not be expected to generate a more virulent virus than the already present wild-type virus (USDA 2011a). Broadening the distribution of ONRAB will not alter this potential.

XVI. SUMMARY

Impacts associated with activities under consideration here are not expected to be "significant". Although some persons will likely remain opposed to the use of recombinant vaccines or the use of human adenovirus type 5 as a component of ORV, and some will remain opposed to the lethal removal of raccoons, skunks, and other wild animals for monitoring, surveillance and to evaluate program progress and success, the analysis in APHIS-WS' ORV EAs (USDA 2009, 2012) and this supplement indicate that ORV and lethal removal for critical sampling and surveillance will not result in significant risk of cumulative adverse impacts on the quality of the human environment. Risks to nontarget species from the proposed program are very low and unlikely to contribute to existing impacts on nontarget species. However, containment and eventual elimination of the rabies virus would have beneficial impacts to both target and nontarget wildlife species susceptible to the rabies virus. Risks to public safety are low.

The addition of those impacts to others associated with past, present, and reasonably foreseeable future actions, as described in USDA (2010) and USDA (2012), will not result in cumulatively significant environmental impacts. Monitoring the impacts of the program on the populations of both target and nontarget species will continue. All ORV activities that may take place will comply with relevant laws, regulations, policies, orders, procedures including the Virus-Serum-Toxin Act; Federal Food, Drug, and Cosmetic Act; and the Animal Medicinal Drug Use Clarification Act of 1994. Table 4.2 of the EA (USDA 2012) presents a summary of relative comparisons of the anticipated impacts of each of the

alternatives as they relate to each of the major issues identified in Chapter 2 of the EA.

XVII. ACRONYMS

AdRG1.3	Human Adenovirus Type-5 Rabies Glycoprotein Recombinant Vaccine
APHIS	Animal and Plant Health Inspection Service
CDC	Centers for Disease Control and Prevention
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations
EA	Environmental Assessment
EIS	Environmental Impact Statement
FONSI	Finding of No Significant Impact
FR	Federal Register
ORV	Oral Rabies Vaccination
NEPA	National Environmental Policy Act
NFS	National Forest System
NPS	National Park Service
NRMP	National Rabies Management Program
RVNA	Rabies Virus Neutralizing Antibodies
SCID	Severed Combined Immunodeficient
SOP	Standard Operating Procedure
T&E	Threatened and Endangered
TVR	Trap Vaccinate Release
USDA	United States Department of Agriculture
USDI	United States Department of the Interior
USFS	United States Forest Service
WS	Wildlife Services
V-RG	Vaccinia-Rabies Glycoprotien
USFWS	United States Fish and Wildlife Service

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APPENDIX A

SPECIES LISTED AS THREATENED OR ENDANGERED

UNDER THE ENDANGERED SPECIES ACT

Information obtained from http://ecos.fws.gov/tess_public/StateListing.do?state=all on April 2013. Listed species based on historic range and population data.

Ohio – 33 listings

Animals – 28

Status	Listing
E	Bat, Indiana (*Myotis sodalis*)
E	Bean, rayed (*Villosa fabalis*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Butterfly, Karner blue (Lycaeides melissa samuelis)
E	Butterfly, Mitchel's satyr (Neonympha mitchellii mitchellii)
E	Catspaw, white (pearlymussel) (Epioblasma obliquata perobliqua)
E	Clubshell Entire Range; except where listed as Experimental Populations (*Pleurobema clava*)
E	Curlew, Eskimo Enitre (*Numenius borealis*)
E	Dragonfly, Hine's emerald (Somatochlora hineana)
E	Fanshell (*Cyprogenia stegaria*)
E	Madtom, Scioto (Noturus trautmani)
E	Mapleleaf, winged Entire; except where listed as experimental populations (Quadrula fragosa)
E	Mucket, pink (pearlymussel) (*Lampsilis abrupta*)
E	Mussel, scaleshell (Leptodea leptodon)
E	Mussel, sheepnose (*Plethobasus cyphyus*)
E	Mussel, snuffbox (*Epioblasma triquetra*)
E	Pearlymussel, cracking Entire Range; except where listed as Experimental Populations (Hemistena lata)
E	Pimpleback, orangefoot (pearlymussel) (Plethobasus cooperianus)
E	Plover, piping Great Lakes watershed (Charadrius melodus)
T	Plover, piping except Great Lakes watershed (Charadrius melodus)
E	Pocketbook, fat (Potamilus capax)
E	Puma (=cougar) eastern (*Felis concolor cougar*)
E	Purple cat's paw (=purple cat's paw pearlymussel) Entire Range; Except where listed as Experimental Populations (Epioblasma obliquata obliquata)
E	Riffleshell, northern (*Epioblasma torulosa rangiana*)
E	Ring pink (mussel) (*Obovaria retusa*)
E	Spectaclecase (mussel) (*Cumberlandia monodonta*)
T	Snake, copperbelly water Indiana north of 40 degrees north latitude, Michigan, Ohio (Nerodia erythrogaster neglecta)
E	Wolf, gray Lower 48 States, except MN, MT, ID, portions of eastern OR, eastern WA, north-central UT, and where EXPN. Mexico (canis lupus)

Plants – 5

Status	Listing
E	Clover, running buffalo (*Trifolium stoloniferum*)
T	Daisy, lakeside (Hymenoxys herbacea)
T	Monkshood, northern wild (Aconitum noveboracense)
T	Orchid, eastern prairie fringed (Platanthera leucophaea)
T	Spirea, Virginia (*Spirea virginiana*)

New Hampshire – 15 listings

Animals – 12

Status	Listing
E	Beetle, American burying (*Nicrophorus americanus*)
E	Butterfly, Karner blue (Lycaeides melissa samuelis)
E	Caibou, woodland Selkirk Mountain population (*Rangifer tarandus caribou*)
E	Curlew, Eskimo Enitre (*Numenius borealis*)
T	Lynx, Canada (Contiguous U.S. DPS) (Lynx canadensis)
T	Plover, piping except Great Lakes watershed (Charadrius melodus)
E	Puma (=cougar) eastern (*Felis concolor cougar*)
E	Sea turtle, leatherback (Dermochelys coriacae)
T	Tiger bettle, Puritan (Cicindela puritan)
E	Wedgemussel, dwarf (Alasmidinta heterodon)
E	Whale, finback (balaenoptera physalus)
E	Wolf, gray U.S.A.: All of AL, Ar, CA, CO, CT, DE, FL, GA, KS, KY, LA, MA, MD, ME, MO, MS, NC, NE, NH, NJ, NV, NY, OK, PA, RI, SC, TN, VA, VT, and WV; those portions of AZ, NM, and TX not included in an experimental population; and portions of IA, IN, IL, ND, OH, OR, SD, UT, and WA. Mexico. (Canus lupus)

Plants – 3

Status	Listing
E	Bulrush, Northeastern (Scirpus ancistrochaetus)
E	Milk-vetch, Jesop's (Astragalus robbinsii var. jesupi)
T	Pogonia, small whorled (*Isotria medeoloides*)

New York – 33 Listings

Animals – 23

Status	Listing
E	Bat, Indiana (*Myotis sodalis*)
E	Bean, rayed (*Villosa fabalis*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Butterfly, Karner blue (Lycaeides melissa samuelis)

