

ANIMAL WELFARE ACT: AWA history, function, & process

Anna Hampton DVM, DCLAM
Assistant Director, Office of Animal Welfare Assurance
Duke University
08-03-13

Disclaimer

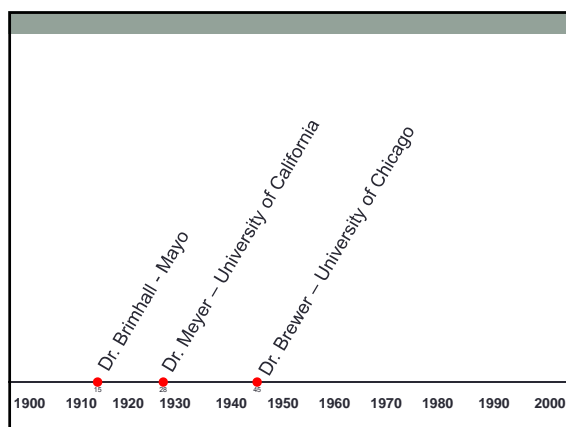
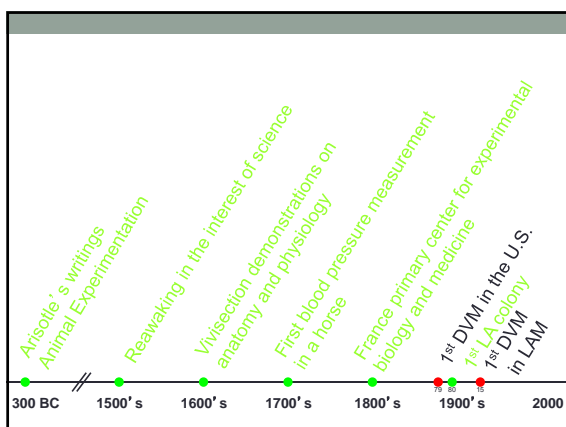
- This is not an ACLAM sanctioned presentation
- All information is deemed reliable and correct
 - No warranty for accuracy
- No information presented is known to be specifically included in the ACLAM Board examinations
- I do not remember what was on the boards
- I do not know what will be on the boards

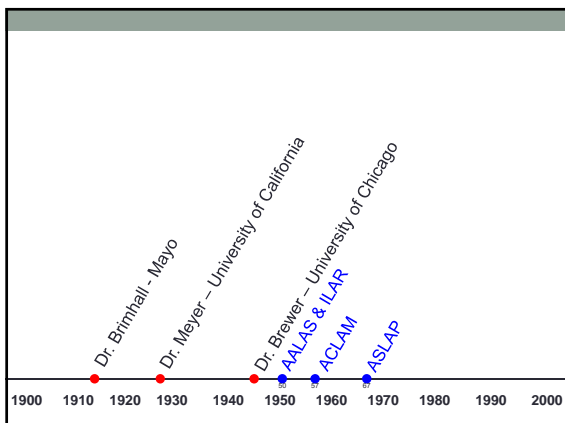
Thank you

- Ron Banks, Director OAWA

This is how I studied

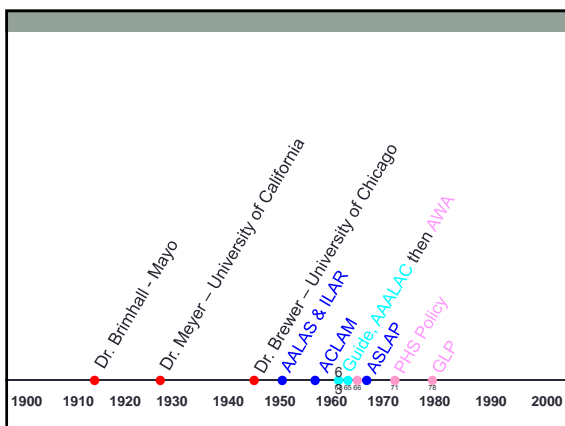
- Gathered BB chapter reviews and other documents
- Studied these
- Wrote my own review of the BB chapter reviews and other documents on the things I didn't think I remembered
- Studied these
- Wrote my own summary of my own review of the BB Chapter reviews and other documents on the things I didn't think I remembered
- Studied these






