This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 93-R-0433 CUSTOMER NO. 9192

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

UNIVERSITY OF CALIFORNIA DAVIS
ONE SHIELDS AVE
DAVIS, CA 95616
(530) 752-2364

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS *(sites)*

See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs		97	338		435
5. Cats	346	289	299		588
6. Guinea Pigs			32		32
7. Hamsters		16	314		330
8. Rabbits		2	243		245
9. Non-Human Primates	4066	123	2185		2308
10. Sheep		30	77		107
11. Pigs		2	53		55
12. Other Farm Animals					
Cattle		156	80		236
13. Other Animals					
Alpaca			1		1
Anteater			2		2
Chipmunk		2	661		663

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all the exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)

(b)(6), (b)(7)c

(Type or Print)

1

DATE SIGNED 11/19/08

APHIS FORM 7023 (AUG 91)

(Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

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This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 93-R-0433 CUSTOMER NO. 9192

FORM APPROVED OMB NO. 0579-0036

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

UNIVERSITY OF CALIFORNIA DAVIS
ONE SHIELDS AVE
DAVIS, CA 95616
(530) 752-2364

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic,analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
Deer mouse			122		122
Dolphin		22			22
Elephant		12			12
Ferret		8	67		75
Fox			143		143
Gerbil		6	58		64
Goat		4	38		42
Horse		45	129		174
Llama			3		3
Opossum	236	43	50		93
Sea Otter		84			84
Squirrel		41	234	60	335
Vole		104	703		807
Wild Mouse	71	6	721		798
Wild Rat			86		86

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all the exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

(b)(6), (b)(7)c

DATE SIGNED 11/18/08

APHIS FORM 7023A (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

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Attachment 1B

EXPLANATION FOR COLUMN E LISTING

(This report must accompany USDA VS APHIS Form 7023(Aug. 91) to support Column E Listing.)

ICD: **Customer ID 9192** **Registration Number 93-R-0433**

Animal Study Proposal Title: Field Efficacy Studies on Zinc Phosphide/Anticoagulant Baiting Strategies for Controlling California Ground Squirrels (*Spermophilus beecheyi*)

Number and Species of Animals Listed in Column E.

Species: California Ground Squirrel **Number: 60**

Brief description of project including reason(s) for species selection:

The purpose of this study is to determine the field efficacy of two zinc phosphide treated rodent baits when applied at two different baiting rates (6 and 10 lbs/acre) to control California ground squirrels on rangeland. The second objective, in the case of unsatisfactory control (less than 90%), is to determine the efficacy of a follow-up anticoagulant treatment using currently registered ground squirrel anticoagulant broadcast baits.

Squirrels are studied because they are economically important crop pests. Squirrels also frequently inhabit the same locations as humans and thus are in close proximity to them, and are vectors for pathogens that pose a risk to public health. Both farmers and environmental health workers are interested in finding more effective methods for controlling populations of ground squirrels to reduce crop damage and health risks.

Rodenticides such as zinc phosphide are often the most effective and efficient method of control of pest species. This study is needed to retain the use of zinc phosphide as a rodenticide for ground squirrel control.

Justification for unrelieved pain or distress:

The goal of this study is to access mortality resulting from ingestion of the test materials. No action will be taken to alleviate adverse effects of the bait. This study aims to simulate a true field application of zinc phosphide and anticoagulants. Euthanasia of sick animals conflicts with the goal of the study since animals that do receive a sub-lethal dose may become lethargic but still have the ability to fully recover. Euthanasia would also interfere with the second project objective of the assessing the efficacy of using anticoagulants as follow up to zinc phosphide treatments.

Please see below e-mail from Dr. William Jacobs, primary efficacy data reviewer for the vertebrate pesticides at the EPA. This e-mail, and subsequent communications with Dr. Jacobs verifies that for rodenticide studies, death is the response that must be assessed.

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-----Original Message-----
From: Jacobs.Bill@epamail.epa.gov [mailto:Jacobs.Bill@epamail.epa.gov]
Sent: Thursday, November 13, 2008 8:58 AM
To: Alan Ekstrand
Subject: Re: Rodenticide studies UC Davis

I do not have the original document that I provided in 2004 handy. The attachment that you have provided seems to be consistent with my experiences and position with regard to the role of euthanasia in efficacy studies involving vertebrate pesticides. I should update the 2004 item by noting that I now have been reviewing vertebrate pesticide efficacy data for 30+ years and that work on revising the product performance guidelines for vertebrate pesticides has been suspended. I should add that the contents of the 2004 response and this note reflect my own experiences and do not constitute a formal position by the U.S. Enviromental Protection Agency.

