United States Department of Agriculture Animal and Plant Health Inspection Service

Wildlife Services Directive

WS 2.430 3/12/2019

ACQUISITION, STORAGE AND USE OF CONTROLLED CHEMICAL IMMOBILIZATION AND EUTHANASIA SUBSTANCES

1. PURPOSE

To establish guidelines for use and training standards for certification of Wildlife Services (WS) personnel who acquire, store, or administer federally regulated controlled substances, veterinary prescription drugs, or other related WS approved immobilization and euthanasia chemicals (hereafter collectively referred to as I & E drugs). This Directive refers to the use of only I & E drugs which are specifically related to the immobilization and euthanasia of wild animals.

2. REPLACEMENT HIGHLIGHTS

This Directive replaces WS Directive 2.430 date July 6, 2009.

3. AUTHORITY

- a. 7 U.S.C. 8351 to 8353, and 16 U.S.C. 667, authorizes officers, agents, and employees of the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Wildlife Services (WS) to conduct a program of wildlife services and to enter into agreements with states, local jurisdictions, individuals, and public and private agencies, organizations, and institutions for the purpose of conducting such services.
- b. Authority to promulgate a policy addressing employee responsibilities is pursuant to U.S. Department of Agriculture (USDA) Departmental Regulation 4070-735-001, dated October 2007.

4. BACKGROUND

a. The WS Immobilization and Euthanasia Sub-Committee, reviews and approves immobilization, euthanasia, and accessory substances. The WS I & E Sub-Committee also establishes training and certification requirements for WS personnel as described in Section 7 of this Directive, and in the WS Field Operations Manual for the Use of I & E Drugs.

- b. Most of the substances used to immobilize and euthanize wildlife are regulated by federal and state laws because of their potential hazards to animals and humans, and potential for substance abuse. Only properly trained WS personnel are certified to possess and use substances listed in Attachment 1, WS Approved I & E Drugs.
 - (1.) The Food and Drug Administration (FDA), under the Federal Food, Drug, and Cosmetic Act, verifies the safety, efficacy, and quality control of drugs and ensures their safe and legal use in wildlife species that can potentially be consumed by humans. The FDA requires most I & E drugs be administered under veterinary supervision, requiring a veterinarian-client-patient relationship.
 - (a.) Animal Medicinal Drug Use Clarification Act (1994) (AMDUCA), allows veterinarians to use FDA approved animal and human drugs for extra-label drug use under certain conditions. I & E certified WS personnel, with consulting veterinarian approval, can use regulated substances, from the WS approved I & E drug list, for conducting official wildlife damage management and research activities as an extra-label use. The Act also requires specific record requirements for extra-label use.
 - (b.) FDA and AMDUCA regulations are set to minimize human exposure of drug residues in food animals. Wildlife harvested for food are considered food animals. Food animals must not be harvested within a drug withdrawal period; unless certain criteria are met, outlined in the WS Field Operations Manual for the Use of I & E Drugs.
 - (2.) The Drug Enforcement Administration (DEA), under the Controlled Substance Act (1970), is responsible for preventing illegal diversion of narcotics and dangerous drugs and regulates drug storage. The DEA establishes classifications for sensitive drugs, i.e., schedules, which outline procedures for drug procurement, storage, and use.

5. POLICY

- a. WS personnel must not possess or use I & E drugs in an official capacity unless they are WS I & E certified.
- b. WS personnel must satisfy the certification requirements described in Section 7 of this Directive to achieve and maintain WS I & E certification.
- c. WS I & E certified personnel must only use I & E drugs listed in Attachment 1, WS Approved I & E Drugs.
- d. The WS I & E Sub-Committee may include additional I & E drugs to Attachment 1, WS Approved I & E Drugs, following their analysis and determination that the additional I & E drug is appropriate for WS use.
- e. USDA-APHIS-WS National Wildlife Research Center (NWRC) personnel may use I & E drugs for immobilizing and euthanizing procedures in accordance with this

Directive and protocols approved by the NWRC Institutional Animal Care and Use Committee (IACUC). The NWRC IACUC has the authority, under the Animal Welfare Act, to approve I & E drugs for NWRC research, including those not in Attachment 1, the WS Approved I & E Drugs.

- f. WS I & E certified personnel may use I & E drugs not listed in Attachment 1, WS Approved I & E Drugs, on a one-time or limited basis when necessary for mission delivery with approval by both the consulting veterinarian and the WS State Director, or the NWRC IACUC as appropriate. Documentation of circumstances for limited drug use and copies of the drug records must be sent to the WS I & E Sub-Committee.
- g. WS Deputy Administrator, Associate Deputy Administrator, WS Regional Directors, NWRC Director, and WS State Directors may request additional I & E drugs be included to Attachment 1, WS Approved I & E Drugs, by submitting a written request to the WS I & E Sub-Committee
- h. WS personnel must acquire, store, and use I & E drugs in accordance with applicable WS program policies, and federal, state, and local laws and regulations.

