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IRB EFFICACY REVIEW

DP Number(s)

335912

IN: 7/12/07
OUT: 8/7/07

PRODUCT NO.: 72500-RR

DATE RECEIVED BY OPP: 10/23/06

DATE OF SUBMISSION: 10/20/06

DATE SUBMISSION ACCEPTED: 7/12/07

TYPE OF PRODUCT: Rodenticide/Insecticide

DATA MRID NOS.: 469665-10, -11, and -12

PRODUCT MANAGER NO.: 07

PRODUCT NAME: KAPUT® FIELD RODENT BAIT B

COMPANY NAME: Scimetrics Ltd. Corp.

SUBMISSION PURPOSE: Obtain §3 registration for a combined rodenticide bait and systemic control agent for certain ectoparasites of ground squirrels, prairie dogs, and lagomorphs

CHEMICAL & FORMULATION: 0.0025% Diphacinone grain bait which also contains Imidacloprid at 0.0250% of product

Efficacy Review: KAPUT® FIELD RODENT BAIT B, 72500-RR
Scimetrics Ltd. Corp.
Wellington, CO 80549

200.0 INTRODUCTION

CONFIDENTIAL BUSINESS INFORMATION (CBI) IS DISCUSSED IN THIS REVIEW. DO NOT DISCLOSE CBI TO UNAUTHORIZED THIRD PARTIES OR TO ANYONE LACKING APPROPRIATE CLEARANCES. THE APPLICANT, THE APPLICANT'S AGENT, AND THE TESTING FACILITY ARE UNAUTHORIZED THIRD PARTIES REGARDING THE INERT COMPOSITION OF THE P.C.Q. BAIT USED IN THE BORCHERT (2006C) STUDY.

200.1 Use

This product is a 0.0025% Diphacinone and 0.0250% Imidacloprid dry bait proposed for registration under §3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended

> to control only squirrels of the genus Spermophilus, prairie dogs of the genus *Cynomys*, and rabbits of the genus [sic] *Sylvilagus* and *Lepus* as well as to kill their fleas. Fleas controlled include (but are not limited to) the plague vector fleas: *Oropsylla montana, Hoplopsyllus anomalus, Oropsylla hirsute* and *Orchopeas sexdentatus*.

The proposed label for 72500-RR lists no specific use sites but does direct prospective users to

> Apply only to areas where ground squirrel, prairie dog, and/or rabbit infestations have occurred.

This product is not proposed to be a restricted use pesticide.

200.2 Background Information

See efficacy review of 2/8/07 for CO-060010 and efficacy review of 7/5/07 for TX-070004. Those products are 0.0025% Diphacinone baits registered under the provisions of §24(c) of FIFRA for "special local needs" to control black-tailed prairie dogs in the States of Colorado and Texas, respectively. Those products are limited to subterranean applications at least 6" down active prairie dog burrows, have seasonal restrictions on use, and are classified as "**RESTRICTED USE PESTICIDES**". See also the essentially concurrent (to be completed later in August of 2007) efficacy review for 72500-RG, a pending 0.025% Warfarin plus 0.020% Imidacloprid bait in 2-oz placepacks (and "Bulk Packaging") proposed for registration under §3 of FIFRA to control commensal rodents, voles, and certain fleas on those rodents – the same fleas that are proposed for 72500-RR. The combining of a flea-control agent with a rodenticide sets 72500-RG and 72500-RR apart from registered rodenticide baits.

Prairie dogs and *Spermophilus* spp. ground squirrels are considered by EPA to be pests of significance to public health, whereas rabbits of the Genus *Sylvilagus* and hares of the Genus *Lepus* are not.[1] Certain fleas that infest voles as well as commensal rodents are considered to be pests of significance to public health.

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[1] These Lagomorpha are not considered by OPP to be pests of significance to public health, although rabbits have been associated with human cases of tularemia. It might be a different story with fleas that can infest multiple hosts, including lagomorphs as well as rodents. Tularemia is vectored by ticks.

This review addresses elements of the initial application for registration of this product. The application was filed on 10/20/06 on Scimetrics' behalf by that company's agent, RegWest Company, LLC, of Greeley, CO. The items routed for efficacy review are listed below.

- "**DATA PACKAGE BEAN SHEET**" dated "**12-Jul-2007**" from Dan Peacock of IRB to me;
- "**DATA PACKAGE BEAN SHEET**" dated "**24-Jan-2007**" from Dan Peacock of IRB to Geri McCann, formerly of IRB;
- a letter of 10/20/06 from Kim Davis of RegWest to Peacock;
- a completed pesticide registration application form (EPA Form 8570-1) signed by Kim Davis and dated "**October 20, 2006**";
- a one-page "**Product Chemistry Data Summary**" for "**Kaput® Field Rodent Bait B**" dated "**October 2006**";
- a one-page "**Product Performance Data Summary**" for "**Kaput® Field Rodent Bait B**" dated "**October 2006**";
- a one-page "**Acute Toxicology Data Summary**" for "**Kaput® Field Rodent Bait B**" dated "**October 2006**";
- a one-page "**Confidential Statement of Formula**" for "**Kaput® Field Rodent Bait B**" dated "**October 20, 2006**";
- one copy each of 3 field efficacy study reports (cited and discussed individually below);
- one copy of a published article pertaining to control of the plague bacterium *Yersinia pestis*;
- one copy of a proposed label for "**Kaput® Field Rodent Bait B**" dated "10/20/06";
- one copy of a letter of 11/20/06 from Barry Cortez of the California Department of Pesticide Regulation (CDPR) to Allison Siekkinen of Scimetrics; and
- one copy of a letter of 8/14/06 from Richard M. Davis of the California Department of Health (CDH) to "Office of Pesticide Programs – 7504P".

The proposed label has "____ **lbs**" entered after "**Net Weight:**". According to the application form of 10/20/06, the product would be sold in containers ranging in net contents from "**1 through 50 pounds**".

In its most immediately relevant part, §2(q) of FIFRA defines "MISBRANDED" as

> (1) A pesticide is misbranded if--
> (A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;...

In <u>40 CFR</u> §156.10(a)(5), the Code of Federal Regulations provides examples of types of statements which categorically are regarded as "false or misleading". These categories (quoted immediately below) are indicated in <u>40 CFR</u> §156.10(a)(5)(I) through (x).

(i) A false or misleading statement concerning the composition of the product;
(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;
(iii) A false or misleading statement concerning the value of the product for purposes other than as a pesticide or device;
(iv) A false or misleading comparison with other pesticides or devices;
(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;
(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;
(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;
(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations.
(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans or pets" with or without such a qualifying phrase as "when used as directed"; and
(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:
(A) "Contains all natural ingredients";
(B) "Among the least toxic chemicals known"
(C) "Pollution approved".

In her letter of 10/20/06, Kim Davis claims "several inimitable attributes" for 72500-RG. Her list is quoted directly below.

- Easy and effective baiting
- Effective at a minimal application rate (2 oz. near burrow), reapplied every other day for only 3 to 4 days
- Systemic kill of fleas and direct kill of host rodents (prairie dogs and squirrels) and rabbits
- Low toxicity: acute oral, dermal and skin irritation effects in EPA Category IV; eye irritation in Category III
- Effective at an active ingredient rate of at least ½ the typical rodent bait concentration [sic]
- Poses no primary or secondary non-target hazards
- Combines the insecticidal properties of Imidacloprid (in rodent/rabbit blood) and the rodenticidal properties of Diphacinone in a formulation proven to be palatable to target organisms in the field

If any of those pronouncements were to be proposed to appear on labeling for 72500-RR, they would have to be rejected as "false or misleading statements" that would misbrand the product -- an "unlawful act" under FIFRA §12(a)(1)(E). There is nothing "Easy" about proper use of rodenticides. Rodenticides registered under FIFRA are held to similar standards. There is nothing "proven" about the palatability of 72500-RR to targeted rodents.

Whether putting 2 oz of bait near active burrows at least twice qualifies as a "minimal application rate" depends upon one's frame of reference. Single applications of teaspoon amounts of certain Zinc Phosphide baits, following prebaiting, have been shown to be very effective against certain types of prairie dogs. Labels for registered Zinc Phosphide baits bear directions for spot placements of teaspoon or tablespoon amounts of bait, following prebating, to control various types of ground squirrels. In each of the two field efficacy trials discussed at length in this review, four rounds of treatment were made. To claim "Effective at a minimal application rate" would be misleading, at best, for 72500-RR.

Claims of safety, whether direct or comparative, are categorically considered to be false or misleading (as noted above). There is nothing especially remarkable about the alleged "Low toxicity" for 72500-RR in comparison with other Diphacinone products. It is clearly false that any anticoagulant bait "Poses no primary or secondary nontarget hazards". Diphacinone has caused primary and secondary poisonings of nontarget species. The notion that halving its concentration would remove hazards to nontarget species is absurd.

The phrase "Effective at an active ingredient rate of at least ½ the typical rodent bait concentration" makes little sense. The product is proposed to be 0.0025% Diphacinone, which is half of the typical active-ingredient concentration for registered Diphacinone baits. In California, there have been §24(c) registrations for 0.01% Diphacinone baits for decades (see below); but baits of that strength have not been registered in other States or under §3. Commensal rodenticide baits containing other anticoagulant active ingredients typically are formulated to toxicant strengths of 0.005% (Brodifacoum, Bromadiolone, Chlorophacinone, and Diphacinone) or 0.0025% (Difethialone), respectively twice and equal to the active-ingredient concentration proposed for Diphacinone in 72500-RR. It is possible that Kim Davis intends to mean, by her use of "at least" in the phrase quoted at the beginning of this paragraph, that only the Diphacinone concentration in this product is ½ or less than that in other Diphacinone baits registered for the similar uses. If made on the labeling for 72500-RR, a claim such as "Effective at an active ingredient rate of at least ½ the typical rodent bait concentration" would be, at best, a false or misleading comparison of efficacy with other pesticides.

201.0 DATA SUMMARY

201.1 Formulation

The CSF dated "**October 20, 2006**" describes a bait consisting of a [redacted] Diphacinone [redacted] at 0.0025%, nominal, of the final formulation; a [redacted] Imidacloprid [redacted] at 0.025%; [redacted] and [redacted] at [redacted] Although the [redacted] all have "Attractant" listed in the "Purpose in Formulation", it seems likely that the latter [redacted] ingredients are intended to act [redacted]

Of the components in the bait, the two active ingredients and the dye would be the ones most likely to diminish its palatability.

In the late 1970's, EPA researched the effects of certain dyes on the palatability of OPP rat and mouse challenge diet in an attempt to determine whether dyes could adversely impact the effectiveness of commensal rodenticide baits containing them. The results of that research, summarized by Palmateer (1979), were that some dyes drastically reduced consumption of treated diet in comparison with untreated challenge diet whereas other dyes affected palatability very little if at all. EPA did very little comparable research with rodents that are native to the U.S. and has no in-house database indicating that specific dyes would or would not be expected to adversely affect the consumption of baits by prairie dogs, ground squirrels, or native rabbits or hares.

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[2] Based on the description of manufacturing process submitted for it, 72500-RR is to be a coated-grain type of bait rather than a bait pellet.

201.2 Efficacy Data

The efficacy reports included with the materials supplied by the CDA are cited and discussed individually below.

Borchert, J.N. (2006a) Field efficacy of Field Rodent Bait for controlling black-tailed prairie dogs (*Cynomys ludovicianus*) of Kaput® Field Rodent Bait B. Unpublished report, Study No. 05009, Genesis Laboratories, Inc., Wellington, CO, 141 pp.

MRID# 469665-10

This report previously was discussed in the efficacy review of 2/8/07 for CO-060010. The discussions below were imported, with editing, from that review.

The bait used in this efficacy trial reportedly was mixed to a Diphacinone concentration in the neighborhood of 0.0025%. Genesis rather than Scimetrics mixed the test bait.

According to information presented on page 49 of Borchert's (2006a) report, the composition of the test material was as follows: [redacted] (0.00286%) "Diphacinone" (source product and active ingredient concentration not indicated), and 12.48 g (0.02748%) "imidacloprid". These are the same ingredients that are listed on the pending CSF of 10/20/06 for 72500-RR. The amounts listed for them in the test bait would put their concentrations within the certified limits range claimed on the pending CSF.

If the Diphacinone source claimed on the CSF of 10/20/06 assayed at its nominal concentration of [redacted] active ingredient and were used to make the test bait, the active ingredient concentration in it would have been [redacted] minus any formulation loss that might have occurred. The formulation page in the Borchert (2006a) report does not indicate the source or purity of the Imidacloprid product used in the test bait.

The analytical report appended to the Borchert (2006a) document states that assays of 4 samples of the test bait, batch "05-TS-8A", yielded averages of "25.2 ± 2.6 ppm" (LOD = 2.24 ppm, LOQ = 5.12 ppm), which is equivalent to 0.00252%. Results of individual sample runs ranged from 0.00215% to 0.00274%, all of which were between the certified limits (0.002-0.003%) that Scimetrics proposes to allow itself for Diphacinone in 72500-RR. The test material apparently was mixed in two batches: (1) the amount (~100 lbs) implied in the preceding sentence, as batch "*05-TS-7*" on 2/16/05; and (2) an "*additional 100 lbs on 3/11/05 (05-TS-8)*". Those batches would have been 27 and 4 days old when the first Diphacinone bait application for this field trial was made. A report of a chemical assay run on "05-TS-7A" is appended to the efficacy report (Borchert, 2006b) discussed next in this review.

Borchert (2006a) reports that the field trial was conducted between 2/23/05 and 4/14/05 in Larimer County, CO. The plots used in this trial were established on two neighboring properties. Two plots were designated for treatment, and two other plots were to be monitored as untreated control (check) areas. The words "North" and "South" were used to distinguish between plots within each treatment category.

Prairie dog activity was assessed before and after treatment using two indices: visual counts and closed burrows. Those census methods commonly are employed in field efficacy trials of semi-fossorial Sciuromorpha such as prairie dogs and ground squirrels and are among the most reliable of census methods for field research on such rodents. As appropriate, the closed-burrows and visual-counts methods were not run concurrently.

Rather, the closed-burrows method was employed after the visual counts method during the pretreatment phase and before the visual counts method during post-treatment. That way, the closed-burrows method was the one run closer, before and after, to the time of treatment. The closed-burrows method is more sensitive than the visual-counts method to the presence of residual burrow activity following rodenticide methods, but the visual-counts method is sensitive to the continued presence of prairie dogs, as opposed to all species that might open closed prairie dog burrows. As discussed further below, brief use of the visual counts procedure also was made during the bait-exposure phase of the study.

