USDA Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Updates from USDA APHIS Animal Care

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Inspections

Noncompliance Statistics (FY24)

- 1,275 inspections
- 409 noncompliances cited during 234 inspections
- 74 critical NCIs
- 9 direct NCIs
- Data gathered on 2-Dec-2024

Top Research Noncompliances Cited

§2.31 Institutional Animal Care and Use Committee	162
§2.38 Miscellaneous	60
§2.33 Attending Veterinarian and Vet Care	39
§3.131 Sanitation	15
§3.125 Facilities General	14
§2.36 Annual Report	14

What if we disagree?

- Must receive appeal within **21 days** for regular inspections and within **7 days** of 3rd prelicense inspection

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Animal Care Tech Note

Inspection Report Appeals Process

Animal Care, a part of the U.S. Department of Agriculture (USDA), conducts inspections to assess whether dealers, exhibitors, research facilities, intermediate handlers, and carriers are in compliance with the Animal Welfare Act (AWA) and its regulations and standards. The following information is a quick reference for these facility operators on the process for appealing an inspection report.

Overview

An appeal is a formal request to USDA Animal Care from an AWA licensee, registrant, or new applicant to reconsider all or part of the content of an inspection report. You may appeal content in a **regular inspection** report (i.e., routine, focused, or attempted inspection types) or a **third prelicense inspection** report that you believe is incorrect, does not consider relevant facts, or is inconsistent with the applicable AWA regulations or standards.

The appeals process provides an objective and thorough way for Animal Care to review any disagreements about the content of an inspection report, without fear of retaliation on the part of the licensee, registrant, or applicant. The process can also lead to a better understanding of the AWA and its regulations and standards among licensees, registrants, and applicants

Appealing an Inspection Report

During an inspection, if a USDA inspector observes conditions that are not in compliance with the AWA and regulations and standards, the inspector will document their observations and professional assessments on an inspection report and explain them to you.

We encourage you to ask your inspector questions about the inspection or the content of the report during the course of the inspection and/or during the exit

https://www.aphis.usda.gov/sites/default/files/fsc-appeals-process.pdf

Annual Report

Must Report to USDA

- Change of operations [§2.30(c)]
- Failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected [§2.31(c)(3)]
- Suspension of a protocol, including reasons for suspension and corrective action(s) [§2.31(d)(7)]
- Annual report [§2.36]

