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Animal and Plant
Health Inspection
Service

Animal Care

ANIMAL CARE POLICY MANUAL

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Safeguarding American Agriculture

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Animal Care Policy Manual

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Subject: Control of Tuberculosis in Regulated Elephants

Policy #1

References: Animal Welfare Act (AWA) Section 243
9 Code of Federal Regulations (CFR) Part 1, Section 240.5(z)

RESCINDED

History: Replaces policy dated April 1, 1998 and previously identified as Policy #21.

Justification: Tuberculosis is a contagious disease that affects elephants, other animals, and humans. If left untreated or if treated improperly, it can cause death. Several elephants owned by licensed exhibitors have either tested culture positive for tuberculosis or have died due to this disease. In addition, elephants with tuberculosis can transmit the disease to other elephants, other animals, and, potentially, to humans. The Animal and Plant Health Inspection Service (APHIS), Animal Care (AC) is requiring the periodic testing of all Animal Welfare Act regulated elephants. Testing will help us to identify those elephants that are infected and ensure that appropriate quarantine and/or treatment measures are instituted.

Policy: As part of the adequate veterinary care standard in the U. S. Department of Agriculture's (USDA) animal welfare regulations, all captive elephants in the United States must be periodically tested for tuberculosis. Any animals found positive on culture will be required to undergo quarantine and/or treatment.

In conjunction with this policy, USDA, APHIS, AC is offering "*Guidelines for the Control of Tuberculosis in Elephants*", a protocol that specifies criteria for the testing, surveillance, and treatment of elephants for tuberculosis. Copies of this protocol are available from all AC Regional Offices and on the AC website at:

http://www.aphis.usda.gov/animal_welfare/publications_and_reports.shtml.

Licensees must either follow the recommended guidelines or provide a comparable testing and monitoring program that is consistent with AC's goals of ensuring the welfare of captive elephants and minimizing the potential spread of tuberculosis.

Any protocol other than the recommended guidelines should be reviewed and approved by AC prior to implementation. Alternate plans should be submitted to the appropriate AC Regional Office.

During the course of routine inspections, AC inspectors will review documentation that assures that elephants are being tested, and, if the animals test positive or are diseased, are treated according to the recommended guidelines or other APHIS approved protocol.

In addition, due to the possibility of humans transmitting tuberculosis to elephants, AC's guidance is that all attendants, handlers, and/or trainees who have direct contact with elephants should be tested for tuberculosis on at least an annual basis. It is the responsibility of each licensee in consultation with a physician or other appropriate medical authority to determine how this procedure should be satisfied.

RESCINDED

10/16/2015

Subject: Submission of Traveling Exhibitor Itinerary

Policy #2

References: AWA Sections 2143, 2147
9 CFR, Part 2, Sections 2.8, 2.12, 2.26

RESCINDED

History: Replaces policy dated April 14, 1997.

Justification: The Animal and Plant Health Inspection Service (APHIS), Animal Care (AC) has been provided the authority to require records or reports that are needed to effectively enforce the Animal Welfare Act (AWA). In order for licensed traveling facilities to comply with the requirement of readily available access to the premises by the APHIS inspector, APHIS must be kept apprised of the location of the facility.

Policy: Exhibitors who are in continuous travel status should update their itinerary as often as necessary to ensure AC knows their whereabouts at all times.

Circuses, petting zoos, and animal acts with an established route should notify AC in advance of departing their home facility and update travel information as needed.

Exhibitors who take animals from their facilities from time to time should notify AC when any animal is gone more than four (4) consecutive days.

Upon request, a licensee shall provide an itinerary of absences of less than four (4) days.

Providing notification ensures the opportunity for access for an unannounced inspection, eliminates unnecessary AC visits when a licensee has been inspected recently, and minimizes resources needed to locate the exhibitor.

The itinerary shall provide the following:

1. Dates away from home facility
2. City and State for all stops
3. Site name or address of all stops

Similar information should be provided for all periods of “lay-over” while traveling.

The licensee may provide this information to AC by any of the following methods:

RESCINDED

- a. Mail information to the Regional office or inspector
- b. Fax information to the Regional office or inspector
- c. Email information to the regional office or inspector

Notice should be made in advance of travel and updated as changes or additions occur.

**New requirements:
9 CFR §2.126(c)**

Subject: **Expired Medical Materials**
 Pharmaceutical-Grade Substances
 Surgery
 Pre- and Post- Procedural Care
 Program of Veterinary Care
 Declawing in Wild/Exotic Carnivores and
 Removal/Reduction of Canine Teeth in Wild /Exotic
 Carnivores and Nonhuman Primates
 Health Records
 Euthanasia

References: AWA Section 2143
 9 CFR, Part 2, Sections 2.31, 2.32, 2.33, 2.40
 9 CFR, Part 3, Section 3.110

History: Replaces memoranda dated May 31, 1990; November 29, 1991;
 April 6, 1992; and September 25, 1992. Replaces policies dated
 April 14, 1997; January 14, 2000; August 18, 2006; July 17,
 2007; and March 25, 2011.

Justification: Provides requested guidance. The Animal Welfare Act (AWA)
 requires that all regulated animals be provided adequate
 veterinary care.

Policy: **Expired Medical Materials**

The use of expired medical materials (e.g., drugs, fluids, sutures, anesthetics, sedatives, or analgesics) during any survival surgical procedure on a regulated species is not considered acceptable veterinary practice and therefore not consistent with adequate veterinary care as required by the regulations promulgated under the Animal Welfare Act.

Research, Teaching, and Testing

Acute Terminal Procedures: Expired medical materials except analgesics, sedatives anesthetics, and euthanasia solutions may be used in acute terminal procedures where an animal is anesthetized during the study and euthanized without recovery if such use does not adversely affect the animal’s well-being or compromise the validity of the scientific study.

Facilities permitting the use of expired medical materials in acute terminal procedures should have a policy on the use, storage, and disposal of such materials which is in accordance with all relevant institutional, local, state, and federal requirements where applicable; and/or require

investigators to describe the intended use in the animal study proposal.

Pharmaceutical-Grade Substances

Pharmaceutical-grade substances are expected to be used whenever they are available, even in acute procedures. This includes but is not limited to: compounds, medications, drugs, vehicles, and diluents. APHIS recognizes that some substances (e.g. test articles, novel compounds, and those resulting from a compounding process) are only available as a non-pharmaceutical grade product.