Borchert (2006a) and those assisting him conducted visual-counts scans from "parked company vehicles at previously determined vantage points", allowing about 15 minutes to pass from when the vehicles were parked to the beginning of scanning activity. From each vantage point, numbers of blacktails visible above ground were counted in 3 scans per day (~15 minutes apart from one another) over a period of 3 consecutive days. The highest number of squirrels seen during the respective phase of the study, pretreatment or post-treatment, was taken as the activity estimate for that plot. Pretreatment visual counts scans were conducted on 3/2-4/05, concluding 11 days prior to the initial application of the 0.0025% Diphacinone oat bait. Post-treatment visual counts scans were performed on 4/12-14/05, commencing 12 days after the fourth and final round of bait applications.

The closed-burrows method involved "shoveling loose soil over the openings" to prairie dog burrows and then checking the holes 48 hours later to determine whether they had been reopened. The pretreatment census period for the closed-burrows method ran from 3/8/05 to 3/10/05, concluding 5 days before the first bait application. The posttreatment census period for closed burrows ran from 4/8/05 to 4/10/05, beginning 8 days after the final bait application.

Activity assessments were made on the two plots designated for treatment and on two check plots. Borchert (2006a) adds that

> Buffer zones, baited with diphacinone bait, extended approximately ~30 feet all directions from the perimeters of the treated census plot. Additional buffer zones, baited [sic] with aluminum phosphide gas pellets were extended from the diphacinone treated buffer zones including the entire area between the treatment plots. This allowed the entire area infested with prairie dogs to be treated. The distance was paced off by personnel estimating distance. The boundary was marked with wire surveying stakes with plastic flagging.

Giving "buffer" areas surrounding poisoned plots treatments with the same product that is used in the census area is a common and appropriate practice for field efficacy trials. Among other things, the procedure offers some protection against having estimates of the effects of treatment distorted by the expansion and immigration of individuals from nearby populations into the suddenly vacated areas. In this trial, however, the buffer zone was only 10 yards wide (paced off); and, outside of it, prairie dogs were poisoned with a completely different kind of product – a fumigant. Such practices could have skewed the apparent test results. For example, if the Aluminum Phosphide (Fumitoxin) pellets were more effective than the Diphacinone bait, the "vacuum" effect of nearby population suppression could have "sucked" prairie dogs from the central area where the bait and census methods were being used into the effectively abandoned periphery.[3]

Borchert (2006a) reports that use of Aluminum Phosphide pellets commenced "on day 8 of the study". That day (which should have been 3/23/05) was midway between the first and

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[3] References here to "vacuum" effects on prairie dog populations are not to be confused with attempts at controlling prairie dogs by attaching large hoses to their burrow openings and literally sucking the animals, and other items, into vacuum chambers.

last application of the Diphacinone bait. Burrows treated with Aluminum Phosphide were closed -- a necessary component of burrow fumigation. Burrows that were reopened following use of Aluminum Phosphide were to be fumigated a second time. Field notes appearing on "Page 64" and "Page 65" of the Borchert (2006a) report seem to indicate that the initial round of Fumitoxin treatment occurred on "*3/22/5*" and involved treating 351 burrows with 2 tablets each. The area treated was calculated to have been "*14.53 (24.2 burrows/acre)*" and encompassed "*The entire area between the N & S treatment plots*". Field notes for "*3/23/5*" regarding the "*Initial Baiting 3/23/5*" summarize Fumitoxin treatments involving the same number of acres, burrows, and tablets as were mentioned in the notes for "*3/22/5*" and add information on the monetary and manpower costs of such treatments.[4]

The north and south plots to be treated with the 0.0025% Diphacinone bait were calculated to have been 3.78 and 3.44 acres, respectively, with the surrounding buffer zones that also were treated with the Diphacinone bait being 1.04 acres and 0.85 acres. Thus, the total area treated with Diphacinone bait was 9.11 acres. That area was less than the 10-acre figure that would seem to trigger the need for an experimental use permit[5] for the trial with the unregistered 0.0025% Diphacinone bait and less than the total area that was treated with Fumitoxin. A printed "Study Notes/ Study Plots" sheet ("Page 74") of the Borchert (2006a) document presents area information on the check plots as well as the baited plots. The north check plot was calculated to be 4.57 acres while the south check plot was 5.57 acres (10.14 acres, total).

Borchert (2006a) reports that "½ cup (~60 g)" of toxic bait was "scattered evenly on bare ground near each active burrow", apparently including a ~10-yard width around the area where the census methods were used. Four such applications were made, one each on days "0, 3, 6 and 16 of the study."[6] Those days were 3/15, 3/18, 3/21, and 3/31/05, respectively. According to the "**EXECUTIVE SUMMARY**" portion of the Borchert (2006a) report, the treatment rates were calculated to be 9.77 lbs bait per acre for the north baited plot and 10.1 lbs bait per acre for the south treated plot. However, those amounts do not square with the totals for the 4 rounds of treatments to the two plots and their buffers that appear in the report's "**Table 2**". If the figures in Borchert's "**Table 2**" are accurate, less than ¼ of the total amount of bait mixed as batches "*05-TS-7*" and "*05-TS-8*" would have

[4] Reportedly, "*3 guys*" were able to treat the 14.52 acres in 4 hours ("*each acre in 16.5 minutes*"). The fumitoxin pellets reportedly cost ~30 cents apiece, so the cost of treating 351 burrows with 2 tablets each was $210.60 or "*$14.49/acre*". The labor costs for 12 man-hours are not indicated.

[5] See 40 CFR §172.3(c)(1). It is possible that the decision to treat outer buffer areas with Aluminum Phosphide was influenced by a desire to keep the area treated with the Diphacinone product not registered for prairie dog control below 10 acres. The protocol for this study, which Scimetrics and Genesis management signed off on 3/8/05, indicates that a treated buffer zone 70 meters wide would "serve this purpose", namely "to prevent immigration of prairie dogs from outside the treated plots during the trials." The copy of the protocol that is appended to the Borchert (2006a) report has two identical copies of "Page 6" followed by "Page 8" (i.e., "Page 7" is missing).

[6] Although up to 4 treatments were planned according to the protocol for this study, the "**PROTOCOL DEVIATION NUMBER __1__**" document appended to Borchert's (2006a) report indicates:

> After 3 applications of bait, it appeared that a 4th application was not needed. After the mid-census was performed, it appeared that a 4th application was necessary.

Whether a mid-treatment census period was part of the original protocol may have been mentioned on the missing "Page 7". "Page 6" mentions only a "Pre-treatment" census period and a "post-treatment period" commencing "about 14-21 days after the initial application.". Field notes for "3/30/5" and "*3/31/5*" indicate that visual counts of prairie dogs were taken on both days before "*JB*", on 3/31/05, "*Decided to perform 4th baiting. Baited all burrows on N treatment and N half of South treatment.*"

been consumed in this bioassay. Much of the rest of the bait apparently was used in other research (see below). Table 1 to this report (essentially a copy of Borchert's "**Table 2**") indicates the amounts of bait reportedly applied in each treated area on each of the 4 rounds of treatment. The final round of baiting, on 3/31/05, did not include all of the south treated plot but rather only its more northerly half plus the "North and west side buffer", according to a printed "Study Note" for "*3/31/5*". The light rate of treatment for the second application might have been due to significant evidence of residual bait from the first. According to field notes for "3/18/05", the date of the second baiting, "Bait was applied to burrows that appeared to need bait."

Field notes for 3/23-29/05 ("Page 67" of the Borchert, 2006a, report) suggest that the fourth bait application might have been performed as early as 3/24/05 had the weather been better at that time. Notes for 3/30-31/05 9 ("Page 68") indicate that the decision to have a fourth round of baiting was reached after "*a rough visual census on both treatment plots*" on 3/30/05, which indicated presence of prairie dogs, and a "*visual census on N & S treatment plot*" on 3/31/05.[7]

As reported by Borchert (2006a), burrow activity on the north treated plot dropped from 39 active burrows to 12 active burrows following 4 rounds of above-ground spot applications of the 0.0025% Diphacinone oat bait used as the test material. Those data suggest a 69% decline in burrow activity. As burrow activity increased on the north check plot from 17 active burrows prior to the time of bait use to 25 active burrows for the 4/8-10/05 post-treatment census period, it does not appear that local factors other than control efforts were likely to have suppressed prairie dog activity on the north plot treated with Diphacinone. However, treatments conducted in the vicinity of that plot included fumigation with Aluminum Phosphide tablets as well as baiting with Diphacinone.

On the south treated plot, there reportedly were 38 burrows active before treatment and just 1 active after treatment, suggesting a 97% decline. As the number of active burrows on the south check plot declined from 63 for the 3/8-10/05 (pretreatment) census period to 53 for the 4/8-10/05 (post-treatment) census period, one conservatively could adjust the estimated level of reduction for the south baited plot for the change occurring in the south check plot. Because the level of reduction was slight in the check plot and nearly absolute in the poisoned plot, however, the adjusted estimated reduction following Diphacinone treatment still rounds to 97% (96.8% after adjustment, 97.4% without adjustment).

Borchert (2006a) elected to pool the results for the check plots in adjusting estimates of treatment effects using the closed-burrows method. Doing so resulted in essentially no adjustment as there were 78 check-plot burrows reportedly active during the post-treatment census period and 80 active check-plot burrows pretreatment. Consequently, his adjusted estimates of control were 68.4% for the north treated plot and 97.3% for the south treated plot. As the two check plots differed greatly in initial numbers of active plots, it could be argued that pooling data from them should be done on a percent change basis rather than by adding numbers of burrows. Because Aluminum Phosphide treatments occurred on lands between the Diphacinone-baited plots and the check plots, the activity data from either type of plot may have been tainted. The acreage treated with Aluminum Phosphide was about 1½ times that treated with the Kaput 0.0025 Diphacinone/0.025% Imidacloprid bait.

[7] A "GENESIS LABORATORIES MEMO" of 3/9/05 from John Baroch to Borchert refers to an "agreement with the landowners" to the effect "that surviving prairie dogs will be controlled with a registered bait", presumably after the experiment work was concluded. Baroch indicated that the study protocol should be amended to reflect that agreement. The signatures on the copy of the study protocol appended to Borchert's (2005a) report all predate 3/9/05.

Other adjustments to the active burrows data might be made according to the percent of closed burrows that were reopened on the various study plots. Based on diagrams that appear on pages 75 to 78 of the Borchert (2006a) report, the numbers of burrows sighted on "*3/21/5*" (the day of the third round of Diphacinone baiting) on the various study plots were 94 on the north treated plot, 128 on the south treated plot, 178 on the north check plot, and 256 on the south check plot. Notes on the closed-burrows method (pages 103-110) do not indicate how many burrows were closed for the pretreatment period. (The pretreatment sheet for the north treated plot is missing, in favor of a repetition of the sheet for the north check plot.) For the post-treatment period, pages 107-110 indicate that the 25 active burrows on the north check plot following treatment were among 86 that had been closed (i.e., 29%). For the other plots, the comparable figures were: 53 of 143 (37%) active on the south check plot, 12 of 87 (14%) active on the north baited plot, and 1 of 96 (1%) active on the south baited plot. As the numbers of burrows treated during the pretreatment census period were not reported, it is not clear to what extent these figures represent changes over pretreatment activity levels. However, the low level of post-treatment activity on the south baited plot likely represents a substantial decline from the pretreatment period.

The visual counts data reported by Borchert (2006a) indicate substantial to absolute declines on both treated plots and declines on the check plots as well. Table 2 summarizes the reported visual counts data and includes within-treatment-area adjustments to the estimates for the baited plots because of the declines in visual counts activity on the check plots. The adjusted post-treatment declines are 92% for the north baited plot and 100% for the south baited plot. Clearly, the adjustment made no difference to the estimate for the south baited plot.

Borchert (2006a) pooled the results for two check plots to derive numbers to factor in to adjust the estimates for the baited plots. The fundamental problem with that approach is that the effects in the two check plots are only treated equally in the event that the pretreatment indices in them are equivalent (which happened to be the case in this trial). The problem with the approach in this particular trial is that between treated and check plots were areas that had been fumigated with Aluminum Phosphide, with such treatments reportedly causing some mortality (see below), perhaps affecting activity estimates in baited and check areas, and clearly confounding the research.

Table 2 also presents the results of the midtreatment census effort on the baited plots that Borchert conducted on 3/31/05. The data for that activity appear on pages 95 and 96 of Borchert's (2006a) report. It seems fair to assume that the ~40% residual prairie dog activity seen in the north baited plot was a primary factor in the decision to bait that plot again. The sighting of some prairie dogs in the south baited plot probably provided the reason why half of it also received a fourth treatment.

As can be seen from Table 2, the visual count census data were recorded by 4 different observers and at various times during the mid-to-late morning and the early-to-mid afternoon. The reported interval of "approximately" 15 minutes between arrival and initial scan seems to have been maintained faithfully, but successive scans sometimes were run less than 15 minutes apart. The possible effects of day (including weather), season (including amount of vegetative growth), time of day, and observer on the number of prairie dogs seen above ground apparently were not researched or controlled for this trial. How any such effects might have combined to influence the results obtained in the Borchert (2006a) trial can only be the subject of speculation at this point. However, it is worth noting that all of the highest pretreatment counts of baited plots were made by Timothy Linder, who also did the pretreatment scans on the check plots on 3/3/05, the day when the highest counts were obtained for both areas (which also might have been due to favorable weather). Linder did none of the post-treatment scans. Five of the 6 sets of post-treatment scans on baited plots were conducted by individuals (Jeff Mach and John Gruening) who had not done any of the pretreatment scans. Borchert did the remaining scans, including all of those conducted on check plots. If Linder either was better at spotting prairie dogs or more prone to double-counting individuals, that he only was involved in obtaining the pretreatment data that were used might have contributed to the apparent declines seen in all areas, especially in the check plots.[8]

Time-of-day effects would be expected as animals' activity patterns vary temporally. This is why scans of the same plot usually are conducted at the same time each day in field efficacy trials.[9] Clearly, weather can affect the number of animals visible above ground, as can the presence of predators or other short-term disturbances. Taking 3 counts on each of 3 successive days per census period and using the highest of the 9 counts obtained as the minimum estimate of the number of live animals on the plot is expected to offset the effects of one or two days of bad weather or the occasional disturbance. Due to the time of year at which this study was run, some early spring growth and general greening-up probably occurred in the study area. Such growth conceivably could have affected the spotting of prairie dogs above ground, but probably not by very much.

