

Research Facility Annual Reports on Animal Usage

Jodie Kulpa-Eddy, USDA-APHIS SACATM Meeting March 10, 2004



Annual Report History

- 1966 Laboratory Animal Welfare Act authorized inspections
- Amended in December 1970; required annual report from research facilities
- 1973 USDA published first compilation





Annual Report

- Registered research facilities
- Department, agency or instrumentality of the United States
- Using "live animals" in research, tests, experiments or for teaching





Category History

□ PL 91-579 (December 1970)

Proposed Rule (1971): Number of experiments conducted involving necessary pain or anxiety to the animals without the use of an appropriate anesthetic, analgesic or tranquilizing drug, and a brief statement explaining the reasons for the same

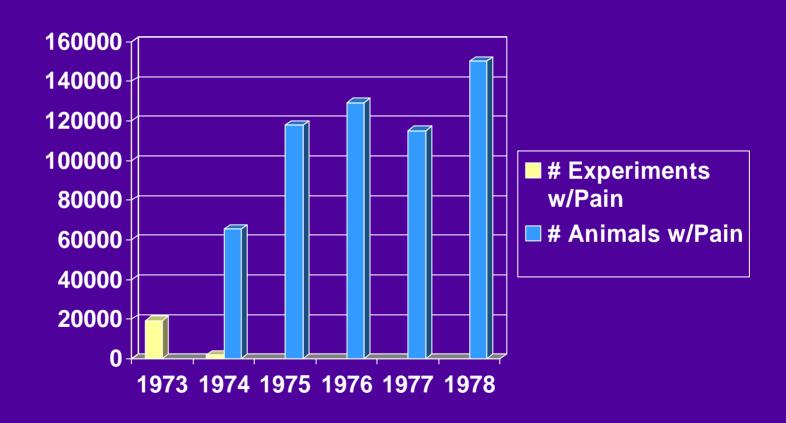


Category History

□ Final Rule (December 1971): Number of experiments conducted involving necessary pain or distress to the animals without the use of an appropriate anesthetic, analgesic or tranquilizing drug and a brief statement explaining the reasons for the same; Provided, however, that routine procedures (e.g., injections, tattooing, and blood sampling) do not need to be reported



Early Reports





Early Reports





■ 1973-77: "Almost all instances of unrelieved pain occurred during research, development or quality control of medicines and other health and cosmetic products. Such tests are required by law to keep products safe, pure and effective. Other occasions for unrelieved pain were safety tests that protect users of chemical products, and experiments involving electroanesthesia, mild electric shock or decompression."



Category History

In the late 1970's, two new reporting categories were added, since it was the practice of the research community at that time to report them and they provided more meaningful information:

- 1. no pain or distress involved
- pain/distress alleviated by drugs



Trends in Animal Use





Category E Today

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Numbers of animals upon which teaching, experiments, research, surgery or tests were conducted involving pain or distress for which the use of anesthetics, analgesics or tranquilizing drugs would have adversely affected the outcome