Research, Teaching, and Testing:

Non- pharmaceutical-grade substances should only be used in regulated animals after specific review and approval by the IACUC. The IACUC should develop a consistent evaluation process which includes but is not limited to the scientific justification and the availability of an acceptable veterinary or human pharmaceutical-grade product.

Cost savings alone is not sufficient justification for using a non-pharmaceutical- grade substance in regulated species, however, unavailability or shortages of pharmaceutical grade substances may lead to cost increases and the IACUC may determine that this justifies the use of the non-pharmaceutical grade substitution.

Exhibitors and Dealers:

Non- pharmaceutical-grade substances should only be used in regulated animals under the approval of the attending veterinarian in accordance with accepted veterinary practice and nursing care.

Surgery

Surgery is to be performed using appropriate anesthesia in accordance with professionally accepted medical and veterinary practice. Current standards preclude food preparation, eating, drinking, or smoking in surgery areas.

Research, Teaching, and Testing:

Survival Surgery: Survival surgery is to be performed using aseptic technique under standards that are in accordance with professionally accepted medical and veterinary practice. The AWA regulations require major operative procedures on nonrodents to be performed in a dedicated surgical facility. For the purposes of this policy, a designated

surgical facility is one that is set up to be cleaned and maintained in an aseptic condition, and not used for other purposes when not in use. It must be maintained in good repair to meet aseptic requirements. Meeting rooms and auditoriums do not qualify as dedicated survival surgical facilities.

Nonsurvival Surgery: Nonsurvival surgery does not require aseptic techniques or dedicated facilities. It should be performed in a clean area, free of clutter, using acceptable veterinary sanitation practices equivalent to those used in a standard examination/treatment room. Personnel present in the area should observe reasonable cleanliness practices for both themselves and the animals.

Pre- and Post-Procedural Care

The attending veterinarian is to ensure there is adequate pre-procedural and post-procedural care in accordance with established veterinary and medical practices.

Research, Teaching, and Testing:

All animal activity proposals involving surgery must provide specific details of pre- through post-procedural care and relief of pain and distress. The principal investigator must involve the attending veterinarian or his/her designee in planning the type of care that may be provided. The appropriate use of drugs to relieve pain and/or distress should be specified in the animal activity proposal to avoid possible delays due to investigator concerns that a treatment regimen may interfere with the study. The withholding of pain and/or distress relieving measures must be scientifically justified in writing and approved by the IACUC. The specified drugs for relief of pain and/or distress must be readily available for use as described in the proposal.

The attending veterinarian retains the authority to alter post-operative care if unexpected pain and/or distress occur in an animal. In the event the attending veterinarian requests a significant change to a protocol to alter post-operative care for the remaining animals, that change must be reviewed and approved by the IACUC before the change is implemented.

In the event the animal is taken to an off-site location, such as a farm for post-operative care, that location should be identified as a site of the research facility or a site of another registered research facility in order for Animal Care (AC) to conduct an inspection. To comply with adequate veterinary care

requirements and in accordance with currently accepted standards of practice, an animal is not to be taken to an off-site location before it fully recovers from anesthesia unless justified in the animal activity proposal.

Appropriate post-operative records should be maintained in accordance with professionally accepted veterinary procedures.

Program of Veterinary Care

Research facilities, dealers, and exhibitors

Establishments which do not have a full-time attending veterinarian must have a written Program of Veterinary Care (PVC). This Program must consist of a properly completed APHIS Form 7002 or an equivalent format. The attending veterinarian must visit the facility on a regular basis, i.e., often enough to provide adequate oversight of the facility's care and use of animals. APHIS recommends this visit occur at least annually. Records of visits by the attending veterinarian should be kept to include dates of the visits and comments or recommendations of the attending veterinarian or other veterinarians.

The PVC should be reviewed and updated whenever necessary (e.g., as a new species of animal or a new attending veterinarian is obtained, or the preventive medical program changes). APHIS recommends that the PVC be initialed and dated by both the attending veterinarian and the facility representative whenever it is changed or reviewed without change. The preventive medical program described in the PVC is expected to be in accordance with professionally accepted veterinary practice (e.g., appropriate vaccinations, diagnostic testing). It should include zoonotic disease prevention measures.

Declawing in Wild /Exotic Carnivores and Removal/Reduction of Canine Teeth in Nonhuman Primates and Wild /Exotic Carnivores

Declawing of wild and exotic carnivores and the removal or reduction of canine teeth in nonhuman primates and wild and exotic carnivores have been used in the past as a means to minimize the dangers during human interaction with these species. These procedures are not innocuous and can cause ongoing pain, discomfort, or other pathological conditions in the animals. In addition, they do not safeguard the public or the animals from biting and predatory behaviors.

The declawing of any wild or exotic carnivore does not constitute

appropriate veterinary care unless prescribed by the attending veterinarian for treatment of individual medical problems of the paws. Any medical treatment should be limited to the affected digit(s) or area.

Tooth reduction that exposes the pulp cavity does not constitute appropriate veterinary care as it may result in oral pathologic conditions and pain. Reduction that does not expose the pulp cavity may be acceptable in some instances such as a behavioral study or a breeding situation.

The American Veterinary Medical Association (AVMA) has developed a policy statement on these issues that supports APHIS' recommendation. It also suggests alternatives to dental surgery such as behavioral modification, environmental enrichment, and changes in group composition. A full text of AVMA Animal Welfare Policy Statements can be found on www.avma.org.

Health Records

Health records are needed to convey necessary information to all people involved in an animal's care. Every facility should have a system of health records sufficiently comprehensive to demonstrate the delivery of adequate health care.

Traveling exhibitors: Information on any chronic or ongoing health problems and information on the most current preventive medical procedures should accompany any traveling animals, but the individual medical history records may be maintained at the home site.

Euthanasia

The method of euthanasia should be consistent with the current AVMA Guidelines for the Euthanasia of Animals:
<https://www.avma.org/KB/Policies/Pages/Euthanasia-Guidelines.aspx>.

Also note that in accordance with the "Expired Medical Materials" section of this policy, the use of expired euthanasia drugs is considered inadequate veterinary care.

Subject: Necropsy Requirements

References: AWA Section 2143
9 CFR, Part 2, Section 2.33 and 2.40(b)(2)

History: Replaces policy dated October 13, 1998 and previously identified as Policy #22.