Borchert and olher Genesis personnel conducted carcass searches of

> census plots and buffer zones during bait application and post application. All carcasses of target and non-target animals were noted. All non-target mammal carcasses found were identified, necropsied immediately and disposed of at the Genesis Laboratories, Inc. facility. Carcasses were examined for signs of test substance ingestion and symptoms of anticoagulant poisoning, bait in the gastro-intestinal tract, hematomas, and hemorrhaging.

Apparently, no carcasses were kept for residue analyses.

Concurrent with carcass searches and other activities, researchers also made observations regarding live vertebrate animals present in study areas and of animal droppings found there. According to the various documents appended to Borchert's (2006a) report, carcass searches were conducted on at least the following posttreatment days: 3/17/05, 3/18/05, 3/20/05, 3/21/05, 3/22/05, 3/24/05, 3/26/05, 3/28/05, 3/30/05, 4/1/05, 4/3/05, 4/5/05, 4/7/05, and 4/9/05.

The carcasses found included:

- a starling thought not to have died from the test bait;
- a pigeon not thought to have died from the test bait;
- a red-winged blackbird thought not to have died from the test bait;
- 17 prairie dogs found "in central area between N and S treatment plots and believed to have been killed by Aluminum Phosphide;
- 3 prairie dogs on check, buffer areas, and beyond thought not to have died from the test bait;
- part of a scavenged prairie dog carcass that was not necropsied;

In addition to these dead animals, 3 moribund prairie dogs were seen (and apparently not collected).

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[8] Field researchers sometimes conduct training sessions for certain techniques in attempting to equalize proficiency among participants. In addition, or alternatively, researchers may use the same individual each time a particular plot is observed so that whatever observer biases might exist will be consistent for that plot across all phases of the study.

[9] The idea is not so much to determine the effects of time of day but rather to control for them. As different plots are to be sampled before or after one another according to a set schedule, time biases may affect results between plots but not before-and-after results within plots.

Summaries of necropsies of 4 of the prairie dogs believed to have been killed by Aluminum Phosphide are appended to Borchert's (2006a) report. Those animals were collected on 3/24/05 (on the surface but near burrow openings), 1-2 days after the fumigant was applied. Some of those animals were found to have vegetation in their gastrointestinal tract but no evidence of bait or red dye. One prairie dog collected from a buffer area on the same day (3/24/05) reportedly had "*presence of pink food in stomach, possibly bait*". That is as close to claiming a bait-killed carcass as the Borchert (2006a) document comes.

Due to the emergence of new-growth vegetation, spring generally is not the optimal season for controlling prairie dogs with grain baits. The study might have been run largely before spring green-up in northern Colorado.

This study was run using a bait formulation similar to that being proposed for 72500-RR. The conduct of the study was confounded in several ways, most conspicuously by the concurrent use of a burrow fumigant in close proximity to the baited plots. Some 17 dead prairie dogs found 9 days into the baiting period were concluded to have been taken by Aluminum Phosphide. That number would include only the subset of fumigation victims that managed to make it to the surface before expiring.

If viewed in the light most favorable to the product, the Borchert (2006a) study suggests that 2+-oz spot surface treatments per active burrow with a 0.0025% Diphacinone oat bait might be of some value in controlling black-tailed prairie dogs, if multiple applications are made. The reported performance of this product in multiple applications does not compare favorably to the performance of 2% Zinc Phosphide baits applied following prebaiting, as reported in Tietjen's (1976) monograph. As discussed in that paper, oat-based baits may out-perform baits made from other grains as agents for controlling blacktails.

Genesis personnel recently have completed other field trials in which 0.005% Diphacinone baits lacking Imidacloprid were used tested for efficacy against black-tailed prairie dogs. In the efficacy review of 7/5/07 for TX-070004, I discussed trials by Borchert (2005) and Poche' (2006) in which baits perhaps corresponding to one or more versions of the Scimetrics product "*Kaput*®-D Pocket Gopher Bait" Scimetrics (EPA Reg. No. 72500-9) were used.

The Borchert (2005) trial was run in Larimer County, CO, concurrently with to the Borchert (2006a) trial on nearby lands, which enabled the same two check plots to be used for both trials. Four rounds of surface applications of the 0.005% Diphacinone bait near burrow openings on the only treated plot resulted in 75% reduction of prairie dog activity, according to the closed burrows method.[10]

Poche' (2006) reports having obtained excellent control (100% for visual counts, 97% for closed-burrows) after two rounds of applying a 0.005% Diphacinone wheat-based (or milo-based) bait at least 6 inches down prairie dog burrows at a test site north of Amarillo, TX.

Borchert, J.N. (2006b) Rock squirrel simulated field study using Field Rodent Bait: 30-day test (*Spermophilus variegates*) [sic] of Kaput® Field Rodent Bait B. Unpublished report, Study No. 05010, Genesis Laboratories, Inc., Wellington, CO, 89 pp.

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[10] When adjusted for the reduction in post-treatment activity in the check plot that was closer to the poisoned plot, the control estimate drops to 71%. Nearby use of Aluminum Phosphide in prairie dog burrows may have affected the results of this trial. Additional details of this study are discussed in the efficacy review of 7/5/07 for TX-070004 and in the efficacy review of 2/8/07 for CO-060010, where a longer report of the same report (with a 2006 date of completion) is reviewed.

Captive wild-type rock squirrels (*Spermophilus variegatus*) were used as subjects in this study. The rock squirrel is a type of ground squirrel indigenous to the southwestern U.S. (AZ, CA, CO, KS, NM, NV, OK, TX, and UT). Rock squirrels vector plague to humans via fleas that bite both rodent and man.

Like the study reported by Borchert (2006a) and discussed above, the Borchert (2006b) study is claimed to have been conducted according to EPA's Good Laboratory Practice Standards (GLPs).

On the title page, Borchert (2006b) refers to the bait used in this trial as "Kaput® Field Rodent Bait B". In the body of the report, the test material is called "Field Rodent Bait", "Field Rodent Bait (0.0025% Diphacinone", and "Diphacinone Field Rodent Bait". The test material reportedly was formulated by Genesis rather than Scimetrics. Genesis "assigned a unique test substance number, 05-TS-7", to the test batch. "Page 83" of the Borchert (2006b) report shows a "**Bait Formulation**" like that used by Borchert (2006a) and bears the hand-written entry "*This was logged into GL as 05-TS-7*". The item is signed "*JB 2/16/5*" and bears the further notation "*Made additional 100 lbs on 3/11/5 (05-TS-8) JB 3/11/5*". A copy of the same sheet appears on "Page 49" of the Borchert (2006a) report.

An analytical report included as an appendix to the Borchert (2006b) report indicates that samples of bait batch "05-TS-7A" were found to average 25.2 $\pm$ 0.6 (0.00252%) Diphacinone (range: 0.00245-0.00260%). The limit of detection reportedly was 0.000224%, and the limit of quantitation was 0.000512%.

Eighteen rock squirrels live-trapped in or near Albuquerque, NM, served as subjects in this study. There were 4 males and 14 females. The animals reportedly were transported to the Genesis facility in Wellington, CO, and acclimated to test circumstances for 13 days before bait-exposure began. The squirrels "were not marked physically with an identifier", which likely meant that individuals within sex classes could not have been distinguished from one another. The animals were inspected by a veterinarian midway through the acclimation period.

The acclimation period reportedly ran from 2/10/07 to 2/22/07, which would have made it 12 days long rather than 13. The bait-exposure phase of the study ran from 2/22/05 to 3/23/05. The timing of the animals' capture may have coincided with the time of emergence of adult squirrels.[11] This study and the Borchert (2006a) field trial were underway simultaneously.

Squirrels apparently were permitted to range throughout "study room A (simulated field environment)". There were "wood shavings and straw bales" on the floor of the room. In addition,

> sections of 4" PVC pipe and wood shelters were located in the middle of the room for cover. Tap water in a galvanized steel waterer was available *ad libitum*.

According to the "**PROTOCOL**" appended to the Borchert (2006b) report, the squirrels were to have been fed "Purina 5001 Rodent Chow ... *ad libitum*" prior to the start of the

[11] Many types of *Spermophilus* spp. hibernate. Hibernation periods tend to be longer in populations located at higher latitudes and/or elevations within the home ranges of the various species. If Borchert's (2006b) squirrels were live-trapped above-ground just before the acclimation period began, they would have been naturally active prior to their collection for this study. *S. variegatus* may hibernate for short periods of time.

bait-exposure period. Material in the hay bales also would have been available as feed for the squirrels.

At the start of the bait-exposure period, the squirrels were offered a total of ~2700 g of test material, equally divided among

> 3 bait stations, commonly used for ground squirrel control, (Modified PVC "T" design, Montana Department of Agriculture, 1991).... The bait stations were placed on the floor of the study room on large metal pans to facilitate retrieval of spilled bait.

Borchert (2006b) reportedly assessed consumption of the test bait at 3-day intervals using weigh-back procedures. Although the "**PROTOCOL**" for this study called for it, no effort was made to assess consumption of the alternate food supplied during the bait-exposure period. The

> Alternative diet was available in the room *ad libitum* and placed in two large piles. Alternative diet was replenished as needed.

The "Alternative diet" used initially "was based on the EPA Field Rodent Challenge Diet Recipe", which is to be a 50%:50% (w/w) mixture of "Rolled oat groats (ground)" and "Commercial rodent laboratory diet" (see OPP Protocol f.215). As mixed by Borchert (2006b),

> The diet contained 50% laboratory chow (Purina 5001), which contained a vitamin K content of 0.5 ppm. In anticoagulant therapy of humans, there has been much study on the interactions of foods containing vitamin K with the anticoagulant. Greenblatt and Moltke (2005) and Khan et al. (2004) found that the variability of anticoagulant response to warfarin is related to fluctuations of dietary vitamin K. The vitamin K content of alternative diets in rodenticide evaluations can influence the outcome of studies. The alternative diet used in this study was changed to avoid possible bias created by originally using an alternative diet high in vitamin K.[12]

The substitute "alternative diet" was "50:50 chopped corn: rolled oat diet."

Vitamin K occurs naturally in a variety of plant materials. Some types of rodents (e.g., Norway rats) seem to be able to identify plants that are relatively rich in Vitamin K and to self-medicate to a degree in the face of health challenges brought on by exposure to anticoagulant rodenticides. "EPA field rodent challenge diet" is 50% oat-based material – which "field" rodents typically find to be very palatable – and 50% commercial rodent diet – which is notoriously unpalatable to rodents in the face of alternative foods but is nutritionally good for them. Thus, the shift in challenge diets by Borchert (2006b) might

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[12] Borchert (2006b) appended to his report abstracts for the articles cited in this quoted passage. The abstracts appear on "Page 84" and "Page 85" of the report. The abstract for the Greenblatt and von Moltke (2005) paper states that "St. John's wort and possibly some ginseng formulations may have the capacity to diminish warfarin antocoagulation" in humans; but "Otherwise, there is no reliable evidence to indicate that any dietary component (other than vitamin K) or any herbal product has an effect on the anticoagulant response to warfarin." The abstract to the Khan, *et al* (2004), paper states that "There was no correlation between warfarin daily dose and average dietary vitamin K intake when calculated over 28d. The regression model for warfarin dose showed that, while dietary vitamin K had no effect, the CYP2C9 genotype (P=2%) and age (P<1%) significantly contributed to inter-patient variability in warfarin dose requirements." The cited items pertain to human clinical literature. Taken at face value, they suggest that, for our species, what one eats is not as likely as one's genetic makeup to affect the efficacy of Warfarin as a therapeutic drug.

have reduced the squirrels' ability to self-medicate at the expense of reducing bait acceptance through use of a more palatable challenge diet.

Borchert (2006b) switched the challenge diet 14 days into the bait-exposure period.

Apparently, no control group of rock squirrels was maintained in captivity under similar conditions to the test group except for exposure to the toxic bait.

In his "**PROTOCOL**", Borchert (2006b) set 70% kill as the effectiveness criterion and 30-days as the duration for the bait-exposure period. The 70% reduction criterion is consistent with that indicated for field tests of rodenticides on farm and rangelands (Section 96-12 of the Product Performance guidelines) and is more lenient than the 90% kill criterion typically used for laboratory efficacy tests. Borchert stopped this study 29 days into the bait-exposure period, 6 days after discovery of the 13th victim brought the mortality figure to 72%. Borchert (2006b) reports some evidence consistent with anticoagulant poisoning in all 13 claimed victims.

The first squirrel mortality reportedly occurred 10 days into the bait-exposure period and the last death on day 23. After 19 days, only 7 (39%) of the squirrels were dead, but 3 more died by day 20 and another 3 by day 23. According to "**PROTOCOL AMENDMENT NUMBER** ~~1~~ *2 JBcc3/8/5*", the switch in challenge diets occurred on 3/8/05, which was 2 weeks into the bait-exposure period. Five squirrels were dead by the time of the switch in challenge diets. Eight squirrels died over the next 9 days. The switch in challenge diets might have been a factor in some of the deaths observed from days 15-23.

All 4 of the male subjects died during this study, and their deaths occurred relatively early (days 13, 14, and 16) in the bait-exposure period. The last 6 rock squirrels to die and all 5 survivors were females.

Borchert reports a calculated consumption of 2313.8 g from the 3 bait stations. From the individual stations, consumption figures of 1015.1 g, 789.0 g, and 509.7 g were reported. A raw data sheet appended to the report ("Page 67") suggests bait replenishments were made after each weigh-back period over the first 3 weeks of bait exposure. It is not clear whether all of the calculated difference represented actual consumption or could have included bait that was scattered or hoarded. The amount of missing bait works out to 128.5 g/squirrel. At 40 g bait/mg of Diphacinone, the amount of poison removed works out to 3.2 mg per squirrel. With the reported initial weight range for squirrels being 529.3 g to 916.0 g, the heaviest squirrel would have consumed about 2.5 mg/kg of body weight if it ate an average amount of bait and it all reported missing bait was consumed.[13] If the 5 surviving squirrels ate average amounts of the bait, their daily consumption would have been on the order of 4.4 g of bait per day. As such a chronic dosage should have been enough to kill them (inferring from rat data from Ashton, *et al*, 1987, and other available information), it seems likely that the survivors did not eat bait steadily throughout the study, that much of the missing bait was not consumed, and/or that there was some antidotal effect from Vitamin K in the original challenge diet. The squirrels that died during the study clearly would have consumed the bait that they ate over periods no longer than 23 days and possibly shorter than 10 days for the initial victim. If the first victim ate an average amount of bait, its consumption would have averaged nearly 13 g/day (assuming that all missing bait was consumed).