Laws, Regulations, and Guidelines

- 1963 - Guide for the Care and Use of Laboratory Animals
 - Guideline
- 1965 – AAALAC
 - Self-regulation
- Milestone – first time standards became available for institutions to evaluate the quality of their animal care program
- Still no federal regulations



Animal Welfare Act USDA Regulations



- 1966: Laboratory Animal Welfare Act
 - USDA charged with developing minimum standards of care and treatment with respect to eight areas:
 - housing,
 - feeding,
 - watering,
 - sanitation,
 - ventilation,
 - shelter from extremes of weather and temperature,
 - separation by species, and
 - adequate veterinary care
 - Principally dealt with dogs

Animal Welfare Act USDA Regulations

- 1970: Renamed Animal Welfare Act
 - Extended oversight beyond the animal holding facilities & into the laboratory.
 - Research facilities were required to provide an annual report:
 - The number of animals used (by species);
 - Whether pain-relieving drugs were administered or a justification for causing pain, if pain-relieving drugs were not used.
 - USDA was required to compile this data in a report to Congress, to be made available to the public.
 - Definition of adequate veterinary care was modified to include appropriate use of anesthetics, analgesics, tranquilizers, and other pain-relieving drugs.
 - Was extended to include all warm-blooded species and additional animal uses. The expansion brought animals in zoos, circuses, shows, and the wholesale pet trade under jurisdiction.

Animal Welfare Act USDA Regulations

- 1976: AWA – 1st Amendment (now called AWA)
 - Extended regulation to commercial carriers and intermediate handlers of animals being transported for research, exhibition, and the wholesale pet trade.
 - The sizes of primary enclosures for transportation were standardized and regulations for ventilation, ambient temperature ranges, and handling procedures were implemented.
 - Secretary promulgated regulations that excluded rats, mice, birds, horses, and farm animals.

Animal Welfare Act USDA Regulations

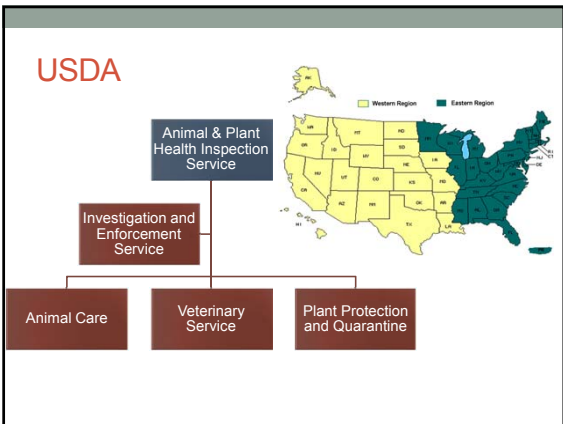
- 1985 (Food Security Act: PL 99-198):
 - Mandated training of all personnel using animals in research.
 - Defined duties and composition of the IACUC.
 - Developed standards for exercise of dogs and promote the psychological well being of primates.
 - Defined one major operative procedure only - unless scientifically justified or veterinary clinical procedure (no research data)
 - Established the search for unnecessary duplication.
 - Requires the search for 'alternatives to painful procedures'
- 1990 (Food, Agriculture, Conservation and Trade Act Protection of Pets: PL 101-624):
 - Mandated a minimum holding period of five days for pounds and shelters before providing any live cat or dog to a "Class B" dealer.

Animal Welfare Act USDA Regulations

- 2002 (Farm Security And Rural Investment Act: PL 107-171):
 - Changed definition of animal: "... excludes birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research, horses not used for research purposes ..."
- AWA is a living document
 - ~2001
 - Rule on marine mammal exhibitors APHIS published a final rule that addressed several issues related to marine, keeping out vermin, necropsy recordkeeping.
 - 2002 – 2007
 - Regulation of wholesale dealers of dogs (vs. hunting, breeding, or security purposes), amended the definition of "dealer" to include only wholesale dealers, more regulations on transportation, enhanced protection of VMO from harassment form both registrants and licensees, more penalties and provisions
- Animal Care policies

Animal Welfare Act

- United States Department of Agriculture
 - Applies only within the USA & territories
 - Selected species covered by the USDA
 - Only applies if using covered species in research, testing, or teaching
 - DOES delineate Field Study vs. Field Research
 - Study = means any study conducted on free-living wild animals in their natural habitat, which does not involve an invasive procedure, and which does not harm or materially alter the behavior of the animals under study (observational, photographs, collection of feces).
 - Research = any study that involves an invasive procedure or the potential to cause harm or materially alter the studied animal's behavior (capture/release, banding, etc.)
- United States Department of Agriculture (USDA):
 - Responsibility for developing the regulations under the Act



Animal Welfare Act & Regulations

Definitions

- An Animal is:
 - Any live or dead dog (all dogs including hunting, security, or breeding), cat, NHP, guinea pig, hamster, rabbit or any other warm-blooded animal intended for use in research, teaching, testing, experimentation, or exhibition purposes, or as a pet.

