

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.

In 2013, APHIS-WS determined there was a need to expand the ONRAB field trial into additional counties in New York that were not previously included in the EA (USDA 2012). After a 30-day public review and comment period, APHIS-WS considered all comments and determined that no new or substantive issues were raised. To fully analyze the potential environmental effects of this expansion, APHIS-WS completed a supplement to the EA (USDA 2013) and issued a FONSI for the EA on July 17, 2013.

This document adds to and updates the 2012 EA and 2013 supplement to the EA. All information and analyses in the 2012 EA and the 2013 supplement to the EA remain valid unless otherwise noted below.

II. PURPOSE

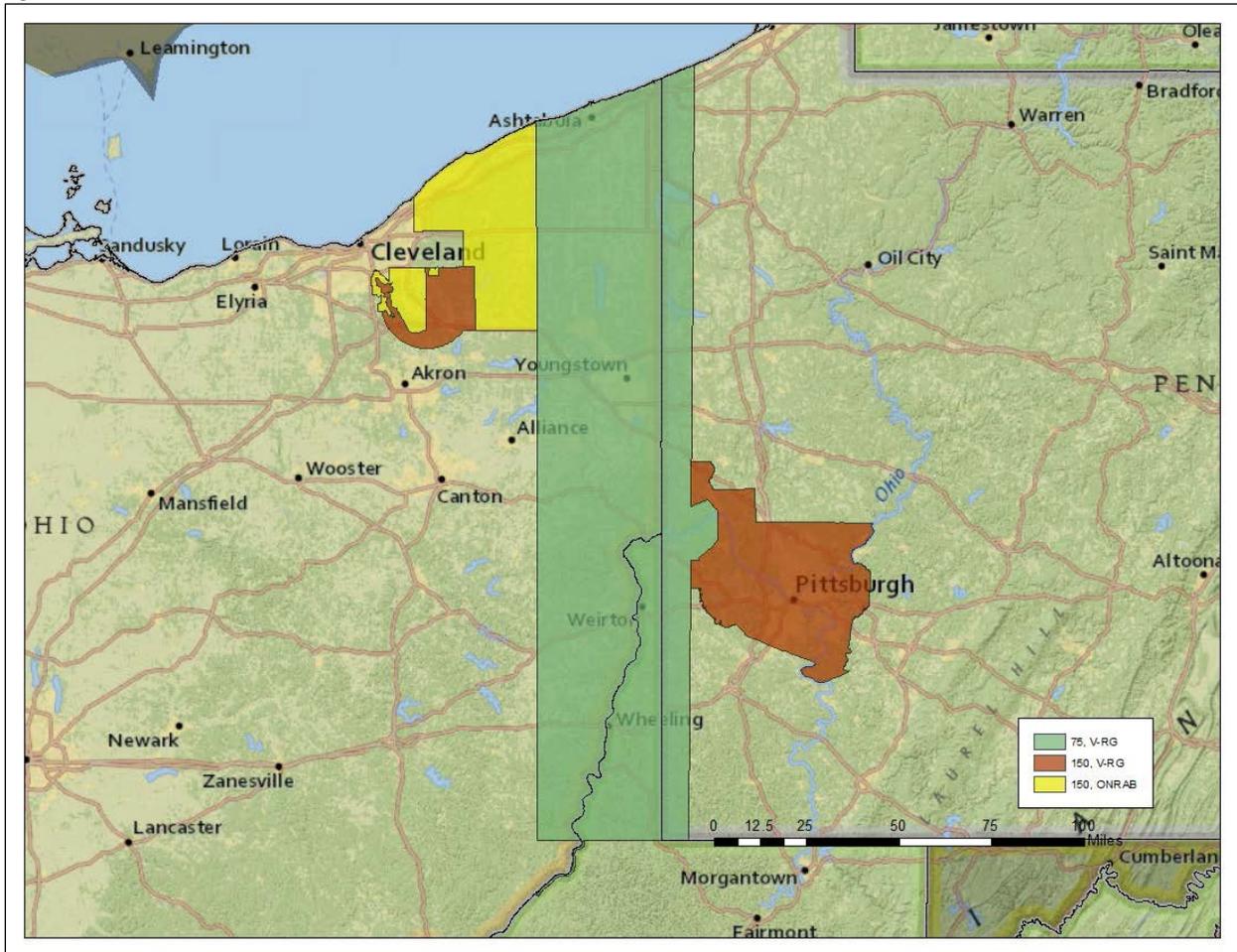
The purpose of the EA remains as addressed in section 1.2 of the EA (USDA 2012). The purpose of this supplement to the EA is to 1) examine potential environmental impacts of APHIS-WS' program as it relates to shifting the geographic range of the field trial zone in Ohio and increasing bait distribution density in portions of the West Virginia field trial zone, 2) clearly communicate to the public the analysis of individual and cumulative impacts of the proposed action since 2012 and the 2013 supplement to the EA, and 3) 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 and the 2013 supplement to 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 (*Procyon lotor*) 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 Ashtabula and Trumbull counties in Ohio, as analyzed in this proposed supplement to the EA.

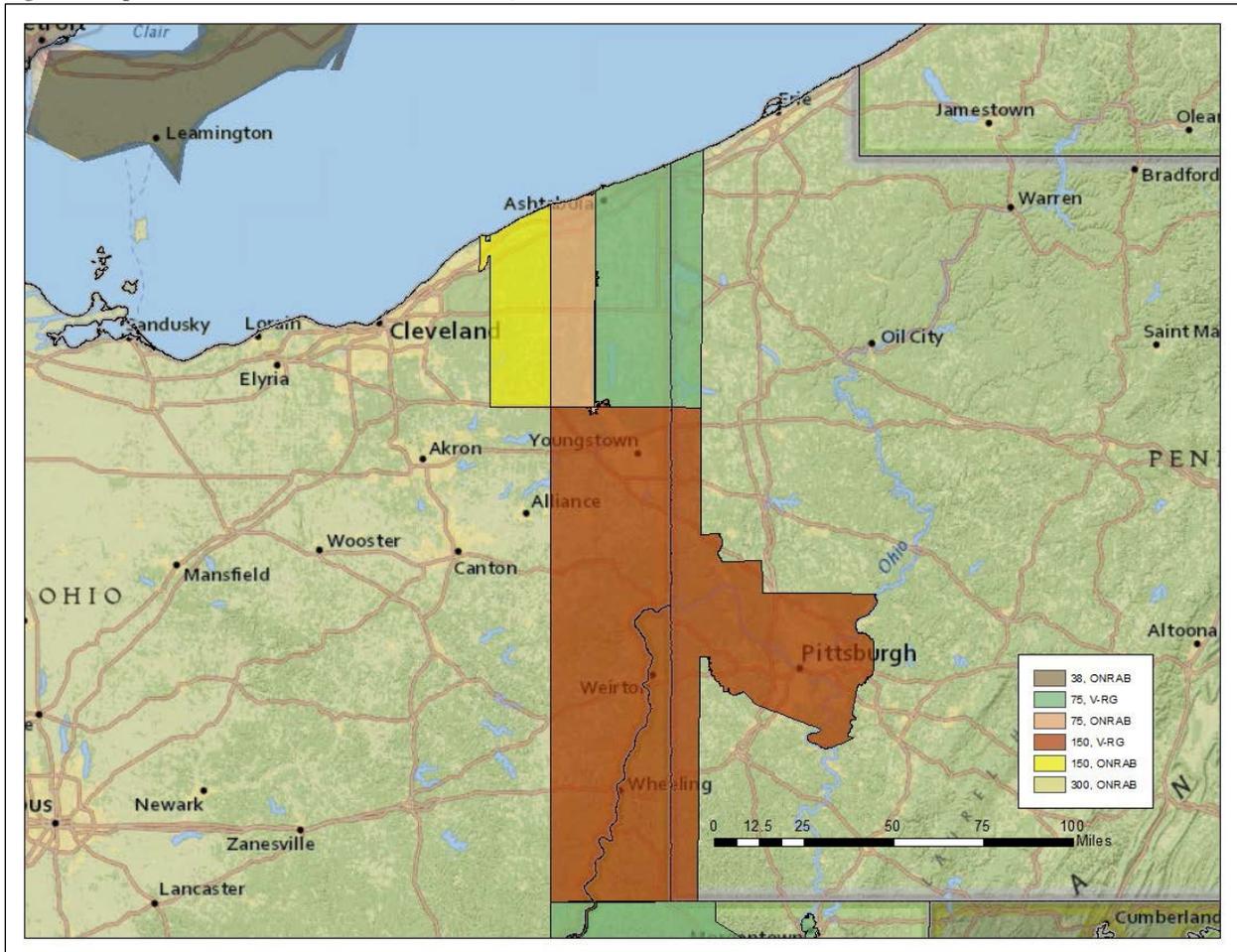
Currently, APHIS-WS conducts an ORV program using the only licensed oral rabies vaccine in the U.S. [vaccinia-rabies glycoprotein (V-RG)] in the above listed Ohio counties as part of a national ORV program. APHIS-WS' use of the V-RG vaccine has resulted in several notable accomplishments including the elimination of canine rabies from sources in Mexico which had spread to coyotes (*Canis latrans*) in south Texas, the successful control of gray fox (*Urocyon cinereoagrestis*) 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.

Figure 1. Ohio ONRAB and V-RG ORV Zones, 2014.



Since 2012, APHIS-WS has been distributing both ONRAB and V-RG vaccine-baits along the western edge of the Ohio ORV zone as part of a contingency¹ response to positive wildlife rabies cases in that area (Figure 1). Since 2011, there have been no additional raccoon rabies cases in that region of the zone, prompting the need to reduce the western edge of the ORV zone in the Ohio contingency area and to move the zone further east (Figure 2). This proposed shift in the ORV zone would allow for two significant benefits. The proposed change would allow APHIS-WS to distribute ONRAB vaccine in a portion of the ORV zone historically baited only with V-RG, but where there continues to be occasional rabies positive wildlife; and the eastern movement of the ORV zone would mark an advancement toward the eventual elimination of wildlife rabies.

Figure 2. Proposed Ohio ONRAB and V-RG ORV Zones, 2015.