I am William W. Jacobs, Jr., Ph.D. I have been EPA's primary efficacy data reviewer for vertebrate pesticides for the past 26 years.

In relevant part, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) defines "pesticide" as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest". Vertebrate pesticides are used to exert such effects on vertebrate animals which have been determined to be pests. Vertebrate pesticides include: (1) products which are claimed to prevent, repel or otherwise mitigate vertebrate pests, and (2) products which are claimed to kill (destroy) vertebrate pests. Most of the toxic rodenticides are applied as baits. For both poisons and repellents, targeted animals' sensory and physiological responses are important factors affecting whether products work as claimed. Consequently, efficacy studies of vertebrate pesticide products are essentially behavioral studies in which animals responses to the products are observed (directly or indirectly) and any physiological effects attributable to the product are noted.

With repellents, an observation consistent with repellency may be attributed to sensory effects (e.g., offensive odor, trigeminal irritant, etc.) or to sensory effects coupled with internal effects (perception of flavor followed by illness leading to a conditioned food aversion). In both cases, the experiment may be continued because it is often is essential to determine the duration of the behavioral effect so that product labeling can tell users how long they can expect the product's effects to last.

For tests of products claimed to kill vertebrate pests, death is the response that must be assessed as it is the endpoint claimed on the label and desired by the user. In efficacy studies involving rodenticide toxicants, it is fundamental that observations of animals continue until the animal succumbs completely to the poison (i.e., dies) or recovers. (Death and recovery are behavioral responses which reflect physiological circumstances.) The entire point of using toxic rodenticides is to kill targeted animals. Put another way, if the product does not kill animals, it is not worth using. If the product is worth using and is registered, it will kill many times more animals in operational use than it does in research.

Efficacy research should continue until the relevant research questions are answered. In studies with toxic rodenticides, the researcher must determine the level of efficacy obtained. In laboratory trials, this involves the proportion of animals that the rodenticide kills. Animals that become symptomatic may, if the study continues, die or recover. Animals that die contribute to establishing the level of efficacy and also provide information about the amount of bait taken, the course of symptoms leading to fatality, the pathology of fatally poisoned animals, and the residue levels in fatally poisoned animals. Were such animals sacrificed prematurely, the information on bait ingestion, symptomology, pathology, and residue levels would have no proper context because it would not be known whether the results pertained to a (likely) victim or a (likely) survivor.

Animals that survive rodenticide laboratory experiments also are of great interest. If an animal survives, the researcher (or reviewer, in my case) should attempt to learn as much as possible from the animal because, in the real world-of rodenticide use, it is the survivors who become the ancestors of the rebounding pest population. How much bait each survivor ate may suggest why it survived. A survivor that ate little bait may have not have ingested enough poison to kill it. If the survivor rejected bait in favor of challenge diet throughout the bait-exposure period, that would suggest that the animal did not find the bait to be palatable. Presenting the same poison in a different bait might lick that problem, unless the poison itself is what made the bait unpalatable. If the animal ate some bait on the first day and none thereafter, that would suggest that the animal had ingested a "symptomatic" amount, associated the physiological effect with the flavor of the bait, and developed a conditioned food aversion ("bait shyness" in rodenticide parlance). Bait-shy animals typically cannot be controlled with a bait having a flavor similar to the one that they learned to avoid.

All of this behavioral information would be lost if, for example, subjects were to be "humanely sacrificed" at the sign of the first symptom. (In what strikes me as utter "scientific" folly, the UK actually requires that rodents in choice feeding trials with anticoagulants be sacrificed 4 days into the test, by which time there would be few toxicant-caused deaths and only very general symptoms suggesting toxicosis. Under such a procedure, more information is arbitrarily discarded than is collected. So the researcher knows how much bait and how much challenge diet was ingested. The researcher does not know the effects of such ingestion, so what was the point in measuring it?)

In field efficacy trials, product performance is assessed through estimating the effects of treatment on the targeted population. As not all members of the population will (or can) be seen prior to treatment, usually indirect and/or sampling indices to animal activity are used rather than counts of all individuals. The carcasses of most victims usually will not be observed. As target species are likely to be at least semi-fossorial, deaths often will occur above ground. Symptomatic animals observed above ground should be allowed to succumb or recover so that estimates of treatment effects are as accurate as possible and so that researchers can assess effects of the treatment scavenger and predator activity. Also, carcasses collected for residue analyses should be identified as belonging to victims.

If I received an efficacy report which described research which was curtailed prematurely, for whatever reason, I would have little uses for the document. A toxicant study curtailed at the first signs of symptoms would not tell me the most important things that I need to know: how many animals died and how many survived. I would have no choice but to reject such a study and suggest that the researcher do it right the next time.

