October 22, 2009

Regulatory Public Docket
Office of Pesticide Programs (OPP)
Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

RE: Comments on new use for Kaput-D (diphacinone and imidacloprid) (EPA-HQ-OPP-2009-0625)

Dear EPA:

The Center for Biological Diversity submits the following comments regarding the recent registration application submitted by Scimetrics Ltd. Corp., which requests the addition of the black-tailed prairie dog and their host fleas for the chemical combination of the anticoagulant rodenticide, diphacinone, and the insecticide, imidacloprid. The Center is a non-profit, public interest, conservation organization dedicated to the protection of native species and their habitats through applying sound science, policy and environmental law.

This application must be rejected in light of the fact that the *target* species (black-tailed prairie dog) recently received a positive 90-day finding for listing under the ESA. In fact, the black-tailed prairie dog may soon be proposed for ESA listing[1] *because* of poisons like Kaput-D. As stated by the USFWS in December of 2008: "[T]he petition [to list the black-tailed prairie dog] presents substantial information to indicate that listing the [species] as a threatened or endangered species may be warranted due to the inadequacy of existing regulatory mechanisms, *particularly regarding poisoning . . . .*"[2] That information alone should cause EPA to reject the application; there can no valid reason to allow more poisoning of a species that is already threatened by poisoning. Moreover, the application must be rejected because it would very likely lead to the harm or death of numerous nontarget species, some of which are ESA protected.

EPA's past efforts on behalf of endangered species have been woefully inadequate. As pointed out in the black-tailed prairie dog 90-day finding:

> The U.S. Environmental Protection Agency (EPA) has not provided annual records to the Service on the amount of acreage poisoned with zinc phosphide or the amount of chemical sold, despite this reporting being included as a "Reasonable and Prudent

[1] A 12-month finding is due on November 30, 2009.

[2] *Endangered and Threatened Wildlife and Plants; 90-Day Finding on a Petition To List the Black-tailed Prairie Dog as Threatened or Endangered*, 73 Fed. Reg. 73211, 73213 (December 2, 2008) (emphasis added)

> Alternative" in a 1993 Biological Opinion (Service 1993, p. II-107). EPA did not agree to collect or provide this data in response to the Biological Opinion. On April 25, 2002, we sent a letter to EPA requesting any records on the amount of zinc phosphide sold or acres poisoned; EPA responded that they were not obligated to provide this information. Having records of this information would enable us to monitor the rangewide effects of poisoning on black-tailed prairie dogs, and the endangered black-footed ferret, whose primary prey is the black-tailed prairie dog.
>
> The EPA has not initiated additional formal consultation, following the 1993 Biological Opinion, regarding the recent permitting of chlorophacinone and diphacinone (both anticoagulants) to poison prairie dogs, despite their statement that additional consultation may be necessary if any new uses of these pesticides are proposed (EPA 1998, p. 109). Use of these two chemicals constitutes new uses because neither poison was registered for field use on prairie dogs at the time of the 1993 Biological Opinion. Secondary poisoning has been documented in the field in a badger and a bald eagle; additionally, many other species, including the black-footed ferret, are known to be highly susceptible to both chlorophacinone and diphacinone.

Given EPA's track record, which shows that EPA is not properly protecting wildlife from already registered rodenticides, EPA should not be considering approving yet another rodenticide use. This is especially so in light of the fact that "the black-tailed prairie dog is considered a keystone species . . . . The black-footed ferret (*Mustela nigripes*), swift fox (*Vulpes velox*), golden eagle (*Aquila chrysaetos*), and ferruginous hawk (*Buteo regalis*) utilize prairie dogs as a food source; the mountain plover (*Charadrius montanus*) and burrowing owl (*Athene cunicularia*) depend on habitat (burrows) created by prairie dogs. Many other species share habitat with prairie dogs, and rely on them to varying degrees."[3] Registering Kaput-D would jeopardize black-footed ferrets, would further endanger black-tailed prairie dogs, and would harm numerous other species. An agency charged with environmental protection should not be allowing such outcomes, and in fact, is required by law to do otherwise.

While public interest groups have pointed out the many reasons that Kaput (as well as Rozol) should be off the market, EPA has failed to even comply with the requests of the USFWS, which has time and again explained to EPA the severe harm that is caused by Kaput-D, and has repeatedly requested that EPA engage in consultation with USFWS. For instance, in a very recent letter to EPA (September 8, 2009),[4] the USFWS demanded that EPA adhere to its ESA duties and "withdraw the registration for Rozol and not issue a registration for prairie dog control for Kaput until EPA completes a formal consultation with the Service on the use of these rodenticides to control black-tailed prairie dogs." The USFWS 2009 letter notes that:

> The Western Association of Fish & Wildlife Agencies expressed similar concerns … in a letter dated August 19, 2008. The issues raised in these communications

[3] *Endangered and Threatened Wildlife and Plants; 90-Day Finding on a Petition To List the Black-tailed Prairie Dog as Threatened or Endangered*, 73 Fed. Reg. 73211, 73213 (December 2, 2008)

[4] Attached as Exhibit A

have not been addressed sufficiently by EPA to warrant registration of these products under Section 3 of FIFRA.

The secondary poisoning risks from Kaput are even greater than those from Rozol (Erickson and Urban 2004). Colvin *et al.* (1988) noted that anticoagulants can pose a substantial hazard to raptors. A study that evaluated the risks of 11 vertebrate pesticides (Littrell 1990) ranked both Rozol and Kaput as the second most hazardous pesticides.

Anticoagulants cause a more prolonged period of distress for the target animal prior to mortality than zinc phosphide. Anticoagulants act as blood thinners, with poisoned animals losing blood through various orifices, including eventually the skin membranes, over a period of weeks. During this period, poisoned prairie dogs may wander around on the surface becoming increasingly debilitated and susceptible to predation. For example, two weeks after an illegal application of Rozol … Service biologists found over 50 dead, dying, and scavenged prairie dogs. … On a follow up visit by both the Service and EPA four weeks after application it was noted that 400-500 prairie dogs had been retrieved from the Rozol treated site during the previous two weeks.

EPA is well aware that it is violating its ESA duties. Section 7(a)(1) of the ESA requires all Federal agencies to use their authorities to conserve listed species. Section 7(a)(2) requires that Federal agencies, in consultation with the USFWS, ensure that any actions they authorize, fund, or carry out are not likely to jeopardize the continued existence of a listed species or adversely modify its critical habitat. Section 7 consultation is required for "any action [that] may affect listed species or critical habitat."[5] Agency "action" is defined in the ESA's implementing regulations to include "(b) the promulgation of regulations; (c) the granting of licenses, contracts, leases, easements, rights-of-way, permits, or grants in- aid; or (d) actions directly or indirectly causing modifications to the land, water, or air."[6] At the completion of consultation, USFWS will issue a biological opinion that determines if the agency action is likely to jeopardize the species at issue. If so, the opinion may specify reasonable and prudent alternatives that will avoid jeopardy and allow the agency to proceed with some action.[7] USFWS may also "suggest modifications" to the action during the course of consultation to "avoid the likelihood of adverse effects" to the listed species even when not necessary to avoid jeopardy.[8]

[5] 50 C.F.R. § 402.14

[6] 50 C.F.R. § 402.02

[7] 16 U.S.C. § 1536(b)

[8] 50 C.F.R. § 402.13

These ESA requirements apply to EPA's permitting of pesticides under FIFRA.[9] Moreover, under FIFRA, EPA retains the authority to withdraw, modify or condition pesticide registrations, giving it ongoing discretion to make any decision regarding the sale and use of pesticides. As discussed in *Wash. Toxics Coalition v. EPA*,[10]

> EPA retains ongoing discretion to register pesticides, alter pesticide registrations, and cancel pesticide registrations. See 7 U.S.C. § 136a-d. Because EPA has continuing authority over pesticide regulation, it has a continuing obligation to follow the requirements of the ESA. We have respected such continuing obligations in well-reasoned authority that binds us here.
>
> In this case, EPA has similar discretion "to inure to the benefit" of listed species. Pesticide registrations under FIFRA are ongoing and have a long-lasting effect even after adoption. EPA retains discretion to alter the registration of pesticides for reasons that include environmental concerns. See 7 U.S.C. §§ 136d(c)(1)-(2), 136(l).