Justification: Current regulatory requirements for the performance of a necropsy are focused on marine mammals. Notwithstanding these requirements, there are times when the performance of one or more necropsies is necessary to provide adequate veterinary care for a facility by providing diagnoses of conditions, thereby allowing for adequate prevention, control, and treatment of the disease.

Policy: When warranted by circumstances including--but not limited to--the list below, and at the discretion of the attending veterinarian, regulated facilities should perform necropsies as part of providing adequate veterinary care. Similarly, the Animal and Plant Health Inspection Service (APHIS) inspector, in consultation with their supervisor, may require a facility to perform necropsies on selected regulated animals which die (including by euthanasia) at that licensed or registered facility. Necropsy records, like other medical information, should be maintained at the facility for at least 1 year or as otherwise specified in the Animal Welfare Act (AWA) regulations and standards, and be made available on request to APHIS personnel. Necropsies should be conducted within an appropriate interval after the death, and/or the body should be kept at appropriate refrigerated temperatures to ensure a meaningful examination. All necropsy reports should be signed and dated by the veterinarian preparing the report.

Circumstances which may warrant a necropsy :

- The facility is undergoing a high death loss.
- There are a significant number of unexplained deaths at the facility.
- There exists a strong chance that an undiagnosed infectious disease is present at the facility (with or without potential zoonoses).
- Circumstances around a death indicate a violation of the AWA may have contributed to the situation.

For the purposes of this policy, a “necropsy” means an appropriate postmortem examination (which complies with currently acceptable professional standards) of the animal performed by or under the direct supervision of a veterinarian experienced with that species. It may include, but is not limited to, a systemic gross pathology examination (internal and external), appropriate microbiological culture and histopathology of lesions, and other indicated testing. All results should be recorded in the animal’s medical record.

Note: For marine mammals, see the requirements relating to necropsies at 9 C.F.R. § 3.110(g).

The above listings are intended as guidance only. Persons selling animals listed in the middle column, or animals not listed may wish to contact the appropriate Animal Care regional office for guidance.

Animal Enclosures

Animals are often maintained at an auction ground in transport enclosures. These animals are considered to be “in transit” and may remain in these enclosures while at the auction as long as all requirements for transport enclosures are met or exceeded. Only the enclosure requirements from the Transportation Standards for the appropriate species will be used to determine compliance. However, if an animal shows obvious physical distress, including signs of behavioral stress, physical harm or unnecessary discomfort while held for long periods in a transport enclosure, the auction owner (and the consignor, if licensed) will be cited for a handling violation. Incompatible animals should not to be held in the same enclosure or close to other animals that may cause them stress.

Handling of Animals

Auction employees must be properly trained and experienced to handle animals during a sale. If the auction does not have any personnel qualified to handle certain animals, those animals should only be handled by the consignor, assuming that person is qualified. Being transferred from a transport enclosure to another larger enclosure can be stressful for many animals and must be accomplished by persons trained in making such transfers. There can be disastrous results if animals are moved by untrained and/or inexperienced persons. If an individual enters the auction facility with an animal (e. g. a primate) that is not consigned, and becomes involved in an incident with that animal, the auction (and the individual, if licensed) may be cited for a handling violation.

Regulatory Responsibilities

Responsibility for care of the animals rests with the consignor (if the consignor is licensed or required to be licensed) as well as the operator of the auction. All regulatory requirements for the animals’ care, including the provision of veterinary care when necessary, must be met. The auction’s responsibility does not extend to animals kept in transport vehicles in auction parking lots, etc. Animals are then the sole responsibility of the persons transporting them. Every covered animal that the auction consigns will be regulated while it is within the auction facility.

Public Exhibition of Animals

Animals are often kept on display for public viewing during an auction. In fact, many members of the public go to auctions simply to see the

animals with no intention of bidding on them. Therefore, operators of auctions should utilize appropriate barriers and/or distance so as to ensure the safety of the animals and public. A sufficient number of readily identifiable attendants should be present at all periods of public contact with the animals.

Subject: Space and Exercise Requirements for
Traveling Exhibitors

Policy #6

References: AWA Section 2143
9 CFR, Part 3 Sections 3.6, 3.8, 3.28, 3.53, 3.80, 3.104, 3.128

History: Replaces memorandum dated June 6, 1984, and policies dated March 5, 1998, and October 13, 1998.

Justification: Some traveling exhibitors maintain animals long term in transport cages during “travel status.” This policy clarifies when the licensee is required to meet full primary enclosure space requirements and/or provide sufficient exercise space and time for animals in traveling exhibits.

Policy: Animals exhibited in traveling shows may be transported in enclosures that meet the space requirements for transport as specified in Sections 3.14, 3.36, 3.61, 3.87, 3.113, and 3.137 **ONLY** during actual transport, i.e., movement in a conveyance between temporary locations. At all other times, they must be provided with space as described below.

- Dogs, cats, rabbits, guinea pigs, hamsters, nonhuman primates, and marine mammals must be housed in primary enclosures that meet the space requirements described in Sections 3.6, 3.28, 3.53, 3.80, and 3.104, respectively.
- Primary enclosures for all other animals must allow space for each animal to express all species-typical postures, social adjustments, behaviors, and movements. For example, animals must be able to lie down with limbs extended in a normal manner without obstruction from enclosure sides or having to extend feet through feeder doors or bars. Animals that normally engage in occasional vertical postures, such as bears and many felines, must have sufficient vertical space available to accommodate these postures. Bears often stand upright on their rear legs and must be allowed sufficient vertical space within their housing enclosure to do so. Many felines also stand on their rear legs, for example, when using scratching posts. If enclosures used while “on the road” (i.e., when away from permanent quarters but not actually in transit) do not provide adequate height for animals that occasionally exhibit vertical postures to engage in such activities, this requirement may be satisfied through release of the affected animals into an exercise pen or equivalent. If a pen is used for this purpose, animals should be released at least once per day and allowed to remain for a reasonable length of time unless otherwise justified. These periods should be in addition to regular performance and practice time.