E	Curlew, Eskimo Enitre (*Numenius borealis*)
T	Lynx, Canada (Contiguous U.S. DPS) (Lynx canadensis)
T	Plover, piping except Great Lakes watershed (Charadrius melodus)
E	Plover, piping Great Lakes watershed (Charadrius melodus)
E	Puma (=cougar) eastern (*Felis concolor cougar*)
T	Sea turtle, green except where endangered (Chelonia mydas)
E	Sea turtle, hawksbill (Eretmochelys imbricate)
E	Sea turtle, Kemp's ridley (Lepidochelys coriacea)
E	Sea turtle, leatherback (Dermochelys coriacae)
T	Snail, Chittenango ovate amber (Succinea chittenangoensis)
E	Sturgeon, shortnose (Acipenser brevirostrum)
E	Tern, roseate northeast U.S. nesting pop. (Sterna dougallii dougallii)
T	Tiger bettle, northeastern beach (Cicindela dorsalis dorsalis)
T	Turtle, bog (=Muhlenberg) northern (Clemmys muhlenbergii)
E	Wedgemussel, dwarf (Alasmidinta heterodon)
E	Whale, finback (balaenoptera physalus)
E	Whale, humpback (Megaptera novaengliae)
E	Whale, North Atlantic Right (Eubalaena glacialis)
E	Wolf, gray Lower 48 States, except MN, MT, ID, portions of eastern OR, eastern WA, north-central UT, and where EXPN. Mexico. (Canus lupus)

Plants – 10

Status	**Listing**
T	Amaranth, seabeach (Amaranthus pumilus)
E	Bulrush, Northeastern (Scirpus ancistrochaetus)
E	Chaffseed, American (Schwalbea Americana)
T	Fern, American hart's tongue (Asplenium scolopendrium var.)
E	Gerardia sandplain (Agalinis acuta)
T	Monkshood, northern wild (Aconitum noveboracense)
T	Orchid, eastern prairie fringed (Platanthera leucophaea)
T	Pink, swamp (Helonias bullata)
T	Pogonia, small whorled (*Isotria medeoloides*)
T	roseroot, Leddy's (Rhodiola integrifolia ssp. leedyi)

Vermont – 12 Listings

Animals – 9

Status	**Listing**
E	Bat, Indiana (*Myotis sodalis*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Caibou, woodland Selkirk Mountain population (*Rangifer tarandus caribou*)
E	Curlew, Eskimo Enitre (*Numenius borealis*)
T	Lynx, Canada (Contiguous U.S. DPS) (Lynx canadensis)
E	Puma (=cougar) eastern (*Felis concolor cougar*)
E	Wedgemussel, dwarf (Alasmidinta heterodon)

T	Tiger bettle, northeastern beach (Cicindela dorsalis dorsalis)
E	Wolf, gray Lower 48 States, except MN, MT, ID, portions of eastern OR, eastern WA, north-central UT, and where EXPN. Mexico. (Canus lupus)

Plants – 3

Status	**Listing**
E	Bulrush, Northeastern (Scirpus ancistrochaetus)
E	Milk-vetch, Jesop's (Astragalus robbinsii var. jesupi)
T	Pogonia, small whorled (*Isotria medeoloides*)

West Virginia – 26 listings

Animals – 20

Status	**Listing**
E	Bat, Indiana (*Myotis sodalis*)
E	Bat, gray (*Myotis grisescens*)
E	Bat, Virginia big-eared (*Plecotus townsendii virginianus*)
E	Bean, rayed (*Villosa fabalis*)
E	Beetle, American burying (*Nicrophorus americanus*)
E	Blossum, tubercled (pearlymussel) Entire Range; Except where listed as Experimental Populations (*Epioblasma torulosa torulosa*)
E	Clubshell Entire Range; except where listed as Experimental Populations (*Pleurobema clava*)
E	Curlew, Eskimo Enitre (*Numenius borealis*)
E	Fanshell (*Cyprogenia stegaria*)
E	Mucket, pink (pearlymussel) (*Lampsilis abrupta*)
E	Mussel, sheepnose (*Plethobasus cyphyus*)
E	Mussel, snuffbox (*Epioblasma triquetra*)
E	Puma (=cougar) eastern (*Felis concolor cougar*)
E	Riffleshell, northern (*Epioblasma torulosa rangiana*)
E	Ring pink (mussel) (Obovaria retusa)
T	Salamander, Cheat Mountain (Plethodon netting)
T	Snail, flat-spired three-toothed (*Triodopsis platysayoides*)
E	Spectaclecase (mussel) (*Cumberlandia monodonta*)
E	Spinymussel, James (*Pleurobema collina*)
E	Wolf, gray Lower 48 States, except MN, MT, iD, portions of eastern OR, eastern WA, north-central UT, and where EXPN. Mexico. (*Canus lupus*)

Plants – 6

Status	**Listing**
E	Bulrush, Northeastern (*Scriptus ancistrochaetus*)
E	Clover, running buffalo (*Trifolium stoloniferum*)
E	Harperella (*Ptilimnium nodosum*)
T	Pogonia, small whorled (*Isotria medeoloides*)
E	Rock-cress, shale barren (*Arabis serotina*)

T	Spirea, Virginia (*Spirea virginiana*)

E=Endangered, T=Threatened

APPENDIX B

SUMMARY OF SPECIES LISTED AS THREATENED, ENDANGERED, OR SPECIAL STATUS UNDER STATE LAW IN STATES PROPOSED FOR APHIS-WS INVOLVEMENT IN CONTINUED OR EXPANDED ONRAB® FIELD TRIALS

Number of State Listed Species by Category
(Species for which concerns about ORV programs might be raised are identified and shown in bold)
Information obtained from http://www.fws.gov/offices/statelinks.html on April 2013.

State	Mammals	Birds	Reptiles	Amphibians	Fish	Invertebrates	Plants
New Hampshire	4E, 1T **Canada lynx, American marten, New England Cottontail, gray wolf**	8E, 7T	3E, 2T	1E	2 E, 1T	9E, 2T	316E, 81T
New York	10E, 1T, 3SC **Canada lynx, New England cottontail, gray wolf, Eastern puma**	10E, 10T, 19SC	7E, 5T, 6SC	2E, 7SC	8E, 11T, 5SC	16E, 8T, 18SC	331E, 135T, 11R
Ohio	4E, 2T, 19SC, 1SI **bobcat, snowshoe hare, American black bear, ermine, American badger**	14E, 5T, 14 SC, 33SI	4E, 4T, 11SC	5E, 1T, 2SC	20E, 13T, 9SC	73E, 29T, 48SC, 12SI	242E, 162T, 113P
Vermont	7E, 1T **Canada lynx, Eastern mountain lion, American marten**	9E, 2T	3E, 3T	1E	4E, 2T	8E, 6T	65E, 93T
West Virginia	6S1, 10S2, 4S3 **West Virginia northern flying squirrel, eastern spotted skunk, Appalachian cottontail**	26S1, 16S2, 13S3	5S1, 11S2, 3S3	5S1, 6S2, 5S3	35S1, 21S2, 10S3	185S1, 76S2, 53S3	248S1, 150S2, 43S3

E=State Endangered; T=State Threatened; SC=Species of Concern; SI=Species of Interest; R=Rare; P=Potentially Threatened; S1, S2, and S3=WV designations for levels of concern.

State	T&E Protections under State Law
New Hampshire	With respect to any endangered or threatened species, it is unlawful to: (a) Export any such species from this state; (b) Take any such species within this state; (c) Possess, process, sell, or offer for sale, deliver, carry, transport, or ship, by any means whatsoever, any such species; (d) Violate any rule adopted under this chapter pertaining to the conservation of such species of wildlife listed pursuant to RSA 212-A:6, IV
New York	Endangered and threatened categories have protections against “take”; “special concern” category has no special additional protection.
Ohio	Unlawful to “take” and endangered species of fish or wildlife; “take” not specifically defined; no exemptions or permits to allow for incidental take; no special protections for “threatened” or “special interest” species; APHIS-WS advised to just release any state listed species if captured or to report accidental mortality.
Vermont	Unlawful to “take” any endangered or threatened species without the issuance of a permit; “take” not specifically defined; state law includes all federally listed species as state listed.
West Virginia	Only lists federal T&E species as having protections; “Species of Concern” are listed, but have no legal status other than that are already federally listed.