Here, until EPA completes consultation with the USFWS regarding the impacts of Kaput-D on ESA listed species, including the black-footed ferret, whooping crane, and American burying beetle, then it may not authorize use of Kaput-D. [11] Furthermore, pursuant to section 7(a)(4) of the ESA, EPA will likely soon be required to confer with USFWS regarding impacts to the black-tailed prairie dog; that said, it should be clear to EPA that authorizing the death of any individual of a species that is likely on its way to being listed under the ESA is absurd.

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[9] *Wash. Toxics Coalition v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005) ("We agree with the Eighth Circuit that even though EPA registers pesticides under FIFRA, it must also comply with the ESA when threatened or endangered species are affected."); *Defenders of Wildlife v. Administration*, 882 F.2d 1294 (8th Cir. 1989) (affirming section 7's application to EPA's registration of pesticides)

[10] 413 F.3d at 1033

[11] *September 2009 FWS letter to EPA* (Attached as Exhibit A): "The 1993 Biological Opinion determined that the registered uses for chlorophacinone would jeopardize the continued existence of 21 Federally listed species. With the 2009 registration by EPA to expand the use of Rozol and potentially Kaput, we expect that the list of adversely affected species would be greater because there are over twice as many species now listed under the Act and the new registration greatly expands the likelihood to nontarget species exposures.";

December 2007 FWS letter to EPA (Attached as Exhibit B): "Federally listed threatened and endangered species that are known to occur in areas on, near, or adjacent to black-tailed prairie dog towns include black-footed ferret, Whooping crane, and American burying beetle.";

January 2006 FWS letter to Nebraska Dept. of Agriculture (Attached as Exhibit C): "[T]he Service has determined that the following federally listed species are known to occur in areas on, near, or adjacent to black-tailed prairie dog towns[:] . . . Black-footed ferret *(Mustela nigripes),* Whooping crane *(Grus americanus),* American burying beetle *(Nicrophorus americanus).*"

While the deaths of black-tailed prairie dogs should be reason enough to reject the application, black-footed ferrets, a non-target species, are one of the most endangered mammals in the world, and would very likely be harmed and/or killed by Kaput-D, and would also lose important habitat due to the deaths of prairie dogs. In fact, historically, most ferrets probably occurred in black-tailed prairie dog habitat;[12] thus, impacts to the black-tailed prairie dog will no doubt significantly limit the ability of the ferret to continue to exist and to recover.

Black-footed ferrets were once prolific in the United States, but were brought to the brink of extinction by the 1980s. Prairie dogs make up 90% of a ferret's diet and a single ferret may eat over 100 prairie dogs in one year. A healthy population of black-footed ferrets thus requires very large prairie dog colonies. Furthermore, ferret dependence on prairie dogs for food, and on prairie dog burrows for shelter, is a large reason for its endangered status, and therefore, poisoning of prairie dogs represents a major threat to the ferret's well being. Poisoning can affect the black-footed ferret directly, through secondary poisoning of the ferret, or indirectly, through the loss of the prairie dog prey base and loss of habitat due to prairie dog deaths.[13] Moreover, new poisons like Kaput are even more deleterious than old poisons. As noted in the recent USFWS 5-Year Review for the ferret, "The anticoagulant rodenticides chlorophacinone (Rozol) and diphacinone (Kaput) …. pose a much greater risk of secondary poisoning to black-footed ferrets than zinc phosphide (Erickson and Urban 2004)."[14] Due to the significant harm that these poisons can cause, both the USFWS and the Western Association of Fish and Wildlife Agencies "are currently encouraging the Environmental Protection Agency to re-address the use of anticoagulants for control of prairie dogs ."[15] In short, given the obvious impacts that would occur to an extremely endangered species should black-tailed prairie dogs be poisoned and further eliminated, this Kaput-D application must be declined.

The ESA aside, however, it should be clear that Kaput-D combo bait should not be registered due to its severe negative impacts to all wildlife, including species protected under the Bald and Golden Eagle Act, and the Migratory Bird Treaty Act. Badgers, coyotes, foxes, raccoons, skunks, and migratory birds such as bald eagles, golden eagles, hawks, owls, and other avian predators are at grave risk of secondary poisoning due to their consumption of prairie dogs or their use of prairie dog habitat.[16] And as already mentioned, the insecticide imidacloprid can severely harm species like the endangered American burying beetle.

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[12] *Black-footed Ferret (Mustela nigripes) 5-Year Status Review: Summary and Evaluation*, U.S. Fish and Wildlife Service, South Dakota Field Office (November 2008)

[13] *Id*.

[14] *Id.*

[15] *Id*.

[16] *September 2009 FWS letter to EPA* (Attached as Exhibit A): "The ferruginous hawk *(Buteo regalis)*, in particular, is very closely linked to prairie dogs and often occurs in large numbers where prairie dogs concentrate (Seery and Matiatos 2000). The ferruginous hawk is a Species of Conservation Concern (U.S. Fish and Wildlife Service 2008) in Service Region 6, where most of the proposed use of Rozol and Kaput would occur. In addition, bald eagles are known kleptoparasitic associates of ferruginous hawks (Jorde and

Finally, it is interesting to note that the proposed label for Kaput-D would read, in part, "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." If taken seriously, this label means there is likely nowhere this product can be used because nontarget species like the ones mentioned above are very likely to be adversely affected virtually everywhere black-tailed prairie dogs are found.

In sum, the authorization of the use of Kaput-D combo bait for the killing of black-tailed prairie dogs would violate the Endangered Species Act, the Bald and Golden Eagle Act, and the Migratory Bird Treaty Act. While EPA should simply deny this application due to the severe impacts it would cause to wildlife, at the very least, EPA must complete consultation with USFWS Service prior to authorizing the use of Kaput-D.