- When elephants are housed on chains while not in transport, chains must be of sufficient length and arrangement so as to permit each elephant to comfortably lie down, get up, self-groom, and move about within a reasonable range. If elephants are kept unchained in a truck or railway car, each elephant must have enough space to make these postural adjustments as well. This also applies to tethered hoofstock.
- When more than one animal is kept in an enclosure at one time, all animals must simultaneously have sufficient space to accommodate the postures and movements as described above.
- Subpart F animals (for example, elephants, hoofstock, and exotic cats) are required to have “sufficient space to allow each animal to make normal postural and social adjustments with adequate freedom of movement.” Enclosures that allow only postural adjustments are inadequate to meet this requirement. APHIS has determined that “adequate freedom of movement” includes the ability to exercise. Since it is sometimes difficult for a traveling exhibitor to provide a primary enclosure large enough to allow an animal sufficient exercise, an enclosure that allows only “normal postural and social adjustments” will be considered acceptable **if** the animal contained therein is released regularly from the primary enclosure into a secure space, such as a ring or corral, that provides the opportunity for species-appropriate exercise. This release should occur at least once per day for an appropriate length of time unless otherwise justified. These periods will be in addition to regular performance and practice time. For some species, an area enclosed by an electrical fence is acceptable for this purpose if monitored at all times. Trained elephants and domestic hoofstock may be walked by a qualified handler for this purpose. These provisions apply only to the need for additional space for exercise. Other than to satisfy the vertical posturing needs of animals that occasionally exhibit such movement, the requirement for “sufficient space to allow each animal to make normal postural and social adjustments” cannot be met by periodic release into a larger enclosure. When a traveling exhibitor is not actually in transit (i.e., when he/she is set/setting up for a show or in a holding location), animals must be kept in enclosures which allow them to express postural adjustments typical of their species.

Subject: Brachiating Species of Nonhuman Primates **Policy #7**

References: AWA Section 2143
9 CFR, Part 3, Section 3.80

History: Replaces memorandum dated July 31, 1991; letter dated June 30, 1992; and policy dated April 14, 1997.

Justification: Clarification is needed to specify brachiating species of nonhuman primates in order to determine proper space requirements.

Policy: In reference to space requirements under Section 3.80, APHIS has determined that brachiating species include:

- a. spider monkeys (*Ateles* spp.)
- b. woolly spider monkeys (*Brachyteles* spp.)
- c. woolly monkeys (*Lagothrix* spp.)
- d. gibbons and siamangs (*Hylobates* spp.)
- e. chimpanzees, bonobo, and young gorillas and orangutans

Brachiating means any primate whose form of locomotion involves using its arms, legs, and/or tail while its body is suspended. The intent of the space regulations is to provide sufficient space for all species-typical postural and locomotive behaviors. Since each of these species engages in brachiating-type movement, the larger space provided for Group 6 primates is appropriate.

Subject: Criteria for Licensing Hoofstock Dealers

Policy #8

References: AWA Section 2133
9 CFR, Part 1, Section 1.1
9 CFR, Part 2, Section 2.1

History: Replaces memoranda dated Feb. 6, 1991; April 4, 1991; June 19, 1991; July 1, 1991; and Sept. 26, 1994. Replaces policies dated October 13, 1998 and August 26, 2002 and previously identified as Policy #23.

Justification: Provides needed clarification.

Policy: The following criteria are examples of when a dealer's license is required for people selling hoofstock:

- Sells animals only for regulated purposes such as biomedical research, exhibition or as pets.
- Sells the majority of their domesticated farm hoofstock (sheep, cattle, goats, pigs, llamas) for regulated purposes and more than 10 animals are sold for regulated purposes in a 12 month period.
- Sells more than 10 wild hoofstock (such as deer, bison, or elk) for regulated purposes in a 12 month period or one or more exotic animals such as a zebra, hippopotami, ibex, camel, giraffe, etc.

The following criteria are examples of activities which we believe do not warrant our inspection of the premises or require the issuance of a license:

- Sales to game ranches, or to private collectors.
- Sales for breeding purposes only.
- Sales for agricultural purposes or to improve food and fiber production.

Generally, farm animals are regulated only for purposes of biomedical research, nonagricultural exhibit, or dealing as defined above. Horses are regulated only when used for biomedical research.

Subject: Adequate Enclosures for Flying Species and Aquatic Species **Policy #9**

References: AWA Section 2143
9 CFR, Part 3, Section 3.128

History: Replaces policy dated October 13, 1998 and previously identified as Policy #24.

Justification: The unique biological and physiological needs of these species require clarification of their space requirements as set forth under the general language of Section 3.128.

Policy: To meet the requirement for sufficient space for normal social and postural adjustments with adequate freedom of movement, Subpart F species that fly (i.e., bats) should be provided with sufficient unobstructed enclosure volume to enable movement by flying and sufficient roosting space to allow all individuals to rest simultaneously.

For Subpart F species that, under natural conditions, spend a significant portion of their time in water (such as capybaras, beavers, river otters, hippopotami, tapirs, etc.), compliance with space requirements means there should be both dry and aquatic portions of the primary enclosure, each of which must, at a minimum, provide sufficient space to allow each animal therein to make “normal postural and social adjustments with adequate freedom of movement.”

“Normal postural and social adjustments” and “adequate freedom of movement” are to be determined according to what is normal for that species under natural conditions.

For example, hippopotami are known to be aquatic during daylight hours and often submerge completely for long periods, sometimes walking underwater, often floating without standing. At night they become terrestrial and graze on the ground. An amount of space that permits “adequate freedom of movement” and “normal postural and social adjustments” should consist of dry and aquatic areas that each allow for at least minimal locomotion of the kind that hippos would normally engage in within that medium.

Aquatic areas of primary enclosures should not contain water which would be detrimental to the health of the animals in those enclosures. This policy is not meant to cover marine mammals, whose requirements are delineated in Subpart E.

the effect of the unconventional introduction of synthetic, species-foreign, or other such genetic material on the phenotype of the animal. Therefore, the facility must be **registered** as a research facility.

A facility which produces cloned animals for regulated purposes utilizing standard veterinary medical practices is considered to be breeding animals, and must be **licensed** as a dealer. Other activities conducted by cloning companies will be reviewed on a case-by-case basis to determine whether they are covered by the AWA.