6. **DEFINITIONS**

- a. Attending Veterinarian: A person who has: graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education, or; has a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates, or; has received equivalent formal education as determined by the (APHIS) Administrator; and who has received training and/or experience in the care and management of the species being attended; and who has direct or delegated authority for activities involving animals at a facility subject to the jurisdiction of the Secretary. (9 CFR 1.1)
- b. <u>Consulting Veterinarian</u>: A veterinarian who is formally consulted, in writing, regarding a veterinary issue including handling, immobilization, anesthesia, analgesia, and euthanasia of wildlife.
- c. <u>Controlled Substance</u>: A drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of Subchapter I of the Controlled Substances Act (1970).
- d. <u>Euthanasia</u>: The humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death. (9 CFR 1.1)
- e. <u>Extra-label use</u>: Actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease or other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration

- other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses. (21 CFR 530.3)
- f. Official Capacity: Performance of actions that are approved or authorized by WS, and that fall within the authority vested in WS personnel by virtue of their status as a federal or non-federal employee, or intern, while conducting official WS duties under the supervision of WS.
- g. <u>Veterinary-Client-Patient Relationship</u>: A valid veterinarian-client-patient relationship is one in which:
 - (1.) A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other care-taker) has agreed to follow the instructions of the veterinarian.
 - (2.) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s).
- h. <u>WS Employee or Personnel</u>: Defined this Directive, includes federal and non-federal employees, and interns who conduct official WS duties under the supervision of WS.

7. TRAINING REQUIREMENTS

- a. Initial I & E Training Requirements. WS personnel who use I & E drugs in the conduct of official duties must adhere to rules in the WS Field Operations Manual for the Use of I & E Drugs. Initial I & E training courses are set at a minimum of 16 hours. Additional training requirements can be identified by WS State Directors and Project Leaders. The following two sources of training may be used:
 - (1.) National Training Academy (NTA) Initial I & E Training Course.
 - (2.) Alternate Training Process Initial I & E Training Course. If the NTA initial I & E training course is not available or feasible, the WS State Director /Project Leader must work with the WS I & E Sub-Committee to arrange an alternate training process. Any non-NTA training course seeking approval for initial I & E training must use the WS Field Operations Manual for the Use of I & E Drugs, as a reference to ensure the course provides consistency and covers all requirements outlined in this Directive. WS State Directors/Project Leaders and WS I & E Sub-Committee must review the alternative training course to ensure that it will meet, and be consistent with, the NTA initial I & E training course.
- b. Completion of the initial I & E certification will require an 80% passing grade on the WS initial I & E certification exam. WS initial I & E certification is valid for 5 years from the date of passing the exam.

- (1.) The NTA initial I & E training course will administer the WS initial I & E certification exam on site where the training occurs.
- (2.) Upon completion of the alternate initial I & E training course WS State Directors/Project Leaders must submit the names to the NTA. The NTA will then administer the WS initial I & E certification exam on-line. The exam must be completed within 30 days of the training course.
- (3.) WS personnel currently certified in I & E are not required to retake the WS initial I & E training course. If a WS employee allows their certification to expire they must take the initial training course again to become certified.
- c. Recertification I & E Requirements. Curriculum for recertification training, set at a minimum of 16 hours, must be approved by the WS I & E Sub-Committee and must include at least 4 hours of veterinarian lead instruction covering drug pharmacology, patient monitoring, species specific chemical immobilization, and veterinary emergencies. The remaining 12 hours of training must include I & E issues covered in the WS Field Operations Manual for the Use of I & E Drugs, such as: policy, record keeping, storage, I & E drugs, dosage calculations, CPR/first aid, sharps training, carcass and drug disposal, safety and personal protective equipment, and safe and ethical animal handling.
 - (1.) Continuing education training can be provided by the NTA, state agencies, other federal agencies, professional society workshops, professional workshops, local and attending veterinarians, qualified (certified and experienced) WS personnel (excluding the 4 hours of veterinarian lead instruction), and other WS I & E Sub-Committee approved venues.
 - (2.) Successful recertification will require an 80% passing grade on the exam. WS I & E recertification is valid for 5 years from the date of passing the exam.
 - (a.) The NTA recertification I & E training course will administer the WS I & E recertification exam on site where the training occurs.
 - (b.) Following completion of 16 hours of continuing education, WS State Directors/Project Leaders must submit the names to the NTA. The NTA will then administered the WS I & E recertification exam on-line.
- d. Interim and Seasonal Training. If there is a critical need, as determined by the WS State Director/Project Leader, for WS personnel to use I & E drugs in their official capacity before they receive WS I & E certification, another I & E certified and experienced WS employee may train the employee(s) in the appropriate policies and procedures. Following completion of the interim training, the WS State Director/Project Leader must contact the NTA to arrange an exam for the employee(s). Successful certification will require an 80% passing grade on the exam. A written description of the training, signed by the WS trainer, must be provided to the WS State Director/Program Leader, WS I & E Sub-Committee, and NTA. Interim training must be valid for no more than one year.