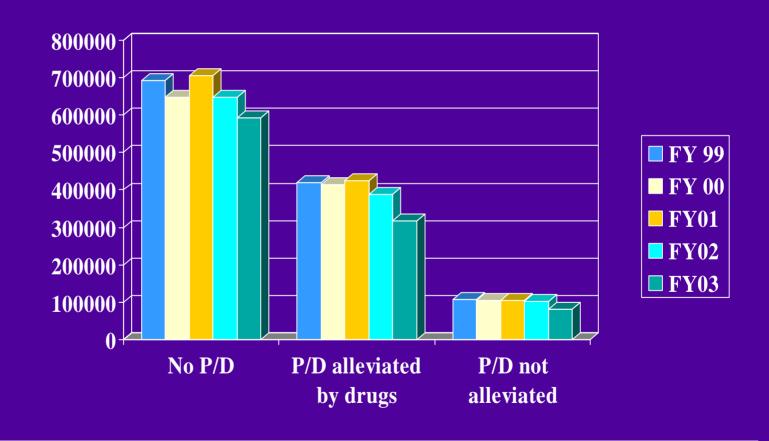


Category E Today

An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to the Annual Report

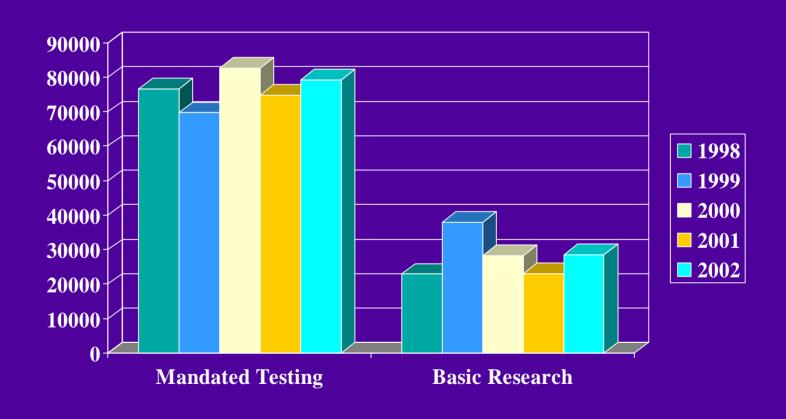


Animal Usage 1999-2003





Animals Experiencing Pain

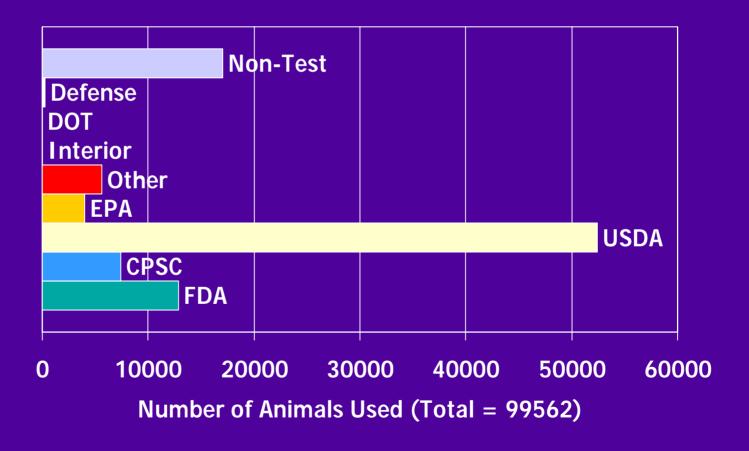




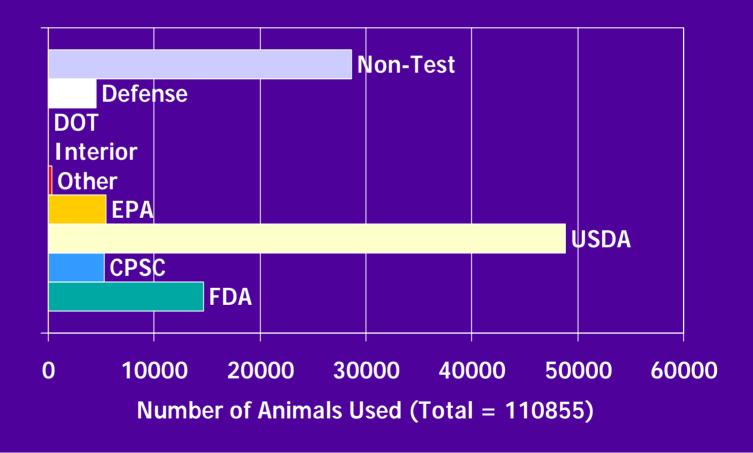
Basic Research

- Drug and Vaccine development
- Infectious disease processes
- Cardiovascular disease
- Antibody production
- Wildlife studies



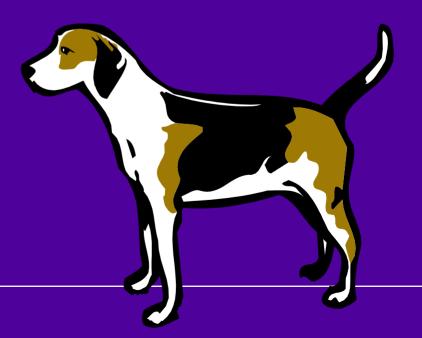








- Investigational/New Drug Application Pharmacology and Toxicology Information
- Rabies Vaccine





- Rabies and Feline Upper Respiratory Vaccines
- New Animal Drug Application
- Acute Oral Toxicity—Pesticides and Toxic Substances



- Diphtheria/Tetanus human vaccines
- Skin sensitization: Pesticides and Toxic Substances, Medical Devices
- Clostridial bacterins for animals





Leptospiral bacterins



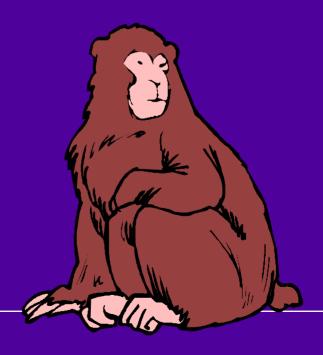


- Primary Eye Irritation
- Acute Skin Irritation and/or Corrosion
- Developmental toxicity



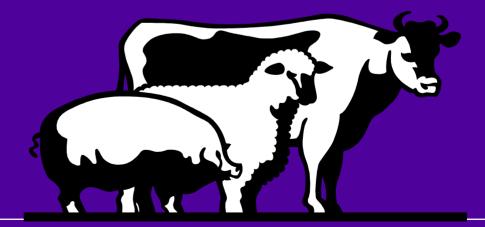


Drug Toxicity/Safety/Kinetic Studies



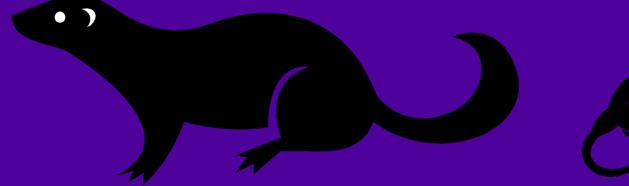


- Vaccine Immunogenicity testing
- Toxicity studies for NDA





- Vaccine potency tests
- Toxicity testing
- Rodenticide efficacy tests







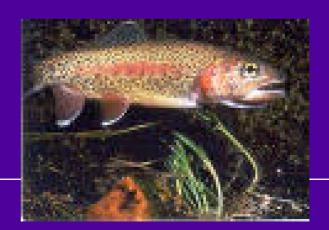
Other Species













Questions?

www.aphis.usda.gov/ac