Activities at Licensed Exhibitors

Licensed exhibitors occasionally collect information on their animals with the intent to improve the nutrition, breeding, management, or care of such animals. APHIS has determined these programs may be exempted from the registration requirements of the regulations as long as the collection methods:

- are performed as an adjunct to normal husbandry or veterinary procedures for the benefit of the animal or species (e.g., routine veterinary care, embryo transfer, artificial insemination, electroejaculation); or
- are not invasive (feed studies); or
- do not cause pain or distress to the animal (behavioral observations).

However, if the licensed exhibitor is conducting biomedical research (using the animals as models for human applications), conducting invasive or painful/distressful procedures for nonhusbandry purposes or if the research involves domestic dogs or cats, then the licensee is **not** exempt from the need for registration.

Producers of Pregnant Mare Urine

Horses used for the production of PMU are not covered by the AWA. This activity is not defined as research, teaching, or testing. People who deal in horses or horse parts are not required to be licensed.

Subject: Painful and Distressful Procedures

Policy #11

References: AWA Section 2143
9 CFR, Part 2, Sections 2.31(d)(1)(i,ii,iv), 2.31(e)(4), 2.33(b)(4), 2.36(b)(5,6,7)

History: Replaces letters dated March 1, 1990; November 9, 1990; November 7, 1991; and May 8, 1992. Replaces policy dated April 14, 1997.

Justification: Inspectors and the regulated community have requested guidance on procedures to avoid or minimize discomfort, distress and/or pain involving animals.

Policy: A painful procedure is defined as “any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure is applied, that is, pain in excess of that caused by injections or other minor procedures”. The Institutional Animal Care and Use Committee (IACUC) is responsible for ensuring that investigators have avoided or minimized discomfort, distress and pain to the animals; appropriately considered alternatives to any procedures that may cause more than slight or momentary pain or distress; and consulted with the attending veterinarian in the planning of the procedures.

Examples of procedures that *may* cause more than momentary or slight pain include, but are not limited to, the following:

Surgery (survival or terminal): considered a painful procedure in which pain is alleviated by anesthesia. Survival surgery may also require the use of peri-operative analgesia.

Freund’s Complete Adjuvant: may cause a severe inflammatory reaction depending on the species and route of administration.

Ocular or Dermal Toxicity Testing: the dosing procedure itself is generally not painful but the reaction caused by the product being tested may cause pain.

Examples of procedures that *may* cause more than momentary or slight distress include, but are not limited to, the following:

Food and/or water deprivation or restriction beyond that necessary for normal presurgical preparation.

Noxious electrical shock or thermal stress that is not immediately

escapable.

Paralysis or immobility in a conscious animal.

Forced exercise (e.g., swimming or treadmill protocols).

Infectious and inflammatory disease models.

Some procedures, including any of those in the lists above, may cause both pain and distress. Examples of procedures that may cause more than momentary or slight pain as well as distress would include studies involving extensive irradiation, inhalation toxicity studies or those involving tumor growth.

Animals exhibiting signs of pain, discomfort, or distress such as weight loss, decreased appetite, abnormal activity level, adverse reactions to touching inoculated areas, open sores/necrotic skin lesions, abscesses, lameness, conjunctivitis, corneal edema, and photophobia are expected to receive appropriate relief unless written scientific justification is provided in the animal activity proposal and approved by the IACUC.

Subject: Consideration of Alternatives to Painful/Distressful Procedures **Policy #12**

References: AWA Section 2143(a)(3)(B)
9 CFR, Part 2, Section 2.31 (d)(1)(ii)and (e); Section 2.32 (c)(2) and (5)(ii)
Principles of Humane Experimental Techniques, William Russell and Rex Burch, 1959
Public Health Service Policy on Humane Care and Use of Laboratory Animals (IV,C,5)
Animal Welfare Information Center

History: Replaces policies dated April 14, 1997, and June 21, 2000.

Justification: The Animal Welfare Act (AWA) regulations require principal investigators to consider alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and provide a written narrative of the methods used and sources consulted to determine the availability of alternatives, including refinements, reductions, and replacements.

Policy: Alternatives or alternative methods, as first described by Russell and Burch in 1959, are generally regarded as those that incorporate some aspect of replacement, reduction, or refinement of animal use in pursuit of the minimization of animal pain and distress consistent with the goals of the research. These include methods that use non-animal systems or less sentient animal species to partially or fully replace animals (for example, the use of an in vitro or insect model to replace a mammalian model), methods that reduce the number of animals to the minimum required to obtain scientifically valid data, and methods that refine animal use by lessening or eliminating pain or distress and, thereby, enhancing animal well-being (for example, the use of appropriate anesthetic drugs). However, methods that do not allow the attainment of the goals of the research are not, by definition, alternatives.

Alternatives should be considered in the planning phase of the animal use proposal. As indicated when these regulations were finalized in 1989, APHIS continues to recommend a database search as the most effective and efficient method for demonstrating compliance with the requirement to consider alternatives to painful/distressful procedures. However, in some circumstances (as in highly specialized fields of study), conferences, colloquia, subject expert consultants, or other sources may provide relevant and up-to-date information regarding alternatives in lieu of, or in addition to, a database search. Sufficient documentation, such as the consultant's name and qualifications and the date and content of the consult, should be provided to the IACUC to demonstrate the expert's knowledge of the availability of

alternatives in the specific field of study. For example, an immunologist cited as a subject expert may or may not possess expertise concerning alternatives to *in vivo* antibody production.

When a database search is the primary means of meeting this requirement, the narrative should include:

1. the name(s) of the databases searched (due to the variation in subject coverage and sources used, one database is seldom adequate);
2. the date the search was performed;
3. the time period covered by the search; and
4. the search strategy (including scientifically relevant terminology) used.

The Animal Welfare Information Center (AWIC) is an information service of the National Agricultural Library specifically established to provide information about alternatives. AWIC offers expertise in formulation of the search strategy and selection of terminology and databases, access to unique databases, on- and off-site training of institute personnel in conducting effective alternatives searches, and is able to perform no-cost or low-cost electronic database searches. AWIC can be contacted at (301) 504-6212, via E-mail at awic@nal.usda.gov, or via its web site at <http://www.awic.nal.usda.gov>. Other excellent resources for assistance with alternative searches are available and may be equally acceptable.