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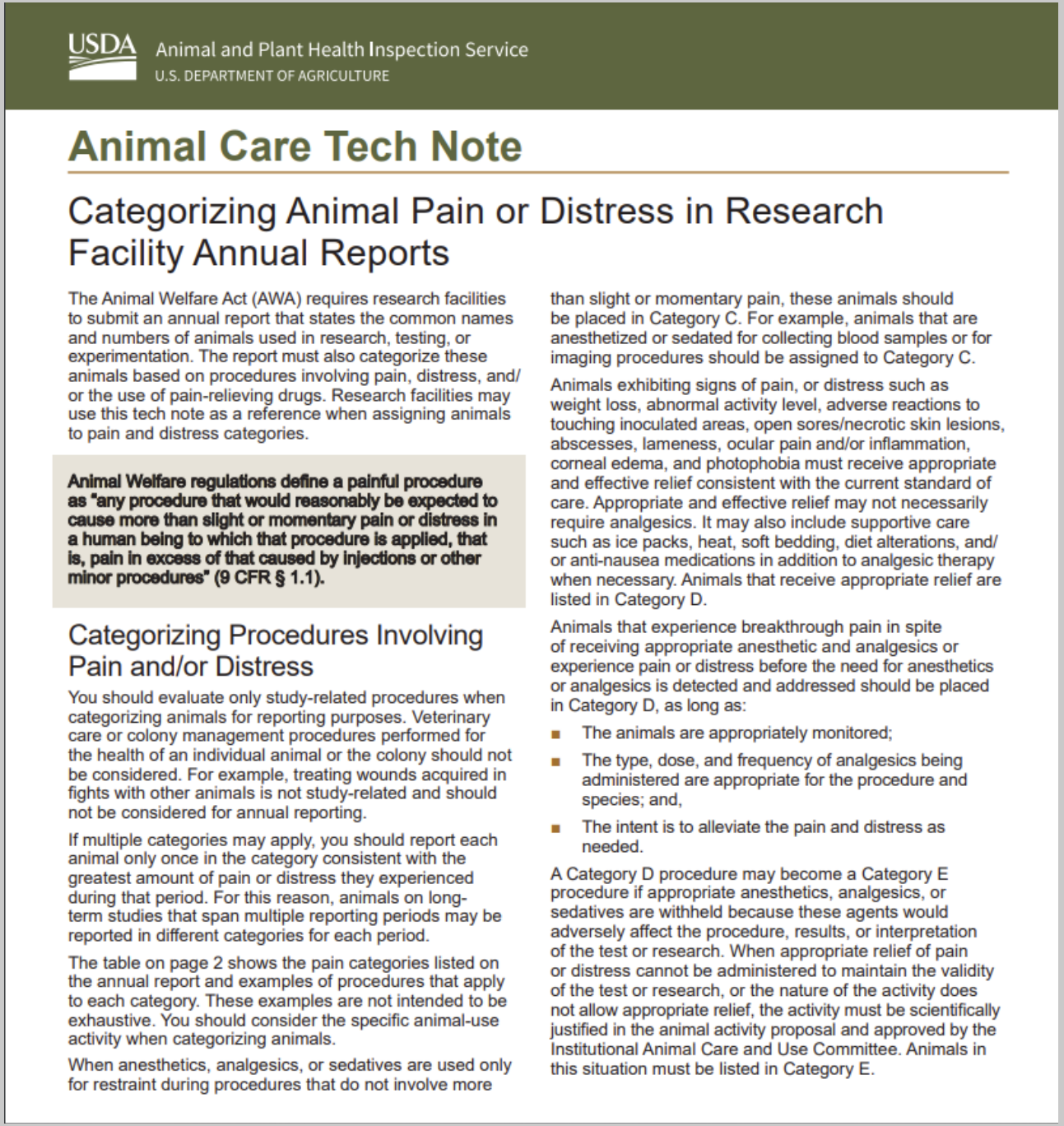
Resource For Categorizing Pain and Distress

www.aphis.usda.gov/sites/default/files/ac-tech-note-categorizing-animal-pain-or-distress.pdf



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Animal Care Tech Note

Categorizing Animal Pain or Distress in Research Facility Annual Reports

The Animal Welfare Act (AWA) requires research facilities to submit an annual report that states the common names and numbers of animals used in research, testing, or experimentation. The report must also categorize these animals based on procedures involving pain, distress, and/or the use of pain-relieving drugs. Research facilities may use this tech note as a reference when assigning animals to pain and distress categories.

Animal Welfare regulations define a painful procedure 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" (9 CFR § 1.1).

Categorizing Procedures Involving Pain and/or Distress

You should evaluate only study-related procedures when categorizing animals for reporting purposes. Veterinary care or colony management procedures performed for the health of an individual animal or the colony should not be considered. For example, treating wounds acquired in fights with other animals is not study-related and should not be considered for annual reporting.

If multiple categories may apply, you should report each animal only once in the category consistent with the greatest amount of pain or distress they experienced during that period. For this reason, animals on long-term studies that span multiple reporting periods may be reported in different categories for each period.

The table on page 2 shows the pain categories listed on the annual report and examples of procedures that apply to each category. These examples are not intended to be exhaustive. You should consider the specific animal-use activity when categorizing animals.

When anesthetics, analgesics, or sedatives are used only for restraint during procedures that do not involve more than slight or momentary pain, these animals should be placed in Category C. For example, animals that are anesthetized or sedated for collecting blood samples or for imaging procedures should be assigned to Category C.

Animals exhibiting signs of pain, or distress such as weight loss, abnormal activity level, adverse reactions to touching inoculated areas, open sores/necrotic skin lesions, abscesses, lameness, ocular pain and/or inflammation, corneal edema, and photophobia must receive appropriate and effective relief consistent with the current standard of care. Appropriate and effective relief may not necessarily require analgesics. It may also include supportive care such as ice packs, heat, soft bedding, diet alterations, and/or anti-nausea medications in addition to analgesic therapy when necessary. Animals that receive appropriate relief are listed in Category D.