Respectfully submitted,

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Lingle 1988). Accordingly, we believe that potential violations of the Migratory Bird Treaty Act, and Bald and Golden Eagle Protection Act may be occurring via use of these products.";

December 2007 FWS letter to EPA (Attached as Exhibit B): "The Service's primary concern regarding the proposed use of Kaput to control BTPDs … is secondary exposure and toxicity to migratory avian predators and scavengers, such as burrowing owls *(Speotyto cunicularia)*, ferruginous hawks *(Buteo [regalis])*, Swainson's hawks *(Buteo swainsoni)*, turkey vultures *(Cathartes aura)*, bald eagles *(Haliaeetus leucocephalus)*, and golden eagles *(Aquila chrysaetos)*. Concerns regarding the exposure and effects of Kaput to these species are similar to those previously described in a May 5,2006, letter to EPA regarding the use of Rozol to control for BTPDs. However, EPA has found that the active ingredient in Kaput (diphacinone) presents a greater secondary risk to avian predators and scavengers than the active ingredient in Rozol (chlorophacinone) (Erickson and Urban, 2004)."

EXHIBIT A

United States Department of the Interior

FISH AND WILDLIFE SERVICE
Washington, D.C. 20240

SEP 8 2009

In Response Reply to:
FWS/AFHC-DEQ/042031

Debbie Edwards, Ph.D.
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Dear Dr. Edwards:

Thank you for the opportunity to comment on the Environmental Protection Agency's (EPA) approval to use two rodenticides to control black-tailed prairie dogs. As communicated previously, the U.S. Fish and Wildlife Service (Service) has strong concerns about the potential impacts of these products on nontarget wildlife protected under the Endangered Species Act and the Migratory Bird Treaty Act. Specifically, the Service's comments address the conditional registration under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for Rozol Prairie Dog Bait (active ingredient: chlorophacinone) to control black-tailed prairie dogs (*Cynomys ludovicianus*) in Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming, and the anticipation of a similar registration for the rodenticide Kaput (active ingredient: diphacinone). We recommend that EPA withdraw the registration for Rozol and not issue a registration for prairie dog control for Kaput until EPA completes a formal consultation with the Service on the use of these rodenticides to control black-tailed prairie dogs.

Service Field Offices provided letters to EPA expressing our concerns regarding special local needs registrations under FIFRA Section 24(c) for both Rozol and Kaput on May 5, 2006 and December 21, 2007, respectively. In addition, our Wyoming Field Office provided comments on this registration of Rozol under separate cover (June 19, 2009). The Western Association of Fish & Wildlife Agencies expressed similar concerns to EPA in a letter dated August 19, 2008. The issues raised in these communications have not been addressed sufficiently by EPA to warrant registration of these products under Section 3 of FIFRA. Our specific concerns include the documented risk from the use of these products to non-target species for which the Service is a federal trustee, including federally listed threatened and endangered species such as the black-footed ferret *(Mustela nigripes)* and migratory birds such as bald eagles *(Haliaeetus leucocephalus)* and golden eagles *(Aquila chrysaeos)*, hawks, and other avian predators and scavengers.

The black-tailed prairie dog occupies an estimated 2.4 million acres in the western U.S. Their colonies are used by many wildlife species that prey on or scavenge prairie dogs

and/or use their burrows for shelter. The high availability of prey at these colonies can result in a disproportionate use by avian and mammalian predators and scavengers. Therefore, the use of rodenticides, with known secondary toxicity to animals that consume poisoned prairie dogs, can have significant impacts to animal populations far beyond the footprint of the colony.

The risk of secondary poisoning to non-target wildlife from anticoagulants such as Rozol and Kaput is much higher than from zinc phosphide, the traditional choice for prairie dog control (Colvin *et al.* 1988, Erickson and Urban 2004). Several EPA documents note the risk from Rozol (EPA 2004, EPA 2006, Erickson and Urban 2004). The most recent document (EPA 2006) repeats a conclusion from Erickson and Urban (2004) that *use of chlorophacinone bait to control prairie dogs has a considerable potential for both primary and secondary risks to birds and nontarget mammals and possibly reptiles. Secondary risks, especially to mammalian predators and scavengers, are likely to be much greater for chlorophacinone than for zinc phosphide.*

The secondary poisoning risks from Kaput are even greater than those from Rozol (Erickson and Urban 2004). Colvin *et al.* (1988) noted that anticoagulants can pose a substantial hazard to raptors. A study that evaluated the risks of 11 vertebrate pesticides (Littrell 1990) ranked both Rozol and Kaput as the second most hazardous pesticides. Strychnine was ranked as the most hazardous; zinc phosphide was ranked fifth.

Anticoagulants cause a more prolonged period of distress for the target animal prior to mortality than zinc phosphide. Anticoagulants act as blood thinners, with poisoned animals losing blood through various orifices, including eventually the skin membranes, over a period of weeks. During this period, poisoned prairie dogs may wander around on the surface becoming increasingly debilitated and susceptible to predation. For example, two weeks after an illegal application of Rozol on 160 acres in South Dakota in 2005, Service biologists found over 50 dead, dying, and scavenged prairie dogs. This information was shared with EPA law enforcement. On a follow-up visit by both the Service and EPA four weeks after application, it was noted that 400-500 prairie dogs had been retrieved from the Rozol treated site during the previous two weeks. Anticoagulants also have a longer persistence in the body tissues of the poisoned prairie dogs than zinc phosphide (Erickson and Urban 2004, Mendenhall and Pank 1980). Consequently, contaminated prey are available to non-target species for a period of weeks versus hours for zinc phosphide. The disoriented, dead, and dying prairie dogs likely attract even more predators and scavengers to the site than might typically occur, further increasing impacts from secondary poisoning.

There appears to be a significant data gap regarding the potential impact of residues of these anticoagulants in prairie dog carcasses. We have received anecdotal information indicating that anticoagulant concentrations in prairie dog tissues are higher than residue levels in other treated rodent species. If so, higher concentrations of the anticoagulants, compounded by the larger body size of prairie dogs compared to many other rodents
(ground squirrels, mice, pocket gophers, voles) that are typically poisoned with anticoagulant, would deliver a substantially larger dose of poison to prairie dog predators and scavengers than would consuming other prey species.

Though laboratory trials have been conducted where poisoned prairie dog carcasses were fed to non-target species, this study did not provide information regarding anticoagulant concentrations in prairie dog tissue either before or after death (Fisher and Timm 1987). In a field efficacy study for Rozol that was sponsored by the manufacturer, LiphaTech, and carried out in conjunction with the National Wildlife Research Center/Animal and Plant Health Inspection Service (NWRC/APHIS), carcasses of black-tailed prairie dogs collected from treated areas were to be analyzed to measure residue levels in whole-body and liver tissue samples (Lee and Hygnstrom 2007). We request that EPA provide information from that study to the Service. Similarly, the Service will provide EPA the results of a study, when completed, with NWRC/APHIS to test tissue residues in prairie dogs at incremental time periods post-exposure.

Threatened and Endangered Species

In 1993 when about 650 species were listed under the Federal Endangered Species Act (ESA), the Service completed a Biological Opinion on 16 vertebrate control agents including chlorophachinone and diphacinone. At that time, the registered uses for these anticoagulants did not include prairie dogs. Consequently, impacts from poisonings at prairie dog colonies were not part of the review. The 1993 Biological Opinion determined that the registered uses for chlorophacinone would jeopardize the continued existence of 21 Federally listed species. With the 2009 registration by EPA to expand the use of Rozol and potentially Kaput, we expect that the list of adversely affected species would be greater because there are over twice as many species now listed under the Act and the new registration greatly expands the likelihood to non-target species exposures. EPA noted in their 1998 Reregistration Eligibility Decision for these rodenticides that additional consultation with the Service may be necessary if new uses of these pesticides are proposed. We consider the use of Rozol and Kaput for the control of prairie dogs to be a new use. We asked EPA to consider reinitiating Section 7 consultation in both a letter to EPA dated May 5, 2006 and in a conference call with EPA on May 19, 2006, however this has not occurred.

