

ANNUAL REPORT OF ANIMALS USED BY GENESIS LABORATORIES, INC. DURING THE 12
MONTH PERIOD OCTOBER 1, 2011 TO SEPTEMBER 30, 2012

HEADQUARTERS OF RESEARCH FACILITY GENESIS LABORATORIES, INC. 10122 N. E. FRONTAGE ROAD WELLINGTON, COLORADO 80549 Registration # 84-R -0051	FACILITY LOCATIONS GENESIS LABORATORIES, INC. 10122 N. E. FRONTAGE ROAD WELLINGTON, COLORADO 80549 Registration #: 84-R -0051
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ANIMALS REPORTED IN COLUMN E

House Mouse (*Mus musculus*)

Forty wild house mice are being reported in column E of the Annual Report. All animals used were used in studies testing rodenticides. These animals were used for testing a rodenticide via feed trials with death of the rodent as the end point.

The research was based upon the USEPA Office of Pesticide Programs (OPP) protocol guidelines which do not allow for the use of anesthetics, analgesics, or tranquilizing drugs to relieve the pain. Animals displaying toxicosis were not euthanized. The USEPA policy on rodenticide testing (Attachment 1) forbids the use of pain-relieving drugs and premature euthanasia. Use of such drugs or procedures would negate the study. There are no alternatives available to this painful procedure. The only alternative to administration of a toxic product (which is intended to kill animals, and cause unavoidable pain in that process) is not to administer the toxic product. Poisonous substances cause tissue damage, which results in pain perception. One potential alternative is to develop products, which create unconsciousness or analgesia prior to death. However, information is not yet available to design such products, which would be effective for rodent control.

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ATTACHMENT 1

The following is an e-mail response from Dr. William Jacobs of the USEPA, explaining his agencies position on the use of pain-relieving drugs or premature euthanasia in pesticide efficacy studies involving rodents. The e-mail was in response to a request by (b) (6), (b) (7) at Genesis Laboratories, to state in writing and clarify the agency policy. Genesis Laboratories had been asked by APHIS, in 2004, to provide more detailed information on why pain relievers were withheld and why death was used as an endpoint in pesticide efficacy studies.

July 6, 2004:

"The issue of euthanasia was not mentioned in the "current" version of the [Pesticide Assessment] Guidelines because it had not come into play with respect to efficacy testing protocols at that time. The Animal Welfare Act had been passed in the early 1970's but there was common understanding that it was not to intrude upon the integrity of the research. In efficacy studies involving toxicants, there must be a yes-or-no answer as to whether the poison killed the animal.

The first instance that I remember encountering an efficacy protocol in which euthanasia was proposed happened in 1988. In that particular case, it appeared that the researchers were so intent on addressing euthanasia that they completely forgot what the research was about. In the course of reviewing that protocol, I drafted a response the gist of which was that the nature of the research was such that it was absolutely necessary to determine whether the poison killed the animal, that animals that recovered from having been poisoned with the rodenticide in question were not only likely to be the founders of the rebounding population but also would be behaviorally resistant (i.e., bait shy) to any bait containing the compound used in the initial trial. (The compound in question was an acute rodenticide.) Those are extremely important things to know about a rodenticide. I may have added that evidence indicating that a rodenticide routinely causes suffering should be considered in determining its suitability for future research and use

I currently am revising the Guidelines and plan to address the issue of euthanasia much as I did in 1988, adding only that it would be permissible to euthanize seemingly moribund animals if not only the event of poison-caused death but also the time to death could be predicted with virtual certainty. This is a very tricky area] however. If we were to register a rodenticide based upon the results of laboratory and field trials in which eager-to-please personnel collected and dispatched every target rodent that they could get their hands on as soon as the animals appeared to be affected to any degree} we might wind up with a real turkey of a rodenticide on the market. A circumstance not quite so extreme but certainly affecting some of the results that were reported occurred a while back and was only discovered when one researcher decided to collect symptomatic animals and cage them to see whether they would recover or die. Many of them recovered. Ultimately, it was determined that the active ingredient concentration needed in baits was double that which was used in the original field testing.

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If I received a report of a laboratory efficacy trial in which it were stated that animals were "humanely dispatched", I would reject the study flat out. Percent mortality is the dependent variable in those trials. Adding additional causes of mortality would render the study useless as efficacy research.

In the case of the Genesis ground squirrel field trials to which you alluded, it seemed to me that field personnel may have been too eager to euthanize animals. I recall a line in the report that said, in effect, that personnel dispatched every squirrel that they could catch but some "were able to slip down their burrows" (approximate quote) before they could be caught. Animals capable of slipping "down their burrows" would not seem to be moribund by anyone's definition, and I recall having responded to that.

If it is decided that a candidate rodenticide causes so much pain that it should not be considered for further use, then animals on test should be euthanized and the results should be written up, not so much as an efficacy study, but as research aborted for humane reasons. Apart from that, I see no proper role for analgesics in rodenticide research. Rodenticide efficacy trials basically are behavioral studies. The effects of the candidate compound must be assessed isolated from other factors which might distort the observations and, of course, the animal's viability and ability to make adaptive responses-- such as slipping down a burrow. There is no way to sensibly use analgesics in field trials of rodenticide baits that would not be likely to interfere with behavior and viability. Even if the animals die after they "slip down their burrows", it is important that they are able to as where they die affects the determination of percent surface kill and the degree to which carcasses are available to nonfossorial scavengers and predators (such as avian raptors).

When we attempt to impose human values on animals' circumstances, we risk deluding ourselves. In general, wild animals are all about survival and will do whatever it takes (even chewing off their own feet) to last as long as they can. (Tranquilizer tabs associated with leg-hold traps turned out to be a good idea because some animals were spared further, self-inflicted injuries on top of what the traps did to them. That, however, is a really exceptional case; and one which does symptoms which clearly look like distress, although humans exposed to the same compounds sometimes had little recollection of the experience. Some have suggested that anticoagulants) with their protracted times to death, "must" be inhumane. However, some humans who have bled severely internally (for one reason or another) have reported little or no discomfort and sought help only because of other symptoms (e.g., lethargy, evidence of occult blood, loss of function, etc). "

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