Regardless of the alternatives sources(s) used, the written narrative should include adequate information for the IACUC to assess that a reasonable and good faith effort was made to determine the availability of alternatives or alternative methods. If a database search or other source identifies a bona fide alternative method (one that could be used to accomplish the goals of the animal use proposal), the IACUC may and should ask the PI to explain why an alternative that had been found was not used. The IACUC, in fact, can withhold approval of the study proposal if the Committee is not satisfied with the procedures the PI plans to use in his study.

The rationale for federally-mandated animal testing (for example, testing product safety/efficacy/potency) should include a citation of the appropriate government agency's regulation and guidance documents. Mandating agency guidelines should be consulted since they may provide alternatives (for example, refinements such as humane endpoints or replacements such as the Murine Local Lymph Node Assay) that are not included in the Code of Federal Regulations. If a mandating agency-accepted alternative is not used, the IACUC must review the proposal to determine adequate rationales have been provided, and pain and discomfort limited to that which is unavoidable.

Significant changes are subject to prior review by the IACUC. If those changes include a painful or distressful procedure, a consideration of alternatives or a revision of the prior search may be required

Although additional attempts to identify alternatives or alternative methods are not required by Animal Care at the time of each annual review of an animal protocol, Animal Care would normally expect the principal investigator to reconsider alternatives at least once every 3 years, consistent with the triennial *de novo* review requirements of the Public Health Service Policy on Humane Care and Use of Laboratory Animals (IV,C,5).

Subject: **Animal Identification**

Policy #13

References: AWA Section 2141
 9 CFR, Part 2, Sections 2.38(g), 2.35(b), 2.50, 2.75(a)

History: Combines previous policies 13, 19 and 20, and replaces those policies dated April 14, 1997; July 17, 2000; and March 25, 2011.

Justification: All dogs and cats must be identified. This policy provides guidance and clarification, and recognizes significant advances in and effectiveness of alternatives concerning identification methods.

Policy: Microchip Implants

The U.S. Department of Agriculture (USDA) has determined that registrants and licensees under the Animal Welfare Act (AWA) may use a microchip to officially identify regulated animals.

The AWA regulations allow registrants to identify animals using a tattoo (9 C.F.R § 2.38(g)), and allow licensees to identify animals using a tattoo, if approved by the Administrator (9 C.F.R. § 2.50). A “tattoo” is defined as “an indelible mark or figure fixed upon the body by insertion of pigment under the skin.” (Merriam-Webster, <http://www.merriam-webster.com/dictionary/tattoo>) Consistent with this definition, and in recognition of significant advances in alternatives for identifying animals, the USDA has determined that the identification of animals using a microchip placed under the skin in a standard anatomical location meets the regulatory intent and purpose of a “tattoo.” Based on this determination, registrants and licensees may use a microchip to officially identify animals as an alternative to the use of a tag or tattoo, without obtaining written approval from USDA, provided that all of the following conditions are met:

1. The microchip must be placed in a standard anatomical location.¹
2. An appropriate microchip scanner device must be functioning and made readily available to Animal and Plant Health Inspection Service (APHIS) officials and/or the facility employee accompanying an APHIS representative.
3. The animal identification records, required under sections 2.35(b) (registrants) and 2.75 (licensees) of the AWA regulations, must identify, for each animal, the microchip number, the location on the animal, and the name of the microchip manufacturer.

¹ See Veterinary List of Recommended Microchip Implantation, available at <http://www.wsava.org/sites/default/files/Veterinary%20List%20of%20Recommended%20Microchip%20Implantation%20Sites%20%20.pdf>

4. Any microchipped animal that is delivered, sold, transferred to, or otherwise in the custody of another registrant/licensee who does not have a compatible scanner, must be identified by a tag or tattoo.

Any registrant or licensee who elects to use a microchip to identify AWA-regulated animals, but who does not meet the four conditions outlined above, must also identify those animals in accordance with sections 2.38(g) or 2.50 of the AWA regulations.

Tattoo Identification of Dogs and Cats

Each licensee who wishes to use a tattoo to identify his/her animals should contact the appropriate Animal Care Regional Office to obtain a code for identification. This code includes the type of business (Class A or Class B) and the State in which he/she is licensed. Examples of the system are as follows:

Class A dealer from Maryland: MDAA through MDAAZ

Class B dealer from Maryland: MDBAA through MDBZZ

In addition to the dealer's code assigned, the dealer will be required to add the necessary numbers to uniquely identify each animal. Dealers of purpose-bred dogs and cats sold only for research purposes may have special tattoos approved by the Administrator.

Identification of Puppies Less than 16 Weeks of Age

Puppies less than 16 weeks of age do not require individual identification if the following requirements are met:

1. The puppies are maintained as distinct litters at the facility where they were whelped.
2. The enclosure containing the puppies is identified with the information required by 9 CFR, Section 2.50 until the puppies are sold or moved from the facility where they were whelped or reach the age of 16 weeks, whichever comes first.

Questions

If you have any questions regarding this policy, please contact the appropriate Animal Care Office in Raleigh, NC at (919) 855-7100 or Fort Collins, CO at (970) 494-7478.

1. An outline of the research proposal for which the procedure(s) is requested;
2. A means by which to uniquely identify the research proposal;
3. The species and the approximate number of animals involved in the exemption request;
4. A method of permanently identifying the individual animals involved;
5. The time frame for the proposed exempt procedure;
6. The number of major operative procedures to be performed on a given animal, the frequency of such procedures, and the period of time between each major operative procedure;
7. Measures to be taken to ensure that pain/distress are minimized;
8. A complete scientific justification for the exemption. Cost is not an acceptable justification.
9. An assurance that all other stipulated requirements of the AWA and regulations will be met in consideration of this exemption; and
10. An assurance that the facility's IACUC has approved the exemption.

The Animal and Plant Health Inspection Service (APHIS) may respond to the formal request by approving the request as written, requesting further information, imposing additional limitations, or denying the request. An annual IACUC evaluation of the exemption is required, which consists of an IACUC assessment of the animals and the effectiveness and soundness of the methods and procedures used. This information is to be included in the report of the IACUC submitted to the Institutional Official. Considerations for the renewal or continuation of the exemption will be based on the IACUC's recommendations following their review. The exemption must be included in the Annual Report (APHIS Form 7023).

Subject: Institutional Official and IACUC Membership

Policy #15

References: AWA Section 2143(b)(1) and (d)
9 CFR, Part 2, Section 2.31(a), (b)(2,3) and Section 2.32(a)
Office of Laboratory Animal Welfare (OLAW) Guidance Documents re
Alternates and Electronic Meetings

History: Replaces policies dated April 14, 1997, and March 7, 2006.

