

Wildlife Services

Protecting People
Protecting Agriculture
Protecting Wildlife

National Wildlife Research Center

FY 2012

Product Registration: Providing Tools for Wildlife Services



Contact Information:

Mr. John D. Eisemann
Registration Manager
NWRC Headquarters
4101 LaPorte Avenue
Fort Collins, CO 80521
Phone: (970) 266-6158
FAX: (970) 266-6157
john.d.eisemann@aphis.usda.gov
www.aphis.usda.gov/wildlife_damage/
nwrc/

Major Cooperators

- Association of Fish and Wildlife Agencies
- International pesticide product developers
- Private pesticide and repellent registrants
- State pesticide regulatory agencies
- State wildlife management agencies
- U.S. Fish and Wildlife Service
- Wildlife Services Operations

Groups Affected By These Problems

- Farmers, ranchers, and livestock producers
- Federal, State, and private natural resource managers
- Urban and suburban residents

National Wildlife Research Center Maintains Chemical Tools for Wildlife Damage Management

The NWRC Registration Unit serves many roles within Wildlife Services (WS), but the majority of its work is focused in three general areas. First, the Registration Unit provides regulatory guidance to NWRC management and scientists on product development. Second, it assists WS Operations personnel with regulatory issues for using chemical control methods to manage wildlife damage. Third, as part of the WS Pesticide Coordinating Committee (PCC), the Registration Unit works closely with other committee members, including APHIS' Policy and Program Development, Environmental and Risk Analysis Services office, WS Operational Support Staff, and the Pocatello Supply Depot to ensure APHIS chemical-based vertebrate pest management tools are current and meet State and Federal regulations.

APHIS holds product registrations with the U.S. Environmental Protection Agency (EPA) for rodenticides, predacides, avicides, repellents, a snake toxicant, an avian repellent and a contraceptive vaccine. APHIS also holds Investigational New Animal Drug (INAD) applications with the U.S. Food and Drug Administration (FDA) for immobilizing agents used in animal damage management. To maintain or expand authorized use of these products, the Registration Unit works closely with NWRC scientists to ensure that studies conducted for regulatory purposes meet EPA and FDA guidelines.

In addition to these primary functions, the Registration Unit also provides technical and regulatory assistance and information to state WS programs, Federal and State agricultural and conservation agencies, academic institutions, non-governmental groups, and private industry. Many of the requests for assistance come from WS Operations personnel seeking new products or improvements to existing products, or looking for help interpreting product labels to ensure proposed applications are legal.

Applying Science and Expertise to Wildlife Challenges

APHIS Pesticide Product Registrations—APHIS currently holds registrations through the EPA for eleven active ingredients formulated into 23 Federally-registered vertebrate pesticide products. These products meet the needs of bird management (five avicide products and one avian repellent), rodent management (11 rodenticide products), predator management for livestock and threatened and endangered species protection (four predacide products), brown treesnake management on Guam (one toxicant), and white-tailed deer, wild horse and wild burro management (a contraceptive vaccine for reducing fertility). In addition, APHIS maintains two INAD permits with the FDA. These INADs allow WS employees to use immobilizing agents when removing problem birds from urban areas and for sedating coyotes and wolves captured during research activities.

Rodenticides—Rodenticide issues continue to be a large focus of the NWRC. With the EPA's rodenticide risk mitigation measures becoming fully implemented in 2012, the array of products available for commensal and agricultural uses is becoming more restricted. To meet the changing market, the NWRC is working closely with private rodenticide manufacturers to investigate new product chemistries or use patterns that will fill the void created by the impact of EPA's mitigation measures. A top priority for this effort is to focus on formulations and uses that minimize the impact on nontarget species and the environment. The NWRC helps to assess the registration potential of rodenticide developments and acts as the liaison between regulators and product developers.

