



Vaccine Guidance for Importation of RHDV2 Vaccine in Affected States

Developed by the NASAHO RHDV2 Subcommittee 6/26/20, Adapted for CDFA 7/1/20

Background

On March 24, 2020, New Mexico received confirmation of the first Rabbit Hemorrhagic Disease Virus Type 2 (RHDV2) case in a domestic rabbit. Wild rabbit die offs had been reported to state officials in the southern part of the state, and in early April, RHDV2 was confirmed in desert cottontails, and black-tailed jackrabbits. This was the first time RHDV was confirmed in wild rabbit species in the US. The disease continues to spread throughout the Southwest in wild species, with an increasing number of domestic and wild rabbit colonies affected in Arizona, California, Colorado, Nevada, and Texas. Mexico has reported domestic and wildlife cases caused by RHDV2 in several states as well.

The strain of RHDV2 in the SW outbreak is phylogenetically distinct from the RHDV2 virus cases confirmed in WA (2019), OH (2018), NY (2020) and British Columbia (2018) indicating that infection is from two distinct points of infection. The RHDV2 virus in those geographic regions does not seem to affect wild rabbits.

Due to the Foreign Animal Disease (FAD) status of this viral disease in the United States, there are no US licensed RHDV2 vaccines available. There are two killed virus vaccines, Eravac and Filavac licensed in the European Union (EU), which may be used in the US by special permit. A third EU licensed vaccine, Nobivac (Merck), is a live, genetically modified product with no safety or environmental testing in the US and is not eligible for import.

The two killed EU vaccines are being allowed for US import and emergency use in states with confirmed RHDV2 cases as a tool to control the outbreaks. This use is only allowed with approval from and under the direction of the state animal health official and the Center for Veterinary Biologics (CVB). Because this is a conditional use permit, vaccination must be done by a veterinarian or veterinary technician under the supervision of a veterinarian and requires an annual booster.

Vaccine Process

1. The State Veterinarian of California (CA) is allowing the vaccine importation process.
 - a. Private CA licensed veterinarians may apply to import vaccine.
 - b. Veterinarians approved to import vaccine into California may redistribute vaccine to other CA licensed veterinarians at cost. Others may not redistribute vaccine.
 - c. The state veterinarian requires a list of all veterinarians sharing vaccine from an approved shipment under the auspices of the veterinarian of record on the importation application.
 - d. The state veterinarian requires recording of all existing identification (ID) for vaccinated rabbits in the state, but is not requiring application of new ID.
 - i. Permanent ID (microchip or tattoo)
 - ii. Animal Name and description including age, sex, breed, coloration

- iii. Records of vaccination, including certificates and medical records, must be retained by the veterinary practice and rabbit owner for two years.
 - iv. California requires veterinarians to submit a vaccination tracking spreadsheet on a weekly basis
 - v. The use of a form notifying clients of the use of an unlicensed product (see below: e.g., “waiver form”, “disclosure form”) is optional at the discretion of the veterinarian
 - e. In general, the California State Veterinarian is not allowing vaccination of wild species intended for release. Contact ahbfeedback@cdfa.ca.gov for special cases.
- 2. Choose which vaccine you want to import and inquire about availability, vaccine and shipping costs, provisions for temperature control, etc.:
 - a. Filavac VHD K C+V (France) <https://www.filavie.fr>
Contact: karina.sorin@filavie.com
 - b. Eravac (Spain)
<https://www.hipra.com/portal/en/hipra/animalhealth/products/detail/eravac>
Contact: michelle.woodward@hipra.com
- 3. The private veterinarian must report back to the California State Veterinarian at ahbfeedback@cdfa.ca.gov to request a vaccine importation approval letter
 - a. Reports should include product chosen, quantity of vaccine to be ordered, veterinarian name, clinic name, address, email contact and phone number (and the same for all veterinarians sharing the order).
 - b. The CVB will not approve the APHIS Form 2005 without written approval from your state veterinarian.
- 4. Complete the online APHIS Form 2005:
 - a. Go to <https://ncahappspub.aphis.usda.gov/NCAHPortal/public/> and log in.
 - b. Click on “CVB,” then “APHIS 2005 submission form.” Step-by-step instructions for access and filling out the form are available at https://www.aphis.usda.gov/animal_health/vet_biologics/publications/27-aphis2005-researchandevaluation.pdf.
 - c. Choose the research and evaluation option.
 - d. Contact USDA’s Center for Veterinary Biologics at CVB@usda.gov if you have questions.
 - e. Attach your state veterinarian’s letter of approval to the electronic application.
- 5. Contact a customs broker
 - a. The chain of custody and cold chain is very important as variation in temperature or mishandling could negatively impact vaccine efficacy.
 - b. Find a broker who has experience with biologicals to assist ease of movement who can ensure cold storage through customs and delivery.
 - i. To find such a broker, do a web search for “customs broker” and your nearest airport.
 - ii. This is a significant additional expense, but this person will be of great value getting this international vaccine through customs as quickly as possible.
- 6. Forward your CVB approved import permit to your chosen EU company and order vaccine.
 - a. They will require a wire transfer of funds prior to shipment.
 - b. Keep in mind the time difference between your location and France or Spain when communicating; return communication may not be as rapid as desired.
 - c. Discuss shipping plans prior to shipment so the vaccine is shipped air cargo to your closest airport, avoiding a long hot truck ride that may affect vaccine efficacy.