Justification: Provides clarification of specified individual roles in the Animal Care and Use Program at research facilities.

Policy: The regulations provide for four specific roles within the Animal Care and Use Program:

1. Institutional Official
2. IACUC Chairperson
3. Attending Veterinarian
4. Nonaffiliated Member

These positions are meant to provide a system of checks and balances which is not normally achieved if any one person fills more than one of these roles. While the regulations do not specifically prohibit one person from filling more than one role, the Animal and Plant Health Inspection Service (APHIS) strongly discourages such assignments because of the potential for conflicts of interest and/or undue influence by one person over the facility's program. However, a veterinarian who is not the attending veterinarian may assume any one of the other program positions.

The Institutional Official (IO) at a research facility is the person authorized to legally commit on behalf of the facility that the requirements of the regulations will be met. The IACUC reports its inspection findings and recommendations to the IO to ensure the IO is aware of deficiencies at the facility and commits facility resources to making corrections. The IO should therefore be someone with the authority to promulgate, implement, and enforce policies across departmental lines. The IO should also have the fiscal authority to provide for adequate staffing, program improvements, facility repairs, and renovations that meet the needs of the institution's program.

The Institutional Animal Care and Use Committee shall be composed of a Chairman and at least two additional members, for a total minimum of at least three persons.

For Animal Welfare Act (AWA) enforcement purposes, the nonaffiliated member of the Institutional Animal Care and Use Committee (IACUC) is to “provide representation for general community interests in the proper care and treatment of animals.” The person filling this position is intended to represent society’s “less specialized” nonscientific concerns regarding the welfare of the animal subjects. APHIS has determined the nonaffiliated member should not be a laboratory animal user at any research facility.

Compensation of the nonaffiliated member is permissible only when it does not jeopardize the member’s status as a nonaffiliated member. Compensation varies but is normally limited to payment for travel and related expenses, such as parking and meals, to modest monetary payments for participation. The dollar amount of compensation, if any, should not be so substantial as to be considered an important source of income or to influence voting on the IACUC.

IACUC members must be qualified to assess the research facility’s animal program, facilities and procedures. The research facility is responsible for ensuring their qualification, and this responsibility is filled in part through the provision of training and instruction. For example, IACUC members should be trained in understanding the Animal Welfare Act, protocol review, and facility inspections.

No IACUC member can review his/her own proposal.

Subject: Proper Diets for Nondomestic Felids

Policy #16

References: AWA Section 2143
9 CFR, Part 2, Section 2.40
9 CFR, Part 3, Section 3.129

History: Replaces policy dated October 13, 1998 and previously identified as Policy #25.

Justification: To clarify what is considered acceptable nutritious food for non-domestic felids (including large felids such as lions, tigers, cougars, pumas, jaguars, leopards, snow leopards, clouded leopards, and cheetahs, and smaller felids such as ocelots, fishing cats, bobcats, lynx, caracals, and servals).

Policy: The diet for non-domestic (i.e., wild or exotic) felids must be wholesome, palatable, and free from contamination. A number of commercially prepared diets are available which are appropriate for the varying needs of exotic or wild felids. If such diets are not used, the attending veterinarian--preferably in consultation with a nutritionist- should approve, in writing, a nutritionally complete alternative diet. The written diet should specify the type, quantity, and frequency of any nutritional supplements. A diet composed exclusively of poultry necks or red muscle meat is nutritionally incomplete, and will result in skeletal structural damage, neurologic problems, or other potentially irreversible health problems including death. A diet based on muscle meat alone will result in a dietary imbalance of calcium, phosphorus and Vitamin D, leading to a nutritional bone disease, as well as potentially leading to a Vitamin A or Vitamin B1 deficiency. These disease processes are manifested more readily in lactating or growing animals. A diet based on muscle meat requires 5 to 6 grams of calcium carbonate per pound of muscle meat fed to provide an appropriate calcium: phosphorous ratio and to prevent metabolic bone disease. Vitamin A deficiencies are most commonly seen in young growing lions and often present as neurologic disorders.

The feeding of roadkill should be discouraged. When used, it must be fresh, wholesome and free of certain types of contamination that can be visually observed (such as pus, maggots or worms). Carcasses or meat should be fed promptly. Carcasses or portions of carcasses should be removed when spoilage begins, or, at a maximum, 12 hours after being placed into the enclosure. If not immediately fed, a carcass must be processed into smaller pieces and frozen for future use in order to meet the requirement of being wholesome and free from contamination. Sick animals, or animals that have died of illness or unknown causes are considered unwholesome and must not be used for food. Animals euthanized with chemical euthanizing agents must not be used for food because of the danger of poisoning. When food animals have been euthanized by gunshot, the lead shot should be removed to prevent

lead poisoning from ingestion of the pellets. Downer animals exhibiting signs of central nervous system disorders, including dairy and beef cows, horses, other livestock (particularly sheep), and wildlife species, must not be used for food because of the risk of transmissible spongiform encephalopathies. This includes animals suffering from scrapie and any chronic wasting disease. If the downer animals were clearly harvested because of physical injuries only, they may be used for food when properly processed. In addition, animals known or suspected of being affected with Johnne's disease should not be fed to felids. Likewise swine from herds identified with pseudorabies should not be fed to any species of felid.

Adherence to a strict feeding schedule is strongly recommended. Scheduled feedings will result in the animals consuming the meal more quickly, and decreasing the time for potential spoilage. Meals should be of proper proportions, to facilitate consumption before they spoil or become contaminated. If spoilage (contamination) does not require earlier removal, food not consumed within 12 hours should be removed and disposed of properly. After this time, APHIS would not consider the food to be wholesome. Likewise, to be considered wholesome, stored meat should be refrigerated, or wrapped and frozen. Frozen meats must be handled appropriately to prevent contamination (e.g., thawed under refrigeration). Grains, cereals, or bakery products are not to be fed since felids do not have the enzymes necessary to digest food with high carbohydrate content. Feeding of such products would be detrimental to the health of the animal and would not be considered to have sufficient nutritive value. Outdated meats from grocery stores may be fed if they are wholesome when acquired and are kept refrigerated or frozen until used. If fish is provided as a part of the diet, it should comprise no more than 20% of the diet, should not be fed daily, and appropriate vitamin E and thiamine supplementation is needed to compensate for thiaminase and high polyunsaturated fatty acid content.