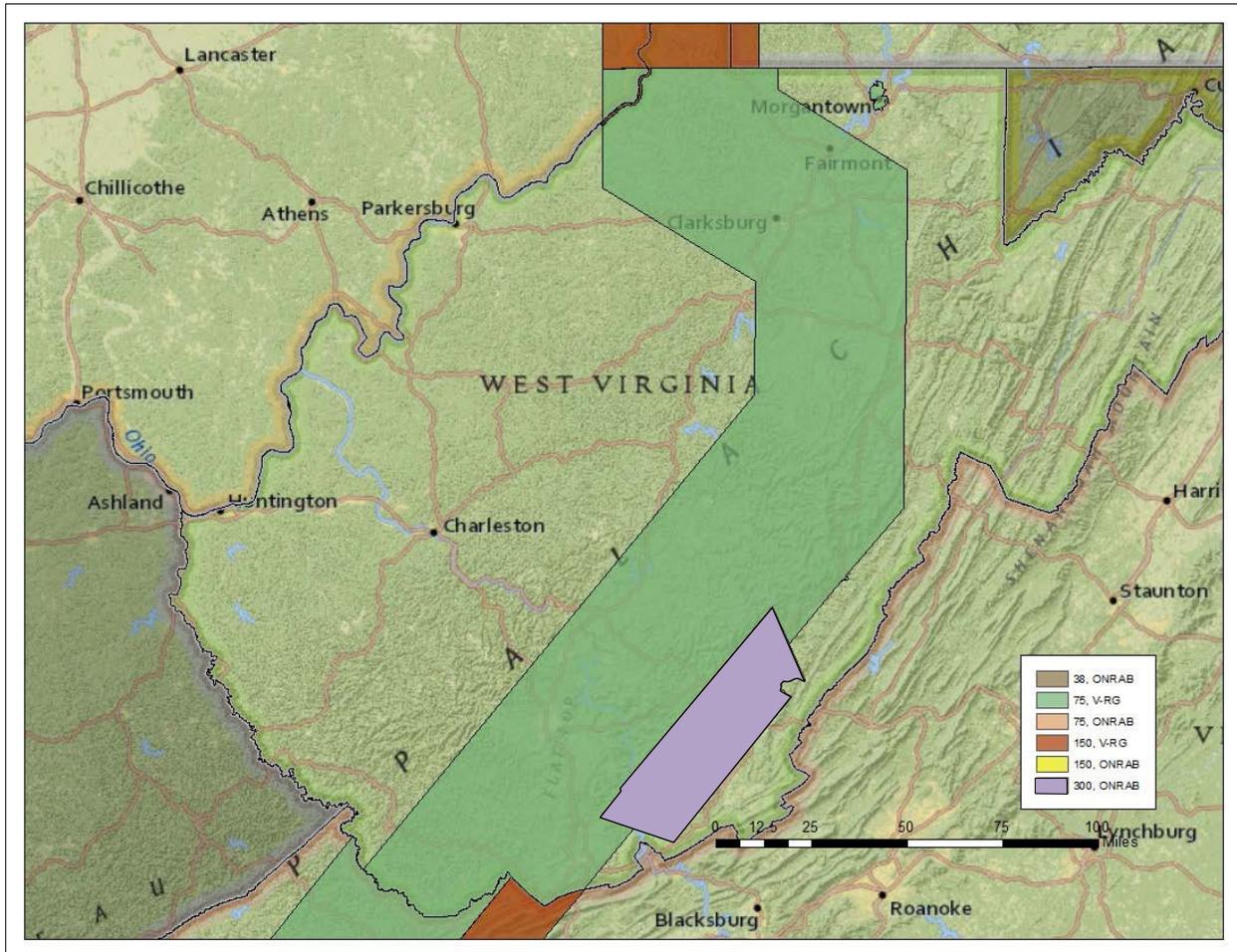


Additionally, APHIS-WS proposes to increase the ONRAB ORV bait distribution density from the program standard rate of 75 – 150 baits/km² (194-388 baits/mi²) to an increased density of 300 baits/km² (776 baits/mi²) over a portion of the current West Virginia field trial zone to test the effectiveness of different baiting densities in Greenbrier, Mercer, Monroe, Pocahontas, and Summers counties in West Virginia and to further study the immunogenicity of the vaccine in striped skunks (Figure 3). Due to the

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

sedentary nature and relatively small home range of striped skunks, it is suggestive that more vaccine baits are required per unit of baitable habitat so that each skunk will find at least one bait in its home range (Rosatte et al. 2011). Additionally, studies have found that increased bait densities (300 baits/km²) and narrower flight lines (250m) lead to greater bait acceptance and meaningful levels of immunity in striped skunks (Rosatte et al. 2009b and Rosatte et al. 2011).

Figure 3. Proposed ORV Zones and Bait Distribution Densities in West Virginia.



This area of the field trial zone was selected for increased bait distribution density for a number of reasons. This site has been used to evaluate ONRAB in raccoons at 75 baits/km² for the previous three years and is strategically at the center of the Appalachian Ridge ORV zone. Due to previous monitoring and surveillance efforts in this location, APHIS-WS has gained an improved knowledge of skunk distribution and catchability here which further supports the logistic feasibility of the proposed study. Additionally, APHIS-WS stands to gain additional immune response data in raccoons at the proposed 300 baits/km² bait distribution density after three years of study at 75 baits/km². Further supporting the selection of this area is a high level of local, county, and state support for the program along with a low density human population (USDC 2014) already familiar with the field trial.

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), the 2013 supplement (USDA 2013) 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.

Further, continuing the current ONRAB field trial would allow APHIS-WS to implement three key recommendations resulting from the initial 2011 ONRAB field trial (Slate 2014). 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, to 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), the 2013 supplement to the EA (USDA 2013), and this supplement evaluate ORV field trial activities in New Hampshire, New York, Ohio, Vermont, and West Virginia. The scope of this analysis remains valid as addressed in the EA [see Section 1.5 of the EA (USDA 2012)]. This supplement analyzes a proposal to shift the geographic boundary of the Ohio portion of the ONRAB field trial to include Ashtabula and Trumbull counties and to increase bait distribution densities in Greenbrier, Mercer, Monroe, Pocahontas, and Summers counties in West Virginia. This supplement to the EA analyzes these changes with regard to the proposed alternative to ensure continued implementation of the selected alternative would not adversely affect the human environment.

Actions Analyzed

The EA, the 2013 supplement to 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 shifting the geographic range of the field trial in Ohio and increasing bait distribution densities in West Virginia with regard to the proposed action.

Native American Lands and Tribes

As discussed in the EA, and the 2013 supplement to the EA, 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 analyses in this supplement indicate that an environmental impact statement (EIS) is not warranted, this EA, as supplemented, would remain valid until APHIS-WS determines that new needs for action, changed conditions, new issues, or new alternatives having different potential environmental impacts must be analyzed. 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 the National Environmental Policy Act (NEPA) and with the appropriate analyses.

Site Specificity

The EA, the 2013 supplement to 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) and in the 2013 supplement to the EA. This supplement analyzes potential environmental impacts from shifting the geographic range of the field trial in Ohio 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 will be made available for public review and comment through the publication of a notice of availability in the *Federal Register*, by posting on the WS stakeholder registry, 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, the 2013 supplement to the EA (USDA 2013), and this supplement.

In the 2012 Field Trial of an Experimental Rabies Vaccine, Human Adenovirus Type 5 Vector EA, APHIS-WS incorporated by reference relevant information from the 1997 EIS, including the 1992 USFWS Biological Opinion, Appendix F of the 1997 EIS; and information regarding acceptable harvest rates for raccoon populations. Further, Section 3.3 of the EA refers to additional discussion of APHIS-WS' SOPs which can be found in the 1997 EIS. APHIS-WS has determined that the field trial of the

experimental rabies vaccine is best assessed at the regional level in an EA. APHIS-WS' decisions and actions regarding the Field Trial of an Experimental Rabies Vaccine, Human Adenovirus Type 5 Vector, rely solely and exclusively on the decision document and record on the 2012 EA, the 2013 supplement, and this supplement. Therefore, the supplements to the 2012 EA will no longer incorporate by reference USDA 1997. The information contained in the USFWS 1992 Biological Opinion remains valid and will from here on be referred to as USWFS 1992. APHIS-WS has determined information regarding acceptable raccoon harvest rates is best supported by Sanderson 1987. All SOPs relevant to ORV field trials are adequately discussed and analyzed in the 2012 EA.

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 under this supplement 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 shift of APHIS-WS' ONRAB field trial in Ohio and increased bait distribution density in West Virginia:

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

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.

