Prepared for:

DRAFT
Programmatic Environmental Impact Statement
Appendices A-L

Hawaiian Monk Seal Recovery Actions

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Appendix D
Vaccination Plan Review

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HAWAIIAN MONK SEALS VACCINATION RESEARCH AND RESPONSE PLAN

NATIONAL MARINE FISHERIES SERVICE (NMFS)

BACKGROUND

Epidemic diseases (referred to as epizootics when occurring in animals rather than humans) are diseases that occur at a time or place that they do not usually occur, or with a greater frequency than expected in a certain period. Severe epidemics may reduce host population density to such an extent that stochastic events or previously unimportant ecological factors may further reduce the host population size (Harwood and Hall 1990). For example, canine distemper dramatically reduced black-footed ferret (Mustela nigripes) populations in Wyoming, bringing them to extinction in the wild (Thorne and Williams 1988); and, avian malaria reduced native Hawaiian honeycreeper (Hemignathus parvus) populations to such small numbers that many were finally eliminated by predation or habitat loss (Warner 1968).

Infectious diseases, especially those that are newly introduced to naïve populations of animals, can cause mass illness and mortality. The best means of preventing the spread of infectious disease among animals are vaccinations. Vaccines are available for two viruses that have been identified as high risks to Hawaiian monk seals: morbillivirus and West Nile virus. Background surveys conducted on Hawaiian monk seals support that they remain naïve to both viruses. These two viruses are the current focus of vaccination research and response planning for Hawaiian monk seals.

Morbilliviruses—These viruses, specifically phocine distemper virus (PDV) and canine distemper virus (CDV), have caused mass die offs of phocids. During 1988, approximately 18,000 (70% of the population) harbor seals (Phoca vitulina) in Europe died from PDV infection (Heide-Jørgensen et al. 1992). A second outbreak of PDV occurred in the North Sea in 2002, which killed over 20,000 harbor seals (Jensen et al. 2002). Outbreaks of canine distemper (CDV) killed 5-10,000 Baikal seals (Pusa sibirica) in 1987-1988 (Grachev et al. 1989), 10,000 Caspian seals (P. caspica) in 2000 (Kennedy et al. 2000) and may have been responsible for the deaths of 2,500 crabeater seals (Lobodon carcinophagus) in the Antarctic in 1955 (Laws and Taylor 1957). While a morbillivirus was isolated from Mediterranean monk seals (Monachus monachus) that died during an epidemic, its importance relative to biotoxins in causing mortality remains controversial (Hernandez et al. 1998). While the susceptibility of Hawaiian monk seals to morbilliviruses is unknown, due to the devastating effects these viruses can have on phocids, there is a need to better understand and prepare for such an event in Hawaii.

West Nile Virus—This virus caused the death of a captive monk seal at SeaWorld San Antonio, Texas, and has caused mortality in captive harbor seals in the mainland U.S. To date this virus has not been identified in wild marine mammals, although it is present along the eastern seaboard and southern California. This mosquito-borne virus is currently not present within Hawaii, and the State has rigorous surveillance and response plans for this virus due to its public health importance. Although neither single cases of disease nor epidemics of West Nile Virus have been reported in wild marine mammals to date, the death of a monk seal in Texas from this infection indicates monk seals are susceptible. Thus, the possibility of extensive mortality in monk seals exists if the virus were to be introduced to Hawaii , warranting a response plan to such a scenario.

Available vaccines—Vaccines currently used for prevention of viral diseases in domestic animals can be divided into three types:

- Vaccines based on a dead inactivated virus;
- Vaccines using live attenuated viruses; and
- Vaccines consisting of recombinant viruses.

Vaccines using a dead virus are considered the safest because the virus cannot replicate in the host or cause disease; however, this lack of replication often means that the immune response generated following vaccination is short-lived and may not be protective. Live vaccines typically generate the most effective immune response. When used in species other than the one for which the vaccine was developed, live vaccines present the risk of the virus replicating in the host and either causing disease in the vaccinated animal, or being shed in secretions and becoming infective to in contact animals.

Recombinant virus vaccines use a vector virus that does not typically infect the target host but expresses antigens from the pathogen of interest to stimulate an immune response against it. A recombinant vaccine to CDV (monovalent recombinant canary pox vector expressing canine distemper virus antigens, Purevax, Merial) licensed for use in ferrets in the U.S., is now used extensively in zoological collections (Bronson et al. 2007). It is the only distemper vaccine recommended by the American Association of Zoological Veterinarians for use in non-domestic carnivores including mustelids (http://www.aazv.org). It is approved generically for animal use in the State of Hawaii. Safety and efficacy trials with this CDV vaccine have been conducted on four captive harbor seals and on one captive Hawaiian monk seal. These preliminary studies demonstrated that the vaccine is safe, and antibodies to canary pox were detected after a second (booster) dose. This vaccine has also proven to be a safe and effective prophylactic treatment for captive southern sea otters (Enhydra lutra nereis) (Jessup et al. 2009).

Inactivated West Nile virus vaccine (Innovator, Fort Dodge) has been used regularly to date on Hawaiian monk seals in captivity in San Antonio, Texas, with no adverse reactions observed (Workshop to Evaluate the Potential for Use of Morbillivirus Vaccination in Hawaiian Monk Seals, Final Report 2005).

VACCINE RESEARCH

To prepare for and respond to an epidemic caused by morbilliviruses or West Nile virus, the following research is proposed.