Of particular concern are effects to the Federally-listed black-footed ferret. Black-footed ferrets are highly dependent upon black-tailed prairie dogs, both for food and for the utilization of their burrows. In November 2008, the Service issued a 5-Year Review of the ferret, citing the poisoning of prairie dogs as a major factor in the decline of ferrets, through both decline of prairie dogs and inadvertent poisoning of ferrets (USFWS 2008). The report recommended that Federal agencies more fully embrace ESA Section 7 (a)(1) responsibilities to restore and manage viable prairie dog complexes to support ferret recovery, and specifically cites the need for EPA to re-address the use of anticoagulants for control of prairie dogs.

Migratory Birds and Other Non-target Species

The Migratory Bird Treaty Act prohibits the take of migratory birds, including avian mortality resulting from exposure to pesticides registered under FIFRA [U.S. v. Corbin Farm Services, 444 F. Supp. 510 (1978)]. We are especially concerned about potential mortality of migratory raptors due to the use of Rozol and Kaput. The ferruginous hawk *(Bueto regalis)*, in particular, is very closely linked to prairie dogs and often occurs in large numbers where prairie dogs concentrate (Seery and Matiatos 2000). The ferruginous hawk is a Species of Conservation Concern (U.S. Fish and Wildlife Service 2008) in Service Region 6, where most of the proposed use of Rozol and Kaput would occur. In addition, bald eagles are known kleptoparasitic associates of ferruginous hawks (Jorde and Lingle 1988). Accordingly, we believe that potential violations of the Migratory Bird Treaty Act, and Bald and Golden Eagle Protection Act may be occurring via use of these products.

Take of Federally protected migratory birds also would be inconsistent with Federal Agency responsibilities stipulated in Executive Order (EO) 13186, which required federal agencies proposing actions that may have measurable effects on migratory birds to develop a Memorandum of Understanding (MOU) with the Service to demonstrate how conservation of migratory birds will be promoted (66 FR 3853). EPA has not completed this MOU. We believe authorization of Rozol and Kaput for prairie dog control has a high likelihood of adversely affecting ferruginous hawks and other raptors at a measurable level. Accordingly, we request that EPA undertake development of the MOU outlined in EO 13186.

Mortalities of badgers *(Taxidea taxus,* Klataske 2009 and Lydick 2006) and a bald eagle (USFWS 2007) were reported to EPA from secondary poisoning by the legal application of chlorophacinone in prairie dog colonies. We believe that the actual number of non-target species impacted is much greater. However, the ability to verify impacts to non-target species is quite limited. Carcass searches to assess hazards to non-target wildlife are of minimal value because of cryptic coloration, vegetative cover, consumption by other scavengers, the ranging ability of many scavengers and predators, and, in the case of anticoagulants, the delayed action of the rodenticide (Colvin *et al.* 1988). Therefore, only a very small percentage of animals that die from secondary poisoning are ever located.

Black-tailed Prairie Dog Conservation

In 2000, the black-tailed prairie dog was designated a candidate species for listing under the ESA. Though candidate status was removed following the discovery of additional colonies, many states subsequently developed black-tailed prairie dog management plans to keep populations stable and prevent future listing. For example, in 2005, the Service and the Texas Parks and Wildlife Department signed a conservation agreement for planning and implementation of the Black-tailed Prairie Dog Conservation and Management Plan. The Texas management plan cites specific acreage needed to support stable prairie dog populations and is part of a larger overall effort by the western states to conserve prairie dogs. Since local registration of Rozol and Kaput in Texas, the Service has observed an increase in prairie dog control. The Service is concerned that the widespread use of Rozol and Kaput on prairie dog

colonies in Texas, as compared with other methods of prairie dog control, may result in the Department failing to achieve its prairie dog conservation goals.

Comments Specific to Current Rozol Label

The Service also has specific concerns and comments with regard to the Rozol label that accompanies the May 13, 2009 registration for this rodenticide. We are concerned that the label requirements needed to ensure non-target exposure are so cumbersome that they will be ignored, especially regarding the retrieval of dead and dying prairie dogs (recommendation #7 below). We have received first hand verbal reports from applicators regarding this issue. A document produced by LiphaTech quoted a County Pest Control Supervisor as stating that *zp* [zinc phosphide] *requires two trips based on the need to pre-bait. That adds up quickly. With an anticoagulant, I can cut the labor costs in half when compared with zinc* (Bruesch undated). If the current requirements for retrieval of dead and dying prairie dogs, which fall short of adequate protection, are being side-stepped, it is unlikely that the actions truly needed to protect nontarget species will be taken. Hence our recommendation that EPA withdraw the registration of Rozol until completion of a formal consultation with the Service. Nonetheless, short of immediate withdrawal of registration, we suggest the following interim modifications to these labels (**Rozol and Kaput)** to minimize potential impacts to non-target species pending consultation with the Service:

- The Notice of Pesticide Registration states that the product is conditionally registered provided certain actions are completed by LiphaTech. Among those actions is a requirement that LiphaTech conduct an Avian Reproduction Study within three years. We suggest all necessary studies be completed before registration.
- There is a lack of field studies designed to assess secondary risks to mammals (Erickson and Urban 2004). We suggest that secondary risk studies also be completed before registration.
- In the Precautionary Statements section of the label, under Environmental Hazards, we suggest that the following statement be added after the second sentence. *Do not apply in prairie dog towns where raptors or other predatory or scavenging migratory birds may occur.*
- In the Storage and Disposal section of the label, specify that only empty pesticide containers be placed in the trash, not waste products that may include pesticide product.
- In the Directions for Use section of the label, under Endangered Species considerations, we suggest that the third sentence be replaced with the following sentence. *Do not use this product within prairie dog towns in the range of the black-footed ferret.* The Service will provide information on the location and range of the ferret to EPA for use in the creation of county bulletins for its Bulletins Live Web site.
- In the Directions for Use section of the label, under Application, change "6 inches down active prairie dog burrows" to 12 inches.
- In the Directions for Use section of the label, under Follow-up, the label instructs applicators to return to the site 5-10 days after bait application and again 14-21 days after bait application to collect and properly dispose of any bait or dead or dying prairie dogs that may have come to the surface. This relaxes requirements of the previous 24 (c) labels for Colorado, Nebraska, Oklahoma, and Texas, which instruct applicators to return

at 1-2 day intervals to collect and properly dispose of bait and dead or dying prairie dogs. Leaving aside the question of how closely this label requirement is adhered to in the field, we suggest that in order to be truly protective of non-target species, the label should require at least twice daily trips at dawn and dusk to retrieve carcasses and bait. This should be done for a minimum of one month or until no more carcasses are found.

- In the Directions for Use section of the label, under Follow-up, eliminate inactive prairie dog burrow as a burial site.
- EPA should request documentation of the collection of dead and dying prairie dogs, including reports of any non-target mortality associated with the application, and involve the Service in the design of any studies that document or investigate any such effects.

