

Wildlife Services

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Technology Transfer and Product Registration: Providing Tools for Wildlife Services and Other Professionals



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National Wildlife Research Center Promotes Technology Transfer and Product Registration for Wildlife Damage Management Tools and Strategies

The National Wildlife Research Center (NWRC) and its predecessor laboratories have a long history of developing materials and methods for managing damage caused by mammals, birds, reptiles, and amphibians. These tools and methods include aversion techniques, attractants, baits, chemical repellents, delivery devices, exclusion devices, fertility control agents, scare devices, surveillance and monitoring devices, toxicants, traps and other capture devices, and vaccines. The NWRC Technology Transfer Program strives to make these products available to Wildlife Services (WS) employees and natural resource managers by partnering with universities, the U.S. Department of Agriculture's (USDA) Agricultural Research Service (ARS), private-sector industries, and others.

Technology Transfer Goals, Objectives, and Measures of Success

USDA defines "technology transfer" as the adoption of research outcomes (i.e., solutions) for public benefit. Through public and private partnerships, NWRC research supports the development of new and improved technologies, processes, products and services that benefit the nation by increasing productivity, increasing efficiency (keeping costs low), and enhancing global competitiveness for the U.S. agricultural sector. Technology transfer is critical to accelerating the use of public research and methods development, creating economic activity, jobs, and sustaining economic development.

WS uses formal instruments of technology transfer, including Confidentiality Agreements, Material Transfer Research Agreements, and Cooperative Research and Development Agreements (CRADAs). In addition, WS transfers technology through patents and invention licenses for commercialization by the private sector. WS has an ongoing formal agreement with ARS' Office of Technology Transfer (ARS OTT) to administer WS patents and licensing and to assist with the development of technology transfer agreements. NWRC's Technology Transfer Program Manager serves as the primary liaison for WS and other APHIS programs to the ARS OTT.

WS transfers knowledge and technology through many other formal and informal mechanisms. Primary among these methods for NWRC scientists is publication in peer-reviewed scientific journals. Other important mechanisms for transferring technology and knowledge include presentations at technical or professional conferences and publications in proceedings; technical assistance to the public or stakeholders; informal and formal exchange of information and products among colleagues; public outreach via factsheets, brochures, web pages, and social media; and laboratory open houses. NWRC provides valuable data and expertise to the public and the scientific community, as well as to the WS program.

WS-NWRC measures success of its technology transfer using several metrics:

- Number of agreements established with collaborators
- Number of technical publications
- Number of registrations obtained with regulatory agencies
- Level of cooperator funding
- Impact of transferred technology

Groups Affected by These Problems:

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

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



United States Department of Agriculture
Animal and Plant Health Inspection Service

In 2015, the NWRC entered into 10 new Confidentiality Agreements and 25 new Material Transfer Agreements with 14 U.S.-based private companies or entities, 2 non-profit organizations, 10 universities, 6 U.S. government agencies, and 6 foreign entities. Additionally, the NWRC is currently partnering with both U.S.-based and foreign parties in 9 Cooperative Research and Development Agreements (CRADA). These agreements provide intellectual property protection for projects ranging from the development and testing of contraceptive and zoonotic disease vaccines, chemicals that are repellent to birds, to the development of a toxicant for feral swine control. In 2015, CRADA partners provided \$193,321 to support NWRC research activities.

Patents and licensing are a priority for NWRC's applied research activities. One of the technology transfer highlights of the past year was the licensing of a contraceptive vaccine patent to a small startup company for developing a market based on managing wild horses and burros. This same company is interested in licensing the same vaccine, under a separate patent which was issued in 2014, as a preventative for the number one cause of death in pet ferrets, adrenal cortical disease (ACD). This vaccine could ultimately be used to prevent ACD in more than 50,000 ferrets annually in the U.S. alone. The U.S. Patent and Trade Office approved a NWRC patent in 2015 that capitalizes on bird's sensitivity to ultraviolet light in an effort to develop agricultural chemicals that are repellent to birds. Licensing of this second invention currently being negotiated with a private pesticide manufacturer. This invention has the potential to be used to protect hundreds of thousands of acres on corn, rice and soybean fields from birds.

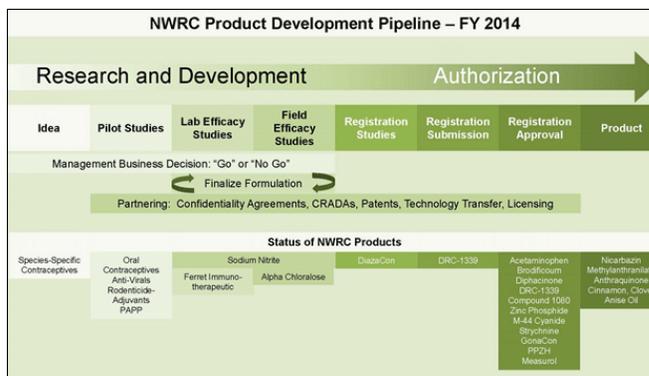
Cooperator funding averages about 16 percent of NWRC's annual budget. It has steadily increased during the last 5 years, generating \$1.8 million in 2010, \$2.4 million in 2011, \$2.4 million in 2012, \$2.7 million in 2013, and \$3.5 million in 2014. Agreements with federal and non-federal cooperators account for approximately 58 and 42 percent of NWRC's annual cooperator funding, respectively.