APPENDIX C

REGIONAL FORESTER SENSITIVE SPECIES for the MONONGAHELA NATIONAL FOREST (USDA 2013)

Federally Listed Species

Gray wolf	*Canis lupus*	Considered Extirpated
Eastern cougar	*Puma concolor couguar*	Considered Extirpated
Virginia big-eared bat	*Corynorlinus townsendii virginianus*	Endangered
Indiana bat	*Myotis sodalist*	Endangered
Cheat Mountain salamander	*Plethodon netting*	Threatened

Regional Forester Sensitive Species

Mammals

WV Northern flying squirrel	*Glaucomys sabrinus fuscus*
Southern rock vole	*Microtus chrotorrhinus carolinensis*
Eastern small-footed bat	*Myotis leibii*
Little brown myotis	*Myotis lucifugus*
Northern myotis	*Myotis septentrionalis*
Allegheny woodrat	*Neotoma magister*
Tri-colored bat	*Perimyotis subflavus*
Long-tailed or rock shrew	*Sorex dispar*
Southern water shrew	*Sorex palustris punctulatus*
Eastern spotted skunk	*Spilogale putoris*
Southern bog lemming	*Synaptomys cooperi*

Birds

Northern goshawk	*Accipiter gentilis*
Henslow's sparrow	*Ammodramus henslowii*
Long-eared owl	*Asio otus*
Olive-sided flycatcher	*Contopus cooperi*
American Peregrine falcon	*Flaco peregrines anatum*
Bald eagle	*Haliaeetus leucocephalus*
Migrant loggerhead shrike	*Lanius ludovicianus migrans*
Red-headed woodpecker	*Melanerpes erythrocephalus*
Vesper sparrow	*Pooecetes gramineus*
Golden-winged warbler	*Vermivora chrysoptera*

Reptiles and Amphibians

Wood turtle	*Glyptemys insculpta*
Timber rattlesnake	*Crotalus horridus*
Green salamander	*Aneides aeneus*

Eastern hellbender	*Cryptobrachus alleghaniensis*
Mud salamander	*Pseudotriton montanus*

Fish and Mollusks

Redside dace	*Clinostomus elongatus*
Candy darter	*Etheostoma osburni*
Pearl dace	*Margariscus margarita*
New River shiner	*Notropis scabriceps*
Cheat minnow	*Pararhinichthys bowersi*
Appalachia darter	*Percina gymnocephala*
Kanawha minnow	*Phenacobious teretulus*
Elktoe	*Alasmindonta marginata*
Green floater	*Lasmigona subviridis*
Organ cavesnail	*Fontigens tartarea*

Insects and Invertebrates

Boreal fan moth	*Brachionycha borealis*
Northern metalmark	*Calephelis borealis*
Appalachian tiger beetle	*Cicindela ancocisconensis*
Northern Barrens tiger beetle	*Cicindela patruela*
Cow path tiger beetle	*Cicindela purpurea*
Early hairstreak	*Erora laeta*
Columbine duskywing	*Erynnis lucillius*
A geometrid moth	*Euchlaena milnei*
Rapids clubtail	*Gomphus quadricolor*
Green-faced clubtail	*Gomphus viridifrons*
A noctuid moth	*Hadena ectypa*
Cobweb skipper	*Hesperia metea*
Bronze Copper	*Lycaena hyllus*
West Virginia white	*Pieris virginiensis*
A cave beetle	*Pseudanophthalmus fuscus*
Timber Ridge cave beetle	*Pseudanophthalmus hadenoecus*
A cave beetle	*Pseudanophthalmus hypertrichosis*
Dry Fork valley cave beetle	*Pseudanophthalmus montanus*
Gandy Creek cave springtail	*Pseudosinella certa*
A springtail	*Pseudosinella gisini*
Southern grizzled skipper	*Pyrgus wyandot*
A springtail	*Sinella agna*
Diana fritillary	*Speyeria Diana*
Dry Fork Valley cave pseudoscorpion	*Apochthonius paucispinosus*
Cheat Valley cave isopod	*Caecidotea cannula*
Greenbrier Valley cave isopod	*Caecidotea holsingeri*
An isopod	*Caecidotea simonini*
An isopod	*Caecidotea sinuncus*
Elk River crayfish	*Cambarus elkensis*
An underground crayfish	*Cambarus nerterius*
Culver's cave isopod	*Stygobromus culveri*
Greenbrier cave amphipod	*Stygobromus emarginatus*

Pocahontas cave amphipod	*Stygobromus nanus*
Minute cave amphipod	*Stygobromus parvus*
Hoffmaster's cave flatworm	*Macrocotyla hoffmasteri*
A cave obligate planarian	*Phagocata angusta*
Greenbrier Valley cave millipede	*Pseudotremia fulgida*
Germany Valley cave millipede	*Pseudotremia lusciosa*
South Branch Valley cave millipede	*Pseudotremia princeps*
Culver's planarium	*Sphalloplana culveri*
Grand Caverns blind cave millipede	*Trichopetalum weyeriensis*
Luray Caverns blind cave millipede	*Trichopetalum whitei*
WV blind cave millipede	*Trichopetalum krekeleri*

APPENDIX D

ONRAB FIELD TRIAL STUDY PROTOCOLS

Outline for Proposed ONRAB Oral Rabies Vaccine Field Trial in Northern New Hampshire, Northeastern New York and Northern Vermont in 2013

PRIMARY GOALS: Determine if ONRAB baiting at 75 baits/km^2 during a second consecutive year of field trials over an area in northern New Hampshire, northeastern New York and northern Vermont and that has been baited at the same bait density with Raboral V-RG® since the late 1990's would result in a significant increase in sero-prevalence in 2013. Determine the sero-prevalence of baiting with ONRAB for a second time in a previously ORV naïve rural area in New York, Vermont and New Hampshire and evaluate these results in the context of the same baiting protocol used in rural West Virginia in 2011-2012. Determine if ONRAB baiting at 75 baits/km^2 or 150 baits/km^2 over an area that has been baited at the same densities with Raboral V-RG® since the late 1990's in the St. Lawrence region of New York would result in a significant increase in sero-prevalence in 2013.