Animal Welfare Act & Regulations

Definitions

- An Animal is NOT:
 - Birds, rats of the genus Rattus, and mice of the genus Mus bred for use in research, or
 - Cold-blooded vertebrates (e.g. fish or frogs), or
 - Invertebrates (e.g. octopus, squid), or
 - Horses and other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.

Definitions

- Institutional Official:
 - The individual who legally commits (on behalf of research facility) that requirements of AWA will be met.
 - The 'Go-To-Jail' guy / gal
- Attending Veterinarian:
 - The individual who is appointed by the Institutional Official to oversee the institution's program of veterinary care, and who has legal obligation to maintain the health and welfare of the institution's animals and those used in research projects

Definitions

- Painful procedure:
 - Any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being
 - Requires Attending Veterinary consultation
 - Requires an 'ALTERNATIVES' search

Definitions

- Study area:
 - Any room, area, enclosure, or other containment outside of a main animal facility where animals are housed for more than 12 hours.
 - Requires minimum environmental conditions which meet or exceed core vivarium conditions for animal wellbeing and support.
- NOTE: For the NIH/PHS, a 'satellite facility' is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours

Definitions

- Random source animals:
 - Dogs and cats obtained from animal pounds or shelters, auction sales, or from any person who did not breed and raise them on his or her premises (Class B)
 - Use of Class B animals (especially dogs / cats) should be scientifically justified ...
 - PHS recent FAQ on use of Class B animals (ends in 2015)
- Primary enclosures:
 - Any structure or device used to restrict an animal or animals, such as a room, pen, or cage
 - Must meet minimums required by the IACUC and the AV
 - Must be inspected at least every 6 months

Definitions

- Veterinary Medical Officer (VMO):
 - An employee of the USDA/AC who has access at any time to any animal <USDA definition of animal>, record for that animal, or procedure involving an animal which is being used for research, testing, or teaching
- Citation:
 - An observation by the VMO of an activity which is <in their opinion> inconsistent with the USDA Regulations/Animal Welfare Act
 - A repeat observation at any time is considered 'continuing non-compliance' and is potentially a finable offense!

Registration and IACUC

- Nonfederal research Facilities
 - Must **REGISTER** with AC
 - Renewed every 3 years
- IACUC
 - Appointed by the CEO (IO)
 - Membership
 - Chairman
 - DVM
 - Non-affiliated
 - At least 3 members
 - No more than 3 members form the same department (or Unit)

Functions of the IACUC

1. Must review the program of animal care & use every 6 months
2. Must inspect animal facilities at least every 6 months
3. Prepare reports to the IO at least every 6 months with significant vs minor deficiencies and a plan
4. Must make recommendations to the program of animal care and use
5. Must review and investigate public complaints of animal use
6. Must review and approve/disapprove proposed activities
7. Must review and approve/disapprove proposed significant changes of on-going activities
8. May suspend an activity involving animals which is non-compliant (will be reportable to PHS / USDA / AAALAC)

Procedures must be in accordance with...

1. Procedures avoid or minimize discomfort, distress, and pain
2. Document the consideration of alternatives to procedures causing pain/distress
3. Written assurance that procedures are not unnecessarily duplicated
4. Painful procedures will be carried out with:
 - Appropriate sedatives, analgesics, or anesthetics
 - Consultation with the attending veterinarian
 - Will not involve the use of paralytics without anesthesia
5. Unalleviated severe or chronic pain will be painlessly euthanized
6. Living conditions appropriate for the species
7. Medical care must be available and provided

Procedures must be in accordance with...