The NWRC serves as the primary WS contact for registration issues related to eradicating rodents from islands for the protection of threatened and endangered species and critical habitats. Since securing three rodenticide registrations in 2007 for this purpose, the NWRC has provided regulatory guidance or direct assistance on nine rodent eradication



United States Department of Agriculture
Animal and Plant Health Inspection Service

projects in the Pacific and the Caribbean regions to protect nesting seabirds and unique island habitats. Many of these projects involved working with the EPA to secure product labeling appropriate for the conditions of each eradication project.

In 2011, the NWRC was an integral part of the largest environmental monitoring effort conducted in conjunction with a U.S. Fish and Wildlife Service-sponsored rodent eradication effort. The eradication project occurred on Palmyra Atoll and employed a rodenticide application rate nearly six times higher than currently allowed on approved product labels. The goal of the eradication effort was to enhance the biodiversity of seabirds, native plants and terrestrial invertebrates on the atoll by removing invasive rats. NWRC scientists evaluated the overall impact of the eradication effort on nontarget species and the environment by measuring the application rate and bait distribution on the ground following aerial application and documented the fate of bait, collected carcasses of potential nontarget mortalities, and systematically collected soil, water, insects, geckos, fish, and crabs to determine environmental residue levels.

NWRC continues to coordinate a consortium of private companies who register zinc phosphide-based rodenticide products. Collectively, this consortium gathers data to maintain EPA registrations of zinc phosphide rodenticides and works to develop appropriate precautionary language on product labels. The consortium has saved WS hundreds of thousands of dollars and saved consortium members millions of dollars by consolidating EPA data requirements and providing clarifying information.

Bird Management Tools—DRC-1339 (Starlicide) continues to be a valuable tool for managing damage caused by birds. APHIS holds EPA registrations for five DRC-1339 based products that are used to manage damage caused by blackbirds and invasive European starlings at feedlots and agricultural fields, gulls at landfills, pigeons roosting on structures, and crows and ravens preying on livestock and threatened and endangered species. In 2012, the EPA began reevaluating DRC-1339 data and product labels under their Registration Evaluation program. As a result of this evaluation, EPA asked APHIS and the other DRC-1339 registrant (Virbac Animal Health) to provide more than 20 new data submissions in areas of terrestrial and aquatic toxicology, environmental persistence and human health and safety. If ultimately required, these data submissions would cost the U.S. Government and the other private registrant nearly \$2.3 million. In response to this request, the NWRC assembled and submitted to EPA existing published and unpublished data, waiver requests and drafted new product label language in an effort to reduce the registration costs.

Over the past decade, the NWRC has responded to an increasing number of requests from WS operational staff for new control tools for addressing crow, raven and blackbird damage problems. As a result, the number of State-specific DRC-1339 registrations has increased to more than 25. In an effort to reduce the administrative burden associated with this high volume of product registrations and to provide WS operational staff with greater flexibility in using DRC-1339 to address crow, raven and blackbird problems, the NWRC and PCC submitted a new product label allowing greater flexibility for use in feedlots. NWRC and PCC are also working to include these uses on the label used to protect field crop, endangered species, and human health and safety. The NWRC also provides significant guidance to scientists and private industry on the development of anthraquinone and currently registered fungicides for avian repellent uses. Current projects are aimed at developing chemical repellents for seed treatment and foliar applications in corn, sunflower, and rice.

Wildlife Contraceptives—The NWRC is a world leader in the development of effective wildlife contraceptives. In 2009, NWRC researchers successfully registered with the EPA the first immunocontraceptive vaccine for use in wildlife when they registered GonaCon™ Immunocontraceptive Vaccine (GonaCon) as single-shot, multi-year vaccine for female white-tailed deer. GonaCon promises to be useful for managing not only urban white-tailed deer where traditional options are limited, but also populations of other species. In January 2013, the EPA registration for GonaCon was expanded to include wild and feral horses and burros. Research has shown GonaCon to be an effective reproductive inhibitor in these species as well as elk, bison, prairie dogs, ground squirrels, and feral dogs and cats. NWRC and its collaborators are investigating the use of GonaCon for reducing the spread of rabies in feral dogs and raccoons, preventing adrenocortical disease in pet ferrets, and preventing the spread of brucellosis in bison. The vaccine is being used for research purposes in the United States, Mexico, Europe, New Zealand, and Australia. Future NWRC research with GonaCon likely will involve studies to support expanded registration to other species, to develop oral delivery systems, and to prevent transmission of wildlife diseases.