Animals that experience breakthrough pain in spite of receiving appropriate anesthetic and analgesics or experience pain or distress before the need for anesthetics or analgesics is detected and addressed should be placed in Category D, as long as:

- The animals are appropriately monitored;
- The type, dose, and frequency of analgesics being administered are appropriate for the procedure and species; and,
- The intent is to alleviate the pain and distress as needed.

A Category D procedure may become a Category E procedure if appropriate anesthetics, analgesics, or sedatives are withheld because these agents would adversely affect the procedure, results, or interpretation of the test or research. When appropriate relief of pain or distress cannot be administered to maintain the validity of the test or research, or the nature of the activity does not allow appropriate relief, the activity must be scientifically justified in the animal activity proposal and approved by the Institutional Animal Care and Use Committee. Animals in this situation must be listed in Category E.

Exceptions on the Annual Report

- Do not report:
  - Exceptions/exemptions provided for in the Regulations or Standards
  - Exemptions to environmental enhancement plan
  - Exceptions to documents other than the Animal Welfare Regulations and Standards
- **Report**:
  - Exceptions approved by the IACUC under 2.38(k)(1)
  - AWR covered bird use starting FY 24

Online Annual Report Submission

Animal Use from 1 Oct. 2023 to 30 Sept. 2024 (FY 24) – Due 1 Dec. 2024

Online Portal:

https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/SA_Obtain_Research_Facility_Annual_Report

Regulatory Changes, Updates, and Clarifications

“Standards for Birds Not Bred for Use in Research Under the Animal Welfare Act”