As amounts of the "alternative" foods missing were not calculated, it is not clear what proportion of the proffered food items removed by squirrels was comprised by the toxic

[13] It appears that squirrels, whether victims or survivors, lost weight during their periods of captivity for this trial. As individuals were not marked individually, it is not possible to determine how much any animal gained or lost.

bait. Conservatively assuming an ounce of total consumption per animal per day would put the total consumption figure for the group at 509 g/day. Such a figure might have held only for the first several days of the bait-exposure period because some of the animals might have become sick. However, no overt symptoms of poisoning were noted ("Page 64" of Borchert, 2006b) until the first victim was found dead ("*FD*").

Borchert (2006b) reports that temperatures were 16-24ºC (~61-75ºF) and that recorded "Relative humidity ranged from 14-24% during the acclimation period." During the bait-exposure phase, room temperatures reportedly were 16-28ºC (~61-82ºF) while recorded relative humidity ranged from 14-23%.[14] Borchert (2006b) reports that "A thermostatically controlled gas furnace supplied heating" whereas "Humidity was ambient and not controlled." It is possible that output from the furnace lowered the relative humidity somewhat. Very low humidity might potentiate the effects of anticoagulant poisoning by promoting skin lesions and increasing needs for consumption and retention of water.

Simulated field efficacy trials occasionally are permitted to be run *in lieu* of some of the actual field trials required to establish a claim of effectiveness for a rodenticide, especially one proposed for structural uses. In theory, a simulated trial trades real-world applicability for somewhat greater experimental control and in full determination of the effects of treatment *via* being able to determine the fate of each subject. As conducted by Borchert (2006b), this field trial showed only fair performance of the test bait despite rather blatant manipulation of the circumstances of the trial for the purpose of obtaining additional mortalities. The material used in this trial seems unlikely to be very helpful in controlling rock squirrels in actual use situations where there are alternative sources of food sufficient for maintaining the infestation. A bait that that is less effective against females than males would seem especially likely to produce unsatisfactory results.

It is possible that the presence of Imidacloprid in this bait adversely affected its palatability to rock squirrels. Bait palatability initially might have been suppressed by the presence of a familiar food – Purina Chow – in the challenge diet used initially during the bait-exposure period, although laboratory rodent diets are notoriously poorly accepted by rodents when offered in competition with whole grains. It is possible that the presence of Vitamin K in the challenge diet enabled the squirrels to combat the effects of Diphacinone somewhat, although wild squirrels likely would have some opportunity to self-medicate with Vitamin K sources in the natural environment after having been exposed to an anticoagulant rodenticide. Seasonality possibly could have affected the palatability of bait, but oats were in the bait and both of the challenge diets used. Post-emergent ground squirrels typically prefer green vegetation when it becomes available but may eat seeds of various types until then. Among grains, oats tend to be well accepted by most types of rodents, including most types of ground squirrels.

Another possibility is that whatever palatability and/or self-medication problems there might have been with the toxic bait could have been offset – at least under test conditions – if the concentration of Diphacinone in the bait had been higher. The typical concentration of Diphacinone in finished rodenticide baits is 0.005%. As noted previously, 0.01% Diphacinone baits have been registered in California for controlling field rodents, including ground squirrels.

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[14] The minimum relative humidity figure recorded during the test phase actually was 2%. In "**Appendix C2**" ("Page 43") to the Borchert (2006b) report, the 2% figure is footnoted with the phrase "Outlier, removed from calculation." On "Page 48", which shows raw entries onto an "**ENVIRONMENTAL MONITORING OF ANIMAL STUDY ROOMS**" form covering the observation in question, the entry "*2*" is footnoted with the phrase "*low reading likely due to malfunction*". The "**Maximum**" relative humidity recorded for the same date (apparently 3/19/05) was "*19*". All squirrels that were going to die in this study were dead already by that date.

The systemic ettects of ingested Imidacloprid on ectoparasites ot rock squirrels were not investigated in the Borchert (2006b) trial.

Borchert, J.N. (2006c) Field efficacy of Field Rodent Bait B: Calitomia ground squirrels (*Spermophilus beecheyi*) and tleas ot Kaput® Field Rodent Bait B. Unpublished report, Study No. 05019, Genesis Laboratories, Inc., Wellington, CO, 371 pp.

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Borchert (2006c) variously calls the primary test material used in this study "Kaput® Field Rodent Bait B", "Field Rodent Bait B", and "FRBB", and describes it as being "0.0025% Diphacinone, 0.025% Imidacloprid". In contrast to the studies described in the reports cited and discussed above, this study included assessments ot the ettects of the bait on tleas as well as ground squirrels. In the "**INTRODUCTION**" to this report, Borchert (2006c) discusses the concept behind 72500-RR, namely to attect tlea control prior to the demise ot the rodent host so that, in theory, there are not host-seeking, infectious live tleas in the treatment area after their preferred hosts have been killed.

During the course ot this review, I spoke with its author, Jett Borchert, and other Genesis personnel on 7/25/05 regarding a page missing trom the MRID# 469665-01 document. "Page 163" is a duplicate ot "Page 163" in the submitted version. Borchert FAX-ed me a copy ot what should have been "Page 163". That page presents raw data tor visual counts on the "*West Treatment*" (check) plot for the pretreatment census period. I also spoke with Borchert on 8/1/07 regarding the mass or weight ot ½ cup ot "Kaput® Field Rodent Bait B".

This tield trial was run trom 6/9/05 through 7/8/05, which is toward the end of the late-spring/early-summer "window" ot opportunity to control Calitornia ground squirrels when all age and sex classes are active above ground and are likely to accept grains. Due to seasonal fluctuations in the extent ot above-ground activity in ground squirrel populations, it is imperative that field etficacy trials include concurrently monitored unpoisoned (check) plots as well as treatment plots. As summer aestivation can begin in July, this post-treatment activity assessments in this study could have included seasonal ettects as well as the ettects of the rodenticide on ground squirrel activity.

The primary test material reportedly was mixed by Scimetrics. Borchert (2006c) states that 2 batches ot bait were prepared for this study. Batch numbers used by Scimetrics do not appear to be indicated in the report. The entry "*NA*" appears in the space atter "Lot #" on the "**BAIT DISPERSAL RECORD**" sheets appended to the report.

Analytical reports appended to the Borchert (2006c) document indicate that 4 samples ot a bait designated as "05-TS-8A" and analyzed on 5/24/05 ranged from 260.8 to 283.2 µg/g Imidacloprid tor a mean concentration ot 267.9 µg/g (±10.4 µg/g), which is equivalent to 0.02679% (w/w). Another 4 samples ot a bait referred to by the same name ("**Field Rodent Bait B**") but perhaps trom another batch were analyzed on 6/16/05 and were found to range from 222.1 to 279.4 µg/g Imidacloprid for a mean concentration of 251.6 µg/g (±23.8 µg/g), or 0.02516% (w/w). Two of the 8 sample results were beyond the certitied limits (0.023-0.028%) proposed for imidacloprid on the CSF ot 10/20/06. As confirmed by Borchert *via* telephone on 8/1/07, notations such as "05-TS-8A" follow a code used by Genesis to identity test materials, primarily to indicate sequence ot preparation. The code is not diagnostic as to tormulation, and the same code at times might be assigned to successively prepared batches ot the same composition.

Additional samples trom the "05-TS-8A" bait were analyzed on 5/26/05 and were tound to range from 26.4 to 28.2 µg/g Diphacinone for a mean concentration of 2759 µg/g (±08 µg/g), which is equivalent to 0.00275% (w/w). Three samples from a bait of the same name but probably a ditterent batch were analyzed on 6/15/05 and were tound to range from 25.5 to 29.7 µg/g Diphacinone for a mean concentration of 27.3 µg/g (±2.2 µg/g), or 0.00273%. None of the 7 sample results were beyond the certified limits (0.0020-0.0030%, ± 20% of nominal) proposed for Diphacinone on the CSF of 10/20/06.

The May chemical assays were conducted before any toxic bait was applied in the Borchert (2006c) study. The June analyses were conducted after the first round of bait applications. The second Imidacloprid assay was conducted on the day of the second bait application in the field trial.

This field study was conducted on Vandenberg Air Force Base in Santa Barbara County, CA. Six plots were set up for this study. These consisted of 2 treated with the Field Rodent Bait B product, 2 "negative control plots which received no bait application" (check plots), and 2 "positive control plots" that were treated with "a commercially available rodenticide bait containing only diphacinone". The product used to treat the "positive control plots" is described as

> P.C.Q. Pelleted Rodent Bait (PCQ, 0.01% diphacinone, Bell Laboratories, Inc., Madison, WI) registered under a Special Local Needs permit in California.

P.C.Q. Rat and Mouse Bait, containing Diphacinone at 0.01%, nominal, remains registered in California under the §24(c) number CA-780146.[15] Bell's 0.005% Diphacinone bait products (12455-19, -29, and -78) which had "P.C.Q." in the brand names sometimes used for them were voluntarily canceled recently.

Surrounding each treated plot, Borchert (2006c) established buffer zones which "extended approximately 60-70 meters in all directions". The plots "were located and established, near human activity" in parts of the base where there were roads, buildings, and parking lots. Consequently, not all of the locations that would qualify as being within 60-70 meters of the monitored treated plots were treated as buffer zones. Beyond the perimeters of each buffer zone, Borchert (2006c) established "a non-target search zone" which extended "70 meters beyond the buffer zones."

Examination of "**Figure 5**" in the Borchert (2006c) report suggests that plots within each treatment group were clustered such that each plot's nearest neighboring plot was a plot that received the same treatment (or non-treatment). The "East Treatment" and "West Treatment" plots, which were treated with the Kaput® bait, were separated from one another by a parking lot.

Table 3 to this review summarizes the information on plot areas and treated buffer areas that I was able to glean from pages 119 and 120 of the Borchert (2006c) report. On those pages, the treated areas are presented in terms of square meters. The narrative portion of the report and its "**Table 1**" provide acreages for individual plots and total treated buffer areas within treatment groups (i.e., pooling buffer areas associated with both plots that were treated with each of the baits).

Borchert (2006c) assessed ground squirrel activity before and after rodenticide application using the visual counts and closed burrow indices. The procedures described for those methods were essentially the same as those discussed above for the Borchert (2006a) prairie dog study. As in that other trial, Borchert (2006c) reports that

[15] According to the CSF for it dated "*4/22/02*", CA-780146 contains [redacted]

A t-day mid-treatment visual index was performed midway through the baiting period. This mid-treatment visual census observation was performed to estimate the baiting efficacy and project the required duration of the application period.

Borchert (2006c) also reports that

a burrow swabbing technique outlined by the CDA Division of Vector Borne Infectious Diseases (CDC date unknown) was performed. Twenty burrows on each plot were swabbed. White flannel (30.5 cm X 30.5 cm) was attached to plumber's flexible wire (2.5 meters) with an alligator clip attached at the end. Additionally, a temperature/humidity probe ... was attached via electrical tape to the plumber's wire. The electrical tape was marked at ½ meter increments. The probe was attached to a digital unit measuring temperature and humidity. The wire was pushed down the burrow until resistance was met, shaking and twisting as it proceeded. The target depth for burrow swabbing was 1.5 m. At this depth, the environmental conditions of the burrow have a high likelihood of being similar among burrows.... The wire, with flannel attached was removed and the flannel placed in a zip-lock bag. The depth of the plumber's wire insertion and the temperature and humidity of the burrow were also recorded. Collected fleas were placed in a freezer for immobilization or immobilized by anesthetic (halothane ...) and saved in rubbing alcohol for later evaluation.... The number of fleas was counted and recorded. Saved fleas were evaluated for presence of remnant blood meal and a sub-sample evaluated for species determination. Burrows were swabbed prior to application of the bait to determine baseline flea populations existing in the burrow and not on the target species (California ground squirrel). Burrows were swabbed at weekly intervals after the application of bait to determine if baseline flea populations changed after squirrels were exposed to the bait.

Burrows were swabbed 3-4 days prior to the first bait application, and 7-8, 14-t5, and 2f-22 days after the first application. These procedures permitted treatments to be compared in terms of numbers fleas remaining alive in burrows associated wilh various treatments. Numbers of fleas killed systemically were not determined.

The Kaput® bait reportedly was applied 4 times, at 3-day intervals, over the first 9 days of the bait-exposure period (i.e., on days 0, 3, 6, and 9). Treatments were made "at rates of ½ cup (~60 g) per active burrow using measuring cups" (which would have measured in volume rather than mass).[16]

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[16] Based on the bulk density of "37.24 pounds/ft^3" reported on the CSF of 10/20/06 for 72500-RR, ½ cup of this product should weigh nearly 3 oz (83.8 g), based on dry-measure units. The label proposed for this product calls for "approximately 2 oz. of bait" to be applied "near the burrows". One-third cup, dry-measure, of this product should weigh about 55 g, which is slightly less than 2 oz. The amount of bait prescribed to be applied per burrow should be consistent with what was used in successful field trials. It seems clear from Borchert's (2006c) narrative that bait placement amounts were determined by volume rather than by weight. Borchert confirmed as much via telephone on 8/1/07. Neither that report nor those by Borchert (2006a, b) seems to present information regarding the weight or mass of a half cup of bait. If the pint size for liquid measure rather than that for dry measure is incorporated into the calculations, the weight of a half cup of bait at the stated bulk density works out to 2.49 oz or about 70 g. On 8/7/07, Borchert told me that Genesis no longer has a sample of the Kaput Field Rodent B bait used in this study. Using a density figure (0.597 g/ml) from a trial conducted by the Genesis product chemistry laboratory on the test bait, Borchert computed that ½ cup of the bait should weigh 70.6 g. That figure is very close to the figure of 70.44 g/½ cup that I calculated using liquid-measure units. Absent subsequent receipt of contrary information, "~2½ oz." and "~70 grams" will be used as weight equivalents for a half cup of this bait.

Borchert (2006c) states that "Positive Control Bait, PCQ, was applied according to label directions." According to the labels on file with EPA for CA-780146, the directions for using that product to control California ground squirrels read as shown below

> Scatter a handful of bait (about 10 baits per pound) evenly over 40 to 50 square feet near active burrows or runways. Retreat every other day for 3 to 4 applications.
>
> An uninterrupted supply of bait should be available for 6 to 8 days. Don't pile bait. The scattering of bait takes advantage of the squirrels' natural foraging habits and limits domestic livestock and wildlife from picking it up.