8. RESPONSIBILITIES

- a. Supervisors must ensure that all WS personnel using I & E drugs complete training requirements in accordance with the guidelines presented in this Directive and WS Field Operations Manual for the Use of I & E Drugs. Supervisors are accountable for WS use of I & E drugs within their area of responsibility. WS State Directors/Project Leaders or other supervisors must provide documentation of trainings to the NTA. WS personnel are responsible for the proper care, use, records, chain of custody, and security of I & E drugs in all locations and circumstances.
- b. WS State Directors must obtain their own state controlled substance permit (when permissible by state law) in order to obtain DEA registration for procurement and storage of controlled substances. In such states where only veterinarians can obtain a state controlled substances permit, WS State Directors can be covered by the consulting veterinarian's permit with a letter of agreement.
- c. WS State Directors must obtain a written agreement with a local consulting veterinarian to document the presence of a veterinarian-client-patient relationship to be compliant with FDA regulations. Federal, state, or private veterinarians can be used as consulting veterinarians.

9. SCOPE

This Directive is applicable to all WS personnel.

10. REFERENCES

- a. Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301-392), as amended Controlled Substances Act (21 U.S.C. 801).
- b. 21 CFR Part 511 New Animal Drugs for Investigational Use.
- c. Section 511.1 New Animal Drugs for Investigational Use exempt from Section 412(a) of the Act.
- d. 21 CFR Part 514 New Animal Drug Applications, Section 514.1(b) 8 Evidence to establish safety and effectiveness.
- e. 21 CFR 1301 Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, Section 1301.21 Persons required to register, Section 1301.22 Separate registration for independent activities, Section 1301.90 Employee screening procedures.
- f. 21 CFR 1308 Schedules of Controlled Substances, Section 1308.03 Administration Controlled Substances Code Number, Sections 1308.11 – 1308.15 Schedules I-V.
- g. 9 CFR, Part 2 Animal Welfare Act Sections 2.30 2.38
- h. Animal Medicinal Drug Use Clarification Act, 1996.
- i. American Veterinary Medical Association. AVMA Guidelines on Euthanasia, 2013.
- j. 21 CFR Part 530.3 Definitions.
- k. 9 CFR Part 1.1 Definitions.

- 1. Wildlife Services. 2017. Field Operations Manual for the Use of Immobilization and Euthanasia Drugs. Dr. Mark Johnson, DVM, and I & E Committee, USDA/APHIS/WS, Riverdale, MD. 120 pp.
- m. WS Directive 2.505, Lethal Control of Animals (5/18/11)
- n. WS Directive 2.601, Safety (10/07/05)

11. ATTACHMENTS

Attachment (1): WS APPROVED I & E DRUGS

Janet L. Bucknall Deputy Administrator

Attachment: 1 WS APPROVED I & E DRUGS

The listed I & E drugs are approved by the WS I & E Sub-Committee for use by WS personnel who are I & E certified. The WS I & E Sub-Committee may approve additional I & E drugs as described in WS Directive 2.430.

a. Anesthetics

- 1. Ketamine HCL: e.g., Ketaset®, Vetalar® (CIII)
- 2. Tiletamine HCL + Zolazapam: i.e., Telazol® (CIII)

b. Sedatives

- 1. Xylazine: e.g., Rompun®, CervizineTM, AnaSed®
- 2. Medetomidine hydrochloride: e.g. Domitor®
- 3. Dexmedetomidine
- 4. Butorphanol
- 5. Azaperone
- 6. Nalbuphine

c. Tranquilizers

1. Acepromazine

d. Accessory Drugs/Substances

- 1. Yohimbine HCL
- 2. Tolazoline
- 3. Doxapram: e.g., Dopram-V®, Dopram®
- 4. Atropine
- 5. Atipamezole hydrochloride: e.g. Antisedan
- 6. Topical Antibiotics (over-the-counter only)

e. Euthanasia Agents

1. Sodium Pentobarbital: e.g., Euthanasia®-D Special, FP-3®, Euthanasia-6®, Euthanasia Solution®, Sleepaway® (CIII)