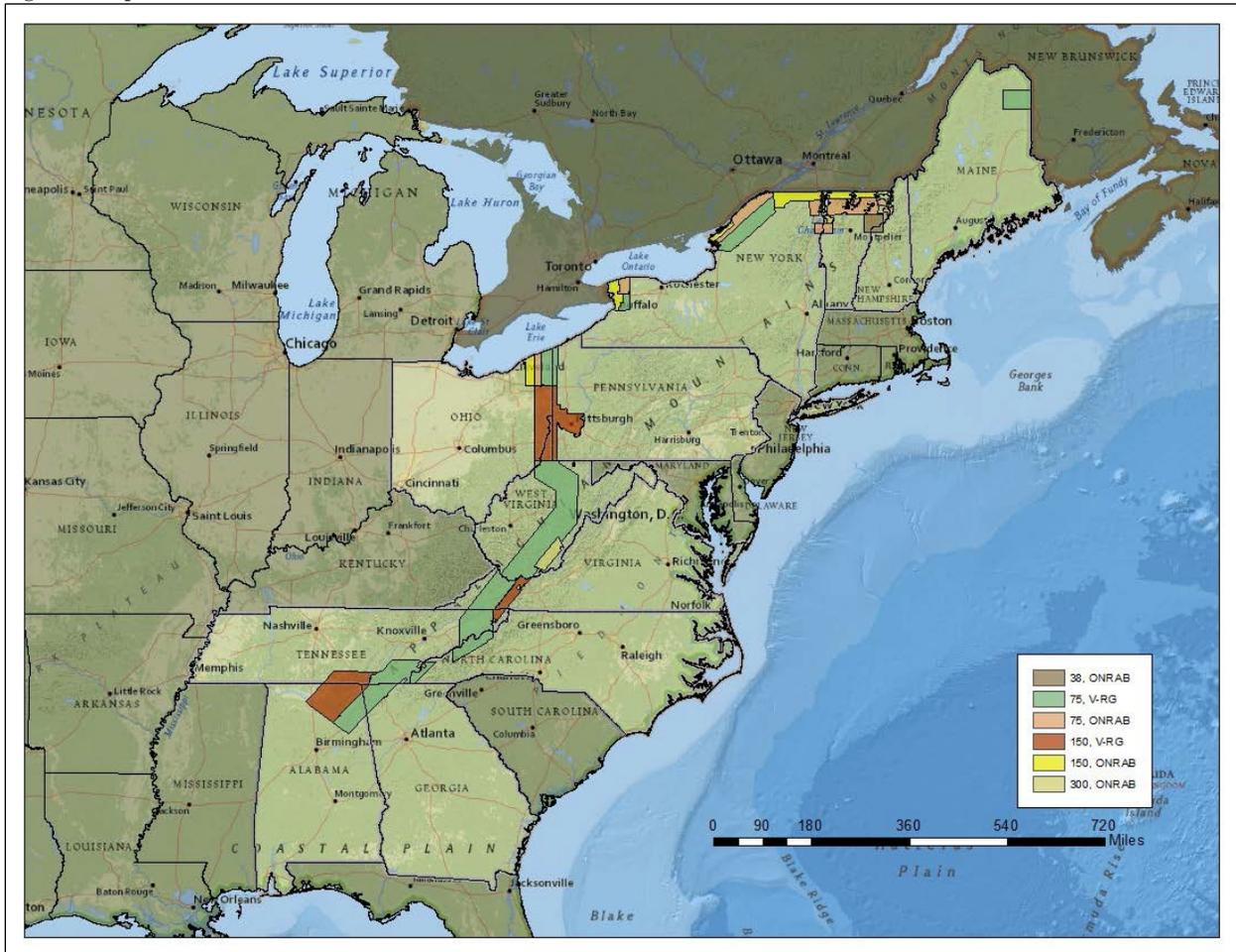
X. AFFECTED ENVIRONMENT

The affected environment was described in section 2.3 of the EA (USDA 2012). APHIS-WS is proposing to shift the geographic boundary of the field trial in Ohio. Currently, as analyzed in the EA (USDA 2012), the ONRAB field trial zone in Ohio includes Cuyahoga, Geauga, Lake, Portage, and Summit counties. APHIS-WS is proposing to shift the ONRAB field trial zone in Ohio to include the following counties: Ashtabula and Trumbull (see Figures 1 and 2). Additionally, APHIS-WS is proposing an increase in bait distribution densities in Greenbrier, Mercer, Monroe, Pocahontas, and Summers counties in West Virginia (see Figure 3).

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 4 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 4: Proposed ONRAB and V-RG distribution zones .



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)USDA 2012, as supplemented (USDA 2013).

Alternative 2. Proposed Action (the Preferred Alternative). This alternative would involve the use of federal funds to shift the geographic range of the ONRAB field trials, described in the EA (USDA 2012) and the 2013 supplement to the EA, to include Ashtabula and Trumbull counties in Ohio; and to increase ONRAB bait distribution density in Greenbrier, Mercer, Monroe, Pocahontas, and Summers counties in West Virginia, as proposed in this supplement. Under this alternative, APHIS-WS would use federal funds to purchase ONRAB oral vaccine-baits and to participate in ORV field trials involving the distribution of ONRAB oral vaccine-baits under the authorities of the appropriate state agencies in New Hampshire, New York, Ohio, Vermont, and West Virginia to evaluate the immunogenic and safety characteristics of the ONRAB vaccine for wildlife rabies under limited field conditions. Under this alternative, as described in the 2012 EA, the 2013 supplement to the EA, and this supplement, APHIS-WS would also assist in monitoring and surveillance efforts by capturing and releasing or killing target species for purposes of obtaining biological samples.

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

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 (USDA 2012)]. APHIS-WS has reviewed the alternatives not analyzed in detail in the EA and has determined that the analysis provided in the EA has not changed and is still appropriate with regard to APHIS-WS' proposed geographic shift of the ONRAB field trial into Ashtabula and Trumbull counties in Ohio and the proposed increased bait distribution density in Greenbrier, Mercer, Monroe, Pocahontas, and Summers counties in West Virginia, as analyzed in this supplement to the EA.

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 (USDA 2012)] remain appropriate for APHIS-WS' ONRAB field trial, including the proposed shift into Ashtabula and Trumbull counties in Ohio and the proposed increased bait distribution density in Greenbrier, Mercer, Monroe, Pocahontas, and Summers counties in West Virginia, as analyzed in this supplement.

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 two additional counties (Ashtabula and Trumbull) within the Ohio portion of the proposed ONRAB field trial zone and an increase in ONRAB bait distribution density in Greenbrier, Mercer, Monroe, Pocahontas, and Summers counties in West Virginia:

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 2014).

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/km² 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 2014).

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).

As discussed in the EA, 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/km²) (Rosatte 2009). As discussed in the 2013 supplement to the EA, 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.

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. Shifting the geographic area of ONRAB field trials into Ashtabula and Trumbull counties in Ohio will continue to result in negligible adverse risks to target species populations with regard to monitoring and surveillance activities. APHIS-WS and cooperating state and local agencies continue to expect to humanely kill less than 1% of the lowest number of raccoons in all ORV program states, including any raccoons that may be humanely killed for critical samples during ONRAB field trials. 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, 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, 2003) indicates that the potential for cumulative impacts to raccoon populations continues to be negligible. Additionally, based on the conservative state-wide striped skunk (*Mephitis mephitis*) 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 field trial proposed in the EA and updated in the 2013 supplement and this supplement, 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.

As discussed in the EA and the 2013 supplement to the EA, 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), the 2013 supplement to the EA, 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 (*Vulpes vulpes*), 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 (*Glaucomys 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 shift of field trial activities in Ohio.

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

Further, based on the analysis in USDA 2012 and above, the proposed increase in bait density in specific counties in the West Virginia portion of the field trial is not expected to result in any adverse effects to target species. Additionally, monitoring and surveillance activities in this area will not differ or increase in intensity from those analyzed in the EA (USDA 2012) and Supplement (USDA 2013), therefore effects on target species will remain within the impact parameters established in the EA and Supplement.

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).

As described in the 2013 supplement to the EA, 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 Ohio, would have no significant adverse effects on nontarget species. Nontarget animals captured in cage traps would normally be released unharmed unless the animal appeared injured or sick. Therefore, monitoring and surveillance should have no effect on nontarget species populations. 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 Ohio counties (Ashtabula and Trumbull). No new listings or presence of T&E species in the expanded Ohio 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 (USDA 2012)] 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 geographic shift of ONRAB field trials will not result in adverse effects to nontarget species, including T&E species, in the additional counties (Ashtabula and Trumbull) in Ohio 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.

Based on the analysis in USDA 2012, the 2013 supplement to the EA, and above, the proposed increase in bait density in specific counties in the West Virginia portion of the field trial is not expected to result in any adverse effects to nontarget species. Additionally, monitoring and surveillance activities in this area will not differ or increase in intensity from those analyzed in the EA (USDA 2012) and Supplement (USDA 2013), therefore effects on nontarget species will remain within the impact parameters established in the EA and Supplement.

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

As described in the EA and the 2013 supplement to the EA, 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).

It is unlikely that there will be any significant increase in the number of humans who may be exposed to ONRAB vaccine-baits due to the proposed changes to the field trial as described in this supplement. While the estimated total area to be baited with ONRAB could increase slightly with the addition of the proposed Ohio counties, the total number of ONRAB baits to be distributed is expected to be slightly less in Ohio in 2015 and beyond than it has been in previous years due to the projected bait distribution densities for those areas. It is unlikely that the effects will vary significantly from those analyzed in section 4.1.3 of the EA. As described below, the effects of Ad5 on people, pets, and livestock will remain unchanged with APHIS-WS' proposed field trial shift into the Ohio counties of Ashtabula and Trumbull and proposed increased bait distribution density in Greenbrier, Mercer, Monroe, Pocahontas, and Summers counties in West Virginia.

Bait exposures² 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. The CDC (2013) reported that following the distribution of 272,034 ONRAB and 504,887 V-RG baits over an area of 11,341 km² in Ohio during 2012 (the first year ONRAB was distributed in Ohio), 89 baits were reported to have been found (Table 1). 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 contacts² with ONRAB baits versus 41 human contacts resulting from the V-RG baits distributed in Ohio (Table 2). 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. In 2013 and 2014 bait contact continued to remain low, with approximately 2 contacts per 100,000 bait distributed for both ONRAB and V-RG vaccine-baits.

Table 1. Human Contacts with ORV baits in Ohio, 2010-2014 (CDC 2013, USDA unpublished data).

Year/Bait Type	# Bait Contacts	# Baits Distributed	# Bait Contacts/100,000 Baits Distributed
2010 V-RG	83	774,714	11
2011 V-RG	83	863,215	10
2012 ONRAB	14	272,034	5
2012 V-RG	41	504,887	8
2013 ONRAB	6	269,100	2
2013 V-RG	11	511,705	2
2014 ONRAB	5	224,550	2
2014 V-RG	11	507,569	2

Of the 765,684 ONRAB baits distributed in Ohio from 2012 through 2014, there were a total of 25 bait contacts resulting in 15 vaccine exposures³. Comparably, 1,5224,161 V-RG baits were distributed during

² “Bait 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. A contact may involve one or more baits.

³ Vaccine exposures involve baits that were not intact and a barrier (e.g., gloves) were not used to handle the bait, leaving the person at risk for vaccine exposure and vaccine virus infection).

the same time period resulting in 63 human contact and 30 human exposures to vaccine (Tables 1 and 2). However, no adverse events were reported.

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, 2010-2014 (CDC 2013, USDA unpublished data).

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 ONRAB	14	11	(79)
2012 V-RG	41	16	(39)
2013 ONRAB	6	2	(33)
2013 V-RG	11	8	(72)
2014 ONRAB	5	2	(40)
2014 V-RG	11	6	(55)

Ohio historically has experienced higher than average bait contacts compared to other ORV states. 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.