Information appended to the Borchert (2006c) report indicates that initial applications of P.C.Q. bait were made literally by hand but that later applications may have included use of a "*measuring cup*" (Page 140). If the P.C.Q. baits truly weigh about 1.6 oz each, they are pretty big as rodent bait pellets go. However, the intended meaning of "about 10 baits per pound" might be "10 bait placements per pound", in which case the individual placements of the P.C.Q. bait would have been about 1.6 oz, slightly less than the ~2.1 oz. that might have been used for the Kaput® bait.

Table 4 to this review summarizes the information on the amounts of the Kaput® and P.C.Q. baits that were applied to each monitored plot and to the buffer areas assigned to each category of baited monitored plot. There does not appear to be anywhere in the Borchert (2006c) report where the amounts of bait applied to the buffers associated with each individual treated monitored plot are reported. Consequently, Table 4 presents data on buffer areas according to the bait that was used on them. It can be seen from Table 4 that, on a pounds/acre basis, the Kaput® bait was applied at nearly twice the rate of the P.C.Q. bait. It is not clear to what extent relative burrow density might have been a factor in these application rats, as opposed to differences in application directions (or factors related to the true mass of ½ of Kaput® bait). Owing to the lower concentration of Diphacinone in the Kaput® bait, more of that ingredient was applied per acre where the P.C.Q. bait was used than where the Kaput® bait was used. Overall, Diphacinone was applied at a rate of 0.00077 lbs/acre in the areas treated with the Kaput® bait and at 0.0017 lbs/acre where P.C.Q. bait was used.

The apparent effects of the bait applications on California ground squirrels are summarized in Tables 5 and 6. It appears that both of the Diphacinone baits used affected substantial control of the targeted species. According to the visual counts census method (Table 5.), there was no activity post-treatment ground squirrel activity on either of the plots treated with the P.C.Q. bait (100% reduction). The single ground squirrels observed during post-treatment census periods on each of the plots treated with the Kaput® bait generated control estimates of 91% and 86% after results were adjusted for the mean (41%) decline in activity on the two check plots. The post-treatment results for the visual-counts method were captured on field note pages because researchers "*ran out of visual data sheets JB 7/9/5*" (account from field notes sheet for 7/9/2005). The sheets and entries pertaining to the post-treatment census period for visual counts (7/9-11/05) appear somewhat out of order in the appendices to the Borchert (2006c) report.

By comparing Tables 4 and 5, it can be seen that the "Mid-treatment" visual counts assessments for the baited plots actually were begun a week after the date of the last bait applications. In effect, the "Mid-treatment" census was an early post-treatment census conducted at a time when some squirrels might have been in the process of succumbing to the bait, although the results of the "Mid-treatment" assessments were similar to those later obtained in the post-treatment census period. Growth of mustard plants (1-2 feet high) interfered with post-treatment visual counts "to *some degree on all plots*".[17] From the field notes appended to the main report, it is clear that there were some live squirrels on buffer areas.

As can be seen from Table 6, there was somewhat more residual activity detected with the closed-burrows method than with the visual-counts procedure. As different numbers of burrows were closed during the pre- and post-treatment census periods on the respective plots, I have presented the results in Table 6 in terms of numbers of burrows that were active and in terms of percent of burrows that were closed that animals reopened. There was a post-treatment decline on the check plots in terms of numbers of burrows opened, but the percent of burrows closed on those plots that animals reopened was higher post-treatment than pretreatment, due to their having been fewer burrows closed for the post-treatment census. Calculated effects of bait applications on numbers of burrows active on the P.C.Q.- and Kaput®-treated plots are adjusted for the 20% mean reduction in numbers of active burrows on the untreated plots. No such adjustments are warranted for percent of closed burrows reopened because that index was higher on untreated plots during the post-treatment phase of the study than it was during the pretreatment census period.

Borchert (2006c) assessed the efficacy of treatments on fleas in terms of numbers of fleas collected per burrow, numbers and percent of burrows with fleas, numbers and percent of fleas collected with evidence of a recent blood meal (fed fleas). Twenty burrows per monitored plot (= 40 burrows/treatment group) were evaluated for flea presence. As noted above, the flea data collected pertain to fleas associated with burrows rather than on live squirrels. The results of the flea portion of this study should be discussed in some detail by an IRB entomologist. For this review, I will summarize the primary findings regarding the apparent effects of the Kaput® bait on fleas, measured indirectly.

Table 7 summarizes the flea-count data obtained via burrow swabbing using the methods described above. Although various means and percents are presented in Table 7, such numbers obscure the highly skewed nature of most of the data collected. For all plots and during all census periods, the modal flea count for the 20 burrows assessed on each plot was 0. Most of the median counts also were 0, with none being higher than 1. Most collections were taken from depths less than the targeted 1.5 m. Depths of swabbing typically were reported to the nearest 0.25 or 0.5 meter. All collected fleas that were identified as to species turned out to be *H. anomalus* or *O. montana*. Examples of both species often were collected from the same burrows. Some fleas that study personnel did not fully "key-out" were thought to be of another species.

Initial flea censuses taken 3-4 days before the first applications of rodenticide baits showed flea indices to be similar among treatment groups (0.1-0.35 fleas/burrow, 10-25% of burrows with fleas, and 0.05-0.20 fed fleas/burrow). While ground squirrel activity was greatly suppressed on all poisoned plots, there was a striking difference in flea abundance between the plots treated with Kaput® B bait and those treated with the P.C.Q. bait. Numbers of burrows positive for fleas and, consequently, the numbers and percents of sampled burrows that showed flea activity were below the pretreatment levels on the plots treated with Kaput® B (Table 7.). On the plots treated with P.C.Q., numbers, rates, and percents of burrows with flea activity increased during the post-treatment flea-census periods (the first of which was performed during the bait-application phase of the study, when some squirrels that later succumbed to the bait probably were still alive). On the check plots, numbers of burrows with flea activity detected typically (5 of 6 cases) were higher during the "post-treatment" phase than they were during the one census taken prior to bait application.

[17] Quoted text is from field notes for "7/9/5", on "Page 150" of Borchert (2006c) report.

The numbers of fleas observed per burrow stayed relatively low on the plots treated with Kaput® B bait. On the "East Treatment" plot, nearly all post-treatment flea activity was at a single locus ("**Burrow No.** 6"), which also was the only burrow swabbed for fleas on that plot where more than one flea was observed during the pretreatment phase. The notation "*baby squirrel present*" appears next to the entry of "*3*" in the "No. of Fleas (Initial and Date) column for burrow number "6" on the "Burrow Swabbing" form of "*6/21/05*" for the first post-treatment collection for the "*East Treatment*" plot.[18] No such notations were made on other data entry forms for burrow number "6" on the "*East Treatment*" plot. If, however, there consistently was residual squirrel activity burrow "6" in the East Treatment plot, the flea-count data from that locus might be the proverbial "exception that proves the rule", meaning that the bait failed only as a systemic flea-control agent where it also failed, at least partially, as a squirrel control agent. In the narrative to his report, Borchert (2006c) specifically mentions residual juvenile ground squirrel activity at burrow number "6" on the "East Treatment" plot. The burrow on the "West Treatment" plot that had 7 fleas observed during the third post-treatment census period had one flea observed during the pretreatment census but none during the first two post-treatment census periods. No fleas were found during the swabbing of 20 burrows on the West Treatment plot during the first post-treatment census.

On the plots treated with the P.C.Q. bait, flea numbers increased following bait application. At some loci on P.C.Q. plots, post-treatment flea counts soared into the hundreds. Such results are consistent with what would be expected -- when the host animals are destroyed, their ectoparasites seek alternate hosts – for a rodenticide bait that lacks an insecticide that works systemically to control ectoparasites. The P.C.Q. bait reportedly contains [redacted]

The peak flea count on the P.C.Q. plots was 312 (including 218 that appeared to have had a blood meal). That count was obtained from "**Burrow No.** 7" on the "South Positive Control" (P.C.Q.) plot during the second post-treatment census, two weeks after the initial bait application. During the final post-treatment flea-census period, 11 of 20 burrows on the "South Positive Control" plot had no fleas, but 7 burrows had 16 or more, including one with 172 ("**Burrow No.** 7") and another with 211 ("**Burrow No.** 5"). During the last flea census on the other P.C.Q. plot ("North Positive Control"), 10 burrows were negative for fleas, but 4 had 15 or more. The peak number for that census was 137, of which 133 showed evidence of having had a blood meal.

Flea results on "Negative Control" (check) plots were somewhat intermediate to those obtained on the plots treated with Kaput® B bait and those treated with the P.C.Q. bait. The check-plot data are presumed to be representative of what happens in the absence of Diphacinone treatment, with or without an effective systemic insecticide being present in the bait. The proportion of burrows with fleas present and the number of fleas per burrow increased from the burrow-swabbing effort on 6/9-10 /05 to a peak during the census of 6/27-28/05, with some decline apparent during the last census period on 7/4-5/05. The peaks in percent of burrows with fleas and in number of fleas per burrow were much lower on the check plots than those observed on the plots treated with the P.C.Q. bait. Numbers of fleas per burrow on check plots were higher on check plots than on those treated with Kaput® B bait during the second post-treatment census period but were equivalent to the number of fleas per burrow on the plots treated with Kaput® B bait during the last post-

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[18] It appears that Dr. Richard M. Davis did some of the flea swabbing and took counts of fleas that he observed and (usually) bagged doing it. Fleas that were bagged and "sedated" were counted subsequently by Genesis technician Michael Zelanak. Where there were discrepancies between Davis's and Zelanak's counts, Zelanak's were used. Davis apparently did not do any of the swabbing at burrow "6" on the East Treatment plot. Clearly, an accurate field count of active fleas would be difficult to perform accurately, especially when large numbers were collected (as at some burrows on plots treated with the P.C.Q. bait).

treatment census period. However, more burrows were positive for fleas on the check plots than on the plots treated with Kaput® B during all post-treatment census periods. The relatively large numbers of fleas at one burrow on each of the plots treated with Kaput® B skewed the fleas per burrow index for those plots during the last census period.

Regardless of treatment and census period, most of the fleas examined typically showed evidence of having had a blood meal. The cases with less than half of the fleas examined showed evidence of a blood meal were 2 collections of 4 fleas each. This index for fleas positive for blood meals trended weakly upward across plots during the course of the study.

As reported, the flea data indicate that there were fewer live fleas collected from burrows that were treated with the "Kaput® B" bait than at P.C.Q.-treated burrows or at burrows on the check plot. Although data on fleas killed by the "Kaput® B" bait were not obtained, the results reported basically mean that there was a lower incidence of fleas where the Diphacinone/Imidacloprid product was used than might have been expected to be there based upon the results obtained with a Diphacinone bait lacking an insecticide or with no treatment at all. From the standpoint of flea abundance, the outcome from using rodenticide alone was worse than that from no bait application at all.

The bottom lines to the flea and ground squirrel efficacy data are that both types of organisms were affected by the Kaput® B bait, that the P.C.Q. bait all but eliminated squirrels but left many fleas alive and host-less at nearly half of the examined burrows, and that using no rodenticide or rodenticide/insecticide permitted the flea numbers and incidences to rise, at least for a time, and squirrel numbers to hold steady, minus deaths to other factors. Early aestivators might have been lost to the final post-treatment assays of squirrel activity as might squirrels not seen due to the growth of mustard plants. If there were plague bacteria in the flea populations at Vandenberg AFB, the likelihood of transfer of the pathogen to base personnel might have been increased if only a rodenticide bait were used on the squirrel population infested with positive fleas. (The P.C.Q. bait seems not to have had a suppressing effect on fleas.) It appears that, in a case such as this one, managing the fleas alone would be a better approach than managing only their hosts; but managing both likely would be optimal, as long as the fleas died first.

Ground squirrel carcasses were not analyzed for pesticide residues in this study. It would have been useful for assessing the potential effects of the baits on fleas if the carcasses had been analyzed for Imidacloprid and [redacted] (As the latter compound is not declared on the label for the P.C.Q. bait, Borchert would not have suspected its presence – if its concentration in that bait is too low to smell.) Analyzing the baits for Diphacinone residues in the two baits would have helped with characterizing their potential primary and secondary hazards to nontarget species.

Borchert (2006c) reports that searches for carcasses of target and non-target species were conducted on 11 occasions following the first bait application and informally on other visits to the test sites. The first formal carcass search was conducted on 6/15/05 and the last on 7/5/05. These searches occasionally yielded ground squirrel carcasses as well as evidence of live animals including: moribund ground squirrels, turkey vultures (*Cathartes aura*) feeding upon dead ground squirrels, and "'larger than normal' burrow openings" which suggested to study personnel that "a non-target animal had attempted to excavate the burrow". Some of the dead ground squirrels were juveniles. Some of those were found, upon necropsy, to have ingested bait whereas other "appeared to have died of starvation" (perhaps because of the death of the mother before significant independent feeding began). During burrow-swabbing activities,

Inert ingredient information may be entitled to confidential treatment two species of frogs [sic], the Western toad (*Bufo boreas*) and the Pacific tree frog (*Pseudacris regilla*) were frequently observed exiting the burrows at the commencement of swabbing. [Page 21]

Exposing such amphibians to above-ground conditions in the Santa Barbara County summer time might not have been very healthy for them

Observations for overt affects of treatments on vertebrate animals yielded no carcasses of nontarget species but did show evidence of feeding on dead squirrels by vultures and apparently interest in squirrels by at least one other carnivore/scavenger (likely a mammal). Such findings are consistent with potential risks to nontarget species and, therefore, are inconsistent with Kim Davis's pronouncement to the effect that there are no nontarget risks associated with 72500-RR. Diphacinone has shown itself to be capable of causing primary and secondary poisoning of nontarget species. Halving the concentration from that of a typical Diphacinone rodent bait (and quartering the concentration claimed for the P.C.Q. bait) might reduce the likelihood of fatal exposures somewhat. However, low levels of Diphacinone exposure over consecutive days – such as might occur with nontarget species discovering new and abundant food sources in the form of applied bait and/or dead and moribund squirrels – has been shown to be capable of causing death at daily exposure levels that are a fraction of the single-dose acute oral LD_{50} level (e.g., Ashton, *et al*, 1987).