8. Personnel conducting procedures must be qualified and trained in the procedures to be performed
9. All surgeries will:
 - Provide appropriate pre- and post-operative care
 - Be performed in facilities dedicated to that purpose
 - Be performed aseptically
10. No animal will be used in more than 1 major operative procedure unless:
 - Scientific justification is given in writing by the investigator
 - Surgery is required for routine veterinary care or to protect the health of the animal
 - In other circumstances as determined by the administrator
11. Methods of euthanasia must be in accordance with the definition, unless scientific justification is provided in writing by the PI

Protocol Review Process

- All IACUC members get a list of proposed activities
- Any IACUC member may request a FCR of an activity
 - No FCR at least one member must review the protocol
- IACUC members cannot vote on their own protocol
- May invite consultants
 - Cannot vote if they are not a member
- Notify investigator in writing of decision; they can respond in writing
- Review activities annually
- Majority of quorum at a convened meeting
 - FCR
 - Protocol suspension
- Suspended activity > IO must report to APHIS and funding agency
- Other officials at the facility may review

Protocols must include

- Species and approximate numbers to be used
- Rationale for animal use and appropriateness of species
- Description of animal use
- Description of procedures to minimize pain

Review options:

1. Approve,
2. Approve with Modifications, or
3. Withhold Approval

Personnel Qualifications

- Research facility must ensure all personnel are qualified
- Training and instruction guidance in
 - Humane methods of care and use
 - Ways to minimize pain/distress
 - Use of anesthetics, analgesics, and tranquilizers
 - Methods to report animal care concerns
- Utilization of services (information finding) for
 - Care and use
 - Alternative techniques
 - Duplication
 - The AWA

Animal Welfare Act & Regulations, Subpart C – Research Facilities

Veterinary Care

- Must have Attending Vet
 - Care to animals
 - Voting member of IACUC
 - Part-time or consulting need a written program and regularly scheduled visits
- Program
 - Appropriate people, stuff, and support
 - Appropriate methods for care, including weekends/holidays
 - Daily observations of animals
 - Guidance on handling, anesthesia, euthanasia, etc.
 - Adequate pre- and post-procedural care

Animal Welfare Act & Regulations, Subpart C – Research Facilities

Recordkeeping Requirements

- Must maintain records:
 - Meeting minutes; Proposed activities and significant changes
 - Semiannual reports
 - Protocol, procedural, animal care records
 - Must keep for three years after completion of project
- Must assure medical records for animals:
 - Dogs / cats: Health certificate, animal description, USDA number, date of acquisition, vendor information, routine health assessments, treatments
 - All records must be available for APHIS and federal agency inspection and copying (FOIA)
 - Must be kept for 3 years after final disposition

Animal Welfare Act & Regulations, Subpart C – Research Facilities

Annual Report to USDA

- Submitted by 1 December (covers federal fiscal year) signed by CEO/IO
 - Covers November 1 – October 30th
- Must confirm acceptable vet care standards (AV) exist
- Must confirm consideration of alternatives to painful procedures
- Must confirm adhering to the AWA standards (or exemptions are duly noted)
- Must confirm Attending Veterinarian has appropriate authority to fulfill oversight, care, and use obligations
- Must list changes in facilities
- Must list animals in ACTUAL pain/distress category

• NOTE: THIS REPORT IS ACCESSIBLE TO THE PUBLIC!

Animal Welfare Act & Regulations, Subpart C – Research Facilities

Other items

- Dog/Cat identification
 - Official tag
 - Information: "USDA", State and Dealer ID, & Animal Number
 - Cannot reuse within 5 year period
 - Keep 1 year after euthanasia/death
 - Official tattoo
 - Other (≤16 weeks old; pups/kittens with dam; microchip)
- Transport of dog, cat, or NHP
 - Health certificate by a licensed veterinarian
 - Animal inspected ≤10 days
 - Free of any infectious disease or physical abnormality*
 - *research exception

Animal Welfare Act & Regulations

Animal Welfare Act & Regulations Part 3

- Specific Provisions for Covered Species:
 - Identification
 - Housing structure; Housing conditions; Housing density
 - Sanitation
 - Transportation
 - Surveillance
 - Veterinary Care; Husbandry Minimums
 - Exercise Program (dogs)
 - Psychological Wellbeing (NHP)
- Exemptions:
 - AV approved (revisited q 30 days)
 - Scientifically justified & IACUC approved (q 12 mths)