Registration of Predicides—APHIS holds four registrations for using sodium cyanide and sodium fluoroacetate (Compound 1080) as predicides. These products are used at the request of ranchers to protect livestock from coyote predation or at the request of conservation organizations for protecting threatened, endangered or economically important species. These compounds are currently being reviewed by the EPA for the adequacy of supporting data and product label restrictions. Given the volume of data APHIS submitted to EPA in response to the 2007 petition to cancel these products and the new restrictions imposed at that time, the NWRC does not anticipate new regulatory actions resulting from EPA's current review of these products.

Given the societal concerns around the use of the traditional predicides described above, the NWRC is investigating new compounds in a search for safer, more humane predicides. In 2011, NWRC began collaborating with a private Australian company to investigate the possibility of developing the compound para-aminopropiophenol (PAPP) as a predicide. PAPP was originally developed in the 1960s as an antidote for human radiation poisoning. In historical pharmaceutical trials, PAPP was found to be specifically more toxic to carnivores than to birds and humans. PAPP is currently registered in New Zealand for the control of stoats and feral cats. Initial product development efforts on PAPP in the United States are ongoing.

Development of a Feral Swine Toxicant—Feral swine are an increasing problem in the United States and around the world. They destroy native vegetation, prey on wildlife and livestock, and transmit diseases to humans and livestock. WS is pursuing an EPA registration of sodium nitrite for use as a feral swine toxicant. Sodium nitrite is a preservative for pork and other meats that happens to be toxic to live swine. NWRC signed a Cooperative Research and Development Agreement with the Invasive Species Cooperative Research Centre in Australia to share existing Australian registration data that may be appropriate to support an EPA product registration. Additionally, NWRC is conducting laboratory studies with sodium nitrite to gather acute oral avian toxicology, avian dietary toxicology, and end-product toxicology data. Field studies on various delivery systems are being conducted in Texas with future efforts planned for Mississippi, Florida, Michigan, and Missouri. This partnership will save APHIS

hundreds of thousands of dollars in EPA registration data development costs. A private Australian company has also partnered with NWRC to provide funding to investigate sodium nitrite as a rodenticide.

International Activities—NWRC helps to transfer WS products and technologies to countries around the world. Over the past 3 years, the NWRC has worked with the governments of American Samoa, Israel, New Zealand, and Australia to improve their ability to manage pest bird populations using DRC-1339 products. The NWRC is also working with Australia, New Zealand, England, and Mexico to transfer wildlife contraceptive technology. Collaborative work with Canada, New Zealand, and numerous small Pacific Island nations has aided in their efforts to use rodenticides as a conservation tool to protect off-shore islands.

Information Sharing: Environmental Risk Assessment and New Management Tools—In 2011, NWRC launched an online searchable NWRC Chemical Effects Database containing historical data for approximately 7,000 chemicals analyzed and evaluated for repellency, toxicity, reproductive inhibition and immobilization on a variety of plants, birds, mammals, and amphibians. The database is useful to researchers worldwide who are involved in environmental risk assessments and the development of new damage management tools.

Selected Publications:

AVERY, M. L., J. D. EISEMANN, K. L. KEACHER, and P. J. SAVARIE. 2011. Acetaminophen and zinc phosphide for lethal management of invasive lizards *Ctenosaura similis*. *Current Zoology* 57:625-629.

EISEMANN, J. D., S. J. WERNER, and J. R. O'HARE. 2011. Registration considerations for chemical bird repellents in fruit crops. *Outlooks on Pest Management* 22:87-91.

ENGEMAN, R. M., W. C. PITT, A. R. BERENTSEN and J. D. EISEMANN. 2012. Assessing spatial variation and overall density of aerially broadcast toxic bait during a rat eradication on Palmyra Atoll. *Environ Sci Pollut Res Int*. DOI 10.1007/s11356-012-1050-6.