Product Registration: Applying Science and Expertise to Wildlife Challenges

As part of the Technology Transfer Program, the NWRC Registration Unit is responsible for providing data and information to support regulatory approval of new or existing products used by WS Operations. These products allow WS to more efficiently address wildlife damage issues and protect agriculture, human health, and endangered species or critical habitats. To meet this responsibility, the Registration Unit works closely with APHIS headquarters staff in Riverdale, MD, and with NWRC scientists to ensure that regulatory studies meet regulatory guidelines of the U.S. Environmental Protection Agency (EPA) and U.S. Food and Drug Administration (FDA). Currently, APHIS holds product registrations with the EPA for rodenticides, predacides, avicides, repellents, a snake toxicant, an avian repellent and a contraceptive vaccine. It also holds Investigational New Animal Drug (INAD) applications with the FDA for immobilizing agents used in wildlife damage management. The NWRC Registration Unit coordinates the maintenance and advancement of the authorized use of these products.

As products are developed, they proceed through the research and development pipeline (Figure 1) and are approved for use by the appropriate regulatory agencies. Products with limited private market potential, but highly desirable to WS Operations, are produced and distributed by the WS Pocatello Supply Depot. Products with significant private market potential are licensed or otherwise provided for sale to private companies.

Figure 1. Product Development Pipeline at the USDA-APHIS-WS National Wildlife Research Center



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 in accordance with federal and state laws.

APHIS Pesticide Product Registrations. — APHIS currently holds registrations through the EPA for 11 active ingredients formulated into 24 federally registered vertebrate pesticide products (Table 1). These products meet the needs of bird management (5 avicide products and an 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 (a toxicant), and white-tailed deer, wild horse and wild burro management (a contraceptive vaccine).

Rodenticides. — Rodenticide development and registration is a key focus of the NWRC, especially as products for commensal and agricultural uses become more restricted. To meet the changing market, the NWRC is working closely with private rodenticide manufacturers to investigate new product chemistries and use patterns. A top priority for this effort is to focus on formulations and uses that minimize rodenticide impacts on non-target species and the environment.

NWRC serves as the primary WS contact for registration issues related to rodent eradication efforts on islands for the protection of threatened and endangered species and critical habitats. Since securing 3 rodenticide registrations in 2007 for this purpose, the NWRC has provided regulatory guidance or direct assistance on nine rodent eradication projects in the Pacific and the Caribbean regions to protect nesting seabirds and unique island habitats.

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 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 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 the face of this investment, the private registrant made a business decision to transfer their manufacturing use product to APHIS. The NWRC submitted to EPA existing published and unpublished data, waiver requests, and drafted new product label language, which resulted in a reduction in data requirements and costs, saving APHIS approximately \$1.8 million. As a result, both APHIS and the private registrant maintained their EPA product registrations and the ability to provide these tools.

Over the past decade, NWRC has responded to an increasing number of requests from WS Operations for new tools to address crow, raven, and blackbird damage. As a result, the number of state-specific (Special Local Needs, SLN) DRC-1339 registrations has increased. To reduce the administrative burden and cost associated with this high volume of SLN registrations and provide WS Operations with greater flexibility in using DRC-1339 at feedlots, the NWRC and the APHIS Pesticide Coordination Committee (PCC) submitted a new product label, which was approved by the EPA in January 2014.

The Registration Unit also provides guidance to scientists and private industry on a wide range of product development efforts. One example is the development of anthraquinone and registered fungicides for use as avian 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 GonaCon Immunocontraceptive Vaccine (GonaCon) as the first, single-shot, multi-year immunocontraceptive vaccine for use in female white-tailed deer. In January 2013, GonaCon was registered for use in wild and feral horses and burros. Research has shown GonaCon to be an effective reproductive inhibitor in other mammal species including elk, bison, prairie dogs, ground squirrels, and feral dogs and cats. NWRC and its collaborators are investigating the use of GonaCon in feral dogs and raccoons in combination with rabies vaccines to reduce the spread of rabies, in pet ferrets to prevent adrenocortical disease, and in bison to prevent the spread of brucellosis. The vaccine is being used for research purposes in the United States, Mexico, Europe, New Zealand, and Australia. NWRC research with GonaCon likely will involve studies to expand its registration for use in other species, to develop oral delivery systems, and to prevent transmission of wildlife diseases.