Table 3. Human Contacts with ORV baits in West Virginia, 2010-2014 (USDA unpublished data).

Year/Bait Type	# Bait Contacts	# Baits Distributed	# Bait Contacts/100,000 Baits Distributed
2010 V-RG	29	1,115,993	3
2011 V-RG	23	1,019,156	2
2011 ONRAB	0	79,027	0
2012 V-RG	35	1,032,457	3
2012 ONRAB	2	132,678	2
2013 V-RG	10	1,021,017	1
2013 ONRAB	1	132,000	1
2013 Unknown⁴	8	N/A	N/A
2014 V-RG	9	1,109,284	1
2014 ONRAB	3	418,500	1
2014 Unknown⁴	4	N/A	N/A

It is highly unlikely that the effects of increased ONRAB bait distribution in the identified WV counties will vary from those analyzed in the EA and Supplement. The WV field trial zone and the area specifically identified for the increase in bait density has a relatively low human population density, ranging from 9.3 people/mi² – 148.6 people/mi² within the affected counties (USDC 2014). Further, following the initial 2011 field trial, which occurred in WV only, there were zero reports of humans finding or contacting ONRAB baits (USDA 2014). Following the expanded field trials there were 2 documented reports in 2012, 1 report in 2013, and 3 reports in 2014 (Table 3) of humans finding or contacting ONRAB baits in WV (USDA unpublished data). These equate to 2 or fewer bait contacts per 100,000 ONRAB baits distributed (Table 3). There was one reported potential human contact with ONRAB vaccine in 2014 (Table 4).

⁴ Bait type not reported or unknown.

Table 4. 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 – West Virginia, 2010-2014 (USDA unpublished data).

Year/Bait Type	No. of Human Contacts	No. of Contacts with Potential Vaccine Exposure	(% of Contacts Resulting in Potential Exposure)
2010 V-RG	29	8	(28)
2011 V-RG	23	1	(4)
2011 ONRAB	0	0	(0)
2012 V-RG	35	7	(20)
2012 ONRAB	2	0	(0)
2013 V-RG	10	3	(30)
2013 ONRAB	1	0	(0)
2013 Unknown⁴	8	0	(0)
2014 V-RG	9	2	(22)
2014 ONRAB	3	1	(33)
2014 Unknown⁴	4	2	(50)

These minimal numbers of reports, along with the relatively low number of contacts in Ohio and West Virginia during the ONRAB field trial (2011-2014) 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).

Table 5. Domestic Animal ORV Bait Contacts in Ohio, 2010 – 2014 (USDA unpublished data).

Year/Bait Type	# Pet-Bait Contacts	# Baits Distributed
2010 V-RG	74	774,714
2011 V-RG	69	863,215
2012 ONRAB & V-RG	38 ⁵	776,921
2013 ONRAB	4	269,100
2013 V-RG	13	511,705
2014 ONRAB	2	224,550
2014 V-RG	11	507,569

Pet exposures following ONRAB distribution in West Virginia have remained low during the field trial. Similar to V-RG, any reports of adverse reactions in pets have been limited to vomiting and/or diarrhea.

⁵ Bait type not differentiated in 2012.

In 2014, a caller reported finding an unknown number of V-RG baits on their property and, at some point subsequent to this, the caller’s dog died. The caller did not report seeing the dog consume baits, however caller was seeking reimbursement for the pet. The caller was referred to the USDA-APHIS-Financial Management Division; however no claim was filed by caller.

Table 6. Domestic Animal ORV Bait Contacts in West Virginia, 2010 – 2014 (USDA unpublished data).

Year/Bait Type	# Pet-Bait Contacts	# Baits Distributed
2010 V-RG	20	1,115,993
2011 V-RG	10	1,019,156
2011 ONRAB	0	79,027
2012 V-RG	11	1,032,457
2012 ONRAB	0	132,678
2013 V-RG	4	1,021,017
2013 ONRAB	1	132,000
2013 Unknown⁴	1	N/A
2014 V-RG	5	1,109,284
2014 ONRAB	2	418,500
2014 Unknown⁴	3	N/A

Pet-vaccine exposures remained low following 2010 through 2014 ORV field seasons (Tables 5 and 6). Domestic animal contacts with baits are typically low 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.

No new or additional impacts to human health and safety are expected beyond those analyzed in the EA and Supplement (USDA 2012, 2013). Hazards to public safety are not expected.

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.

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

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

As discussed in section 4.1.5 of the EA (USDA 2012), under the proposed program baits will be distributed at common densities of 75 baits/km² (194 baits/mi²) or 150 baits/km² (388 baits/mi²). Additionally, APHIS-WS is proposing to increase bait density in Greenbrier, Mercer, Monroe, Pocahontas, and Summers counties of the West Virginia portion of the field trial to 300 baits/km² (776 baits/mi²). These densities, including the increased densities in some counties in West Virginia, are sparse enough to predict that the chance of a person being struck and harmed by falling bait is remote. The negligible risk of being struck is further supported by the fact that out of more than 150 million baits distributed in the U.S. by APHIS-WS during other ORV programs between 1995 and 2014, only 11 incidents have been reported in which a person claimed to have been struck by a falling bait (0.000007% chance of being struck by a bait or 1 strike per 13.6 million baits dropped) (USDA unpublished). Additionally, the West Virginia portion of the field trial proposed for increased bait distribution density is an area of relatively sparse human population (USDC) and where there is significant local support and familiarity with the field trial. 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 new geographic area in the Ohio state portion of the field trial zone and increase baiting density in portions of the West Virginia field trial zone, the analysis in the EA (USDA 2012) as well as the EA for APHIS-WS' current V-RG ORV program (USDA 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) and in the 2013 supplement to the EA, 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 with regard to the changes proposed in this supplement. 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, 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, or increasing the baiting density, 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 2010, 2012, 2013) 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), USDA (2012), and USDA (2013), 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.

XVI. 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
DPI	Days Post-Innoculation
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
WS Wildlife Services
V-RG Vaccinia-Rabies Glycoprotein
USFWS United States Fish and Wildlife Service

XVII. LITERATURE CITED

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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 May 2015. Listed species based on historic range and population data. There may be other federally listed species that are not currently known or expected to occur in these states but are covered by the ESA wherever they are found; thus if new surveys detect them in these states they are still covered by the ESA.

New Hampshire – 12 listings

Animals – 9

Status	Listing
T	Bat, Northern long-eared (<i>Myotis septentrionalis</i>)
E	Butterfly, Karner blue (<i>Lycaeides melissa samuelis</i>)
T	Plover, piping except Great Lakes watershed (<i>Charadrius melodus</i>)
T	Sea turtle, green Except where endangered (<i>Chelonia mydas</i>)
T	Sea turtle, hawksbill Entire (<i>Eretmochelys imbricate</i>)
E	Sea turtle, leatherback (<i>Dermochelys coriaca</i>)
E	Tern, roseate northeast U.S. nesting pop. (<i>Sterna dougalli dougalli</i>)
E	Wedgemussel, dwarf (<i>Alasmidonta heterodon</i>)
E	Whale, finback (<i>Balaenoptera physalus</i>)

Plants – 3

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

New York – 28 Listings

Animals – 20

Status	Listing
E	Bat, Indiana (<i>Myotis sodalis</i>)
T	Bat, Northern long-eared (<i>Myotis septentrionalis</i>)
E	Bean, rayed (<i>Villosa fabalis</i>)
E	Butterfly, Karner blue (<i>Lycaeides melissa samuelis</i>)
E	Clubshell Entire Range; except where listed as Experimental Populations (<i>Pleurobema clava</i>)
T	Knot, red (<i>Calidris canutus rufa</i>)
T	Plover, piping except Great Lakes watershed (<i>Charadrius melodus</i>)
E	Plover, piping Great Lakes watershed (<i>Charadrius melodus</i>)

T	Sea turtle, green except where endangered (<i>Chelonia mydas</i>)
E	Sea turtle, hawksbill (<i>Eretmochelys imbricate</i>)
E	Sea turtle, Kemp's ridley (<i>Lepidochelys coriacea</i>)
E	Sea turtle, leatherback (<i>Dermochelys coriacea</i>)
T	Snail, Chittenango ovate amber (<i>Succinea chittenangoensis</i>)
E	Sturgeon, shortnose (<i>Acipenser brevirostrum</i>)
E	Tern, roseate northeast U.S. nesting pop. (<i>Sterna dougallii dougallii</i>)
T	Turtle, bog (=Muhlenberg) northern (<i>Clemmys muhlenbergii</i>)
E	Wedgemussel, dwarf (<i>Alasmidonta heterodon</i>)
E	Whale, finback (<i>balaenoptera physalus</i>)
E	Whale, humpback (<i>Megaptera novaengliae</i>)
E	Whale, North Atlantic Right (<i>Eubalaena glacialis</i>)

Plants – 8

Status	Listing
T	Amaranth, seabeach (<i>Amaranthus pumilus</i>)
E	Bulrush, Northeastern (<i>Scirpus ancistrochaetus</i>)
T	Fern, American hart's tongue (<i>Asplenium scolopendrium</i> var.)
E	Gerardia sandplain (<i>Agalinis acuta</i>)
T	Goldenrod, Houghton's (<i>Solidago houghtonii</i>)
T	Monkshood, northern wild (<i>Aconitum noveboracense</i>)
T	Pogonia, small whorled (<i>Isotria medeoloides</i>)
T	roseroot, Leddy's (<i>Rhodiola integrifolia</i> ssp. leedyi)