Final Rule: February 21, 2023

Implementation Dates

Current Licensees & Registrants:
August 21, 2023

New Licensees & Registrants:
February 21, 2024

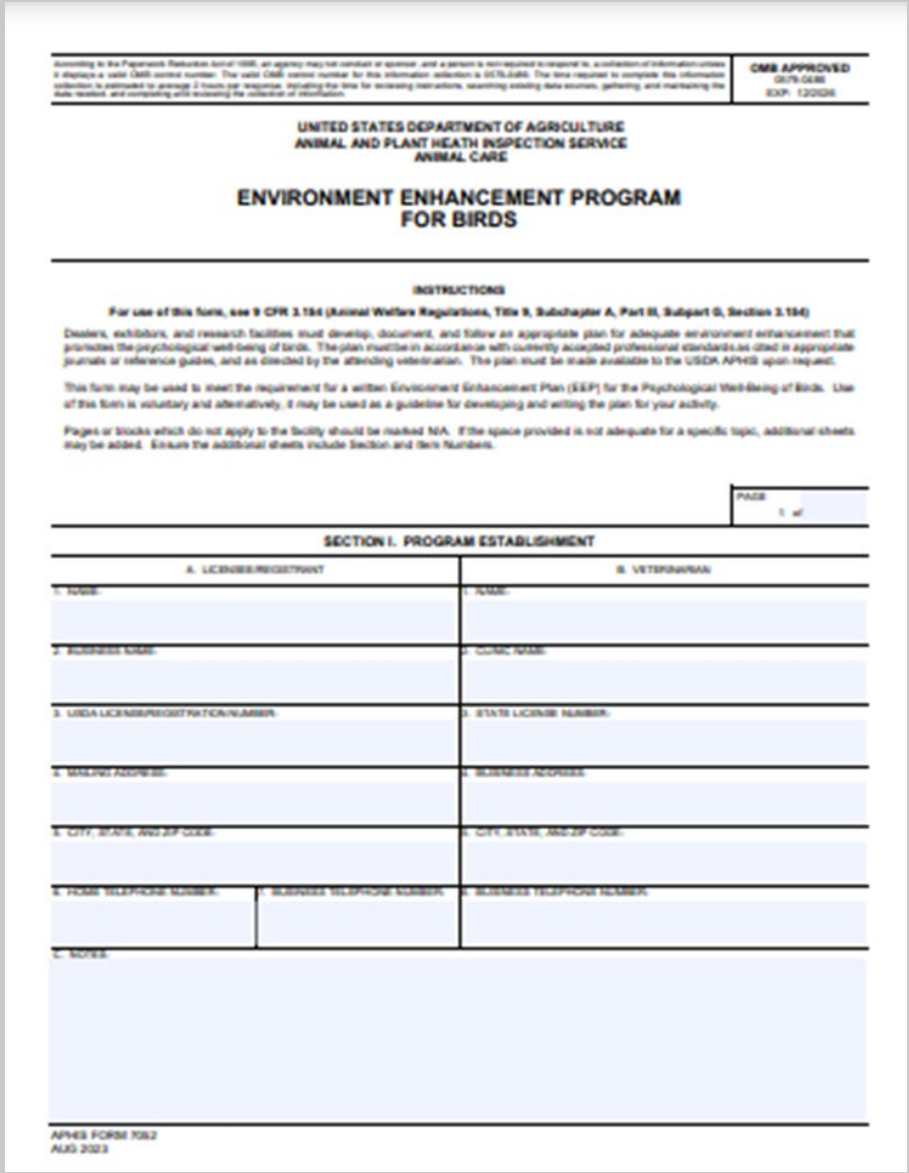
https://www.shutterstock.com

Birds Under the Animal Welfare Act

- Birds that are bred for use in research are not covered by the Animal Welfare Act.

- “Bred for use in research” means an animal that is bred in captivity and used for research, teaching, testing or experimentation purposes.
- Avian Enrichment Welfare Symposium https://www.aphis.usda.gov/animal-care/caw

Avian Environmental Enhancement Plan https://www.aphis.usda.gov/sites/default/files/aphis-7052.pdf



OMB APPROVED
0579-0430
EXP: 12/2026

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
ANIMAL CARE

ENVIRONMENT ENHANCEMENT PROGRAM
FOR BIRDS

INSTRUCTIONS

For use of this form, see 9 CFR 3.184 (Animal Welfare Regulations, Title 9, Subchapter A, Part III, Subpart G, Section 3.184)

Dealers, exhibitors, and research facilities must develop, document, and follow an appropriate plan for adequate environment enhancement that promotes the psychological well-being of birds. The plan must be in accordance with currently accepted professional standards as cited in appropriate journals or reference guides, and as directed by the attending veterinarian. The plan must be made available to the USDA APHIS upon request.

This form may be used to meet the requirement for a written Environment Enhancement Plan (EEP) for the Psychological Well-Being of Birds. Use of this form is voluntary and alternatively, it may be used as a guideline for developing and writing the plan for your activity.

Pages or blocks which do not apply to the facility should be marked N/A. If the space provided is not adequate for a specific topic, additional sheets may be added. Ensure the additional sheets include Section and Item Numbers.

PAGE
1 of

SECTION I. PROGRAM ESTABLISHMENT

A. LICENSEE/REGISTRANT	B. VETERINARIAN
1. NAME:	1. NAME:
2. BUSINESS NAME:	2. CLINIC NAME:
3. USDA LICENSE/REGISTRATION NUMBER:	3. STATE LICENSE NUMBER:
4. MAILING ADDRESS:	4. BUSINESS ADDRESS:
5. CITY, STATE, AND ZIP CODE:	5. CITY, STATE, AND ZIP CODE:
6. HOME TELEPHONE NUMBER: / 7. BUSINESS TELEPHONE NUMBER:	6. BUSINESS TELEPHONE NUMBER:
8. EMAIL:	

APHIS FORM 7052
AUG 2023

Exceptions

- Field studies that do not materially alter the birds, such as observational studies
- Studies for the purpose of supporting agriculture (intended to improve the qualify of food or feathers)
- Animal, pest, and population management studies for the purposes of limiting wildlife damage and human interaction

Exclusions

- Studies involving avian patients in clinical trials under a veterinary-client-patient relationship

- Use of only dead biologic specimens (no live animals)

https://wpvet.com/general-care/avian-exotic-pet/avian-wellness-care/

Field Study

A study conducted on free-living wild animals in their natural habitat.