Registration of Predacides. — APHIS holds four registrations for using sodium cyanide and sodium fluoroacetate (Compound 1080) as predacides. These products are used at the request of ranchers to protect livestock from coyote predation and wildlife agencies for protecting threatened, endangered or economically important species.

Given the societal concerns around the use of the traditional predacides, the NWRC is investigating new compounds in a search for more safe and effective predacides. In 2011, NWRC began collaborating with a private Australian company to investigate the compound para-aminopropiophenol (PAPP) as a predacide. PAPP was originally developed in the 1960s as an antidote for human radiation poisoning. In historical pharmaceutical trials, PAPP was found to be 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 and riparian areas, prey on wildlife and livestock, and transmit diseases to humans and livestock. Research has shown that sodium nitrite, a common meat preservative, is toxic to swine in high doses. NWRC signed a CRADA with the Invasive Species Cooperative Research Centre in Australia to share existing Australian registration data to support an U.S. EPA product registration as a toxicant for managing feral swine. 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. Additional studies will be conducted in Mississippi, Florida, Michigan, and Missouri. This partnership will save APHIS hundreds of thousands of dollars in EPA registration costs.

Immobilizing Agents for Animal Sedation and Capture. — In addition to pesticide products for the management of wildlife conflicts, APHIS maintains two INAD authorizations with the FDA. These INADs allow WS employees to use immobilizing agents to reduce stress and minimize potential injury when removing problem birds from urban areas and for sedating coyotes and wolves captured during research activities.

Automated Bait Cartridge and Delivery System for Controlling Brown Treesnakes. — Automated Bait Cartridge and Delivery System for Controlling Brown Treesnakes. The invasive brown treesnake (BTS) was introduced to Guam nearly seventy years ago, probably via post-World War II cargo shipments. Since its introduction, the snake has colonized the entire island, at densities of up to 33 snakes per acre. These venomous snakes have caused the extinction of most of Guam's native birds, bats, and lizards. They feed on young poultry and other small livestock and threaten human health and safety. They also cause power outages throughout Guam causing millions of dollars in structural damages and lost revenue. In 2009, NWRC and Applied Design Corporation (ADC) entered into a series of cooperative agreements to design a bait cartridge, automated manufacturing system, and aerial bait delivery system for the distribution of acetaminophen-based toxicant to BTS in remote and inaccessible areas on Guam. The NWRC provided information on BTS ecology and behavior, guidance regarding EPA's pesticide regulations, and early prototype concepts. Working together, NWRC scientists and ADC experts designed a biodegradable bait cartridge and delivery system that can disperse bait cartridges per second via helicopter or fixed wing aircraft, thus allowing for large-scale control of the snakes.

This technology was selected by the Federal Laboratory Consortium for the 2015 Excellence in Technology Transfer Award. In January 2015, ADC and NWRC jointly filed for a U.S. patent for the bait cartridge and ADC plans to file two additional patents related to its automated bait delivery system and bait manufacturing process. ADC plans to commercialize this technology for use in wildlife damage management world-wide.

International Activities. — NWRC helps to transfer WS products and technologies to countries around the world. Over the past three years, 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. 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 efforts to use rodenticides as a conservation tool to protect island biodiversity.

Selected Publications:

EVERY, 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-Hoppera-) 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 Accomplishments:

- WS-NWRC received the Federal Laboratory Consortium's 2015 Award for Excellence in Technology Transfer for its work with Applied Design Corporation to develop an automated bait cartridge and delivery system for controlling brown treesnakes.
- The EPA approved a major revision to the avian toxicant DRC-1339 Feedlot Label that allows for more flexibility in the type of bait used in confined animal feeding operations.
- As part of the PCC, NWRC's Registration Unit successfully negotiated a \$1.8 million reduction in new data requirements under EPA's Registration Evaluation.
- In 2014, GonaCon Immunocontraceptive Vaccine was approved for use in wild horse and burro management in Nevada.
- Acetaminophen for brown treesnake control on Guam was successfully reregistered with the EPA, paving the way for further operational snake control programs on the island.

Table 1. Vertebrate control products currently authorized for use by USDA APHIS

Management Goal	APHIS Products	Mode of Action	Species	Uses Unique to APHIS
RODENT CONTROL	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	Lethal	Prairie dogs, ground squirrels, woodchucks, marmots	No
	Diphacinone	Lethal	Invasive rodents on islands	Yes
	Brodifacoum (2 products)	Lethal	Invasive rodents on islands	Yes
CANINE PREDATOR CONTROL	Large Gas Cartridge	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

MAMMAL FERTILITY CONTROL	GonaCon Immunocontraceptive Vaccine (2 products)	Non-lethal Contraceptive	White-tailed deer, wild horses and burros	Yes
BIRD CONTROL	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
	Sodium laurel sulfate	Lethal	European starlings	Yes
	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
SNAKE CONTROL	Acetaminophen	Lethal	Brown treesnakes	Yes
	Cinnamon, Clove and Anise Oil	Non-lethal Repellent	Snakes	No

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