Animal Welfare Act & Regulations, Part 3

Dog and Cat Facilities Highlights

- Common sense items
- Hard surfaces in contact with D/C spot-cleaned daily
- Temperature range: 45°F - 85°F (with exceptions if >4hrs)
- Outdoor housing: Shelter must be large enough to allow all animals to sit, stand, lie, and turn freely
- CATS
 - 3:4kg:4 24
 - Clean litter can be floor space (not food/water)
 - ≤ 12 adults in one room
 - Elevated resting surface
- DOGS
 - $\frac{(\text{length} + 6")^2}{144}$ 6" above head
 - ≤ 12 adults in one room
 - Innovative = approved by IACUC

Animal Welfare Act & Regulations, Part 3

Dog and Cat Care Highlights

- Common sense items
- Exercise for dogs
 - Develop, document, and follow a plan
 - Plan must be approved by AV
 - >12 weeks old in individual pens < 2x required floor space or
 - Grouped with <100% floor space per dog
 - Isolated, then needs positive physical contact with a human daily
 - Cannot force exercise
 - Exempted
 - AV deems appropriate; non-permanent then vet reviews Q30d
 - Scientific justification approved by IACUC
 - Reviewed annually
- Feed at least SID
- Items sanitized every 2 weeks
 - Live steam
 - Hot water (180°F)
 - Detergents and disinfectants

Animal Welfare Act & Regulations, Part 3

Dog and Cat Transportation Highlights

- In general things happen in 4 hours
 - Max time accepted before departure
 - Max time food/water offered before departure
 - Time out of temp range (except 45mins on the move)
 - Observed (ground transport or accessible during flight)
- Temperature certification
 - If <50°F but not lower than XXX
 - Veterinarian has to sign within 10 days
- Terminal facility and no one is home, contact attempt every 6 hours for 24 hours; return after 48 hours
- Top and one side: "Live Animal" with 1" high letters
- Ventilation
- Maximum occupancy during travel
- Offer food Q24 hours and water Q12 hours

Animal Welfare Act & Regulations, Part 3

Guinea Pig and Hamsters Highlights

- Common sense items
- Temperature range: 60°F - 85°F
- Outdoor housing: NOT HAMSTERS; GP require Deputy Administrator approval
- GUINEA PIG
 - 60:350g; 101 7
- HAMSTERS
 - 10:60g; 13:80g; 16:100g; 19 6
 - Can be fed on the ground
- Transportation
 - Need vet certificate if out of temperature ranges (45°F - 85°F)
 - ≤15 guinea pigs and ≤50 hamsters per container
 - Minimum space
 - Food and water Q6hrs

Animal Welfare Act & Regulations, Part 3

Rabbit Highlights

- Common sense items
- Temperature range: 40°F - 85°F; Indoor don't need heat
- Solid bottom need litter
- Dam with litter need nest box
- Cleaned Q7 days; Sanitized Q30 days
- RABBITS
 - 1.5:2kg; 3:4kg; 4:5.4kg; 5 14
- RABBIT with LITTER
 - 4:2kg; 5:4kg; 6:5.4kg; 7.5 14
- Transportation
 - Need vet certificate if out of temperature ranges (45°F - 85°F)
 - ≤ 15 per container
 - Minimum space
 - Food and water Q6hrs

Animal Welfare Act & Regulations, Part 3

NHP Highlights

- Common sense items
- Hard surfaces in contact with D/C spot-cleaned daily; sanitized every 2 weeks
- Temperature range: 45°F - 85°F (with exceptions if >4hrs)
- Outdoor housing: Shelter must fit all and need a perimeter fence (6' high and 3' from primary enclosure)
- Space requirement based on category...
- Restraint >12 hours require daily unrestrained activity for one continuous hour during period of restraint
- TRANSPORTATION

Animal Welfare Act & Regulations, Part 3

Environmental enhancement adequate to promote the psychological well being of NHP

- Plan in accordance with professional standards
- Directed by the AV
- Provisions for social needs (unless aggressive, debilitated, contagious, or incompatible)
- Means of expressing species-typical behavior (swings, perches, toys, foraging)
- Special cases:
 - infants and juveniles
 - those that show signs of being in psychological distress
 - those on protocols that require restricted activity
 - NHPs that cannot see or hear NHPs of their species
 - great apes >50kg
- Exemptions: AV Q30days or IACUC approved

More to come for the USDA...