1) SITE LOCATION (Figure 1)

- States: New Hampshire, New York and Vermont
- Counties:
  - New Hampshire: Coos, Grafton
  - New York: Clinton, Essex, St. Lawrence, Jefferson
  - Vermont: Addison, Essex, Franklin, Grand Isle, Orleans, Lamoille, Caledonia, Chittenden, Washington
- Towns with some ground baiting:
  - New Hampshire: Colebrook, Lancaster
  - New York: Alexandria Bay, Altona, Brasher Falls, Canton, Cape Vincent, Chazy, Clayton, Massena, Moors, Norfolk, Norwood, Ogdensburg, Plattsburgh, Potsdam, Rouses Point, Winthrop
  - Vermont: Burlington, Derby Center, Derby Line, Enosburg, Jericho, Lyndonville, Milton, Newport, North Troy, Richford, St. Albans, St. Johnsbury, Swanton, Waterville

2) RATIONALE FOR FIELD TRIAL SITE SELECTION

- North American Rabies Management Plan collaboration in a high risk corridor for raccoon rabies to spread from the U.S. back into Quebec and Ontario
- Raccoons and skunks present
- Raccoon rabies present in the U.S. but no cases in Quebec since July 2009 and in Ontario since September 2005
- Local support within state and county and the Provinces of Quebec and Ontario
- WS infrastructure in place

3) FIELD TRIAL PLOT SIZE

- Total ONRAB ORV zone: 13,482.71 km^2 including 366.41 km^2 ground baiting
- 10 distance buffered 126.84 km^2cells (11.2 x 11.2 km) for pre and post-ORV sampling

4) BAITING CHARACTERISTICS

- Total ONRAB baits: 864,900 (838,800 fixed wing and 26,100 ground)
- Bait density: 75/150 baits/km^2 (75 baits/km^2 in all sampling cells)
- Approximately 14,000 ONRAB baits/sampling cell
- Flight line spacing: 375/750 meters (750 meters in all sampling cells)
- Overall Off-time: 29.5% average for fixed wing and 25% average for ground using NLCD to determine "baitable" habitat
- Projected baiting dates: August 20-26, 2013
- Baiting duration: 5 days, 5 planes and ground crews for hand-baiting

5) BAIT-VACCINE CHARACTERISTICS

- Each bait contains 1.8 ± 0.1ml of ONRAB vaccine (titer of not < $10^{9.5}$ cell culture infectious dose 50% [$CCID_{50}$]/ml)
- Bait matrix is comprised of partially hydrogenated vegetable shortening (34%), Microbond wax (30%), stearine (12.5%), Icing sugar (20%), vegetable oil (1%), artificial marshmallow flavor (1%), artificial sweet flavor (1%), and a fat-soluble food dye (0.5%)
- Bait matrix contains 100 mg of tetracycline hydrochloride as a biomarker
- Each vaccine-bait weighs approximately 4g
- The body of the blister pack is an elongated oval with dimensions of 30x14x10mm (1.81 x 0.55 x 0.39in)
- Each bait contains a conspicuous advisory label with a toll free number in the event of a bait contact and potential vaccine exposure

6) PRE-ORV SAMPLING (BASELINES) AND ACTIVITIES

- Enhanced rabies surveillance has been in place for more than 1 year
- In late summer 2013, 150 raccoon-sized cage traps will be tended for 10 consecutive days within each of the 10 sampling cells (4 historically ORV naïve cells, but baited with ONRAB in 2012 and 6 cells historically baited at 75 baits/km^2 with Raboral V-RG® but baited with ONRAB in 2012)
- Traps will be deployed within half a mile (800 meters) of predetermined random trapping locations
- Expect capture rate of ~100 raccoons/cell based on recent previous trapping efforts in area
- Attempt to maximize skunk captures by additional targeted trapping if practical
- From raccoons and skunks: collect pertinent biological, physical and spatial-temporal data; sera for rabies serological analysis (at least 2 vials per animal if practical); first premolar teeth for age determination and biomarker analysis; mark and release at site of capture

- Euthanize target species with unusual lesions or behaviors for analysis
- Opportunistic sampling for additional target and nontarget species (e.g., roadkills or live animals) that display abnormal behavior or have lesions that should be evaluated
- Use various media outlets to advise the public when and where baiting will occur and precautions to be followed to reduce chance of vaccine exposure

7) POST-ORV SAMPLING (TREATMENT EFFECTS) AND ACTIVITIES

- Continue enhanced rabies surveillance
- Continue opportunistic sampling for target and nontarget species (e.g., roadkills, hunter harvest) that display abnormal behavior or have lesions that should be evaluated for pathological context
- 5 weeks post ORV sample ~100 raccoons and as many skunks as practical within each of the 10 sampling cells using the pre-ORV target species trapping protocol
- Collect pertinent biological, physical and spatial-temporal data from raccoons and skunks as well as sera for rabies serological analysis (at least 2 vials per animal if practical), and first premolar teeth for age determination and biomarker analysis
- Use acceptable algorithm with appropriate public health, agriculture and wildlife officials to ensure bait contacts are received through a legible, toll-free phone number on each bait or other sources are reported and addressed by the proper expertise (e.g., Vermont Rabies Hotline)

8) SAMPLE ANALYSIS

- Rabies virus titers to be determined by Wadsworth Laboratory, New York State Department of Health, Albany, NY
- Specific age determination and biomarker detection by Matson's Laboratory, Milltown, MT

9) REPORT FINDINGS

- Expect results from analysis of field data by April 2014
- Draft report by June 2014

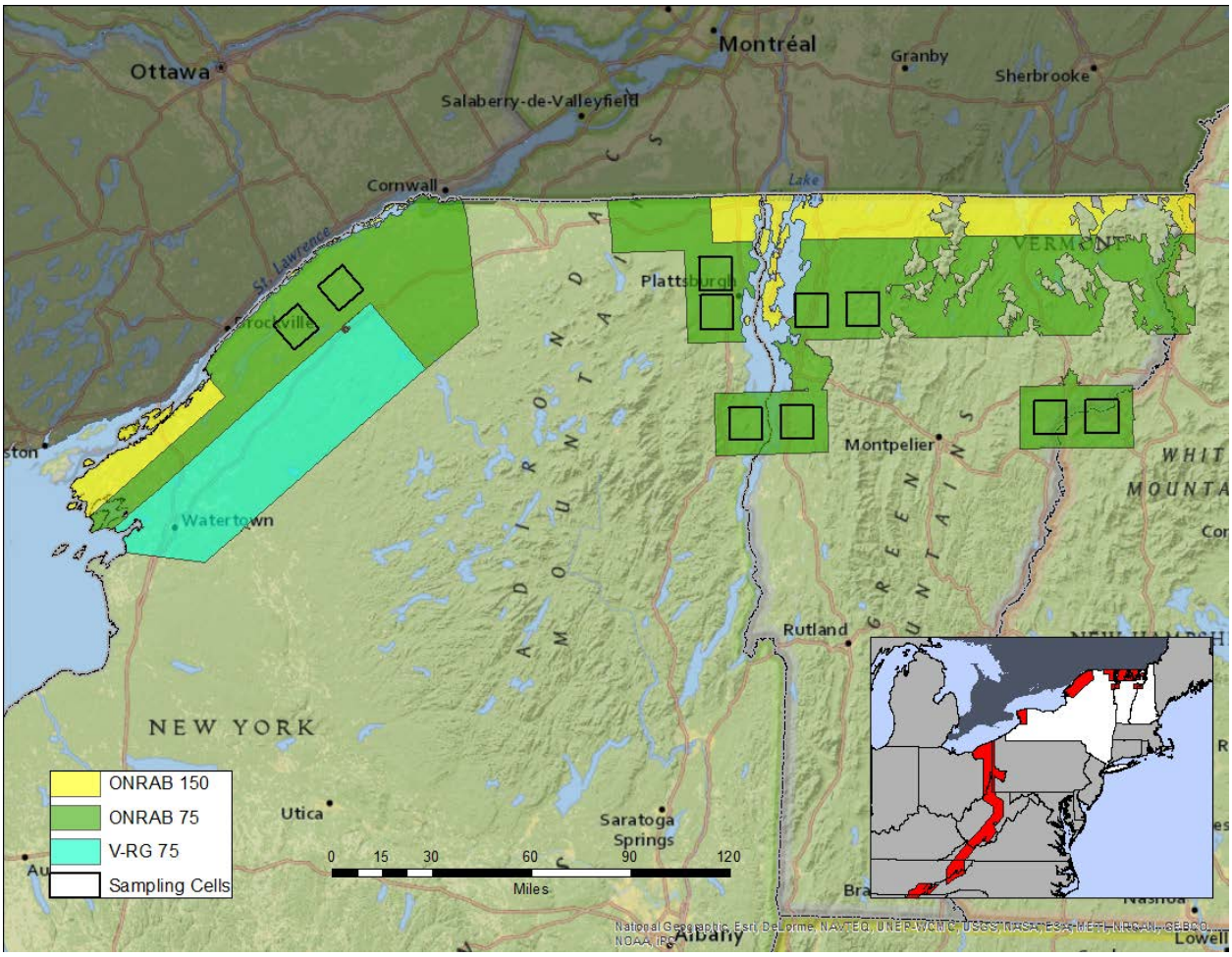

Figure 1. Baiting plan for the northern New Hampshire, northeastern New York and northern Vermont ONRAB field trial in 2013, including ten sampling cells.