Unlike the Borchert (2006a) prairie dog trial discussed above, the Borchert (2006c) trial seems to have been conducted well and to have shown considerable target-species efficacy. Unlike the Borchert (2006b) simulated field trial with rock squirrels, the Borchert (2006c) strongly suggests that the 0.0025% Diphacinone concentration, paired with Imidacloprid at 0.025%, is effective against California ground squirrels. Perhaps, the 0.0025% concentration does not provide sufficient Diphacinone per amount of bait consumed to kill rock squirrels efficiently. It also is possible that the presence of Imidacloprid in the bait is more of a turn-off to rock squirrels than to California ground squirrels, or that the insecticide is more of a potentiator of the rodenticide with the latter species. Borchert's (2006b) theory regarding Vitamin K in the original challenge diet used in the rock squirrel trial might have some merit. If so, California ground squirrels in habitats other than the grounds surrounding human-use areas of Vandenberg AFB might be less susceptible to the 72500-RR bait than were the squirrels in Borchert's (2006c) trial.

Borchert, J.N. (2004) Epizoology and response to the bioweapon use of the plague organism, *Yersinia pestis*, in commensal rodents. Proceedings: 21st Vertebrate Pest Conference, Timm, R.M. and Gorenzel, W.P. (eds.), University of California, Davis, CA, 209-216.

In this paper, Borchert (2004) summarizes the history of plague as a disease of humans and as a weapon of war and terror. The first offensive use of plague reportedly involved the catapulting of carcasses of human plague victims by Muslims at Christians across battle lines in Crimea during the 14th century, AD. The Japanese reportedly used plague as an offensive weapon during World War II, with mixed results. If plague were released as a weapon of war or terror, Borchert (2004) writes that humans likely would be affected directly and that collateral infections of rodent populations could lead to a "'secondary epidemic' in humans". Such an outcome reportedly occurred in China following an aerial area drop (by the Japanese) of

> a mixture of paper, rice, cotton, wheat, and other material (as well as presumably infected fleas).

In recent years, human cases of plague in the U.S. have been associated with populations of native rodents. Among the enzootic rodent hosts associated with the "maintenance" of plague in the U.S. are the deer mouse (*Peromyscus maniculatus*) and microtine voles, notably the California vole (*Microtus californicus*). Enzootic hosts typically are not very susceptible to the plague bacterium (*Yersinia pestis*) but permit that organism to be transferred to other species with fleas acting as the vector. According to Borchert (2004),

> Maintenance hosts are characterized by the following traits: 1) moderately high resistance to plague morbidity and mortality, 2) broad heterogeneity to challenge with *Y. pestis* within a population. 3) a long, multi-estrus breeding season with successive multiple litters and high reproductive potential and 4) short natural life expectancy and a high rate of replacement of individuals in a population.

Amplifying hosts are rodent species that are more directly responsible for transferring plague to humans. Unlike enzootic hosts, the amplifying species typically succumb to the disease themselves, which leaves their fleas in need of new hosts. Borchert (2004) writes that

> Amplifying hosts are characterized by the following traits: 1) low to moderate resistance to plague morbidity and mortality, 2) relatively little population heterogeneity in response to challenge with *Y. pestis*, and 3) capability of supporting vector populations under appropriate external environmental conditions.

In the old world, commensal rats, *Rattus* spp., have been primary amplifying hosts for plague and probably were responsible, along with their fleas, for bringing the disease to the Americas. The last plague outbreak in humans that was associated with commensal rats (*Rattus* spp.) in the U.S. occurred in Los Angeles, CA, in the 1920's.

According to Borchert (2004),

> In the U.S., the most common wild rodents associated with plague epizootics are ground squirrels of the genus *Spermophilus*, prairie dogs of the genus *Cynomys*, chipmunks of the genus *Tamias*, and woodrats of the genus *Neotoma*.

72500-RR is proposed to target rodents of 2 of those Genera. The 3 organisms for which efficacy data were submitted: *Spermophilus beecheyi*, *S. variegatus*, and *Cynomys ludovicianus* are among the native species most commonly associated with cases of plague in humans over the past 50 years or so.

The types of fleas that are most efficient in transferring plague from one animal to another are those which are subject to blocking of the proventriculus in response to the presence of *Y. pestis*. That effect prevents blood meals from entering the stomach of the flea, causing it to attempt to feed repeatedly. When they do, the contents of the esophagus, including *Y. pestis*, are ejected, infecting the next host organism. If the flea is of a species that is not very host-specific, it can transfer plague to a new species of mammal. A flea, *Xenopsylla cheopis*, common on commensal rats is not very specific to them and, therefore, serves as an efficient vector of plague from rats to other species. In contrast, the fleas common to the house mouse, *Mus musculus*, reportedly are not "efficient flea vectors".

Borchert (2004) notes that the World Health Organization (WHO) has developed a flea index which is based upon the average number of fleas per rodent in a population. If that index is 1.0 or more, the WHO considers the threshold for supporting a plague epizootic to have been exceeded. That index might apply only to circumstances related to *Rattus* spp. and *X. cheopis*. However, it is worth observing that California ground squirrels are amplifying hosts for plague and that fleas/burrow indices (rather than fleas/rodent) for them

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were well above 1.0 on plots treated with the P.C.Q. bait in the Borchert (2006c) study and that any removal of rodents without prior or simultaneous flea control likely will increase the fleas/rodent index as well as the numbers of rodent-less fleas seeking new hosts. Borchert (2004) cites a case in Tanzania in which rodent control without prior flea control lead to an epidemic of plague in humans.

Summarizing data from other sources, Borchert (2004) reports that *X. cheopis* flea indices above 1.0 were commonly found in the U.S. in the 1920's and 1930's, when much of the monitoring was related to concerns about murine typhus. Less monitoring has occurred recently, but *X. cheopis* indices well above 1.0 reportedly were obtained in San Bernardino, CA, in 1971 and in Los Angeles in 1984-1985. That few have been looking at flea indices lately would make it difficult to rule out (or in) rodent involvement quickly were an outbreak of plague to occur in most parts of the U.S. Lack of such information also would make outbreaks of flea-vectored diseases in general less likely to be detected efficiently.

201.3 Letters of Support

In his letter of 8/14/06 to OPP, Richard Davis of the CDH expresses support for the proposed registration of new products being proposed by Scimetrics which combine a rodenticide active ingredient with an insecticide intended to kill rodent fleas systemically while also killing the rodent. Richard Davis does not mention the products or their active ingredients by name, but it seems clear enough that he is talking about 72500-RR and the commensal rodent/vole bait pending a registration decision under file symbol 72500-RG. Richard Davis claims to have worked "with Scimetrics/Genesis personnel last year during the trials with these products". It is clear from the report by Borchert (2006c), that Richard Davis was involved with that project.

Basically, Richard Davis cites needs for combination rodenticide/insecticide products due to the reported disappearance of all but one registered product for controlling fleas in burrows in California and because of the practical advantages and efficiencies gained through killing fleas on rodents shortly before the rodents themselves are killed. Richard Davis predicts increased potential for a plague outbreak in California in 2007 due to anticipated increases in rodent populations.

In his letter of 10/20/06, Cortez of the CDPR indicates to Scimetrics that "Concurrent review is granted." That statement apparently means that the CDPR will review 72500-RR at the same time that EPA reviews it rather than waiting for the product to be Federally registered before proceeding.

201.4 Label

The efficacy-related portions of the label proposed for 72500-RR are not very well thought out, written, or organized. Problems arise with the proposed front-panel claims of effectiveness and with virtually all of the use directions. Due to an organizational error, the "**DIRECTIONS FOR USE**" section seems to include only the statement of general misuse ("It is a violation of ... labeling"), and the "Read **this Label:**" and "**IMPORTANT:**" subsections. Those paragraphs are followed by seemingly independent sections entitled "**USE RESTRICTIONS:**", "**SELECTION OF TREATMENT AREAS:**", and "**APPLICATION DIRECTIONS**".

The proposed "**USE RESTRICTIONS:**" paragraph does not present limits on the sites where it would be legal to use the product and only slightly limits the target species claims. Under "**IMPORTANT:**", the proposed label states that this product is only to be applied in "areas where ground squirrel, prairie dog and/or rabbit infestations have occurred." Because there are no tolerances for Diphacinone on any food or feed crops or commodities, use of this type of product on rangelands and pastures would have to be prohibited unless legal uses were limited to applications that are considered to be "non-food" uses, or unless a suitable post-treatment grazing prohibition were imposed. (With no relevant environmental chemistry data before me, I would have to set one year as the default interval.)

For field rodenticide baits, "non-food" use status has been conferred if rangeland applications are made in appropriately designed (tamper-resistant, or at least spill-resistant) bait stations, if applications are made at least 6 inches down burrow entrances (if not completely underground), or if applications are made on bare ground around burrows (where, presumably, there is nothing growing that might capture bait particles or incorporate the rodenticide systemically). Of these application categories, only scattering bait near burrow openings is proposed for 72500-RR.

Tolerance issues pertaining to Imidacloprid also must be considered (40 CFR §180.472). There are tolerances for that insecticide in certain forage crops and in various meats and meat byproducts but not specifically for rangelands and pastures.

The "**SELECTION OF TREATMENT AREAS:**" paragraph consists only of the sentence quoted below.

> The presence of ground squirrels or prairie dogs may be indicated by a network of surface conical mounds of earth pushed up from deep burrows.

The term "conical mounds" is use on labels for mole-control agents to draw a distinction between mole hills and fan-shaped pocket gopher mounds, which also are likely to form a network. Because moles and pocket gophers are seldom seen above ground, it is necessary to assess evidence of their excavations to determine whether either is present and, if so, which type. Ground squirrels and prairie dogs, on the other hand, are large, diurnal rodents the presence of which can be determined by observing live animals during active seasons. When the animals are in hibernation (ground squirrels and some types of prairie dogs) or aestivation (ground squirrels), there would be no point to baiting them.

The proposed "**APPLICATION DIRECTIONS**" call for manually scattering "approximately 2 oz. of bait near the burrows" to control "ground squirrels, prairie dogs, and rabbits". The label specifically commands, "Do not pile the bait." Such directions would be appropriate, more or less, for most types of ground squirrels and for prairie dogs, but not for "rabbits of the genus *Sylvilagus* and *Lepus*" [sic]. *Sylvilagus* spp. rabbits make shallow excavations but do not dig burrows as such – although they may use other species' burrows, if available.[19] Lagomorpha of the Genus *Lepus* are hares rather than true rabbits. North American hares that may achieve pest status in the "lower 48" of the U.S. include black-tailed jackrabbit (*L. californicus*), the white-tailed jackrabbit (*L. townsendi*) and the snowshoe hare (*L. americanus*). Those species are not much for burrowing, either. Baiting strategies commonly employed for controlling jackrabbits include use of bait stations and placing bait in piles. As these animals are relatively large and can achieve high densities locally, the amounts of bait needed to be placed at one locus to control them will be relatively great (e.g., 1-5 lbs, Knight, 1994).

The front panel of the label bears the claims "**Rodent, Rabbit and Flea Control Bait**" and

> Kills the Fleas of Wild Rodents and Rabbits while Simultaneously Killing the Rodent or Rabbit Host.

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[19] The European rabbit (*Oryctolagus cuniculus*) burrows extensively and is known for creating colonial "warrens". Domesticated rabbits sold in pet stores in the U.S. are of this species and will burrow (and escape from peoples' fenced backyards) if given the opportunity to do so.

Scimetrics has submitted no efficacy data regarding the effectiveness of this product against any species of lagomorph. The list of studies include in Kim Davis's letter of 10/20/06 does not include citations for any efficacy reports other than the Borchert (2006a,b,c) papers. Therefore, it appears that nothing on fleas has been submitted for the 72500-RR product other than the Borchert (2006c) product. Given that the degree of self-administration of bait by rodents may have been greater in that study than in the other two, where control levels were lower, it would be something of a leap to extrapolate from the results of Borchert (2006c) to claims for controlling ectoparasites on other Sciuromorpha, much less to rodents in general or to non-rodents such as rabbits and hares. The ectoparasites associated with spreading tularemia from rabbits to humans are ticks rather than fleas (Robinson and Bolen).

In light of the data that have been submitted for 72500-RR to this point, the broad front-panel claims should not be accepted as proposed. Use of the word "Simultaneously" in the second of those claims presents the additional problem of not being exactly true, or desirable. What seems to be true, and desirable, is that the systemic Imidacloprid kills the fleas (on California ground squirrels, at least) while the rodent is still alive and behaving relatively normally. From accounts cited by Borchert (2004), systemic Imidacloprid might be more efficient at killing fleas that bite rodents not infected with *Y. pestis* as the fleas in that case would not be suffering from proventricular blockage.

Each of the problems with the proposed label could be belabored further here, but that would accomplish relatively little. It seems likely that the proposed label was drafted by someone who was working off of other Scimetrics labels and who has relatively little knowledge of the relevant biological issues. Therefore, I have decided to indicate, under "CONCLUSIONS", the claims and directions that could be accepted at this point, given the data submitted on the applicant's behalf, the constraints of FIFRA, and historical policies. The use directions may have to be modified additionally to accommodate concerns raised by other Divisions within OPP.

This product is a claimed to control various types of small- and medium-sized mammals with surface applications of a rodenticide bait and to kill fleas that parasitize such mammals. Products registered for use to control rodents in similar situations (imagining use sites for 72500-RR as they are not proposed) are classified as "Restricted Use Pesticides" or are headed that way at the time of reregistration. This product also should be a restricted use pesticide. One reason for such classification would be "Hazard to Nontarget Organisms". Going to 0.0025% Diphacinone rather than twice or 4X that concentration would not render the product free of hazard. The proposed label direction to prevent exposure of the bait to nontarget animals cannot reasonably be expected to be met for a product that users are to apply, unprotected, to the ground surface.

202.0 CONCLUSIONS

1. Accounts in the reports for the Borchert (2006a, MRID No. 469665-10) and Borchert (2006b, 469665-11) reports indicate that the testing facility rather than the applicant prepared a bait consistent with the proposed formulation for 72500-RR, as described by the Confidential Statement of Formula (CSF) dated "**October 20, 2006**", and that such bait was used in those efficacy trials. The bait used in the Borchert (2006c, MRID No. 469665-12) efficacy trial involving California ground squirrels reportedly was prepared by the applicant but does not seem to be identified according to a batch number from the company. The specific composition of each bait batch used in the efficacy studies submitted for this product must be documented.

2. The report of the field efficacy trial with black-tailed prairie dogs by Borchert (2006a, MRID No. 469665-10) suggests that some control of black-tailed prairie dogs might have resulted from multiple above-ground spot applications of a 0.0025%

Diphacinone oat bait. However, any inferences drawn from that study must be tempered due to the concurrent use of Aluminum Phosphide to treat a larger total acreage than was treated with the test bait. Aluminum Phosphide may have been applied as close as 30 feet to baited land where estimates of prairie dog activity were taken. Due to that confounding factor, the Borchert (2006a) trial is not accepted. Additional evidence that this product is effective against black-tailed prairie dogs must be submitted or cited it that claim is to be accepted for this product.