Ohio – 25 listings

Animals – 19

Status	Listing
E	Bat, Indiana (<i>Myotis sodalis</i>)
T	Bat, Northern long-eared (<i>Myotis septentrionalis</i>)
E	Bean, rayed (<i>Villosa fabalis</i>)
E	Beetle, American burying (<i>Nicrophorus americanus</i>)
E	Butterfly, Karner blue (<i>Lycaeides melissa samuelis</i>)
E	Butterfly, Mitchel's satyr (<i>Neonympha mitchellii mitchellii</i>)
E	Catspaw, white (pearlymussel) (<i>Epioblasma obliquata perobliqua</i>)
E	Clubshell Entire Range; except where listed as Experimental Populations (<i>Pleurobema clava</i>)
E	Fanshell (<i>Cyprogenia stegaria</i>)
T	Knot, red (<i>Calidris canutus rufa</i>)
E	Madtom, Scioto (<i>Noturus trautmani</i>)
E	Mucket, pink (pearlymussel) (<i>Lampsilis abrupta</i>)
E	Mussel, scaleshell (<i>Leptodea leptodon</i>)
E	Mussel, sheepnose (<i>Plethobasus cyphus</i>)
E	Mussel, snuffbox (<i>Epioblasma triquetra</i>)
E	Plover, piping Great Lakes watershed (<i>Charadrius melodus</i>)
E	Purple, Cat's paw (= Purple Cat's paw pearlymussel) Entire Range; Except where listed as Experimental Populations (<i>Epioblasma obliquata obliquata</i>)

E	Rabbitsfoot (<i>Quadrula cylindrica cylindrical</i>)
E	Riffleshell, northern (<i>Epioblasma torulosa rangiana</i>)
T	Snake, copperbelly water Indiana north of 40 degrees north latitude, Michigan, Ohio (<i>Nerodia erythrogaster neglecta</i>)

Plants – 6

Status	Listing
E	Clover, running buffalo (<i>Trifolium stoloniferum</i>)
T	Daisy, lakeside (<i>Hymenoxys herbacea</i>)
T	Monkshood, northern wild (<i>Aconitum noveboracense</i>)
T	Orchid, eastern prairie fringed (<i>Platanthera leucophaea</i>)
T	Pogonia, small whorled (<i>Isotria medeoloides</i>)
T	Spirea, Virginia (<i>Spirea virginiana</i>)

Vermont – 5 Listings

Animals – 3

Status	Listing
E	Bat, Indiana (<i>Myotis sodalis</i>)
T	Bat, Northern long-eared (<i>Myotis septentrionalis</i>)
E	Wedgemussel, dwarf (<i>Alasmidinta heterodon</i>)

Plants – 2

Status	Listing
E	Bulrush, Northeastern (<i>Scirpus ancistrochaetus</i>)
E	Milk-vetch, Jesop's (<i>Astragalus robbinsii</i> var. <i>jesupi</i>)

West Virginia – 24 listings

Animals – 18

Status	Listing
E	Bat, Indiana (<i>Myotis sodalis</i>)
E	Bat, gray (<i>Myotis grisescens</i>)
T	Bat, Northern long-eared (<i>Myotis septentrionalis</i>)
E	Bat, Virginia big-eared (<i>Plecotus townsendii virginianus</i>)
E	Blossum, tubercled (pearlymussel) Entire Range; Except where listed as Experimental Populations (<i>Epioblasma torulosa torulosa</i>)
E	Clubshell Entire Range; except where listed as Experimental Populations (<i>Pleurobema clava</i>)
E	Darter, diamond (<i>Crystallaria cincotta</i>)
E	Fanshell (<i>Cyprogenia stegaria</i>)
T	Isopod, Madison cave Entire (<i>Antrolana lira</i>)

T	Knot, red (<i>Calidris canutus rufa</i>)
E	Mucket, pink (pearlymussel) (<i>Lampsilis abrupta</i>)
E	Mussel, sheepnose (<i>Plethobasus cyphus</i>)
E	Mussel, snuffbox (<i>Epioblasma triquetra</i>)
E	Riffleshell, northern (<i>Epioblasma torulosa rangiana</i>)
T	Salamander, Cheat Mountain (Plethodon netting)
T	Snail, flat-spined three-toothed (<i>Triodopsis platysayoides</i>)
E	Spectaclecase (mussel) (<i>Cumberlandia monodonta</i>)
E	Spinymussel, James (<i>Pleurobema collina</i>)

Plants – 6

Status	Listing
E	Bulrush, Northeastern (<i>Scirpus ancistrochaetus</i>)
E	Clover, running buffalo (<i>Trifolium stoloniferum</i>)
E	Harperella (<i>Ptilimnium nodosum</i>)
T	Pogonia, small whorled (<i>Isotria medeoloides</i>)
E	Rock-cress, shale barren (<i>Arabis serotina</i>)
T	Spirea, Virginia (<i>Spirea virginiana</i>)

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 May 2015.							
State	Mammals	Birds	Reptiles	Amphibians	Fish	Invertebrates	Plants
New Hampshire	2E, 1T, 7SC Canada lynx, American marten, New England Cottontail	11E, 7T, 12SC	1E, 1T, 4SC	1E, 3SC	2 E	6E, 3T	317E, 80T
New York	1E, 1T, 3SC Canada lynx, New England cottontail,	7E, 10T, 19SC	3E, 3T, 6SC	2E, 7SC	7E, 11T, 5SC	11E, 8T, 18SC	331E, 135T, 11R
Ohio	2E, 1T, 19SC, 1SI Snowshoe hare, American black bear, ermine, American badger	11E, 5T, 14 SC, 33SI	4E, 4T, 11SC	5E, 1T, 2SC	19E, 13T, 9SC	53E, 29T, 48SC, 12SI	253E, 162T, 113P
Vermont	4E, 1T, 3SC American marten	10E, 2T, 32SC	3E, 3T, 4SC	2E, 4SC	4E, 2T, 10SC	9E, 14T, 7SC	66E, 94T
West Virginia	6S1, 10S2, 3S3 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= 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 2013b)

Federally Listed Species

Gray wolf	<i>Canis lupus</i>	Considered Extirpated
Eastern cougar	<i>Puma concolor cougar</i>	Considered Extirpated
Virginia big-eared bat	<i>Corynorhinus townsendii virginianus</i>	Endangered
Indiana bat	<i>Myotis sodalist</i>	Endangered
Cheat Mountain salamander	<i>Plethodon netting</i>	Threatened

Regional Forester Sensitive Species

Mammals

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

Birds

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

Reptiles and Amphibians

Wood turtle	<i>Glyptemys insculpta</i>
Timber rattlesnake	<i>Crotalus horridus</i>
Green salamander	<i>Aneides aeneus</i>
Eastern hellbender	<i>Cryptobrachus alleghaniensis</i>

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

Phenacobius teretulus

Elktoe

Alasmodonta 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	<i>Macrocotyla hoffmasteri</i>
A cave obligate planarian	<i>Phagocata angusta</i>
Greenbrier Valley cave millipede	<i>Pseudotremia fulgida</i>
Germany Valley cave millipede	<i>Pseudotremia lusciosa</i>
South Branch Valley cave millipede	<i>Pseudotremia princeps</i>
Culver's planarium	<i>Sphalloplana culveri</i>
Grand Caverns blind cave millipede	<i>Trichopetalum weyeriense</i>
Luray Caverns blind cave millipede	<i>Trichopetalum whitei</i>
WV blind cave millipede	<i>Trichopetalum krekeleri</i>

APPENDIX D

ONRAB FIELD TRIAL STUDY PROTOCOLS

Outline for Proposed ONRAB Oral Rabies Vaccine Field Trial in Northern New Hampshire, New York and Northern Vermont in 2015

PRIMARY GOALS: Determine if ground distribution of ONRAB at 150 baits/km² in urban/suburban habitats with varying levels of human development will result in significantly higher sero-prevalence (Burlington, Vermont area). Determine if aerial distribution of ONRAB at 37.5 baits/km² in a rural, forested area of eastern Vermont with low raccoon densities will still result in adequate sero-prevalence. Determine if ONRAB baiting at 75 baits/km² during a third consecutive year of a field trial in St. Lawrence County, New York will result in significantly higher sero-prevalence.

1) SITE LOCATION (Figure 1)

- States: New Hampshire, New York and Vermont
- Counties:
 - New Hampshire: Coos, Grafton
 - New York: Clinton, Essex, Franklin, Jefferson, St. Lawrence
 - Vermont: Addison, Caledonia, Chittenden, Essex, Franklin, Grand Isle, Lamoille, Orleans, Washington
- Towns with some ground baiting:
 - New Hampshire: Colebrook, Littleton
 - New York: Alexandria Bay, Brasher Falls-Winthrop, Canton, Cape Vincent, Clayton, Malone, Massena, Norwood, Ogdensburg, Plattsburgh, Potsdam, Rouses Point
 - Vermont: Burlington, Colchester, Essex, Milton, Newport City, South Burlington, St. Albans City, St. Johnsbury, Swanton, Williston, Winooski

2) RATIONALE FOR FIELD TRIAL SITE SELECTION

- North American Rabies Management Plan collaboration in high risk corridors for raccoon rabies to spread from the U.S. back into Quebec and Ontario
- Selection of the Burlington, VT area was based partially on the need for improved oral rabies vaccination (ORV) performance and the ability to evaluate high density (150 baits/km²) ground baiting, a commonly used ORV tactic in urban/suburban settings
- Selection of the eastern VT area was based on 3 years of relatively high sero-prevalence (>70%) in the area and the need to evaluate a low density (37.5 baits/km²) baiting in a rural, forested area with low raccoon densities to determine if adequate sero-prevalence can still be achieved
- Raccoons and skunks present in both areas
- Raccoon rabies present in the U.S. but only 1 case in Quebec since July 2009 and none 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: 14,948 km² including 382 km² ground baiting

- 12 - 1 km² cells (1 x 1 km) in the Burlington, VT area (150 baits/km²) for pre- and post-ORV sampling; cells randomly selected based on high, medium and low levels of human development in a ground baited urban/suburban zone (Figure 2)
- 2 buffered 133 km² cells (11.5 x 11.5 km) in eastern VT (37.5 baits/km²) for pre- and post-ORV sampling
- 2 buffered 128 km² cells (11.3 x 11.3 km) in St. Lawrence County, NY (75 baits/km²) for pre- and post-ORV sampling