In order to mimic natural feeding behaviors and when approved by the attending veterinarian, animals that fall within a normal weight range may be fasted for 1 or 2 nonconsecutive days per week. Normal weight range means that the animal would not be considered too thin by the attending veterinarian or another knowledgeable big cat expert. Underweight animals should not be fasted. During fasting, long femur bones, oxtails, horsetails, or rawhides should be fed in order to promote periodontal health and provide an opportunity for the animals to engage in more natural feeding behaviors. This is a good practice even when the animals (such as those that are underweight) are not fasted. The exclusive feeding of soft diets has become a significant problem for nondomestic cats, and may result in oral disease. Diet formulations that require no chewing or tearing may contribute to excessive dental plaque and calculus formation when fed for prolonged periods. This, in turn, may lead to gingivitis, loose teeth, abscesses in the oral cavity and, ultimately bacteremia.

If young felids are not kept with the dam until weaned, a balanced formula and an appropriate feeding schedule should be approved in writing by the attending veterinarian. If any puppy milk replacer products are selected, then taurine must be added to the formula daily to meet the needs of the neonates. If taurine is not added to puppy milk replacer products, the result could be death to the felid.

Subject: Regulation of Agricultural Animals

Policy #17

References: AWA Sections 2132, 2143
9 CFR, Part 3, Subpart F

History: Combines previous policies 26 and 29, and replaces those policies dated November 17, 1998, and February 11, 2000.

Justification: The Animal Welfare Act (AWA) regulations cover farm animals that are used in activities that are regulated by the AWA.

Policy: Farm animals, such as domestic cattle, horses, sheep, swine, and goats that are used for traditional, production agricultural purposes are exempt from coverage by the AWA. Traditional production agricultural purposes include use as food and fiber, for improvement of animal nutrition, breeding, management, or production efficiency, or for improvement of the quality of food or fiber.

The following criteria should be used to determine whether the activities require licensing or registration:

Farm Animals in Research

Regulated

- Farm animals used to manufacture or test biologics for nonagricultural or nonproduction animals, or humans. This includes biologics that are produced or tested for possible use in either agricultural or nonagricultural species, such as multispecies rabies vaccines.
- Farm animals that are used as models for human subjects or nonagricultural animals (e.g., using calves to develop an artificial heart for humans).
- Farm animals used for biomedical teaching; that is, the training of human or veterinary medical personnel in medical methods and procedures, such as surgery, diagnostic techniques, anesthesia and analgesia.

Exempt

- Farm animals used to manufacture or test veterinary biological products intended for use in the diagnosis, treatment, or prevention of diseases in agricultural animals.
- Farm animals used in agricultural teaching, such as farm or ranch

management procedures (e.g., hoof trimming, shearing), handling practices and breeding techniques.

Farm Animals in Exhibition

Regulated

- Farm animal exhibit intended to draw or entice customers to a nonagricultural enterprise, such as a petting zoo at a restaurant.
- Farm animal exhibit whose main purpose is to allow public contact with the animals, such as a petting zoo or photo op setting.
- “Agricultural” exhibits that also exhibit nonagricultural animals.
- Nonagricultural animals exhibited at an agricultural venue, such as a county fair.

Exempt

- Farm animal exhibits intended to advance the agricultural arts and sciences.
- Agricultural animals in livestock shows, fairs, FFA or 4-H venues, or rodeos.
- Incidental exhibition of farm animals, such as public access (viewing) of a working bison farm, where people driving by can see the animals. They are not being kept for the intent of exhibition, nor are they advertised for viewing purposes.
- Historic farm parks that are accurate representations of the farm setting and are intended to educate the public as to that way of life.

All farm (agricultural) animals being used for regulated purposes must be handled and maintained in accordance with the AWA regulations and standards. There are reference materials available, such as the “Guide for the Care and Use of Laboratory Animals,” published by the Institute for Laboratory Animal Research (ILAR) and the “Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching”, published by the Federation of Animal Science Societies (FASS), that may provide supplemental information. However, it should be noted that not all sections of these guides are applicable under the AWA. Further, nothing in the guides shall be used to reduce or lessen any of the requirements in the AWA regulations and standards.

Subject: Capture Methods of Prairie Dogs

Policy #19

References: AWA Section 2143
9 CFR, Part 2, Section 2.131(a)(1), and Section 2.126

History: Replaces policies dated February 23, 1999; November 17, 2000; February 9, 2001; and September 21, 2001 and previously identified as Policy #27.

Justification: Provides clarification regarding methods for capturing prairie dogs

Policy: As required by Section 2143 of the Animal Welfare Act (AWA) and further explained in 9 CFR, Part 2, Section 2.131(a)(1), handling of animals must be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort. Methods used to capture prairie dogs from natural habitats for covered purposes must be done in a humane manner.

The introduction of water, chemicals or noxious gas into prairie dog burrows and the use of vacuum equipment are not in compliance with Section 2.131(a)(1).

Live trapping of prairie dogs must only be done with humane traps that do not injure the prairie dog upon capture. The traps must be checked with sufficient frequency to assure that the animal does not go without food, water or shelter for an unnecessary period of time.

Subject: **Licensing Sales of Dead Animals**

Policy #20

References: AWA Sections 2131 and 2132(f)
 9 CFR, Part 1

History: Replaces policy dated September 30, 1999 and previously identified as Policy #28.

Justification: The definition of “dealer” in the Animal Welfare Act (AWA) states that a dealer “is any person who . . . buys or sells . . . any dog or other animal whether alive or dead for research, teaching, exhibition, or use as a pet” This policy provides clarification regarding the licensing requirements for persons who sell dead animals and/or animal parts.

Policy: The following persons who sell dead animals or animal parts require a license:

- Any person who acquires any live covered animal and subsequently euthanizes that animal to sell for a covered purpose.
- Any person who acquires a dead dog or cat (or parts) from private, unlicensed sources, to sell for covered purposes.

The following persons who sell dead animals do not require a license:

- Any person who acquires a dead animal (other than a dog or cat) and then sells it.
- Any person who acquires a dead dog or cat (or parts) from a USDA licensed dealer or municipal, county, or state pound/shelter and then sells it.