Outline for Proposed ONRAB Oral Rabies Vaccine Field Trial in Western New York in 2013 – Collaboration with Cornell University

PRIMARY GOALS - To determine if ONRAB deployment at a target density of 75 baits/km^2 will effect a greater proportion of seropositive raccoons, when compared to 14 years of historical Raboral V-RG® data (Table 1) from the same oral rabies vaccination (ORV) zone (1995-2012). To evaluate a potential contingency response strategy (CRS) incorporating a greater ONRAB distribution density of 150 baits/km^2. The proposed ONRAB field trial planned for the Buffalo/Niagara region of western New York is a collaborative effort led by Cornell University in cooperation with USDA, APHIS, Wildlife Services. Cornell University will serve as the lead investigating organization for this study, will purchase ONRAB baits, distribute ground baits in residential areas, and will conduct all pre- and post-ORV sampling and activities. Wildlife Services will purchase Raboral V-RG® baits, provide aviation support, and distribute all ORV baits (both ONRAB and V-RG) designated for fixed-wing and helicopter bait distribution.

1) SITE LOCATION

- State: New York
- Counties: Erie, Niagara (Figure 2)
- Towns within ONRAB zone

  Residential: Lockport, Niagara Falls, North Tonawanda, Grand Island, Tonawanda, Amherst, Buffalo, Lackawana (part), Cheektowaga (part), Clarence (part), West Seneca (part)

  Rural: Porter, Wilson, Newfane, Somerset, Hartland, Lockport, Cambria, Lewiston, Niagara, Pendleton, Wheatfield, Royalton, Amherst (part), Clarence (part), Newstead (part), Tuscarora Nation, Tonawanda Nation (part)

2) RATIONALE FOR FIELD TRIAL SITE SELECTION

- Terrestrial rabies cases have consistently been confirmed in target and nontarget (i.e., domestic and wild) mammals since ORV was initiated during 1995 (Niagara County) and 2002 (Erie County)
- The epizootic front has remained static since 1995; however, the North American Rabies Management Plan identifies Western NY as a high-risk corridor for spread of the raccoon variant of rabies virus to Ontario, Canada
- Cornell infrastructure in place
- State funding provided for ONRAB 2013 trial
- Ontario funding for ONRAB 2013 trial anticipated
- In-kind support provided by federal, state, county and provincial sources
- Raccoons and skunks are present

3) FIELD TRIAL PLOT SIZE

- Total ONRAB ORV zone: 1902.7 km^2 including 575.8 km^2 of residential habitats

4) BAITING CHARACTERISTICS

- Methods of bait distribution
  - Rural: Fixed-wing aircraft
  - Residential: Helicopter and bait station
- Total ONRAB baits: 177,247
  - Rural: 94,309
  - Residential: 82,938
- Bait density: 75 and 150 baits/km^2
- Flight line spacing:
  - Rural: 750 meters
  - Residential: 500 meters
- Average Off-time:
  - Rural: 32%
  - Residential: 0%
- Projected ORV Distribution: Late August 2013
- Baiting duration: 2 weeks

5) BAIT-VACCINE CHARACTERISTICS

- Each bait contains 1.8 ± 0.1ml of ONRAB vaccine (titer not less than $10^{9.5}$ cell culture infectious dose 50% [$TCID_{50}$]/ml)
- Bait matrix comprised of partially hydrogenated vegetable shortening (34%), Microbond wax (30%), stearine (12.5%), Icing sugar (20%), vegetable oil (1%), artificial marshmallow flavor (1%), artificial sweet flavor (1%), and a fat-soluble food dye (0.5%)
- Bait matrix contains 100 mg of tetracycline hydrochloride as a biomarker
- Each vaccine-bait weighs approximately 4g
- The body of the blister pack is an elongated oval with dimensions of 30x14x10mm (1.81 x 0.55 x 0.39 in)
- Each bait contains a conspicuous advisory label with a toll free number in the event of a bait contact and potential vaccine exposure

6) PRE-ORV SAMPLING AND ACTIVITIES

- Enhanced rabies surveillance
- Number live-trapping cells: 3
- Target collection of 100 raccoons from each cell
- Record biological, physical and spatiotemporal data; aspirate blood for virus neutralization assay; extract first-premolar tooth for age determination and biomarker analyses; ear-tag and release at capture site
- Ancillary data and samples will be collected from skunks
- Animals exhibiting unusual lesions or behaviors will be euthanized for subsequent testing
- Three public meetings within the ONRAB zone will be scheduled; local agencies, furbearer hunting and trapping groups will be notified; additional media outreach will be exploited to

provide health professionals, veterinarians, and the public with information relative to ORV details

7) POST-ORV SAMPLING AND ACTIVITIES

- Continue enhanced rabies surveillance within ORV zone
- Continue opportunistic sampling for target and non-target species (e.g., roadkills, hunter harvest) that display abnormal behavior or exhibit lesions that should be evaluated for pathological context
- Live-trap 100 raccoons/cell and as many skunks as practical
- Record biological, physical and spatiotemporal data; aspirate blood for virus neutralization assay; extract first-premolar tooth for age determination and biomarker analyses; ear-tag and release at capture site
- Use USDA bait contact procedures in cooperation with local and state officials to ensure that bait contacts are received through a legible, toll-free phone number

8) SAMPLE ANALYSES

- Rabies virus neutralization assay performed at Wadsworth Center, New York State Department of Health Rabies Laboratory, Albany, NY
- Age determination and biomarker analyses performed by Matson's Laboratory, Milltown, MT

9) REPORT FINDINGS

- Expect results from analysis of field data by April 2014
- Draft report by May 2014