What I have discussed thus far is so "common sense" that, until recently, there appeared to be no need to set a "standard" requiring that efficacy studies of vertebrate toxicants be continued until the subjects' ultimate fates (death or survival) were determined. As questions such as the ones before you have arisen in recent years, the subject of experimental endpoints will be addressed in the revised product performance guidelines for vertebrate pesticides. I am working on revising those guidelines at present.

All of this having been said, I should note that it would make sense to curtail an efficacy research study prematurely if poisoned subjects appeared to be in such conscious pain or other distress that it became clear that the poison was inappropriate for further development as a rodenticide.

University of California, Davis
Addendum to Annual Report of Research Facility

A. USDA Exceptions to Provisions of the Act:

1. The USDA Administrator granted an exception to the number of cesarean-sections that can be performed on female nonhuman primates. This exception applied to 35 animals during the reporting period.

Justification for cesarean-sections:

Studies that focus on fetal inherited illnesses, other illnesses, and various corrective therapies for these illnesses, require that the animals be delivered by cesarean-section at a standardized time point. This is important for several reasons. First, the fetuses and newborns are valuable research animals from which substantial information can be obtained, and delivery by cesarean-section decreases the risk of parturition-related mortality. In addition, animals that deliver spontaneously typically do so over a large range of gestational ages, which makes it very difficult to accurately assess a number of significant normal developmental, physiological and behavioral milestones. Delivering the infant by cesarean-section is the best method for obtaining viable, healthy offspring without confounding variables.

Justification for multiple cesarean-sections in the same animal:

Multiple cesarean-sections are routinely performed on humans. Nonhuman primates that undergo comparable procedures at the Primate Center rarely have post-surgical complications and, as borne out by numerous years of experience (>20 years), are fertile post-operatively. Any animal with prior evidence of complications is not included in this exception. Similar to humans, extensive years of experience indicate that post-operatively these animals do not exhibit any problems or ill health.

The practice has been to maintain a breeding colony of rhesus and long-tailed macaques at the Primate Center that can provide the required number of pregnancies for research purposes. Using animals more than once reduces the number of animals that have to be imported. As an example, if 100 animals are used per year for these studies, and if these animals could not be returned to the breeding colony, it would be necessary to import additional animals to replace these animals. The net effect of using these animals only once would be that an increased number of nonhuman primates would be needed, and that many valuable, healthy research animals would be euthanized because of their surgical history. With multiple use, and using procedures routinely used in humans, these animals can remain productive for many years, thus reducing the number of animals overall that are needed. This exception allows for up to four cesarean-sections per animal.

B. Fluid Regulation:

In studies involving 35 animals, the IACUC has granted exceptions to allow non-human primates to be maintained on regimens of fluid regulation. These are studies in which the animals receive water or other liquids as a reward for performing tasks. If the animals were allowed to satiate themselves with water outside of the study period, they would not be motivated to perform the tasks. The animals receive their necessary water during the day as they perform the tasks.

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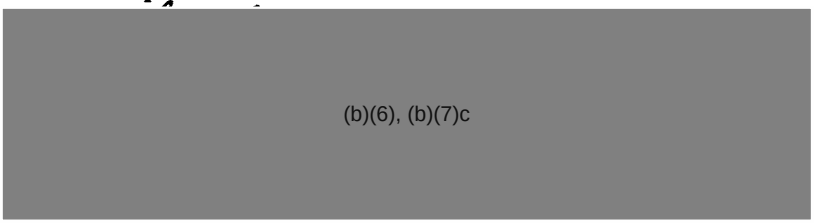
The IACUC has developed detailed guidelines to ensure that these animals receive adequate amounts of water each day to support their health and well-being. In order to assure that only animals that are physiologically, as well as psychologically, capable of adapting to chronic fluid regulation are placed in these studies, all animals first undergo a careful screening process.

During periods of fluid regulation, the animals are allotted carefully calculated amounts of water appropriate to their physiologic needs, and within the IACUC policy guidelines. Neither weight loss nor dehydration has been shown to result when these guidelines are followed. The animals are monitored very closely by veterinary staff and animal care staff when fluid regulation protocols are used.

C. Reduced Housing Temperature

In studies involving 12 hamsters, the IACUC has approved a reduced temperature acclimation range of 35-40 degree Fahrenheit and a reduced photoperiod of 8 hours light/16 hours darkness. This study assesses how photoperiod disrupts the normal relationship between leptin, body fat, and food intake in order to enhance understanding of the neural and physiologic alterations accompanying hibernation. The hamsters involved in this study are genetically bred to readily hibernate when photoperiod adapted and cold exposed. The hamsters are housed in these conditions for approximately 8 weeks.



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