October 1993

STATUS OF ALPHA CHLORALOSE AND OTHER IMMOBILIZING/ EUTHANIZING CHEMICALS WITHIN THE ANIMAL DAMAGE CONTROL PROGRAM

Paul P. Woronecki
USDA Denver Wildlife Research Center, Sandusky, OH

William L. Thomas
USDA Hyattsville, MD

STATUS OF ALPHA CHLORALOSE AND OTHER IMMOBILIZING/EUTHANIZING CHEMICALS WITHIN THE ANIMAL DAMAGE CONTROL PROGRAM

PAUL P. WORONECKI, U.S. Department of Agriculture, Denver Wildlife Research Center, 6100 Columbus Avenue, Sandusky, OH 44870

WILLIAM L. THOMAS, U.S. Department of Agriculture, Office of Support Staff, 6505 Belcrest Road, Room 820, Federal Building, Hyattsville, MD 20782

ABSTRACT: In 1992 the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Animal Damage Control (ADC) program was granted approval from the U.S. Food and Drug Administration (FDA), under a continuing Investigational New Animal Drug agreement, to use Alpha-chloralose (A-C) nationwide for capturing nuisance waterfowl, coots, and pigeons. FDA and ADC have imposed several requirements, restrictions and conditions on the operational use of A-C. Training and certification are required to use A-C and other approved immobilizing and euthanizing agents.

Proc. East. Wild]. Damage Control Conf. 6:123-127. 1995.

The first studies on the anesthetic action of Alpha-chloralose (A-C) on animals (rats, cats and dogs) were done in France prior to 1900 (Hanriot and Richet 1897). During World War II some research workers in France, prompted by the short supply of strychnine (New Zealand Pesticide Board 1977), Experimented with A-C as a soporific for capturing or killing corvids and other birds (Borg 1955). Borg (1955) concluded that the use of A-C to capture birds was humane and efficient and that the risks of secondary or accidental poisoning were small if suitable pre-baiting was carried out.

Since 1959, wood-pigeons (*Columba palumbus*) and other species have been caught in Great Britain under a wide range of experimental conditions using various baits coated with A-C (Murton et a]. 1963, Feare et al. 1981).

In the United States, the first published use of A-C with wildlife was in Florida in 1964 (Williams et al. 1966), where it was used to capture red-winged blackbirds (*Agelaius phoeniceus*), house sparrows Passer (*Passer domesticus*) and wild turkeys (*Meleagris gallopavo*) A-C is marketed as a rodenticide in Italy, Germany and Great Britain and has been registered as an avian control agent in Great Britain, France, New Zealand, and Australia (Woronecki et al. 1990). However, until now, A-C has never been registered or approved for use as an immobilizing or control agent for wildlife in the United States. From 1988 through early 1990, scientists at the USDA's Denver Wildlife Research Center (DWRC) used A-C experimentally in the United States to immobilize and remove nuisance waterfowl, coots (*Fulica americana*) and rock doves or pigeons (*Columba livia*) from commercial and residential sites (Woronecki et al. 1990). Based on these promising results, DEC decided in 1990 to pursue FDA approval to use A-C operationally nationwide in the Animal Damage Control program. The objective of this paper is to summarize the status of A-C within FDA and the ADC program as of October 1993. The status of other immobilizing/euthanizing chemicals is also discussed. The Appendix provides a list of acronyms used in the text.

We thank the many biologists at Denver Wildlife Research Center and throughout the ADC program who assisted in the development of A-C as a management tool.

STATUS OF A-C WITH FOOD AND DRUG ADMINISTRATION

In February 1990, through a contract with Wildlife Pharmaceuticals (WP), Fort Collins, Colorado, the FDA, Center for Veterinary Medicine granted the authority for APHIS/ADC, DWRC to use A-C to develop research data under an Investigational New Animal Drug (INAD) Agreement. The development of A-C as a bird immobilizing agent was APHIS' first foray into the FDA regulation arena.

During 1990 and 1991, the required Quality-Assured safety, efficacy and clinical trials were conducted to obtain FDA authorization for ADC to use A-C operationally for capturing nuisance waterfowl, coots and pigeons. The application for a New Animal Drug Authorization (NADA) for A-C was submitted to FDA in October 1991 and included information on identification of the product, draft labeling, analytical methods, safety, and efficacy with authorization or registration anticipated in 1992 (Woronecki et al. 1992).

Although the original intent of the DWRC was to obtain a NADA, the FDA was reluctant because of the 1986 Generic Drug Law which only allows a 4-5 year period of exclusivity for new drugs after which anyone can sell the drug. If a NADA was obtained, anyone with a prescription from a veterinarian would be able to obtain the drug to capture waterfowl, coots and pigeons. Therefore, FDA restricted the use of A-C to the APHIS/ADC program under a perpetual INAD agreement with the following conditions:

1. Only trained ADC personnel or trained designees will be allowed to use A-C for capturing nuisance waterfowl, coots and pigeons.