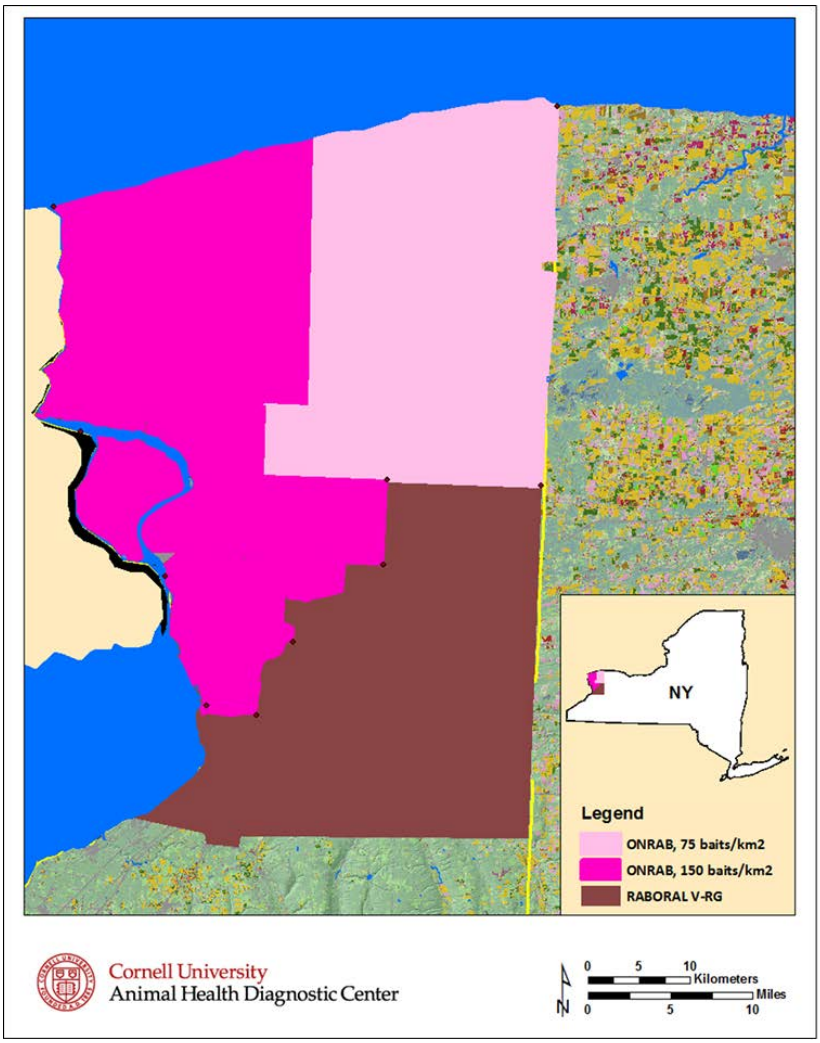

Figure 2. Proposed ONRAB field trial and Raboral V-RG® ORV Zones in Western NY in 2013.

Outline for Proposed ONRAB Oral Rabies Vaccine Field Trial in Northeast Ohio in 2013

PRIMARY GOALS: Determine if ground distribution of ONRAB at 150 baits/km^2 during a second consecutive year of field trials would result in significantly higher sero-prevalence in an area that has often been subjected to twice/year and high density baiting (150 baits/km^2) with Raboral V-RG® and trap-vaccine-release. A primary focus will be on the ORV and TVR naïve juvenile cohort. Raboral V-RG® ground cells will be included in this field trial for comparative context.

1) SITE LOCATION (Figure 3)

- State: Ohio
- Counties: portions of Cuyahoga, Geauga, Lake, Portage and Summit
- Towns: Aurora, Beachwood, Bedford, Bedford Heights, Bentleyville Chagrin Falls, Boston Heights, Burton, Chardon, Cleveland, Cleveland Heights, Cleveland Metro Parks, Concord, East Cleveland, Eastlake, Euclid, Garfield Heights, Gates Mills, Glenwillow, Highland Heights, Highland Hills, Hudson, Hunting Valley, Independence, Kirkland, Kirkland Hills, Lyndhurst, Macedonia, Madison, Maple Heights, Mayfield, Mayfield Heights, Mentor, Mentor on the Lake, Middlefield, Moreland Hills, North Randall, Northfield, Northfield Center, Oakwood, Orange, Painesville, Pepper Pike, Perry, Reminderville, Richmond Heights, Sagamore Hills, Shaker Heights, Solon, South Euclid, South Russell, Twinsburg, University Heights, Valley View, Waite Hills, Warrensville Heights, Wickliffe, Willoughby, Willoughby Hills, Willowick, Woodmere

2) RATIONALE FOR FIELD TRIAL SITE SELECTION

- The area has been intensively managed since 2007 through contingency actions (high density baiting at 150 baits/km^2, often twice/year baiting over much of the area, and TVR) because it continues to represent a high risk corridor for raccoon rabies spread to the West
- Selection was based partially on the need for improved ORV performance and the ability to evaluate high density ground baiting, a commonly used ORV tactic in urban-suburban settings
- All Ohio field trial cells will be ground baited at 150 baits/km^2 of the baitable habitat
- Raccoons and skunks present
- Raccoon rabies present east of existing area and detected in skunks within the ORV zone
- Continued local support within state and county
- WS infrastructure in place

3) FIELD TRIAL PLOT SIZE

- Total area: 2,434.36 km^2 including 1,123.67 km^2 ground and helicopter baiting
- 24 ONRAB and 12 Raboral V-RG® 1 km^2 cells (1 x 1 km) will be selected from 30 and 32 available cells, respectively for pre and post-ORV sampling

4) BAITING CHARACTERISTICS

- Total ONRAB baits: 269,100 (144,000 fixed wing and 125,100 ground and helicopter)
- Bait density: 150 baits/km^2
- Total Raboral V-RG® baits: 45,720 (ground, helicopter and fixed wing distributed)
- Approximately 116 ONRAB or Raboral V-RG® baits will be distributed by hand/1km^2 sampling cell
- Flight line spacing: 375 meters
- Off-time: 33% for fixed wing and an average of 23% for ground and helicopter using National Land Class Dataset to determine "baitable" habitat
- Projected baiting dates: August 28-September 1, 2013
- Baiting duration: 4 days, 3 planes, 1 helicopter and ground crews for hand-baiting

5) BAIT-VACCINE CHARACTERISTICS

- Each bait contains 1.8 ± 0.1ml of ONRAB vaccine (titer of not < $10^{9.5}$ cell culture infectious dose 50% [$CCID_{50}$]/ml)
- Bait matrix is comprised of partially hydrogenated vegetable shortening (34%), Microbond wax (30%), stearine (12.5%), Icing sugar (20%), vegetable oil (1%), artificial marshmallow flavor (1%), artificial sweet flavor (1%), and a fat-soluble food dye (0.5%)
- Bait matrix contains 100 mg of tetracycline hydrochloride as a biomarker
- Each vaccine-bait weighs approximately 4g
- The body of the blister pack is an elongated oval with dimensions of 30x14x10mm (1.81 x 0.55 x 0.39in)
- Each bait contains a conspicuous advisory label with a toll free number in the event of a bait contact and potential vaccine exposure

6) PRE-ORV SAMPLING (BASELINES) AND ACTIVITIES

- Enhanced rabies surveillance has been in place since 2004, with no raccoon rabies variant cases detected in 2013 (including as spillover in skunks) in the study area to date
- In late summer 2013, 25 raccoon-sized cage traps will be tended for 10 consecutive days within each of the 36 sampling cells (24 ONRAB and 12 Raboral V-RG®)
- Traps will be deployed based on past trapping trends to ensure adequate property access in this highly residential and commercial landscape
- Target for juvenile captures is 12 raccoons/cell as young of the year represent the only ORV naïve cohort in the sample; maximize recaptures
- Maximize skunk captures by additional targeted trapping where practical
- From raccoons and skunks: collect pertinent biological, physical and spatial-temporal data; sera for rabies serological analysis (at least 2 vials per animal if practical); first premolar teeth for age determination and biomarker analysis; mark and release at site of capture
- Euthanize target species with unusual lesions or behaviors for analysis
- Opportunistic sampling for additional target and nontarget species (e.g., roadkills or live animals) that display abnormal behavior or have lesions that should be evaluated

- Use various media outlets to advise the public when and where baiting will occur and precautions to be followed to reduce chance of vaccine exposure