4) BAITING CHARACTERISTICS

- Total ONRAB baits: 1,018,443 (984,889 fixed wing and 33,554 ground)
- ONRAB bait density: 150 baits/km² in the Burlington, VT study area; 37.5 baits/km² in the eastern VT study area; 75 baits/km² in the St. Lawrence County study area
- Flight line spacing: 375 m for 150 baits/km² and 750 m for 37.5 and 75 baits/km²
- Overall Off-time: 32% average for fixed wing and 30% average for ground using NLCD to determine “baitable” habitat
- Approximately 105 ONRAB baits in each 1 km² Burlington sampling cell; approximately 3,545 ONRAB baits in each 133 km² eastern VT sampling cell; approximately 6,795 ONRAB baits in each 128 km² St. Lawrence County sampling cell
- Projected baiting dates: August 11-19, 2015
- Baiting duration: 4.5 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% [CCID₅₀]/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 at least 2007 for the entire ONRAB zone (longer in some of the study areas) and should continue throughout the zone
- In July 2015 in the Burlington, VT study area: 25 cage traps (10”x12”x32”) will be tended for 10 consecutive days within each of the 12 sampling cells; traps will be deployed based on past trapping trends to ensure adequate property access in this highly residential and commercial landscape
- In July 2015 in the eastern VT and St. Lawrence NY study areas: 150 cage traps (10”x12”x32”) will be tended for 10 consecutive days within each of the 4 sampling cells; 6 traps will be deployed within half a mile (800 meters) of 25 predetermined random trapping locations within each cell
- Target of ≥20 raccoons per cell in the Burlington area and ≥100 raccoons per cell in the eastern VT and St. Lawrence NY areas based on previous trapping efforts

- For raccoons and skunks: collect pertinent biological, physical and spatial-temporal data; sera for rabies serological analysis (at least 3 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
- Conduct opportunistic sampling of additional target and nontarget species (e.g., roadkills or live animals) that display abnormal behavior or have lesions that should be submitted for rabies testing (blood, teeth, brainstem samples when possible)
- Use various media outlets to advise the public of when and where baiting will occur and the precautions to be followed to reduce the chance of vaccine exposure

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

- Continue enhanced rabies surveillance throughout the ONRAB zone
- Continue opportunistic sampling of target and nontarget species (e.g., roadkills, hunter harvest) that display abnormal behavior or have lesions that should be submitted for rabies testing (blood, teeth, brainstem samples when possible)
- 6 weeks post-ONRAB distribution begin evaluation in the Burlington, VT and eastern VT study areas using the same trapping protocol as pre-ORV sampling (see above)
- 5 weeks post-ONRAB distribution begin evaluation in the St. Lawrence NY study area using the same trapping protocol as pre-ORV sampling (see above)
- Use acceptable procedures developed cooperatively 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 Wadsworth Laboratory, New York State Department of Health, Albany, NY
- Specific age determination and biomarker detection by Matson's Laboratory, Missoula, MT

9) REPORT FINDINGS

- Expect results from analysis of field data by April 2016
- Draft report by June 2016

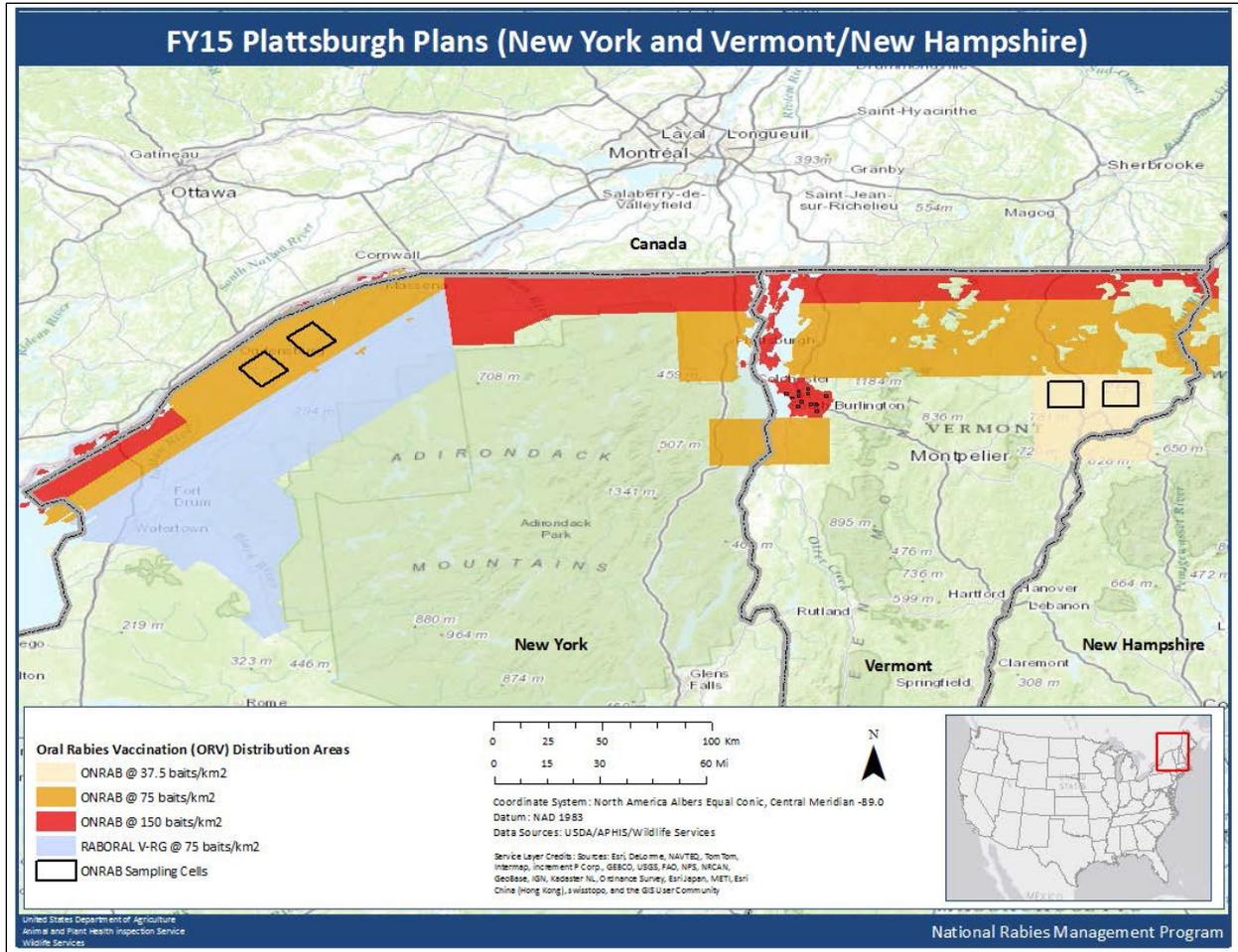


Figure 1. Baiting plan for ONRAB field trials targeting raccoons at 37.5, 75 and 150 baits/km² in New Hampshire, New York and Vermont, 2015.

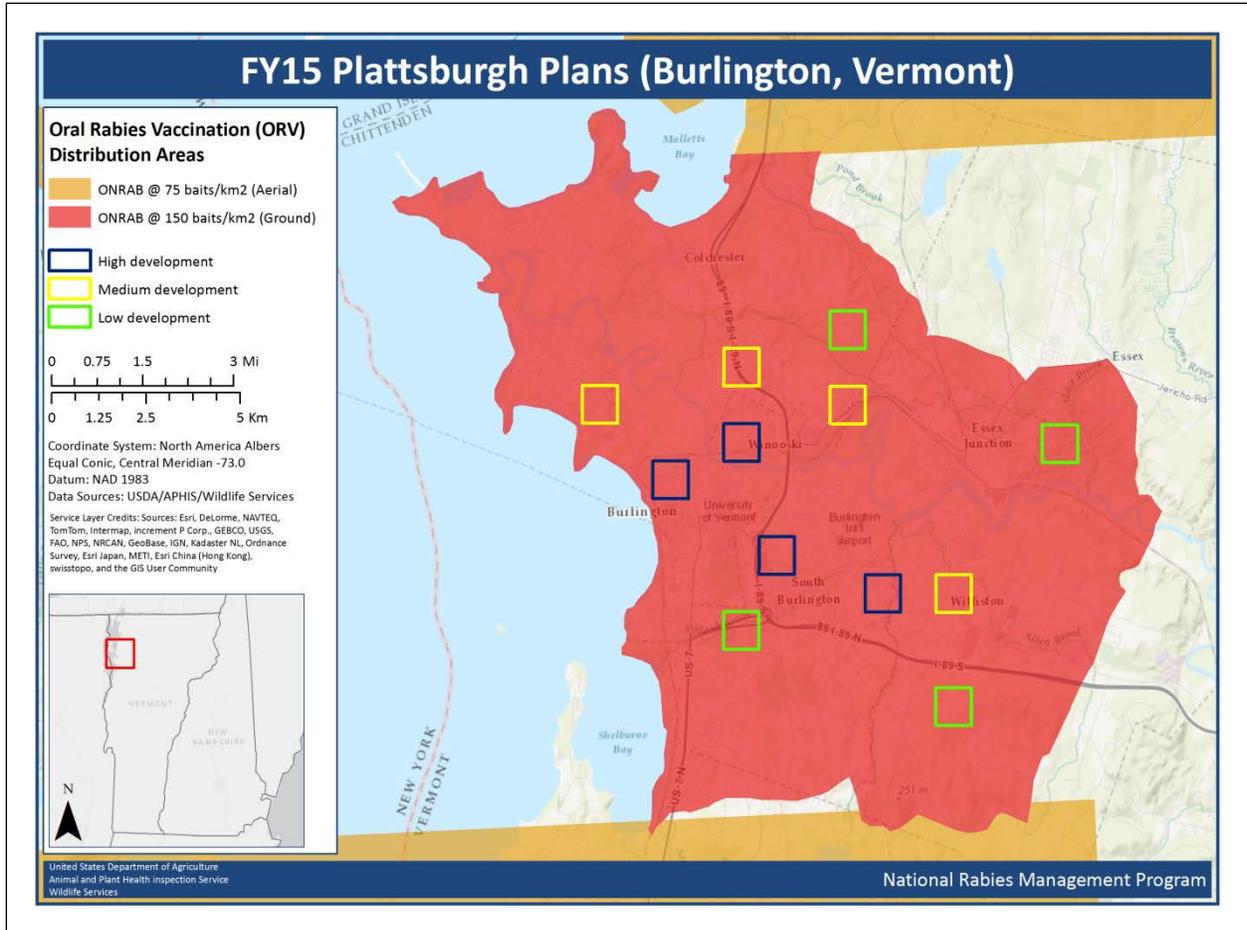


Figure 2. Baiting plan for ONRAB field trial targeting raccoons at 150 baits/km² in the Burlington, Vermont area, 2015.