In conclusion, we are very concerned about this registration and encourage EPA not to finalize any registration of chlorophacinone or diphacinone for prairie dog control due to the risks of secondary poisoning to predatory and scavenging wildlife. In summary, we find that:

- The labels for both of these products have been issued without the appropriate studies to assess risks to non-target wildlife and to provide adequate protective recommendations.
- The cost-benefit studies have not been realistically evaluated inasmuch as post-application surveys have been inadequate.
- The protections offered to nontarget wildlife under the current labels are insufficient in light of the concerns and evidence to date brought to EPA's attention by federal and state wildlife agencies.

Therefore we recommend that EPA withdraw the registration for Rozol and not issue a registration for prairie dog control for Kaput until EPA completes a formal consultation with the Service on the use of these rodenticides to control black-tailed prairie dogs. We also request that EPA undertake development of the MOU outlined in EO 13186 regarding migratory birds.

Please contact Dr. Roger C. Helm, Division of Environmental Quality, at (703) 358-2148 if you have any questions about these comments or to arrange for consultation.

Sincerely,

Assistant Director for Fisheries
and Habitat Conservation

cc: Donald Koch
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Citations

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EXHIBIT B

United States Department of the Interior

FISH AND WILDLIFE SERVICE
Mountain-Prairie Region

IN REPLY REFER TO:
FWS/R6
FR-ES

MAILING ADDRESS:
P.O. Box 25486, DFC
Denver, Colorado 80225-0486

STREET LOCATION:
134 Union Boulevard
Lakewood, Colorado 80228-1807

DEC 21 2007

Dr. Debbie Edwards
Office of Pesticide Programs
U.S. Environmental Protection Agency
Ariel Rios Building, Mailstop 7501C
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

Dear Dr. Edwards :

The U.S. Fish and Wildlife Service (Service) has learned that the Nebraska Department of Agriculture (NDA) has approved a Section 24(c) special local needs registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 et seq.) to register Kaput-D® Prairie Dog Bait (Kaput) (EPA Registration Number 72500-9) for the control of black-tailed prairie dogs (BTPD) (*Cynomys ludovicianus*) in Nebraska rangeland and non-crop areas. Accordingly, NDA has submitted its approved special local need request and 24(c) supplemental label for Kaput (EPA SLN Number NE-07-0002) to the U.S. Environmental Protection Agency (EPA) for review and approval by EPA.

The Service provided comments and identified several concerns regarding the special local needs registration of Kaput to control BTPDs to NDA on two separate occasions. Initial comments were provided to NDA in an August 10, 2007, email for distribution to the Nebraska Pesticide Board (Board). The Service also attended the August 16, 2007, Board meeting to approve or deny the 24(c) request for Kaput. Although the Nebraska Game and Parks Commission (NGPC) expressed similar concerns regarding the use of Kaput at the August 10 Board meeting, the Board approved a special local needs registration request for Kaput and voted to extend the label expiration date from one to two seasons.

The Service recommends that EPA disapprove the Kaput special local needs registration for Nebraska, based on an increased risk to non-target species for which the Service is a Federal trustee. Federal trust fish and wildlife species at risk include federally listed threatened and endangered species, avian predators including bald and golden eagles, and other migratory birds.

The Service's primary concern regarding the proposed use of Kaput to control BTPDs in Nebraska is secondary exposure and toxicity to migratory avian predators and scavengers, such as burrowing owls (*Speotyto cunicularia*), ferruginous hawks (*Buteo lagopus*), Swainson's hawks (*Buteo swainsoni*), turkey vultures (*Cathartes aura*), bald eagles (*Haliaeetus leucocephalus*), and golden eagles (*Aquila chrysaetos*). Concerns regarding the exposure and effects of Kaput to these species are similar to those previously described in a May 5, 2006, letter to EPA regarding the use of Rozol to control for BTPDs. However, EPA has found that the active ingredient in Kaput (diphacinone) presents a greater secondary risk to avian predators and scavengers than the active ingredient in Rozol (chlorophacinone) (Erickson and Urban, 2004). In addition, Rozol is currently available for use in Nebraska, and use of Kaput would further increase risk to non-target species due to the potential for cumulative exposures.

Enclosed is a detailed description of the Services concerns regarding use of Kaput to control BTPDs in Nebraska. Also enclosed is information on the authorities under which the Service operates when making this request. This letter has been prepared in coordination with the NGPC, which will be providing a separate letter to EPA that specifically addresses its concerns.

The Service appreciates EPA's consideration of our comments, concerns, and recommendations regarding its action on the NDA's special local needs registration for Kaput-D® Prairie Dog Bait. Should you have any questions regarding these comments, please contact Mr. John Cochnar, Acting Nebraska Field Supervisor, at (308) 382-6468, extension 20.

Sincerely,

Gary S. Moore

Acting Deputy Regional Director

Enclosures

U.S. FISH AND WILDLIFE SERVICE CONCERNS REGARDING USE OF KAPUT RODENTICIDE FOR PRAIRIE DOG CONTROL IN NEBRASKA

1. **There are many non-target species of concern in Nebraska that are susceptible to primary and/or secondary toxicity risks associated with use of anticoagulant rodenticides (chlorophacinone and diphacinone).**

Toxicity Risks Associated with Chlorophacinone and Diphacinone.

The active ingredient in Kaput, diphacinone, is an anticoagulant. There is already an anticoagulant rodenticide (Rozol) registered under 24(c) for use to control black-tailed prairie dogs in Nebraska. The active ingredient in Rozol is chlorophacinone. Diphacinone and chlorophacinone act in the body by disrupting normal blood-clotting mechanisms and causing capillary damage (Erickson and Urban, 2004). Multiple feedings on treated bait are generally needed for sufficient population control (Erickson and Urban, 2004). Exposed animals may exhibit weakness, disorientation, behavioral modifications, and other signs of illness. Death is a result of internal, and at times external, bleeding (Erickson and Urban, 2004). Death also occurs over an extended period of time in which the exposed animal will continue to move about. This can lead to the animal dying aboveground and being scavenged by other animals (Erickson and Urban, 2004). Because anticoagulants can remain in the tissues of animals that are initially exposed, there is a secondary poisoning risk to wildlife species that may feed on the poisoned animals.

The Service is aware that EPA has compared the risks of nine rodenticides, including chlorophacinone and diphacinone, to birds and non-target mammals (Erickson and Urban, 2004). This assessment found that diphacinone, when compared to chlorophacinone, presents a greater secondary toxicity risk to avian predators and an overall (i.e., primary and secondary) greater risk to non-target mammals and birds. In addition, the Service believes that EPA's risk assessment for chlorophacinone and diphacinone underestimates the true risk to non-target species when considering uncertainty factors not addressed in their assessment. Such uncertainty factors include missing toxicity data, not accounting for exposure differences and frequencies, not accounting for sublethal effects including internal hemorrhaging or potential reproductive effects, and not accounting for bioaccumulation associated with repeated sublethal exposures of poisoned prey to predators and scavengers (Erickson and Urban, 2004).

Non-target Species of Concern in Nebraska.

Species of concern to the Service that may be affected by the proposed use of Kaput include species that are federally protected under the Endangered Species Act, the Bald and Golden Eagle Protection Act, and the Migratory Bird Treaty Act, as well as at-risk species identified by the Nebraska Natural Legacy Project.