3. In the simulated field efficacy trial by Borchert (2006b, MRID No. 469665-11), it took more than 3 weeks of exposure to the toxic bait plus a switch in challenge diet for slightly more than 70% (13 of 18) of captive wild-caught rock squirrels to die. Nine of the 14 females (64%) died, as did all 4 males. The 72% composite mortality score was obtained during (at least) a 29-day period of exposure to bait, during which test conditions were manipulated halfway through for the purpose of obtaining additional mortalities. That all 5 survivors and the last 6 squirrels killed in this study were females suggests that this product would not be very effective at managing rock squirrel populations.

   Borchert (2006b) suggests that the survival of squirrels in this trial was enhanced by the reported presence of Vitamin K in the challenge diet used initially. Additional mortalities did occur after the challenge diet was altered. However, an anticoagulant bait should be formulated strong enough that it can compete with and overcome the effects ot natural sources of Vitamin K.

   Claims for controlling rock squirrels with the formulation proposed for 72500-RR are not supported at this time. It is possible that a higher concentration (e.g., 0.005%) of Diphacinone in the bait would work better against rock squirrels. If the presence of Imidacloprid in the bait causes rock squirrels to reject the bait initially or to form a conditioned aversion to it, a new insecticide component or a lower concentration of Imidacloprid might be needed to control rock squirrels effectively.

4. The Borchert (2006c, MRID No. 469665-12) field trial assessed the efficacy of a 0.0025% Diphacinone, 0.025% Imidacloprid bait on California ground squirrels and fleas associated with them. The study was reasonably well conducted and showed positive effects against California ground squirrels and their fleas. The level of control of California ground squirrels reported in this study greatly exceeded the minimum criterion for field tests of rodenticide baits. The trial also showed that a registered "special local needs" 0.01% Diphacinone bait was highly effective against California ground squirrels under the conditions of testing but left many fleas alive "off rodent" and likely in search of new hosts. This study is acceptable.

   As noted above, the specific composition of the test material used in this trial must be documented before the efficacy study can be applied to 72500-RR.

5. At the top of the front panel of the proposed label, insert a box containing the text shown below.

RESTRICTED USE PESTICIDE
Due to Hazards to Nontarget Organisms

For retail sale and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

The words "**RESTRICTED USE PESTICIDE**" must be in the same 18-point type if the area of the front panel of the printed label exceeds 30 square inches. If the label is

15-30 square inches, the minimum type size required for "**RESTRICTED USE PESTICIDE**" is 14-point. These minimum type sizes correspond to those set for the signal word on label panels of the same area range. See 40 CFR §156.10(j)(2)(i)(A) and §156.60(b)(1).

6. On the front panel of the proposed label, change the proposed claim "**Rodent, Rabbit and Flea Control Bait**" to "**A Bait for Controlling California Ground Squirrels**". This product is not a "**Flea Control Bait**". It does not attract fleas, and fleas do not consume it. The only efficacy directly established for it to this point pertains to California ground squirrels at a single site. Control of fleas associated with California ground squirrels at that site was not demonstrated directly but is reasonably inferred from differences in certain post-treatment flea indices for burrows on the plots where the Kaput® B bait was used as compared to burrows on plots that were baited with a rodenticide lacking Imidacloprid or were not baited at all.

7. On the front panel of the proposed label, change the proposed claim

    Kills the Fleas of Wild Rodents and Rabbits while Simultaneously Killing the Rodent or Rabbit Host

    to

    Kills California ground squirrels with a rodenticide and also contains an insecticide to kill fleas on California ground squirrels that consume the bait.

    If modified as indicated above, the claim would be consistent with the results of the only efficacy study accepted for this product. Until more and better data are provided for other species, the claims made should be limited to what has been shown.

    Simultaneous control of fleas and rodents has not been demonstrated. The combination of slow-acting rodenticide with an insecticide gives this product a chance to kill fleas systemically before the rodent dies. As discussed by Borchert (2004), such a result is desirable.

8. The proposed "**DIRECTIONS FOR USE**" section and the other text that belongs within it are poorly organized and generally deficient. The text fails to set appropriate limits on permissible use sites or target species. As the only target species claims supported at this time are those for California ground squirrels and their fleas, all other claims must be dropped. Based upon limited information submitted for rock squirrels and the unlikelihood that this or any other grain bait would be very effective against Belding's ground squirrels, a general claim for controlling the Genus *Spermophilus* is neither warranted nor supported. Claims for controlling all Cynomys spp. prairie dogs will not be accepted at any time because the Utah prairie dog, *C. parvidens,* is a listed species.

    Some of the proposed claims are for control of Lagomorpha that do little burrowing, if any. For that reason and others, the proposed application directions are not appropriate for controlling *Sylvilagus* spp. rabbits or *Lepus* spp. hares. Claims for control of such lagomorphs are not accepted at this time. Research into effective methods of controlling lagomorphs with this product is needed. Due to the ectoparasite claims associated with this product, there is a public health aspect to all proposed uses for 72500-RR.

    The expression "conical mounds" appears on labels for certain baits registered to control moles and has little relevance to the diurnal species that the 72500-RR is proposed to control. The presence of ground squirrels, prairie dogs, rabbits, and hares typically is determined observing live individuals and evidence of damage caused by them. For ground squirrels and prairie dogs, burrowing activity also will be evident from entrance holes and the mounds associated with them.

Replace the proposed text with the wording shown below.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This label must be in the user's possession at the time of application of this product.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other domestic animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children, pets, and other animals.

2. Apply this product only as specified on this label.

3. Post treated areas with warning signs indicating that a combination rodenticide/insecticide has been applied and that the product is hazardous to dogs and other pets. Keep pets and livestock out of treated areas. Isolate treated areas using existing fencing, if present.

4. Dispose of product container, unused, spoiled and unconsumed bait as directed by this label.

USE RESTRICTIONS: This product may be used to control California ground squirrels (*Spermophilus beecheyi*) in parks, golf courses, non-crop rights-of-way and other non-crop areas. Use of this product to control California ground squirrels on rangelands and pastures is permitted only if bait applications are limited to placements on bare ground around burrow openings or if the treated area is closed to grazing for 366 days, beginning with the date of bait application. The insecticide in this product may act systemically to kill fleas that infest California ground squirrels. The types of fleas that might be controlled include, but are not necessarily limited to, *Oropsylla montana* and *Hoplopsyllus anomalus*. Apply this product only at times of year when California ground squirrels are readily accepting grains. Do not use this product in any manner other than that prescribed by this label.

Do not use this product where nontarget species are likely to be adversely affected by it or where threatened or endangered species potentially at risk from it are present. Do not apply bait over roads, walkways, or water.

Do not allow young children, pets, domesticated animals, or persons not associated with the application to be in areas where the bait is being applied.

Wear gloves when applying bait. With detergent and hot water, wash all utensils used for applying bait. Do not use these utensils for mixing, holding, or transferring foods or feeds.

BAITING: Manually scatter ½ cup of bait (approximately 2½ ounces or 70 grams) on ground near each burrow opening being used by California ground squirrels. Bait spoons, measuring cups, or other suitable implements may be used to measure and distribute bait. The area around each burrow over which bait is distributed may be no larger than 50 square feet (e.g., a circular area no more than 8 feet in diameter). Re-apply bait to the same area at intervals of 2 to 3 days for a total of 3 to 4 applications, if ground squirrels remain active and continue to consume bait. A continuous supply of bait is needed for 6 to 12 days to ensure that all squirrels present have opportunity to feed on bait for on least 5 consecutive days. Do not exceed the maximum application rate of ½ cup of bait per burrow for 4 applications.

SURVEILLANCE AND FOLLOW-UP: Dead ground squirrels should begin to appear in or near treated areas within 4 to 5 days after the first bait application. Visit the application site to monitor the effects of treatment 4 days after the first application and at subsequent intervals of 1 to 2 days. Collect and properly dispose of visible carcasses of ground squirrels and other species found in or near treated areas. Dead animals buried on site must be buried a minimum of 18 inches below the ground surface, preferably deeper. Continue to collect and dispose of dead ground squirrels and search for non-target animals for at least two weeks after the last bait application, or longer if carcasses still are being found at that time. Carcass collection and burial should be performed in the late afternoon, near sundown, to reduce the potential for nocturnal scavengers or predators to find carcasses on the ground surface. Wear water-proof gloves and use leak-proof plastic bags or other suitable containers for transporting carcasses not buried on site.

William W. Jacobs
Insecticide-Rodenticide Branch
August 7, 2007

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Table 1. Amounts of 0.0025% Diphacinone bait (in kg) applied to control black-tailed prairie dogs at North and South treated plots and associated buffer zones during 4 rounds of treatment in Borchert (2006a) study (MRID# 469665-10).

TREATMENT DATE	NORTH TREATED PLOT AND BUFFER	SOUTH TREATED PLOT AND BUFFER*	TOTALS FOR BOTH AREAS
3/15/05	6.218	8.022	14.240
3/18/05	1.586	1.440	3.026
3/21/05	6.360	6.184	12.544
3/31/05	7.198	3.740	10.938
ALL	21.362	19.386	40.748

* Treatment on 3/31/05 was limited to "North and west side buffer/ north ½ of south treatment".

Table 2. Pretreatment, midtreatment, and posttreatment visual counts data for baited and check plots associated with use of 0.0025% Diphacinone bait applied to control black-tailed prairie dogs in Borchert (2006a) study (MRID# 469665-10).

PLOT	DATE	TIME OF DAY	FIRST SCAN	SECOND SCAN	THIRD SCAN	SELECTED NUMBER	SCANNER	PERCENT Raw	CHANGE Adjusted
PRETREATMENT CENSUS									
North Check	3/2/2005	12:45-1:07 PM	13	11	7		Borchert		
	3/3/2005	2:45-3:15 PM	12	13	16	16	Linder		
	3/4/2005	1:10 AM - 1:40 PM	9	8	9		Borchert		
North Baited	3/2/2005	12:05-12:35 PM	21	21	23	23	Linder		
	3/3/2005	11:40 AM -12:10 PM	17	22	20		Linder		
	3/4/2005	11:45 AM - 12:15 PM	14	18	18		Linder		
South Check	3/2/2005	12:05-12:25 PM	8	11	9		Borchert		
	3/3/2005	1:50-2:20 PM	16	16	14	16	Linder		
	3/4/2005	11:55 AM - 12:25 PM	13	13	10		Borchert		
South Baited	3/2/2005	1:00-1:30 PM	19	21	22		Linder		
	3/3/2005	12:35-1:05 PM	16	22	18		Linder		
	3/4/2005	12:45-1:15 PM	18	20	22	22	Linder		
MIDTREATMENT CENSUS									
North Baited	3/31/2005	1:05-1:30 PM	7	7	9	9	Borchert	-61%	
South Baited	3/31/2005	1:50-2:20 PM	1	2	1	2	Borchert	-91%	
POSTTREATMENT CENSUS									
North Check	4/12/2005	10:50-11:20 AM	2	2	4		Borchert		
	4/13/2005	10:35-11:05 AM	4	6	9	9	Borchert	-44%	
	4/14/2005	11:10-11:40 AM	5	5	7		Borchert		
North Baited	4/12/2005	9:55-10:25 AM	1	1	1	1	Mach	-96%	-92%
	4/13/2005	11:45 AM-12:15 PM	0	1	1		Bruening		
	4/14/2005	11:15-11:45	1	1	1		Bruening		
South Check	4/12/2005	9:55-10:25 AM	5	6	9		Borchert		
	4/13/2005	12:05-12:35 PM	10	9	12	12	Borchert	-25%	
	4/14/2005	12:25-12:55 PM	11	8	8		Borchert		
South Baited	3/2/2005	10:45-11:15 AM	0	0	0		Mach		
	4/13/2005	1:10-1:40 PM	0	0	0		Borchert		
	3/4/2005	12:15-12:45	0	0	0	0	Bruening	-100%	-100%

Table 3. Areas of monitored plots and associated buffer zones in field efficacy trial of Kaput® Field Rodent Bait B at Vandenberg AFB, Santa Barbara County, CA, for controlling California ground squirrels (Borchert, 2006c, MRID# 469665-12).

PLOT DESCRIPTION	BAIT USED	PLOT AREA (acres)	BUFFER AREA (acres)	TOTAL AREA (acres)
East Treatment	Kaput®	1.38	3.95	5.33
West Treatment	Kaput®	1.11	2.71	3.82
TOTAL	Kaput®	2.49	6.66	9.15
North Positive Control	P.C.Q.	2.49	10.99	13.48
South Positive Control	P.C.Q.	3.21	5.98	9.19
TOTAL	P.C.Q.	5.70	16.97	22.67
Negative Control #1	None	1.75	na	1.75
Negative Control #2	None	1.39	na	1.39
TOTAL	None	3.14	na	3.14

Note: Acreages for plots and buffer areas were calculated from information on pages 119-120 of Borchert (2006c) report.

Table 4. Treatments of monitored plots and associated buffer zones in field efficacy trial of Kapul® Field Rodent Bait at Vandenberg AFB, Santa Barbara County, CA, for controlling California ground squirrels (Borchert, 2006c, MRID# 469665-12).