WAIVER FOR RABBIT HEMORRHAGIC DISEASE (RHD) VACCINATION

I have elected to have my rabbit(s), _____ (patient name(s)) vaccinated with _____ vaccine, as an attempt to protect against Rabbit Hemorrhagic Disease Virus Serotype 2 (RHDV2). I understand the following:

1. This vaccine is not licensed in the US and is being used under a special research and evaluation import permit from the USDA (US Department of Agriculture).
2. This vaccine does not guarantee full protection against the disease, rabbit hemorrhagic disease.
3. For best efficacy, it is recommended that rabbits over 1 month of age receive the vaccine and then are given a booster vaccine every year. **Please note that booster vaccines will only be available if additional vaccine importation is permitted by the state veterinarian's office and USDA.**
4. The vaccine will take a minimum of 7 days to provide some protection.
5. Side effects have been documented in rabbits given the vaccine, including but not limited to: lethargy, fever, digestive upset, nodule or swelling at vaccination site, anaphylactic reaction, and death. If my rabbit develops any side effects from the _____ vaccine or the vaccination procedure, I do not hold the _____ or the veterinarians responsible, and as the owner of this rabbit, will assume full responsibility for any treatment costs associated with said side effects.
6. I acknowledge that there may be other, unknown risks and that the long-term effects and risks of this vaccine are not known at this time.
7. The effects of this vaccine on fertility have not been determined and the risk of abortion in pregnant does is undetermined at this time.
8. There is currently no medical data on the interaction of this vaccine with other medical products.
9. Because rabbits are considered by some for meat production, USDA requires a 21-day withdrawal period for meat consumption, to avoid potential risks to US food supplies.
10. We ask that you stay (in your car) for 15 minutes after vaccination in case there is an adverse reaction.

I have read and fully understand the terms and conditions set forth above. I, as the undersigned owner (or agent) of the pet identified below, authorize the staff of _____ to vaccinate my rabbit with the vaccine.

Owner name (printed)

Date

Owner signature

Witness signature

Label for FILAVAC:

4.2. Indications for use, specifying the target species For active immunisation of rabbits (fattening and future breeders) from 10 weeks of age, to reduce mortality due to rabbit haemorrhagic disease caused by classical (RHDV1) and type 2 (RHDV2) virus strains.

Onset of immunity: 7 days.

Duration of immunity: 12 months.

Label for ERAVAC:

INDICATION(S):

For active immunisation of rabbits from the age of 30 days to reduce mortality caused by the rabbit haemorrhagic disease type 2 virus (RHDV2).

Onset of immunity: 1 week.

Duration of immunity: 9 months demonstrated by challenge.