Outline for Proposed ONRAB Oral Rabies Vaccine Field Trial in Western New York in 2015 – Cornell University, Ithaca, NY

PRIMARY GOALS: To determine if a third year replicate of ONRAB at a target density of 75 baits/km² 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/km².

1) SITE LOCATION (Figure 1)

- State: New York
- Counties: Erie, Niagara
- 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 non-target (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
- Two ONRAB trials already conducted (2013-2014)
- Cornell infrastructure in place
- State funding provided for ONRAB 2015 trial
- Ontario funding for ONRAB 2015 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: 2,691 km² including 128 km² of ground baiting
- Two trapping cells in 75 baits/km² area: one cell is 176 km² and the other is 184 km²

4) BAITING CHARACTERISTICS

- Total ONRAB baits: 168,013 (95,690 fixed wing, 61,984 helicopter and 10,339 ground)
- ONRAB bait density: 75 and 150 baits/km²
- Flight line spacing: 750 m for 75 baits/km² and 375 m for 150 baits/km²

- Overall Off-time: 33% average for fixed wing, 50% average for helicopter and 49% average for ground using NLCD to determine “baitable” habitat
- Approximately 9,093 ONRAB baits in the 176 km² trap cell and 17,950 ONRAB baits in the 184 km² trap cell
- Projected baiting dates: August 18-21, 2015
- Baiting duration: 1.5 days for aerial operations, 2 weeks for ground distribution including bait stations

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% [TCID₅₀]/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: 2
- 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 2016
- Draft report by May 2016

Table 1. Percent seroconversion summary (V-RG) for Western NY

14 Years:	Serological Cutoff	
	0.125 IU/ml	0.5 IU/ml
Mean	24.2	12.7
Std Error	2.5	1.9
Std Dev	9.4	6.9
Min	11.1	4.3
Max	40.6	25.5
Range	29.5	21.2
95% CI	5.4	4.2

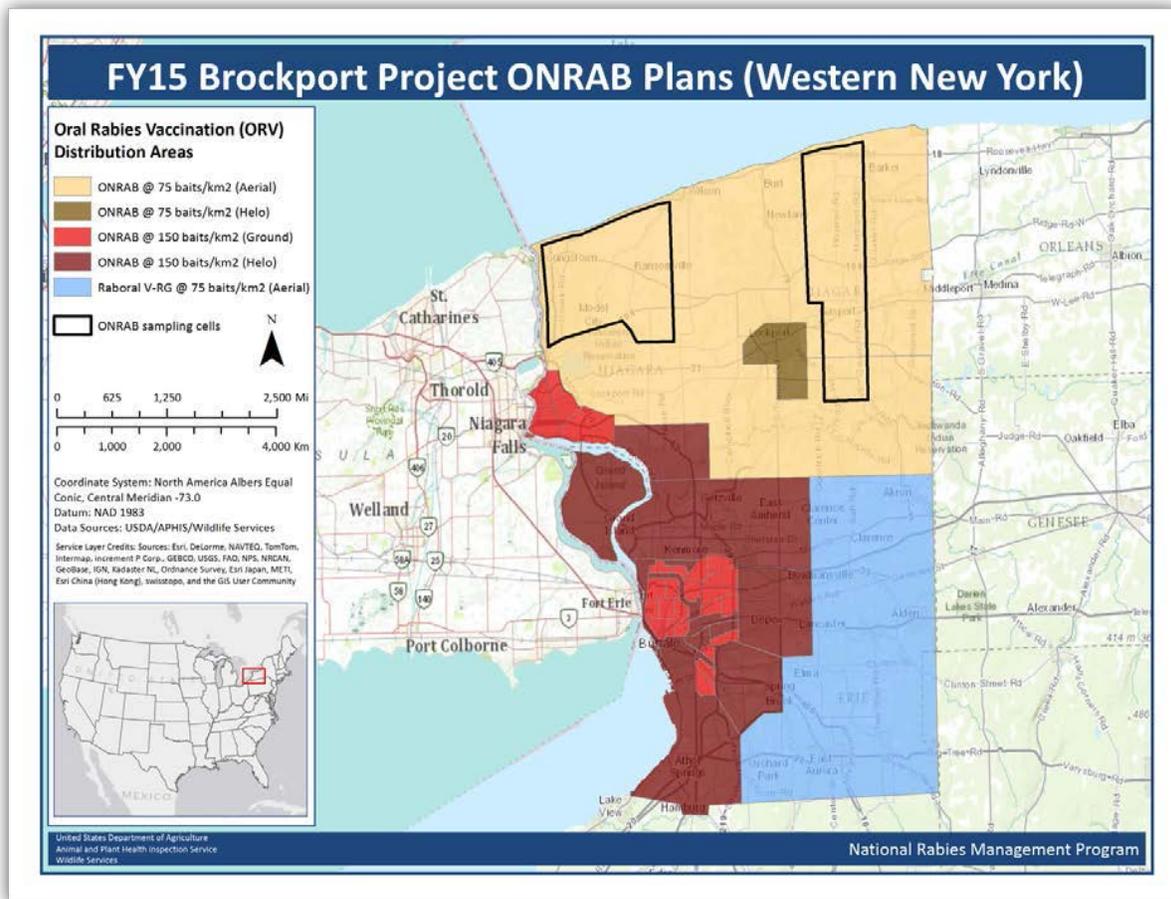


Figure 1. Baiting plan for an ONRAB field trial targeting raccoons at 75 and 150 baits/km² in Western New York, 2015.

Outline for Proposed ONRAB Oral Rabies Vaccine Field Trial in Northeast Ohio in 2015

PRIMARY GOALS: Determine if ONRAB baiting at 75 baits/km² in northeastern Ohio over an area that has been baited at the same density with RABORAL V-RG[®] since the late 1990's would result in a significant increase in sero-prevalence in 2015 and reduce raccoon rabies cases in the area.

1) SITE LOCATION (Figure 1)

- State: Ohio
- Counties: portions of Ashtabula, Geauga, Lake, Portage and Trumbull
- Towns with some ground baiting: Beaty Landing, Burton, Chardon, Concord, Lakefront Park in Fairport Harbor, Geneva, Grand River Landing, Madison, Painesville, Perry, Red Mill Valley, Rome, Warren

2) RATIONALE FOR FIELD TRIAL SITE SELECTION

- The western area of the ORV zone (ONRAB @ 150 baits/km² in Figure 1) has been intensively managed since 2007 through contingency actions (high density baiting at 150 baits/km², often twice/year baiting over much of the area, and trap-vaccinate-release) because it continues to represent a high risk corridor for potential raccoon rabies spread to the West
- The western area has been baited with ONRAB at 150 baits/km² since 2012 and has had no cases of raccoon rabies; continued baiting may help keep this area free of raccoon rabies
- The eastern area of the ORV zone (ONRAB @ 75 baits/km² in Figure 1) continues to have raccoon rabies cases and has been baited with RABORAL V-RG[®] at 75 baits/km² since the late 1990's; baiting with ONRAB will determine if there is a significant increase in sero-prevalence and reduction in cases
- Raccoons and skunks present
- Continued local support within state and county
- WS infrastructure in place

3) FIELD TRIAL PLOT SIZE

- Total area: 2,416 km² including 88 km² ground baiting
- Eastern area (75 baits/km²) will be buffered 3 km to minimize edge effect for sampling

4) BAITING CHARACTERISTICS

- Total ONRAB baits: 192,548 (184,162 fixed-wing and 8,386 ground)
- ONRAB bait density: 150 baits/km² in western area and 75 baits/km² in eastern area
- Flight line spacing: 375 m for 150 baits/km² and 750 m for 75 baits/km²
- Overall Off-time: 32% average for fixed wing and 29% average for ground using NLCD to determine "baitable" habitat
- Approximately 55,592 ONRAB baits in the eastern (75 baits/km²) evaluation area
- Projected baiting dates: August 20-26, 2015
- Baiting duration: 1.5 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% [CCID₅₀]/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 to call in the event of a bait contact and potential vaccine exposure

6) PRE-ORV SAMPLING (BASELINES)

- Enhanced rabies surveillance has been in place since 2004 in the ONRAB zone (both areas) and should continue throughout the zone
- In July 2015, cage traps (10"x12"x32") will be tended for 10 consecutive days throughout the eastern area (75 baits/km²)
- Target of ≥100 raccoons in the eastern area based on previous trapping efforts
- For raccoons and skunks: collect pertinent biological, physical and spatial-temporal data; sera for rabies serological analysis (at least 3 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 rabies diagnostic testing
- Conduct opportunistic sampling of additional target and nontarget species (e.g., roadkills or live animals) that display abnormal behavior or have lesions that should be submitted for rabies testing (blood, teeth, brainstem samples when possible)
- Use various media outlets to advise the public of when and where baiting will occur and the precautions to be followed to reduce the chance of vaccine exposure

7) POST-ORV SAMPLING (TREATMENT EFFECTS)

- Continue enhanced rabies surveillance throughout the ONRAB zone (west and east)
- Continue opportunistic sampling of target and nontarget species (e.g., roadkills, hunter harvest) that display abnormal behavior or have lesions that should be submitted for rabies testing (blood, teeth, brainstem samples when possible)
- 6 weeks post-ONRAB distribution begin evaluation using the same trapping protocol as pre-ORV sampling (see above)
- Use acceptable procedures developed cooperatively 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 Wadsworth Laboratory, New York State Department of Health, Albany, NY
- Specific age determination and biomarker detection by Matson's Laboratory, Missoula, MT

9) REPORT FINDINGS

- Expect results from analysis of field data by April 2016
- Draft report by June 2016