PLOT DESCRIPTION	BAIT USED	TREATMENT DATE	PLOT AREA (acres)	AMOUNT OF BAIT APPLIED (lbs)	TREATMENT RATE - PLOTS (lbs/acre)	BUFFER AREA (acres)	AMOUNT OF BAIT APPLIED (lbs)	TREATMENT RATE - BUFFERS (lbs/acre)	TOTAL AREA TREATED (acres)	AMOUNT OF BAIT APPLIED (lbs)	TREATMENT RATE - TOTAL (lbs/acre)
East Treatment	Kapul®	6/13/05	1.38	7.92	5.74	3.95			5.33		
		6/16/05	1.38	9.90	7.17						
		6/19/05	1.38	9.90	7.17						
		6/22/05	1.38	7.92	5.74						
Plot Totals		All	1.38	35.64	25.83						
West Treatment	Kapul®	6/13/05	1.11	11.88	10.70	2.71			3.82		
		6/16/05	1.11	15.40	13.87						
		6/19/05	1.11	12.32	11.10						
		6/22/05	1.11	9.68	8.72						
Plot Totals		All	1.11	49.28	44.40						
All Kapul	Kapul®	6/13/05	2.49	19.80	7.95	6.66	51.04	7.66	9.15	70.84	7.74
		6/16/05	2.49	25.30	10.16	6.66	78.10	11.73	9.15	103.40	11.30
		6/19/05	2.49	22.22	8.92	6.66	22.88	3.44	9.15	45.10	4.93
		6/22/05	2.49	17.60	7.07	6.66	46.64	7.00	9.15	64.24	7.02
TOTAL	Kapul®	All	2.49	84.92	34.10	6.66	198.66	29.83	9.15	283.58	30.99
North Positive Control	P.C.Q.	6/13/05	2.49	13.42	5.39	10.99			13.48		
		6/16/05	2.49	15.62	6.27						
		6/19/05	2.49	12.10	4.86						
		6/22/05	2.49	8.14	3.27						
Plot Totals		All	2.49	49.28	19.79						
South Positive Control	P.C.Q.	6/13/05	3.21	13.42	4.18	5.98			9.19		
		6/16/05	3.21	18.06	5.00						
		6/19/05	3.21	13.64	4.25						
		6/22/05	3.21	11.00	3.43						
Plot Totals		All	3.21	54.12	16.86						
All P.C.Q.		6/13/05	5.70	26.84	4.71	16.97	71.28	4.20	22.67	98.12	4.33
		6/16/05	5.70	31.68	5.56	16.97	81.84	4.82	22.67	113.52	5.01
		6/19/05	5.70	25.74	4.52	16.97	54.34	3.20	22.67	80.08	3.53
		6/22/05	5.70	19.14	3.36	16.97	70.62	4.16	22.67	89.76	3.96
TOTAL	P.C.Q.	All	5.70	103.40	18.14	16.97	278.08	16.39	22.67	381.48	16.83

Note: Acreages for plots and buffer areas were calculated from information on pages 119-120 of Borchert (2006c) report.

Table 5. Pretreatment, midtreatment, and posttreatment visual counts data /or baited and check plots associated with use of 0.0025% Diphacinone/0.025% Imidacloprid bait applied to control black-tailed prairie dogs in Borchert (2006c) study (MRID# 469665-10).

PLOT	DATE	TIME OF DAY	FIRST SCAN	SECOND SCAN	THIRD SCAN	SELECTED NUMBER	SCANNER	PERCENT Raw	CHANGE Adjusted
PRETREATMENT CENSUS									
Treatment West - Kaput®	6/3/2005	9:15-9:45 AM	7	13	12		Borchert		
	6/4/2005	8:35-9:05 AM	19	10	15	19	Borchert		
	6/5/2005	8:50-9:05 AM	7	8	5		Zelazak		
Treatment East - Kaput®	6/3/2005	10:10-10:40 AM	7	11	12		Borchert		
	6/4/2005	9:25-9:55 AM	6	3	3		Borchert		
	6/5/2005	10:35-11:05 AM	10	12	9	12	Borchert		
	6/6/2005	8:41-9:11 AM	14	12	10		Linder		
North Positive Control - P.C.Q.	6/3/2005	12:10-12:40 PM	18	22	15	22	Linder		
	6/4/2005	12:32-1:02 PM	16	16	17		Linder		
	6/5/2005	11:34-12:04 PM	12	10	21		Linder		
South Positive Control - P.C.Q.	6/3/2005	12:10-12:40 PM	15	12	12		Borchert		
	6/4/2005	11:32 AM -12:02 PM	25	23	23		Linder		
	6/5/2005	11:35 AM-12:05 PM	26	22	14	26	Borchert		
Negative Control #1 - West	6/3/2005	11:00-11:30 AM	21	27	31		Borchert		
	6/4/2005	11:10-11:40 AM	6	10	17		Borchert		
	6/5/2005	9:45-10:15 AM	27	31	24	31	Borchert		
Negative Control #2 - West	6/4/2005	2:00-2:30 PM	32	34	34	34	Borchert		
	6/5/2005	9:45-10:15 AM	33	27	31		Zelazak		
	6/6/2005	8:37-9:07 AM	31	29	30		Borchert		
MIDTREATMENT CENSUS									
Treatment West - Kaput®	6/29/2005	11:42 AM-12:12 PM	0	0	0		Zelazak		
	6/30/2005	11:15-11:45 AM	0	0	0	0	Zelazak	-100%	
Treatment East - Kaput®	6/29/2005	10:55-11:25 AM	0	0	0	0	Zelazak	-100%	
	6/30/2005	10:25-10:55 AM	0	0	0		Zelazak		
North Positive Control - P.C.Q.	6/29/2005	12:30-1:00 PM	0	0	0	0	Zelazak	-100%	
	6/30/2005	12:03-12:33 PM	0	0	0		Borchert		
South Positive Control - P.C.Q.	6/29/2005	10:05-10:35 AM	0	1	1	1	Borchert	-96%	
	6/30/2005	9:37-10:07 AM	0	0	0		Borchert		
POSTTREATMENT CENSUS									
Treatment West - Kaput®	7/9/2005	9:50-10:20 AM	0	0	0		Borchert		
	7/10/2005	10:50-11:20 AM	0	0	0		Borchert		
	7/11/2005	10:47-11:17 AM	0	1	0	1	Borchert	-95%	-91%
Treatment East - Kaput®	7/9/2005	10:40-11:10 AM	0	0	0		Borchert		
	7/10/2005	10:55-11:25 AM	0	0	1		Borchert		
	7/11/2005	10:45-11:15 AM	0	1	0	1	Borchert	-92%	-86%
North Positive Control - P.C.Q.	7/9/2005	2:10-2:40 PM	0	0	0	0	Borchert	-100%	-100%
	7/10/2005	11:50 AM- 12:20 PM	0	0	0		Borchert		
	7/11/2005	9:50-10:20 AM	0	0	0		Borchert		
South Positive Control - P.C.Q.	7/9/2005	2:12-2:42 PM	0	0	0		Borchert		
	7/10/2005	9:55-10:25 AM	0	0	0	0	Borchert	-100%	-100%
	7/11/2005	11:40 AM-12:20 PM	0	0	0		Borchert		
Negative Control #1 - West	7/9/2005	11:30 AM-12:00 PM	13	14	16	21	Borchert	-32%	
	7/10/2005	1:03-1:33 PM	15	17	17		Zelazak		
	7/11/2005	12:45-1:15 PM	21	18	20		Borchert		
Negative Control #2 - West	7/9/2005	12:20-12:50 PM	3	7	12		Borchert		
	7/10/2005	1:00-1:30 PM	B	9	12		Borchert		
	7/11/2005	1:35-2:05 PM	13	15	17	17	Borchert	-50%	

Table 6. Pretreatment and posttreatment data from the closed-burrows method for baited and check plots associated with use of 0.0025% Diphacinone/0.025% Imidacloprid bait applied to control black-tailed prairie dogs in Borchert (2006c) study (MRID# 469665-10).

PLOT	DATES (closed-checked)	TIMES OF DAY (closed-checked)	NUMBER CLOSED	NUMBER ACTIVE	PERCENT ACTIVE	CHECKER	CHANGE IN NO. OF BURROWS ACTIVE		CHANGE IN PERCENT OF BURROWS ACTIVE	
							Raw	Adjusted	Raw	Adjusted
PRETREATMENT CENSUS										
Treatment West - Kaput®	6/6-8/2005	11:00 AM-9:25 AM	170	55	32%	Borchert				
Treatment East - Kaput®	6/6-8/2005	10:30 AM-8:30 AM	135	35	26%	Borchert				
North Positive Control - P.C.Q.	6/6-8/2005	2:30 PM-2:10 PM	185	63	34%	Borchert				
South Positive Control - P.C.Q.	6/6-8/2005	4:00 PM-2:30 PM	176	66	38%	Borchert				
Negative Control #1 - West	6/6-8/2005	12:00 PM-10:30 AM	281	93	33%	Borchert				
Negative Control #2 - West	6/6-8/2005	1:00 PM-12:00 PM	307	57	19%	Borchert				
POSTTREATMENT CENSUS										
Treatment West - Kaput®	6/6-8/2005	2:00 PM-3:00 PM	114	5	4%	Borchert/Zelazak	-91%	-89%	-86%	NA
Treatment East - Kaput®	7/7-9/2005	12:55 PM-3:05 PM	67	7	10%	Borchert/Zelazak	-80%	-75%	-60%	NA
North Positive Control - P.C.Q.	7/7-9/2005	11:00 AM-9:10 AM	103	2	2%	Zelazak	-97%	-96%	-94%	NA
South Positive Control - P.C.Q.	7/7-9/2005	11:50 AM-1:50 PM	113	4	4%	Borchert/Zelazak	-94%	-92%	-91%	NA
Negative Control #1 - West	7/7-9/2005	9:15 AM-8:10 AM	155	68	44%	Borchert/Zelazak	-27%		33%	
Negative Control #2 - West	7/7-9/2005	10:05 AM-8:45 AM	156	50	32%	Borchert/Zelazak	-12%		73%	

Table 7. Data on fleas observed through burrow-swabbing in field trial of Kaput® B bait (0.025% Imidacloprid/0.0025% Diphacinone) in Borchert (2006c) California ground squirrel field efficacy trial (MRID# 469865-12).

CENSUS PERIOD	WEST KAPUT® PLOT	EAST KAPUT® PLOT	NORTH P.C.Q. PLOT	SOUTH P.C.Q. PLOT	CHECK PLOT #1	CHECK PLOT #2
PRETREATMENT (3-4 days: 6/9-10/05)						
Number of Burrows Swabbed	20	20	20	20	20	20
Number of Burrows Positive for Fleas	4	3	5	3	4	2
Percent of Burrows Positive for Fleas	20%	15%	25%	15%	20%	10%
Number of Fleas Observed	4	7	5	3	6	2
Number of Fleas per Burrow	0.20	0.35	0.25	0.15	0.30	0.10
Range in Fleas per Burrow	0-1	0-5	0-1	0-1	0-2	0-1
Number of Fleas Positive for Blood Meal	1	4	3	3	3	1
Number of Fed Fleas per Burrow*	0.05	0.20	0.17	0.15	0.15	0.05
Range in Fed Fleas per Burrow	0-1	0-3	0-1	0-1	0-1	0-1
Percent of Fleas Positive for Blood Meal†	25%	57%	60%	100%	60%	50%
1ST POST-TREATMENT (7-8 days: 6/20-21/05)						
Number of Burrows Swabbed	20	20	20	20	20	20
Number of Burrows Positive for Fleas	0	2	8	9	3	3
Percent of Burrows Positive for Fleas	0%	10%	30%	45%	15%	15%
% Change from Pretreatment in Burrows + for Fleas	-100%	-33%	20%	200%	-25%	50%
Number of Fleas Observed	0	4	20	22	10	5
Number of Fleas per Burrow	0.00	0.20	1.00	1.10	0.50	0.25
% Change from Pretreatment in Fleas per Burrow	-100%	-43%	300%	633%	67%	150%
Range in Fleas per Burrow	0	0-3	0-12	0-4	0-7	0-3
Number of Fleas Positive for Blood Meal	0	0	11	11	6	2
Number of Fed Fleas per Burrow*	0.00	0.00	0.55	0.55	0.30	0.11
% Change from Pretreatment in # Fed Fleas per Burrow	-100%	-100%	230%	267%	100%	111%
Range in Fed Fleas per Burrow	0	0	0-7	0-2	0-1	0-2
Percent of Fleas Positive for Blood Meal†	undefined	0%	55%	50%	60%	40%
% Change from Pretreatment in % of Fleas + for Blood Meal	NA	-100%	-8%	-50%	0%	-20%
2ND POST-TREATMENT (14-15 days: 6/27-28/05)						
Number of Burrows Swabbed	20	20	20	20	20	20
Number of Burrows Positive for Fleas	1	1	9	9	11	9
Percent of Burrows Positive for Fleas	5%	5%	45%	45%	55%	45%
% Change from Pretreatment in Burrows + for Fleas	-75%	-67%	80%	200%	175%	350%
Number of Fleas Observed	1	8	37	367	65	22
Number of Fleas per Burrow	0.05	0.40	1.85	18.35	3.25	1.10
% Change from Pretreatment In Fleas per Burrow	-75%	14%	640%	12133%	983%	1000%
Range in Fleas per Burrow	0-1	0-8	0-17	0-312	0-20	0-5
Number of Fleas Positive for Blood Meal	1	7	33	263	41	16
Number of Fed Fleas per Burrow*	0.05	0.35	1.65	13.84	2.05	0.84
% Change from Pretreatment in # Fed Fleas per Burrow	0%	75%	890%	9128%	1267%	1584%
Range in Fed Fleas per Burrow	0-1	0-7	0-17	0-218	0-13	0-3
Percent of Fleas Positive for Blood Meal†	100%	88%	89%	72%	63%	73%
% Change from Pretreatment in % of Fleas + for Blood Meal	300%	53%	49%	-28%	5%	45%
3RD POST-TREATMENT (21-22 days: 7/4-5/05)						
Number of Burrows Swabbed	20	20	20	20	20	20
Number of Burrows Positive for Fleas	3	1	10	9	7	6
Percent of Burrows Positive for Fleas	15%	5%	50%	45%	35%	30%
% Change from Pretreatment in Burrows + for Fleas	-25%	-67%	100%	200%	75%	200%
Number of Fleas Observed	15	18	209	509	19	13
Number of Fleas per Burrow	0.75	0.90	10.45	25.45	0.95	0.65
% Change from Pretreatment in Fleas per Burrow	275%	157%	4080%	16867%	217%	550%
Range in Fleas per Burrow	0-10	0-18	0-137	0-211	0-9	0-4
Number of Fleas Positive for Blood Meal	10	18	182	455	13	9
Number of Fed Fleas per Burrow*	0.50	0.90	9.10	22.75	0.65	0.47
% Change from Pretreatment In # Fed Fleas per Burrow	900%	350%	5360%	15067%	333%	847%
Range in Fed Fleas per Burrow	0-1	0-18	0-133	0-201	0-4	0-3
Percent of Fleas Positive for Blood Meal†	87%	100%	87%	89%	68%	69%
% Change from Pretreatment in % of Fleas + for Blood Meal	167%	75%	45%	-11%	14%	38%

*Burrows for which observed flea was not saved for blood meal evaluation were dropped for this calculation.
Burrows were included in calculation if at least one of the fleas collected was examined for evidence of blood meal.
†Fleas lost prior to blood meal examination are excluded from denominator in this calculation.