Federally listed threatened and endangered species that are known to occur in areas on, near, or adjacent to black-tailed prairie dog towns include black-footed ferret, whooping crane, and American burying beetle. Of these federally listed species, exposure to American burying beetle may be the most probable. Although there is no primary or secondary diphacinone toxicity data for terrestrial invertebrate species, diphacinone is considered moderately toxic to aquatic invertebrates on an acute basis (EPA, 1998).

The Nebraska Natural Legacy Project was developed in coordination with the Service and includes a listing of Tier I and Tier II at-risk species of concern (Schneider et al., 2005). Tier I species are defined as those that are globally or nationally most at-risk of extinction, and which occur in Nebraska. Examples of Tier I species that are associated with prairie dogs include bald eagle, ferruginous hawk, swift fox, burrowing owl, short eared owl, and mountain plover. Tier II species include those that do not meet the Tier I criteria but were ranked by the Nebraska Natural Heritage Program as either State Critically Imperiled, State Imperiled, or State Vulnerable. Examples of Tier II avian predatory species that are associated with prairie dogs include golden eagle, red-shouldered hawk, Swainson's hawk, northern harrier, and prairie falcon.

2. **Recent observations and laboratory data indicate that avian predators/scavengers are poisoned when anticoagulant prairie dog rodenticides are used.**

<u>2007 Bald Eagle Death from Exposure to an Anticoagulant Rodenticide used for Prairie Dog control in Nebraska</u>.

In January 2007, an adult female bald eagle was recovered by Service law enforcement and submitted to the National Fish and Wildlife Forensics Laboratory in Ashland, Oregon. The eagle was in good condition when received by the laboratory and was x-rayed, dissected, and examined for gross pathological lesions. Liver samples were analyzed for lead and anticoagulant rodenticides.

Necropsy findings included:

- A small hemorrhagic skin laceration on the dorsal elbow region of the right wing.
- Extensive tissue hemorrhage of right wing from the shoulder to below the elbow.
- Pericardial sac surrounding the heart distended with serosanguinous liquid
- Generalized pale (anemic) tissues
- Toxic concentration of cholorophacinone in the liver.

The laboratory diagnosis revealed that poisoning with chlorophacinone and physical trauma had occurred. The lab report concluded that "the observed small hemorrhagic skin laceration on the dorsal elbow region of the right wing was caused by trauma from and undetermined source. This trauma may have initiated the extensive hemorrhaging caused by the presence of the anticoagulant rodenticide in the eagle." Chlorophacinone was detected in the eagle's liver at 0.30 micrograms per gram (µg/g), a concentration similar to that detected in the liver of a red-tailed hawk (0.34 µg/g) that was recovered after it had succumbed to chlorophacinone poisoning (Erickson and Urban, 2004).

The Service Special Agent working on the Nebraska bald eagle mortality case interviewed a licensed applicator regarding the incident. The applicator remarked that even when label directions for Rozol are followed, prairie dogs are often seen above ground in a morbid state of stupor that leaves them vulnerable to capture or predation.

It should be noted that there is no coordinated effort by Nebraska Department of Agriculture or the Service to evaluate non-target field mortalities associated with the use anticoagulant rodenticides to control black-tailed prairie dogs in Nebraska and that the recovered eagle was a chance encounter. Due to the slow death mechanism of action and the fact that pesticide mortality carcasses are quickly scavenged in the wild (Vyas, 1999), the number of non-target avian species affected from exposure to anticoagulant rodenticides is expected to greatly exceed the number of species recovered.

A Report Provided by Scimetrics Further Indicates Secondary Toxicity Risk to Avian Predators.

According to a field study sponsored by Scimetrics, the registrant for Kaput, sick and lethargic prairie dogs were observed above ground following a Kaput application (Bruening, 2007). The researches also observed "a bald eagle seen flying off the treatment plot with a prairie dog in its talons." Other predatory/scavenger avian species observed multiple times near or on the study plot included red-tailed hawks, golden eagles, magpies, and turkey vultures (Bruening, 2007), indicating that these species are attracted to the Kaput treated prairie dog towns.

3. **Risk to non-target avian and mammal species from use of Kaput would be greater than risk associated with Rozol, due to differences in diphacionone and chlorophacinone toxicity and retention times.**

Scimetrics claims that less amount of active ingredient in their Kaput formulation (25 ppm diphacinone) results in less risk to non-targets than the currently available Rozol formulation of 50 ppm chlorophacionone. However, this is clearly not the case according to EPA's risk assessment (Erickson and Urban, 2004). Diphacionone use represents the greatest secondary risk to mammalian species among eight rodenticides evaluated, including zinc phosphide (Figure 1). In addition, EPA also concluded that the overall potential risk to non-target birds and mammals from direct ingestion of bait and ingestion of poisoned animals is approximately 33% greater for diphacinone than chlorophacinone rodenticides. Furthermore, secondary risk to birds (i.e., risk to birds that eat prairie dogs) is approximately 100 times greater for diphacinone than chlorophacinone rodenticides (Figure 1). These differences in secondary and overall toxicity are, in part, a result of diphacionone's greater retention time in blood and liver tissues. Retention time for chlorophacionone in blood was 0.4 days compared to 17.5 days for diphacionone (Erikson and Urban, 2004, Table 41). No data for chlorophacinone retention time in liver was available; however, the diphacinone retention time in liver was estimated at 90 days.