2. Records must be maintained by each user on the amount of technical material on hand, material used, dates of use, and number and species of animals captured. Information will be compiled and reported to FDA annually. All correspondence with FDA, use records, individual data sheets, and summary sheets will be archived.
3. The INAD will be the only legal way to use A-C as a wildlife immobilizing agent. A-C only can be used as a capture agent and not as a avicide.
4. The only source of A-C for the ADC program will be a Good Manufacturing Practice (GMP) distributor within the ADC program.
5. The use of A-C 30 days prior to and during the legal hunting season in populations that are hunted will be prohibited. Use in humans, and the use of edible products of animals captured (unless authorized by FDA and USDA) will be prohibited.
6. The current INAD or additional INAD agreements will allow for expansion of uses of A-C and other species of birds. This can be done by submitting research proposals and protocols for DWRC approval and FDA acceptance. After baseline safety and efficacy data are collected and use instructions developed, the final report has to be approved by DWRC and the proposed expansion of the uses of A-C has to be accepted by FDA. If accepted, the additional uses and species will be added to the current INAD or an additional INAD agreement may be granted.

STATUS OF A-C IN ADC PROGRAM

In 1992, when the contract with WP ended, the responsibility of support for drug approval compliance and FDA liaison was assumed by APHIS' Technical and Scientific Services (TSS)/Biotechnology, Biologics, and Environmental Protection. The responsibility for coordinating training and certification was given to the Operational Support Staff (055), the responsibility of GMP compliance was entrusted to the Pocatello Supply Depot (PSD) and the responsibility of research, data development and archiving was delegated to DWRC. To develop operational procedures for the use of A-C, personnel from WP, TSS, OSS, PSD, ADC, and DWRC held meetings to coordinate the requirements for making A-C operational and to assist PSD, OSS and TSS in developing: a packaging system for A-C distribution; an A-C training program; A-C use certification, record-keeping and reporting procedures; and A-C data and report forms.

In addition to the conditions restricting the use of A-C imposed on the ADC program by FDA, the following APHIS/ADC requirements, restrictions and conditions were adopted to further regulate A-C use:

1. PSD will be the only supplier for use on avian species.
2. A-C will be distributed through ADC State Directors who have employees or cooperators that are certified by regional or DWRC directors as applicators.
3. A-C use will be restricted to ADC trained and certified personnel or their trained designees.
4. Training will be restricted to ADC and other federal and state personnel responsible for the management of waterfowl, coots and pigeons.
5. State Director's, if not trained or certified, must be knowledgeable of all use restrictions and be fully accountable for the inventory of A-C in their respective state(s).
6. Comprehensive records of purchases, uses, distribution, supplies on hand, and disposal of A-C will be maintained by the PSD, State Directors and applicators.
7. All applicators will be responsible for conducting projects in compliance with local, state and federal laws, regulations, and guidelines (e.g. FDA, Environmental Protection Agency, Migratory Bird Treaty Act, National Environmental Policy Act).
8. Applicators will possess the necessary permits (state and federal) for taking migratory birds and have state and local authorization.
9. Disposition of birds captured will be coordinated through state and federal wildlife agencies.

A Working Group developed an A-C Handbook, forms, training course and examination for certification in 1993. A designated Task Force will train ADC personnel in the operational use of A-C for capturing waterfowl, coots and pigeons.

The first A-C workshop and training course was held at DWRC in March 1993. Seven ADC biologists with previous experience in the use of A-C were selected as the first trainees. The trainees reviewed drafts of the handbook, the training course and APHIS forms and then constructed an examination for certification. A-C kits without the chemical were available to the trainees and exercises in calculating dosages were conducted. The trainees were recommended by the ADC Immobilizing and Euthanizing Chemical Committee (I/E Committee) for certification by the Regional and DWRC Directors as Trainer/Applicators (T/A). T/As are able to use A-C, train additional ADC personnel, and administer exams for certification of Applicators. The Applicators are able to use A-C but not train personnel. A-C was officially made available by the PSD for operational use 29 March 1993.

The second training course was held at the ADC State Director's Office in Portland, Oregon in July 1993. Eight ADC biologists satisfactorily completed T/A training and were certified. Since March 1993, an additional 4 ADC biologists have been trained and certified as Applicators. Additional T/A training courses and workshops are being scheduled.

In order to be trained in the use of A-C, a State Director must submit names of personnel requiring training to the I/E Committee who will make arrangements and schedule an appropriate training course. Following completion of training and examination, the I/E Committee will recommend individuals to be certified. The committee will maintain a record of all certifications. State Directors can purchase A-C from PSD as soon as they have certified personnel.

ADC USE OF OTHER IMMOBILIZING AND EUTHANIZING CHEMICALS

Training and certification is also required to use other immobilizing and euthanizing (I/E) chemicals within the ADC program. This requirement was established with ADC Directive 2.430 which states that "ADC personnel who use I/E chemicals, receive specific training to ensure use in a professional and proper manner in compliance with all applicable laws and regulations." The ADC Deputy Administrator delegated the I/E Committee to establish guidelines, approve specific I/E chemicals and training programs that will be available for use by the ADC employees. The directive makes State Directors and the DWRC Director responsible for use of I/E chemicals by their employees and ensures all personnel receive adequate training and use only approved chemicals in accordance with I/E Committee guidelines.