7) POST-ORV SAMPLING (TREATMENT EFFECTS) AND ACTIVITIES

- Continue enhanced rabies surveillance
- Continue opportunistic sampling for target and nontarget species (e.g., roadkills, hunter harvest) that display abnormal behavior or have lesions that should be evaluated
- 5 weeks post-ORV sample at least 30 raccoons/cell and as many skunks as practical within each of the 36 sampling cells using the pre-ORV target species trapping protocol
- Collect pertinent biological, physical and spatial-temporal data from raccoons and skunks as well as sera for rabies serological analysis (at least 2 vials per animal if practical) and first premolar teeth for age determination and biomarker analysis
- Use acceptable algorithm with appropriate public health, agriculture and wildlife officials to ensure bait contacts are reported through a legible, toll-free phone number on each bait or other sources and addressed by the proper expertise

8) SAMPLE ANALYSIS

- Rabies virus titers to be determined by CDC or GARC, Atlanta, GA
- Specific age determination and biomarker detection by Matson's Laboratory, Milltown, MT

9) REPORT FINDINGS

- Expect results from analysis of field data by April 2014
- Draft report by June 2014

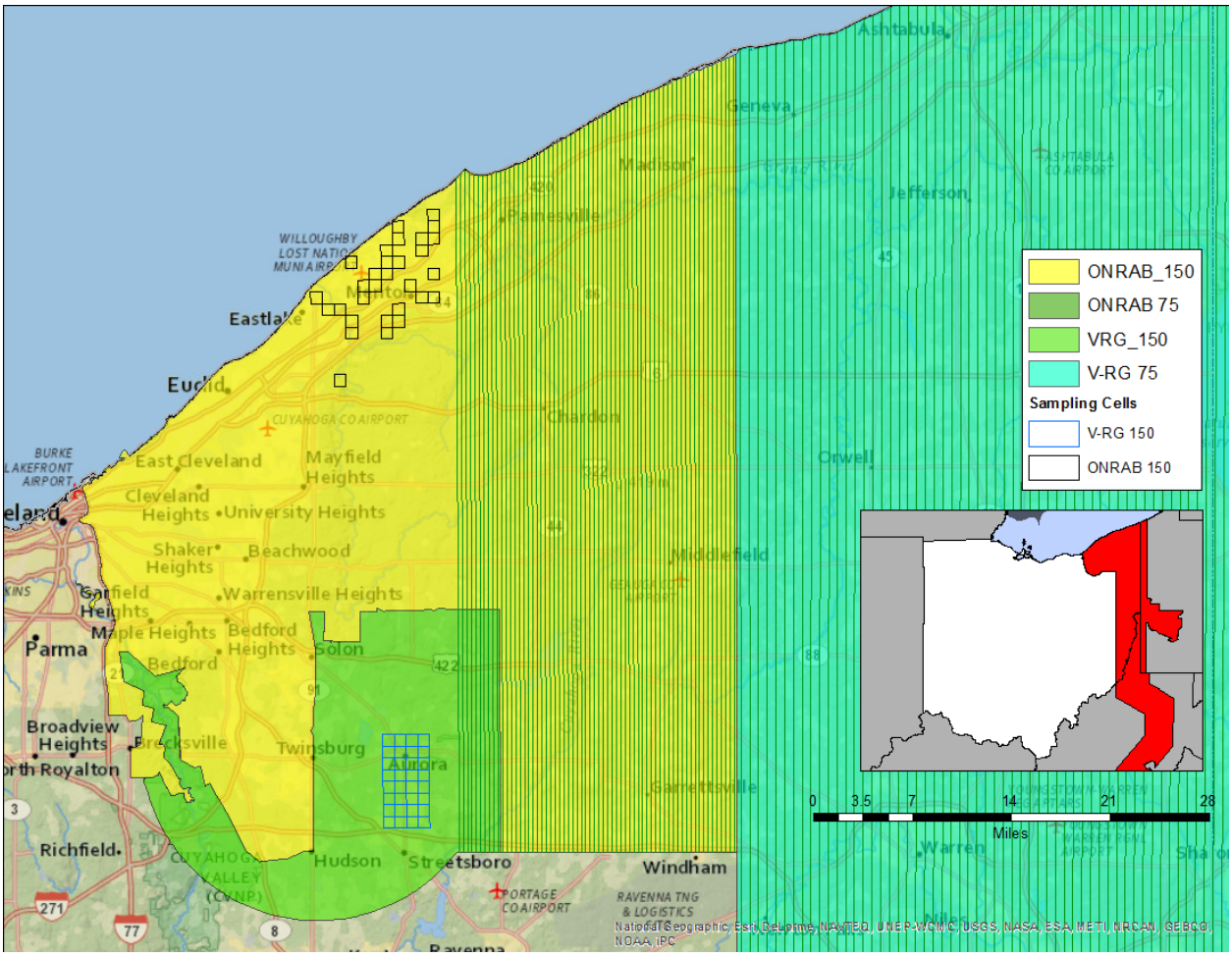

Figure 3. Baiting plan for the Ohio ONRAB field trials in 2013, including locations of ONRAB and Raboral V-RG® 1 km^2 sampling cells.

Outline for Proposed Replicate of ONRAB Oral Rabies Vaccine Field Trial in Southeastern West Virginia in 2013

PRIMARY GOALS: Determine if replication of the 2011 and 2012 West Virginia ONRAB trials through a third annual ORV campaign at 75 baits/km^2 would result in significantly increased sero-prevalence in 2013. Compare ONRAB to Raboral V-RG® sero-prevalence in 2013. Sero-prevalence would be derived from sampling cells in established Raboral V-RG® ORV zones in West Virginia since 2001 that have been baited annually at 75 baits/km^2.

1) SITE LOCATION (Figure 4)

- State: West Virginia
- Counties: Fayette, Greenbrier, Mercer, Monroe, Pocahontas, Raleigh, Summers
- Towns: Alderson, Fairlea, Falling Springs, Hinton, Lewisburg, Ronceverte

2) RATIONALE FOR FIELD TRIAL SITE SELECTION

- Site of first and second field trials with ONRAB in 2011 and 2012, allowing for replication to evaluate sero-prevalence after a third year of ONRAB baiting in 2013
- Ability to add two sampling cells in the adjacent historic Raboral V-RG® zone in West Virginia to facilitate a more formal comparison
- In 2011, post-ORV sampling from the closest historic Raboral V-RG® area in Virginia was used for reference; due to rare high seroprevalence this area was formally sampled pre and post-ORV with Raboral V-RG® in 2012 but will not be formally sampled again in 2013
- Raccoons and skunks present
- Raccoon rabies present east of existing ORV zone
- Continued local support within state and county
- WS infrastructure in place

3) FIELD TRIAL PLOT SIZE

- Total area: 2,342.84 km^2 including 26.85 km^2 ground baiting
- 6 distance buffered (4 ONRAB and 2 Raboral V-RG®) 126.84 km^2 cells (11.2 x 11.2 km) for pre and post-ORV sampling in West Virginia

4) BAITING CHARACTERISTICS

- Total baits in ONRAB zone: 131,400 (129,876 fixed-wing and 1,524 ground)
- Bait density: 75 baits/km^2(ONRAB and Raboral V-RG®)
- Approximately 14,000 ONRAB or Raboral V-RG® baits/sampling cell
- Flight line spacing: 750 m
- Off-time: 27% for fixed wing and an average of 24% for ground using NLCD to determine "baitable" habitat
- Projected baiting dates: August 31-September 5, 2013
- Baiting duration: 1 day, 5 planes and ground crews for hand-baiting