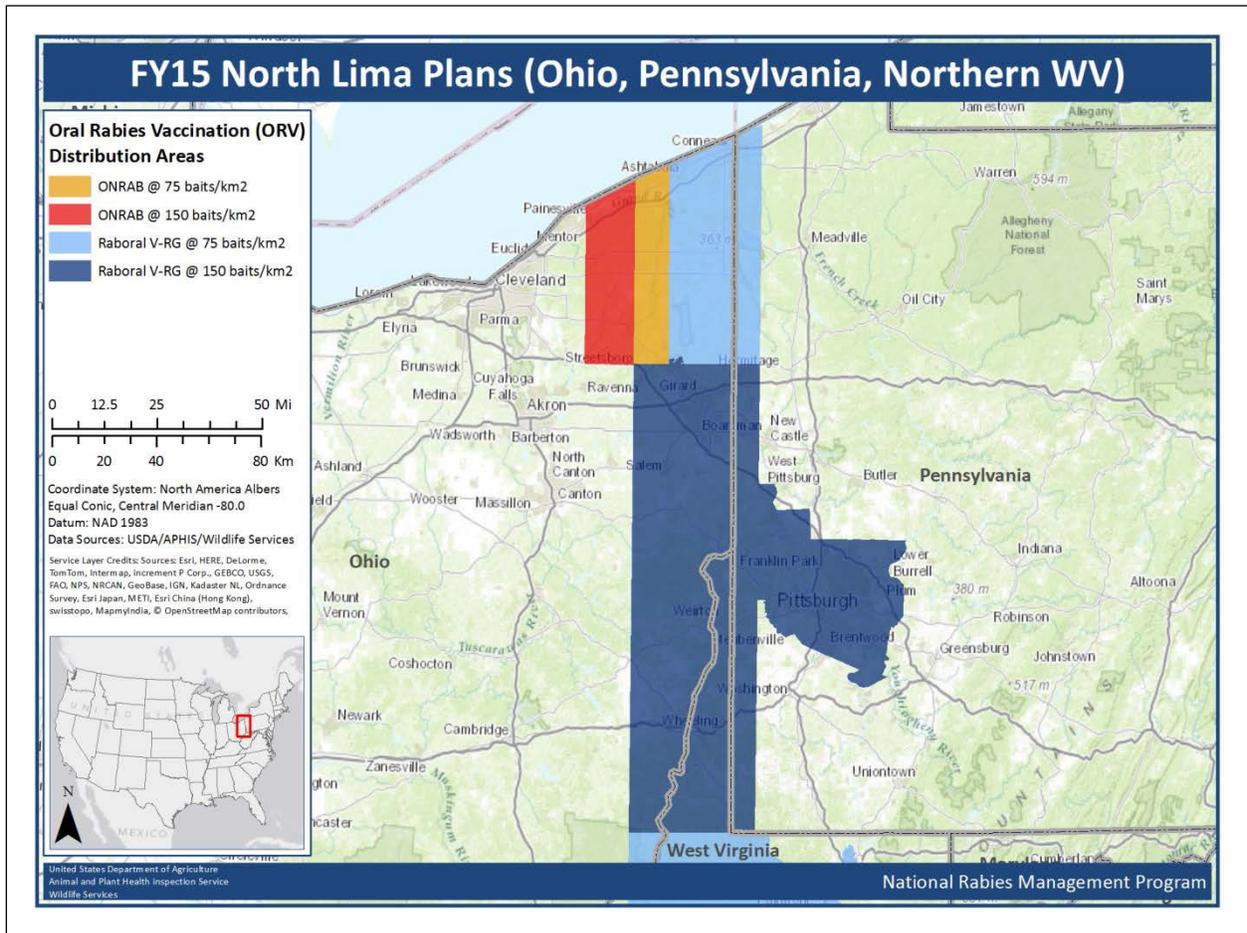


Figure 1. Baiting plan for an ONRAB field trial targeting raccoons at 75 and 150 baits/km² in Ohio, 2015.

Outline for Proposed Replicate of ONRAB Oral Rabies Vaccine Field Trial in Southeastern West Virginia in 2015

PRIMARY GOALS: Determine if replication of the 2014 West Virginia ONRAB trial targeting skunks through a second annual oral rabies vaccination (ORV) campaign at 300 baits/km² and 250m flight line spacing would result in significantly increased sero-prevalence in 2015.

1) SITE LOCATION (Figure 1)

- State: West Virginia
- Counties: portions of Greenbrier, Monroe, Summers
- Towns with some ground baiting: Alderson, Falling Springs, Lewisburg, Ronceverte

2) RATIONALE FOR FIELD TRIAL SITE SELECTION

- Site of three field trials with ONRAB from 2011-2013 targeting raccoons at 75 baits/km² and 750m flight line spacing and first field trial in 2014 targeting skunks at 300 baits/km² and 250m flight line spacing
- Using same area allows for replication to evaluate sero-prevalence in raccoons and skunks after five years of ONRAB baiting in 2015 and after a significant increase in bait density
- 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: 3,755 km² including 28 km² ground baiting
- 3 buffered 127 km² cells (11.2 x 11.2 km) for pre- and post-ORV sampling

4) BAITING CHARACTERISTICS

- Total ONRAB baits: 408,884 (402,826 fixed-wing and 6,058 ground)
- ONRAB bait density: 300 baits/km²
- Flight line spacing: 250 m
- Overall Off-time: 28% average for fixed wing and 24% average for ground using NLCD to determine “baitable” habitat
- Approximately 27,397 ONRAB baits in each 127 km² sampling cell
- Projected baiting dates: August 25-September 4, 2015
- Baiting duration: 2.5 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% [CCID₅₀]/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 to call in the event of a bait contact and potential vaccine exposure

6) PRE-ORV SAMPLING (BASELINES)

- Enhanced rabies surveillance has been in place since 2010 in the ONRAB zone and should continue throughout the zone
- In July 2015, 150 cage traps (10"x12"x32") will be tended for 10 consecutive days within each of the 3 sampling cells; 6 traps will be deployed within half a mile (800 meters) of 25 predetermined random trapping locations within each cell
- Attempt to maximize skunk captures by targeted trapping and other methods (skunk detection dogs, etc.) if practical
- Target of ≥ 30 skunks and ≥ 100 raccoons per cell based on previous trapping efforts
- For raccoons and skunks: collect pertinent biological, physical and spatial-temporal data; sera for rabies serological analysis (at least 3 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 rabies diagnostic testing
- Conduct opportunistic sampling of additional target and nontarget species (e.g., roadkills or live animals) that display abnormal behavior or have lesions that should be submitted for rabies testing (blood, teeth, brainstem samples when possible)
- Use various media outlets to advise the public of when and where baiting will occur and the precautions to be followed to reduce the chance of vaccine exposure

7) POST-ORV SAMPLING (TREATMENT EFFECTS)

- Continue enhanced rabies surveillance throughout the ONRAB zone
- Continue opportunistic sampling of target and nontarget species (e.g., roadkills, hunter harvest) that display abnormal behavior or have lesions that should be submitted for rabies testing (blood, teeth, brainstem samples when possible)
- 5 weeks post-ONRAB distribution begin evaluation using the same trapping protocol as pre-ORV sampling (see above)
- Use acceptable procedures developed cooperatively 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 Wadsworth Laboratory, New York State Department of Health, Albany, NY
- Specific age determination and biomarker detection by Matson's Laboratory, Missoula, MT

9) REPORT FINDINGS

- Expect results from analysis of field data by April 2016
- Draft report by June 2016

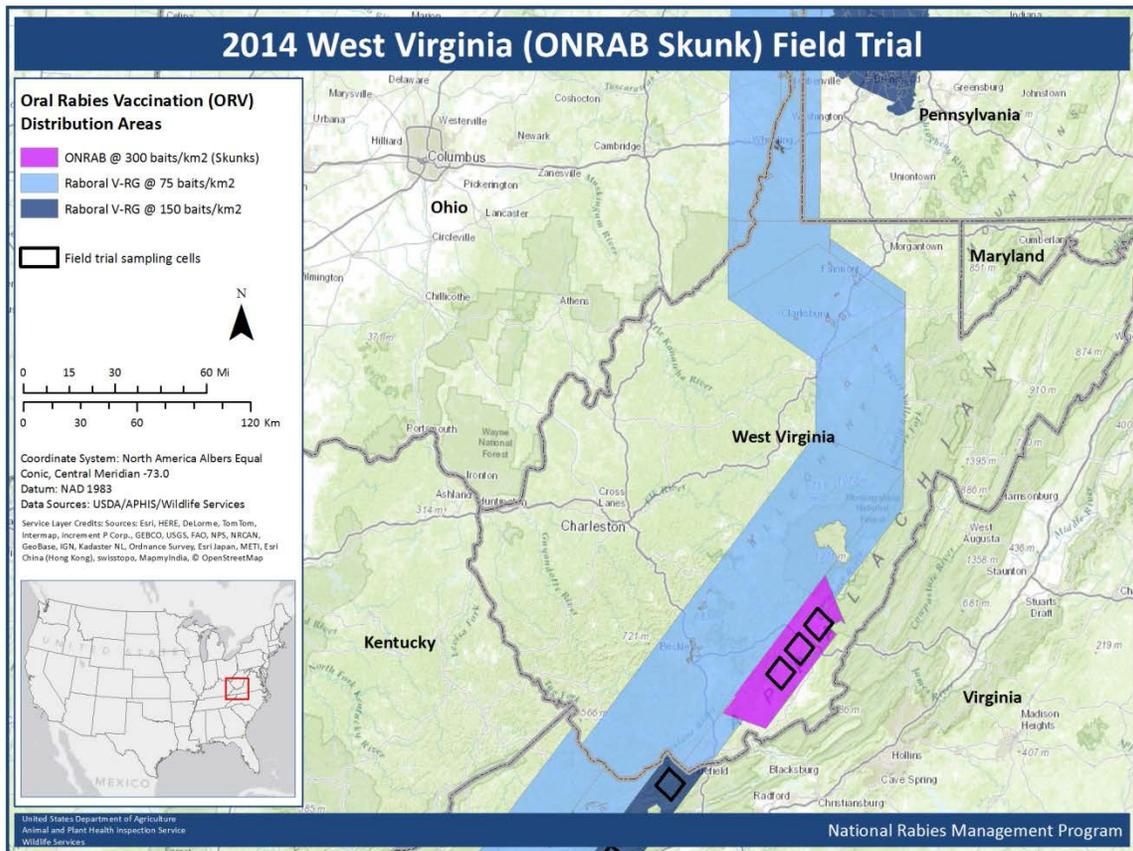


Figure 1. Baiting plan for an ONRAB field trial targeting skunks at 300 baits/km² in West Virginia, 2015.