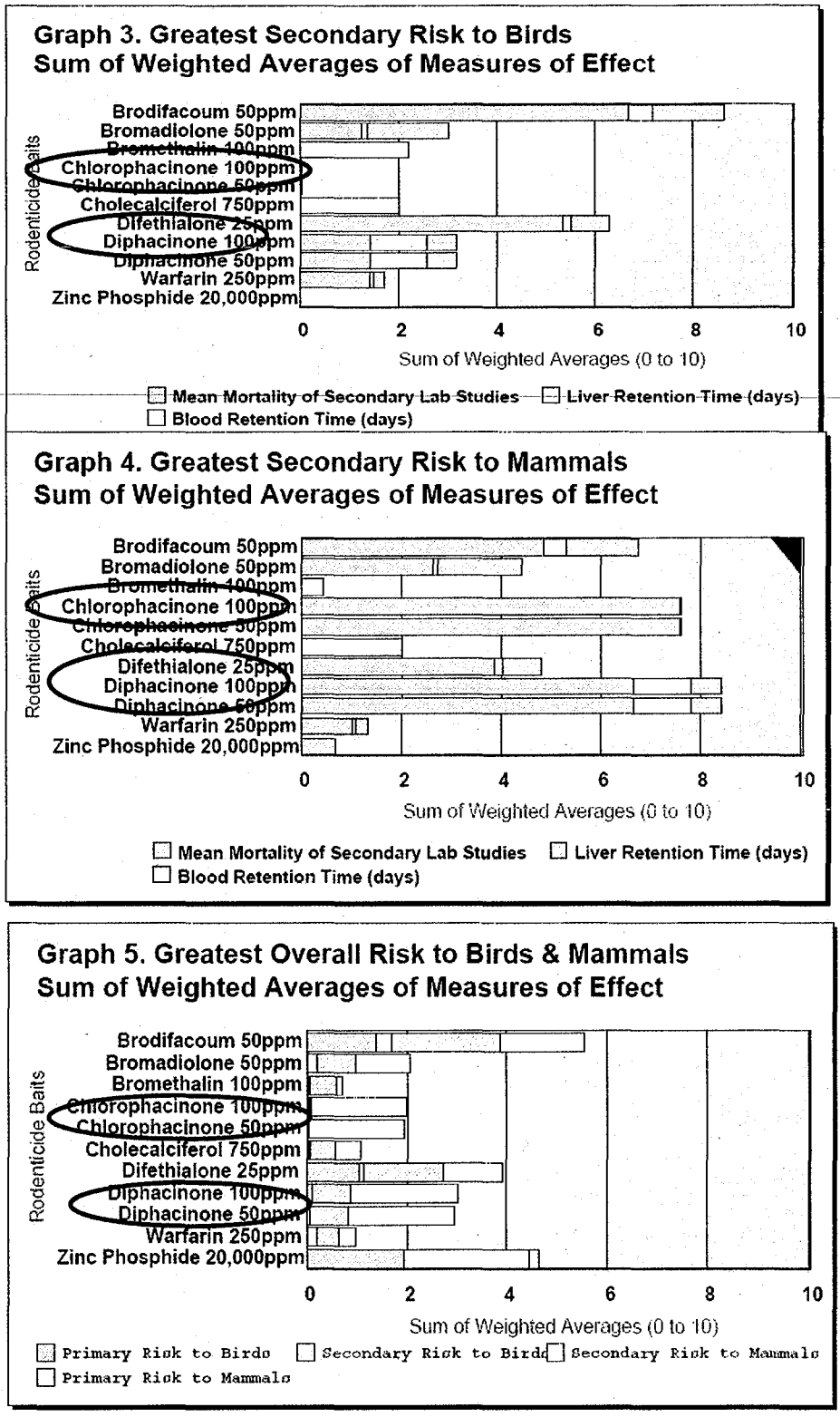

FIGURE 1. Secondary and overall risk to non-target birds and mammals from exposure to rodenticides as evaluated by the U.S. Environmental Protection Agency using a Sum of Weighted Averages approach for measures of effect. Note: Graphs 3, 4 and 5 above were taken directly from Erickson and Urban (2004) with the exception that red ovals were added for emphasis.

EPA's evaluation of lab studies and incident reports also indicate that diphacinone represents a greater risk to avian species than chlorophacinone (Erickson and Urban, 2004). Exposure to diphacinone in the lab (3 studies with 34 individuals) resulted in about 9% mortality. Test species were barn owls, great horned owls, saw-whet owls, golden eagles, and American crows. Thirteen (42%) of the survivors displayed some signs of toxicity. Incident reports indicate that diphacinone can result in death to a number of different non-target species including owls and other raptors, deer, and rabbits.

4. **The addition of a diphacinone product for use in Nebraska, at a time when Rozol is approved for use, may increase risk to non-targets based on increased risk from cumulative exposure and chemical interaction.**

Cumulative exposure refers to the total exposure to a group of compounds with similar modes of toxicity. For example, if a prairie dog town is treated twice with Kaput-D and then twice with Rozol, as permitted by respective labels, then the overall exposure and risk to non-targets is increased, especially to avian predators that might prey upon several prairie dog towns while migrating. The increased retention time of diphacinone also contributes to increased risk to non-target species from cumulative exposure. The Nebraska label for Kaput indicates that a second bait application may be made within 1 – 2 months after the first application; therefore, avian predators/scavengers that may have survived feeding on prairie dogs poisoned by the first bait application would still have diphacinone in their liver during the onset of the second bait application resulting in an increased probability of succumbing to diphacinone toxicity.

Chemical interaction refers to the effects of two chemicals given simultaneously. The combined effects may be additive, synergistic or antagonistic. An additive effect occurs when the combined effect of two chemicals is equal to the sum of the effects of each agent given alone (e.g., 2 + 3 = 5). A synergistic effect occurs when the combined effects are much greater that the sum of the effects given alone (e.g., 2 + 3 = 10). Antagonism occurs when two chemicals interfere with each others actions resulting in a effect less than the sum of the effects of each agent given alone (e.g., (2 + 3 = 2). If non-targets are exposed to both diphacinone and chlorophacinone, it is unclear whether the effects would be additive, antagonistic, or synergistic.

<u>In Summary</u>

The active ingredient in Kaput (diphacinone) presents a substantially greater secondary risk (i.e., risk from scavenging poisoned carcasses) to birds and mammals than the active ingredient in Rozol (chlorophacinone). Diphacinone is similar to chlorophacinone in that both are "first generation" anticoagulants and cause death by internal bleeding; therefore, non-targets may be at increased risk from cumulative exposure to these rodenticides, especially given that both can kill animals in a single feeding, and multiple feedings are recommended for sufficient population control of target species. Habits of black-tailed prairie dogs place them above ground on a regular basis and observations by researchers and applicators indicate that black-tailed prairie dogs poisoned with Kaput or Rozol are lethargic and less alert, making them more prone to predation by above ground predators. Non-target wildlife at risk from use of Kaput to control

black-tailed prairie dogs includes federally listed species, federally protected migratory birds, and Nebraska "species of concern." The recovery of a bald eagle in Nebraska that died from exposure to an anticoagulant rodenticide in Nebraska demonstrates the potential for secondary exposure to non-target avian predators and scavengers.

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EXHIBIT C

United States Department of the Interior

FISH AND WILDLIFE SERVICE
Ecological Services
Nebraska Field Office
203 West Second Street
Grand Island, Nebraska 68801

January 13, 2006

Greg Ibach, Director
Nebraska Department of Agriculture
P.O. Box 94947
Lincoln, NE 68509-4947

Dear Mr. Ibach:

The U.S. Fish and Wildlife Service (Service) has become aware of a request by LiphaTech and the Nebraska Cattlemen for the Nebraska Department of Agriculture to register Rozol Pocket Gopher Bait® as a new Section 24(c) "Special Local Need" pesticide product to control black-tailed prairie dogs (*Cynomys ludovicianus*) in Nebraska under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*). Pursuant to FIFRA, the Service is providing these comments and recommendations under the authorities of the Endangered Species Act (ESA) of 1973 (87 Stat. 884, as amended; 16 U.S.C. 1531 *et seq.*), the Bald and Golden Eagle Protection Act (BGEPA) (16 U.S.C. 688-688d, as amended), and the Migratory Bird Treaty Act (MBTA) (16 U.S.C. 703-712: Ch. 128 *as amended*).

In accordance with section 7(c) of ESA, the Service has determined that the following federally listed species are known to occur in areas on, near, or adjacent to black-tailed prairie dog (BTPD) towns and may be affected by the proposed use of Rozol.

Listed Species	Expected Occurrence
Black-footed ferret (*Mustela nigripes*)	Resident – prairie dog towns
Bald eagle (*Haliaeetus leucocephalus*)	Migration, nesting, and wintering
Whooping crane *(Grus americanus)*	Migration – roosting
American burying beetle (*Nicrophorus americanus*)	Mesic tall-grass prairie and wet meadows

The Service is requesting that the Nebraska Department of Agriculture disapprove or reject this application request. Our reasons for this request are discussed below.