However, this term excludes any study that involves an invasive procedure, harms, or materially alters the behavior of an animal under study.

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Animal Care Tech Note

Research With Free-Living Wild Animals in Their Natural Habitat and the Animal Welfare Act

The Animal Welfare Act (AWA) and regulations set standards of care and treatment for certain animals used in research, experimentation, teaching, and/or testing. While the AWA regulations cover many types of activities, they include some exceptions for field research involving wild animals in their natural habitat.

The following is quick guidance to assist Institutional Animal Care and Use Committees (IACUCs) at research facilities in determining whether an activity meets the AWA regulatory definition of "field study" and is therefore exempt from oversight or is otherwise covered under the AWA regulations. The AWA itself establishes the legal requirements and standards facilities must follow. For details, refer to the AWA (*United States Code*, Title 7, Chapter 54, Sections 2131–2159) and the Animal Welfare Regulations (*Code of Federal Regulations*, Title 9, Chapter 1, Subchapter A, Parts 1–4).

AWA Regulatory Definitions

Field study: A study conducted on free-living wild animals in their natural habitat. However, this term excludes any study that involves an invasive procedure, harms, or materially alters the behavior of an animal under study.

Wild animal: Any animal that is now or historically has been found in the wild, or in a wild state, within the boundaries of the United States, its Territories, or possessions. This term includes but is not limited to animals such as deer, skunk, opossum, raccoon, mink, armadillo, coyote, squirrel, fox, and wolf.

Major operative procedure: Any surgical intervention that penetrates and exposes a body cavity or any procedure which produces permanent impairment of physical or physiological functions.

Euthanasia: 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.

Role of the IACUC

All research facilities must have an IACUC. Per the AWA, the IACUC is responsible for overseeing and assessing all aspects of the facility's animal program, including inspecting animal facilities and study areas, investigating complaints of inhumane animal care, and approving or suspending animal research activities. The IACUC is therefore responsible for evaluating whether an activity with wild animals is regulated under the AWA. Note: Animal areas containing free-living animals in their natural habitat need not be included in inspections.

The IACUC is to be composed of members with sufficient experience and expertise to evaluate a research facility's animal program, facilities, and procedures using animals. Ad hoc consultants may be invited to assist with the evaluations. For example, IACUC members may have sufficient expertise in-house to evaluate biomedical research activities but may need to consult outside experts to advise on field research with wild animals.

If the IACUC determines a research activity is regulated under the AWA, that activity falls under IACUC oversight and must be reviewed semiannually. If the IACUC determines an activity is not AWA-regulated, that activity is not subject to IACUC review.

"Wild and Exotic Animal Handling, Training of Personnel Involved With Public Handling of Wild and Exotic Animals, and Environmental Enrichment for Species"

Advance Notice of Proposed Rulemaking

214,000 Comments Received

https://blog.wildfloridairboats.com/vip-sloth-experience-hugging-a-sloth-for-a-good-cause

Clarification of Requirements for Semiannual Inspections and Program Reviews

https://www.freepik.com/premium-photo/guinea-pig_15324757.htm

- Subcommittees of at least 2 Committee members may conduct the inspection and program review
  - Both members must physically inspect all of the animal facilities.
- The inspection and program review must be presented to a convened quorum for their review and approval.

Contingency Planning

The **contingency planning rule** took effect on January 3, 2022.

- Required for all licensees and registrants
  - Identify emergency situations common to facility's local area
  - Outline specific tasks in response to identified emergencies / disasters
  - Identify chain of command
  - Address recovery
- A documented review at least annually
- Employee training
- APHIS Form 7093 (optional)

Contingency Planning Workshop

Contingency Planning and Training of Personnel Rule (APHIS-2020-0101), One Year of Implementation - A Workshop

https://www.nationalacademies.org/event/42260_06-2024_contingency-planning-and-training-of-personnel-rule-aphis-2020-0101-one-year-of-implementation-2-day-workshop

Please Contact Us!

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WEBSITE

https://www.aphis.usda.gov/animal-care

LOCAL INSPECTOR