Surveillance for morbillivirus and West Nile infections—To enable detection of novel viral infections in the Hawaiian monk seal population, there is a need to routinely and actively monitor for infections. Monitoring wild monk seals for these viruses may include tests for antibodies against the virus in blood (e.g., enzyme linked immunosorbent assays), tests for actual virus in blood, feces, or nasal swabs (e.g., polymerase catalyzed reaction assays), and syndrome-based surveillance. Sample and data collection for these tests would be conducted in concert with existing population health screening.

Assess the safety and efficacy of the recombinant CDV vaccine—Currently, only one captive Hawaiian monk seal has been vaccinated against morbillivirus. Vaccination of additional Hawaiian monk seals would better elucidate their ability to mount a proper immune response, the number of vaccines (including boosters) needed to generate this response, and the duration of immunity against morbilliviruses. Vaccination of additional captive Hawaiian monk seals will be pursued , and vaccination of future monk seals brought into captive care will be considered for this PEIS.

Outbreak response

Vaccination of monk seals may occur either in response to an outbreak or prophylactically in the absence of disease in Hawaii. NMFS proposes to vaccinate in response to disease outbreaks as diagnosed by a series of triggers described below. If the risk of morbillivirus or West Nile virus epidemics to monk seals changes from the current situation, this approach may be modified.

Morbillivirus

Triggers

Any of the following incidents could trigger implementation of CDV vaccinations in wild Hawaiian monk seals:

- Case of confirmed canine distemper virus in a domestic dog outside quarantine in the main Hawaiian islands;

- Case of morbillivirus in a Hawaiian monk seal diagnosed by histology and immunohistochemistry in a dead animal, or seroconversion with clinical signs of disease in a live animal;
- An Unusual Mortality Event of cetaceans in the Hawaiian Archipelago caused by a morbillivirus; or
- A morbillivirus outbreak outside of Hawaii in the Pacific (for example, on the West Coast of the U.S.).

First occurrence of a trigger

The initial response to any of the first three triggers above would be to vaccinate all accessible monk seals on the island where the trigger occurred. Each seal will be vaccinated with Purevax (Merial, Purevax Ferret Distemper Vaccine; 1 ml of reconstituted vaccine subcutaneously). Administration can be achieved by capture and restraint of the animal or via pole-syringe or hand injection without restraint. A second injection (booster) of the same vaccine will be administered approximately one month after the initial vaccination. Survival, development of antibodies, and potential for viral shedding will be monitored in vaccinated seals. Recapture to sample blood for antibodies and nasal secretions for viral shedding will occur 2-3 months after the second vaccination.

In response to the fourth trigger above (outbreak elsewhere in the Pacific), Hawaiian monk seals would be vaccinated opportunistically throughout the Hawaiian Archipelago when handled for other reasons (e.g., tagging) and, if logistics allow seals to be recaptured for subsequent booster and follow up sampling as described above.

Expanded scope of vaccination

Preparations would be made for broader (up to population-wide) vaccination against morbillivirus should this be deemed prudent (based upon current understanding of safety and efficacy, disease threat, and the best scientific information available regarding advisability of prophylactic vaccination). However, no further vaccination will occur after the initial response (on the island where the trigger occurred) until results of serology and shedding have been obtained, unless further cases of morbillivirus disease occur in other monk seals at locations remote from the initial trigger (i.e., at such a distance that the infections are unlikely to have occurred due to contact with a seal from the initial triggering event).

Future Triggers

Results of the response to the first trigger event will be used to refine responses to subsequent trigger events. In particular, records will be taken on:

- Time between trigger and administration of first and second dose of vaccine;

- Number of seals vaccinated;
- Time required to vaccinate all or most animals on island;
- Age distribution of vaccinated animals; and
- Resightings of vaccinated animals.

These data will be used to develop a model that investigates the effect of response time on outbreak spread. Additional data collected will include the overt body condition and health status of vaccinated animals, observations of short-term reactions to vaccinations, and health status of animals when resighted. Data from serological and blood for antibodies and nasal secretions for viral shedding will also be incorporated into the analysis.

West Nile Virus

Trigger

The following incidents could trigger implementation of West Nile virus vaccinations in wild Hawaiian monk seals:

1. A case of West Nile virus in the Hawaiian Archipelago in humans or wildlife, with activation of the State emergency response for West Nile virus control.

Response

In response to the above, all accessible seals would be vaccinated with West Nile virus vaccine (Innovator, Fort Dodge) on the island where the case occurred. Preparations would also be undertaken for broader (up to population-wide) vaccination against West Nile virus as deemed prudent (again, based upon current understanding of safety and efficacy, disease threat, and the best scientific information available regarding advisability of prophylactic vaccination). Given the proven safety of the current West Nile virus vaccine in Hawaiian monk seals, a broad vaccination program is a realistic approach to protecting against infection.

Potential prophylactic vaccination

The best way to protect Hawaiian monk seals against these viral infections is to vaccinate prior to population-wide exposures. This is especially true if multiple doses of vaccines are required to gain immunity against infections, or if immunity responses take weeks to months to develop. Conversely, vaccines that mount short-term responses against infections or have higher risks of side effects may best be delivered only in the face of population-wide exposures. Based upon the information gained from research and any outbreak response, it will be determined whether prophylactic or solely response-driven vaccinations against morbillivirus and West nile virus are needed.

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