LAPIDGE, S. J., J. WISHART, L. STAPLES, K. A. FAGERSTONE, T. A. CAMPBELL, and J. D. EISEMANN. 2012. Development of a Feral Swine Toxic Bait (Hog-Gone®) and Bait Hopper (Hog-Hopper™) in Australia and the USA. Pages 19-24 in S. N. Frey, editor. *Proceedings of the Fourteenth Wildlife Damage Management Conference*, Nebraska City, NE. The Wildlife Damage Management Working Group of The Wildlife Society.

RATTNER, B. A., K. E. HORAK, R. S. LAZARUS, K. M. EISENREICH, C. U. METEYER, S. F. VOLKER, C. M. CAMPTON, J. D. EISEMANN, and J. J. JOHNSTON. 2012. Assessment of toxicity and potential risk of the anticoagulant rodenticide diphacinone using Eastern screech-owls (*Megascops asio*). *Ecotoxicology* 21:832-846.

RATTNER, B. A., K. E. HORAK, S. E. WARNER, D. D. DAY, C. U. METEYER, S. F. VOLKER, J. D. EISEMANN, and J. J. JOHNSTON. 2011. Acute toxicity, histopathology, and coagulopathy in American kestrels (*Falco sparverius*) following administration of the rodenticide diphacinone. *Environmental Toxicology and Chemistry* 30:1213-1222.

Major Registration Accomplishments:

- APHIS was granted an EPA registration for the use of the GonaCon™ Immunocontraceptive Vaccine to manage fertility in wild and feral horses and burros. WS continues to conduct research to expand the vaccine's registration to other species.
- WS was an integral part of the largest environmental monitoring effort conducted for a U.S. rodent eradication effort on Palmyra Atoll (a remote island in the Pacific Ocean, approximately 1,000 miles south of Hawaii).

Vertebrate Control Products Currently Registered or Approved for Use by USDA APHIS

Taxa	APHIS Products	Mode of Action	Species	Uses Unique to APHIS
RODENTS	Zinc Phosphide (3 products)	Lethal	Voles, mice, rats, hares, woodchucks, ground squirrels, muskrats, nutria, prairie dogs	Some
	Strychnine (4 products)	Lethal	Pocket gophers	No
	Gas Cartridge (1 product)	Lethal	Prairie dogs, ground squirrels, woodchucks, marmots	No
	Diphacinone (1 product)	Lethal	Invasive rodents on islands	Yes
	Brodifacoum (2 products)	Lethal	Invasive rodents on islands	Yes
CANINE PREDATORS	Large Gas Cartridge (1 product)	Lethal	Coyotes, red foxes, striped skunks	Yes
	M-44 Cyanide Capsules (2 products)	Lethal	Coyotes, red foxes, gray foxes, arctic foxes, feral dogs	Some
	Livestock Protection Collar Compound 1080	Lethal	Coyotes	Yes
	Tranquilizer Trap Device	Non-lethal Immobilizing Agent	Wolves, coyotes, feral dogs	Yes
CERVIDS	GonaCon Immunocontraceptive Vaccine	Non-lethal Contraceptive	White-tailed deer, wild horses and burros	Yes
BIRDS	Compound DRC-1339 Concentrate (4 labels)	Lethal	Gulls, pigeons, ravens, crows, magpies, starlings, blackbirds	Yes
	Compound DRC-1339 Concentrate—Feedlots	Lethal	Blackbirds, starlings, grackles, cowbirds	Some
	MesuroI Aversive Conditioning Egg Treatment	Non-lethal	Crows, ravens	Yes
	Alpha-chloralose	Non-lethal	Geese, ducks, coots, pigeons, ravens	Yes
	Corn Oil	Non-Lethal	Canada geese	No
SNAKES	Acetaminophen	Lethal	Brown treesnakes	Yes
	Cinnamon, Clove and Anise Oil	Non-lethal Repellent	Snakes	No