5) BAIT-VACCINE CHARACTERISTICS

- Each bait contains 1.8 ± 0.1ml of ONRAB vaccine (titer of not < $10^{9.5}$ cell culture infectious dose 50% [$CCID_{50}$]/ml)
- Bait matrix is comprised of partially hydrogenated vegetable shortening (34%), Microbond wax (30%), stearine (12.5%), Icing sugar (20%), vegetable oil (1%), artificial marshmallow flavor (1%), artificial sweet flavor (1%), and a fat-soluble food dye (0.5%)
- Bait matrix contains 100 mg of tetracycline hydrochloride as a biomarker
- Each vaccine-bait weighs approximately 4g
- The body of the blister pack is an elongated oval with dimensions of 30 x 14 x 10mm (1.81 x 0.55 x 0.39in)
- Each bait contains a conspicuous advisory label with a toll free number in the event of a bait contact and potential vaccine exposure

6) PRE-ORV SAMPLING (BASELINES)

- Enhanced rabies surveillance has been in place for more than 1 year
- In late summer 2013, 150 raccoon-sized cage traps will be tended for 10 consecutive days within each of the 6 sampling cells (4 ONRAB and 2 Raboral V-RG®); Traps will be deployed within half a mile (800 meters) of predetermined random trapping locations
- Expect capture rate of~100 raccoons/cell based on recent previous trapping efforts in area
- Attempt to maximize skunk captures by additional targeted trapping if practical
- From raccoons and skunks: collect pertinent biological, physical and spatial-temporal data; sera for rabies and human adenovirus serological analysis (at least 2 vials per animal if practical); first premolar teeth for age determination and biomarker analysis; mark and release at site of capture
- Euthanize target species with unusual lesions or behaviors for analysis
- Opportunistic sampling for additional target and nontarget species (e.g., roadkills or live animals) that display abnormal behavior or have lesions that should be evaluated
- Use various media outlets to advise the public when and where baiting will occur and precautions to be followed to reduce chance of vaccine exposure

7) POST-ORV SAMPLING (TREATMENT EFFECTS)

- Continue enhanced rabies surveillance
- Continue opportunistic sampling for target and nontarget species (e.g., roadkills, hunter harvest) that display abnormal behavior or have lesions that should be submitted for analysis
- 5 weeks post ORV sample for a target of ~100 raccoons and as many skunks as practical within each of the 6 cells using the pre-ORV target species trapping protocol
- Collect pertinent biological, physical and spatial-temporal data from raccoons and skunks as well as sera for rabies and human adenovirus analysis (at least 2 vials per animal if practical) and first premolar teeth for age determination and biomarker analysis
- Use acceptable algorithm with appropriate public health, agriculture and wildlife officials to ensure bait contacts are reported through a legible, toll-free phone number on each bait or other sources and addressed by the proper expertise

8) SAMPLE ANALYSIS

- Rabies virus titers to be determined by CDC or GARC, Atlanta, GA
- Human adenovirus titers to be determined by Dr. Dubovi, Cornell University, Ithaca, NY
- Specific age determination and biomarker detection by Matson's Laboratory, Milltown, MT

9) REPORT FINDINGS

- Expect results from analysis of field data by April 2014
- Draft report by June 2014

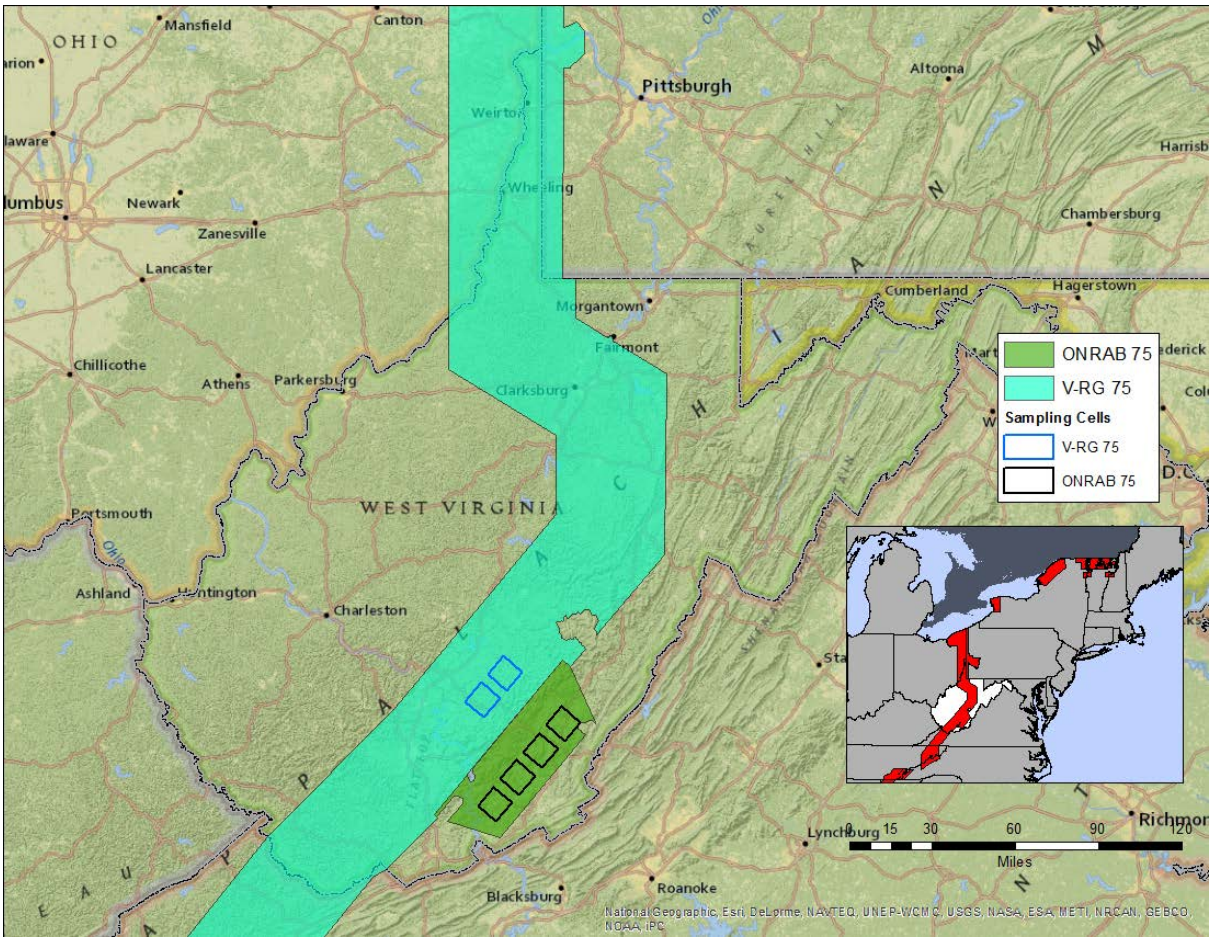

Figure 4. Baiting plan for the West Virginia ONRAB field trial in 2013, including location of the four ONRAB field trial sampling cells and the two Raboral V-RG® sampling cells.

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 aerially dropped baits to strike and injure people or domestic animals.
- Humaneness of methods used to collect wild animal species critical for timely program evaluation.

Those issues identified during the development of the 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-Jewtoukoff and Perricaudet 1995, Artemis 2010).

Subsequent to the completion of the EA (USDA 2012), APHIS-WS' National Wildlife Research Center (NWRC) conducted research expanding on the species evaluated by Knowles et al. (2009) to investigate the safety of ONRAB in wildlife species likely to come into contact with the vaccine-bait as a result of WS' ORV distribution (Fry et al. 2013). A 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/km^2 (194 baits/mi^2) or 150 baits/km^2 (388 baits/mi^2). 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 issued 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.

Joanne Garrett

William Clay, Deputy Administrator
APHIS-WS
for

7/17/13
Date

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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 anlaysis; 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 milions 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 (*Oryctologus 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 scrofra) 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.

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