State Directors requiring personnel to use I/E chemicals other than A-C will provide evidence of training to the I/E Committee. The committee will review credentials and make recommendations regarding certification eligibility to the respective Regional or the DWRC Directors. Certification will be the responsibility of the Regional or the DEC Directors. The committee will maintain a record of all personnel certified in the use of specific I/E chemicals and issue appropriate certificates of training and certification.

ADC APPROVED IMMOBILIZING AND EUTHANIZING CHEMICALS

The immobilizing and euthanizing chemicals presently approved and certified by the I/E Committee for ADC use are found in Table 1. Additional chemicals must meet certain guidelines and must be approved and certified by the ADC I/E Committee prior to use. Scheduled drugs are regulated by the Drug Enforcement Administration (DEA) but all chemicals used on or in animals must be approved by the FDA. Both FDA and DEA set standards for accountability and storage requirements. The acquisition, storage, and use of all I/E chemicals by ADC shall be in compliance with applicable federal, state, and local laws and regulations.

Table 1. Immobilizing and euthanizing chemicals that are presently approved and certified by the I/E Committee for ADC use.

Chemical[a]	Registration	Uses[b]
Immobilizing		
Ketamine HCL + Xylazine	Unscheduled drugs regulated by FDA. Schedule III drug in California. Subject to regulation	feral dogs, mountain lions bears, elk, mule deer, white-tailed deer, foxes, coyotes, raccoons, skunks, wolves
Telarol (Tiletamine + Zolazapam)	Schedule III drug regulated by DEA and FDA	raccoons, buffalo, wolves, bears, white-tailed deer, mountain lions, feral swine
Ketamine HCL + Acepromazine	Unscheduled drugs regulated by FDA. Schedule III in California. Subject to regulation	feral swine
Alpha-chloralose	Unscheduled drug regulated by FDA	waterfowl, coots pigeons
Euthanizing[c]		
Beuthanasia-D® regulated by DEA and FDA	Scheduled III drug	dogs
Potassium chloride	Unregulated drug	animals must be anesthetized prior to administering
Carbon monoxide	Unregulated gas	many species
Carbon dioxide	Unregulated gas	many species

[a]Some of the chemical names are trade names and may be available under different names from different companies. This list is subject to change.

[b]List of species are not meant to be inclusive. Depending on the situation, the listed chemicals may be used independently or in combinations

[c]Approved by the American Veterinary Medical Association as euthanizing agents. Some agents (e.g., potassium chloride) may require that the animal be anesthetized prior to administering the euthanizing agent.

LITERATURE CITED

Borg, K. 1955. Chloralose and its use for catching crows, gulls, pigeons etc. Viltrevy Jaktbiologisk Tidskrift 1:88-121.

Hanriot, M., and C. Richet. 1897. Les chloraloses. Arch. I. Pharmacodyn. 3:191-211.

Feare, C. J., A. J. Isaacson, P. A. Sheppard, and J. M. Hogan. 1981. Attempts to reduce starling damage at dairy farms. Prot. Ecol. 3:173-181.

Murton, R. K., A. J. Isaacson, and N. J. Westwood. 1963. The use of baits treated with chloralose to catch wood-pigeons. Ann. Appl. Biol. 52:271-293.

New Zealand Pesticide Board. 1977. The agricultural chemicals (vertebrate pest control) regulations 1977: Alpha-chloralose for bird control. Inf. Serv., Min. of Agric. and Fish., Wellington. 12pp.

Williams, L. E., Jr., D. H. Austin, and J. Peoples. 1966. Progress in capturing turkeys with drugs applied to baits. Proc. Southeast. Game and Fish Comm. 20:219-226.

Woronecki, P. P., R. A. Dolbeer, and T. W. Seamans. 1990. Use of alpha-chloralose to remove waterfowl from nuisance and damage situations. Proc. Vertebr. Pest Conf. 14:343-349.

_____, _____, _____, and W. R. Lance. 1992. Alpba-chloralose efficacy in capturing nuisance waterfowl and pigeons and current status of FDA registration. Proc. Vertebr. Pest Conf. 15:72-78.

Appendix. Acronyms used in text.

Acronym	Name
A-C	Alpha-Chloralose
ADC	Animal Damage Control
APHIS	Animal and Plant Health Inspection Service
DEA	Drug Enforcement Administration
DWRC	Denver Wildlife Research Center
FDA	Food and Drug Administration
GMP	Good Manufacturing Practice
I/E	Immobilizing and Euthanizing Chemical
INAD	Investigational New Animal Drug
NADA	New Animal Drug Authorization
OSS	Operational Support Staff
PSD	Pocatello Supply Depot
T/A	Trainer/Applicator
TSS	Technical and Scientific Services
USDA	United States Department of Agriculture
WP	Wildlife Pharmaceuticals