1. There is not a valid special local need (SLN) for Rozol.

Several pesticide products (such as aluminum phosphide, zinc phosphide, and different gas cartridges) are currently federally registered for BTPD control and can be used in Nebraska. Upon examination of the proposed Rozol label, we do not find any uses or application methods that cannot be met by these currently registered pesticides. For example, Rozol is being proposed for use in the control of BTPDs on rangeland and noncrop areas. Current registered pesticide products also can be applied to these types of land areas. Additionally, the proposed application of Rozol for the control of BTPDs is for placement in the burrow. There are current pesticide products that can be used within the burrow. Finally, the proposed Rozol label provides an application timeframe between October 1 and March 15 of the following year before spring green-up of vegetation occurs. Currently, there are pesticide products that can be used during this timeframe. The combined use of existing pesticide products actually allows for a longer available application timeframe than the proposed Rozol label would permit.

2. There is not enough information about Rozol's impacts to nontarget wildlife species.

The active ingredient in Rozol, chlorophacinone, is an anticoagulant. Anticoagulants act in the body by disrupting normal blood-clotting mechanisms and causing capillary damage (Pelfrene 1991 as cited in EPA 2004a). Multiple feedings on treated bait are generally needed for sufficient population control (Timm 1994 as cited in EPA 2004a). Exposed animals may exhibit weakness, disorientation, behavioral modifications, and other signs of illness. Death is a result of internal, and at times external, bleeding (EPA 2004a). Death also occurs over an extended period of time in which the exposed animal will continue to move about. This can lead to the animal dying aboveground and being scavenged by other animals (EPA 2004a). Because anticoagulants can remain in the tissues of animals that are initially exposed, there is a secondary poisoning risk to wildlife species or domestic animals, such as dogs, that may feed on the poisoned animals.

Although there is some toxicity information available for Rozol, its toxicity profile is incomplete or inadequate for certain wildlife species. For example, there is no primary or secondary toxicity data for terrestrial invertebrate species. However, it is known that Rozol is highly toxic to freshwater invertebrates (EPA 2004a). The federally listed endangered American burying beetle (*Nicrophorus americanus*) can be found in parts of Nebraska where BTPDs occur. Accordingly, there is a need to determine the primary and secondary toxic effects of Rozol on terrestrial invertebrate species before using Rozol in areas where the American burying beetle occurs, especially given the dietary and reproductive habits of the beetle.

We also have concerns about the secondary toxicity of Rozol to birds and mammals. In 1998, the U.S. Environmental Protection Agency (EPA) published a Reregistration Eligibility Decision (RED) document that evaluated several rodenticides, including chlorophacinone (Rozol) (EPA 1998). The RED determined that secondary toxicity data were not available for birds and mammals, and, as a result, EPA required secondary toxicity tests to be conducted (EPA 1998). In 2004, EPA published a comparative risk assessment of nine rodenticides, including chlorophacinone (EPA 2004a). This document does provide a summary of studies that have examined Rozol's secondary toxicity in birds and mammals. However, we have concerns about the adequacy and usefulness of these studies due to their small sample sizes (EPA 2004a).

Accordingly, additional information on the secondary toxicity of Rozol is necessary prior to authorizing and registering this product for uses that are expected to leave carcasses aboveground.

The Nebraska Cattlemen December 21, 2005, letter requesting the Nebraska Department of Agriculture approval of the 24(c) application for Rozol to control BTPDs in Nebraska indicates that research by Kansas State University has examined the secondary hazard of Rozol to predators and scavengers that may feed upon poisoned prairie dogs. References for this research are unknown; the only research from Kansas that we have encountered is focused on the efficacy of Rozol and not on secondary impacts. The December 21 letter further states that Nebraska Cattlemen "is communicating with the University of Nebraska to conduct further risk assessment in western Nebraska relative to concerns of a secondary hazard to predators and scavengers that may feed upon poisoned prairie dogs." The letter also indicates that this research is anticipated to duplicate the results found in the Kansas State University project. The Service is not aware of any research conducted by Dr. Charles Lee or any other researcher from Kansas State University that has specifically examined the secondary toxicity of Rozol to wildlife species. Like the Nebraska Cattlemen, the Service supports the use of sound, peer-reviewed scientific research. However, we are not aware of substantive, peer-reviewed scientific research that has adequately examined the risks of secondary poisoning from Rozol to nontarget wildlife species. Additionally, as discussed above, some would argue that there is no sound, peer-reviewed scientific research given the small sample sizes of the existing Rozol studies that have been published and summarized in EPA's 2004 risk assessment (EPA 2004a).

In summary, the Service has determined there are still significant data gaps on the toxicity of Rozol to nontarget wildlife species that need to be filled in order to adequately conclude little to no adverse effects. There are a large number of nontarget avian and mammalian species that will either prey upon Rozol-poisoned BTPDs or scavenge upon their carcasses. The unknown toxicological impacts to these nontarget species, especially those that are federal trust resources, lead us to request that the Nebraska Department of Agriculture disapprove the 24(c) application for Rozol to control BTPDs.

3. In-burrow application of Rozol may not effectively minimize nontarget wildlife exposure.

We do recognize that the in-burrow application of Rozol may reduce exposure to granivorous bird species if it is properly placed in the burrow according to label instructions and actually remains in the burrow. However, other small mammals, especially rodents, can enter a BTPD burrow and be exposed directly to Rozol-poisoned bait. Since the mode of action for Rozol does not cause immediate death, it can take several days before a poisoned animal dies (EPA 2004a). These protracted timeframes allow the poisoned target, or potentially nontarget, animal to exit the burrow, move to other locations, and/or die aboveground. This sets the stage for secondary exposure and potential secondary poisoning of predators and scavengers that encounter the poisoned prey animal. Thus, secondary toxicity is a concern for nontarget wildlife species regardless of where poisoned bait is applied with respect to the ground surface.

The delayed timeframe between the consumption of Rozol and actual death of the poisoned animal is likely to allow the animal to continue consuming Rozol-treated bait well above the amount necessary for a lethal dose. This may result in poisoned animals that contain very high concentrations of the active ingredient in their body tissues and fluids. Exposure of these particularly "hot" poisoned animals to predators and scavengers may exacerbate the risk of secondary poisoning.

Second, the Service is concerned that the treated bait will not remain in the burrow. There is a likelihood that the bait would be re-distributed outside of the burrow or brought to the surface by the ingress and egress movements of various wildlife species that use BTPD burrows. The attempt to minimize exposure to nontarget species would then be rendered ineffective.

Third, the proposed label instructions seem to be unclear, which could lead to the improper application of Rozol. The draft label states that "bait must be applied at least 6 inches down prairie dog burrows, measuring from the portion of the burrow that is farthest back into the tunnel. Usually this will be the top part of the burrow." The label is vague about the distinction between prairie dog burrows and tunnels and exactly where the 6-inch measurement is supposed to be taken. This may result in the bait being placed too close to the surface where it could be seen and more readily accessed by other wildlife species. Again, this would negate the intention of minimizing the risk of nontarget species' exposure to Rozol through the in-burrow application. An additional concern of improper application is the potential for the applicator to purposefully place bait aboveground (perhaps due to confusing label instructions or the time involved in proper bait placement), despite the illegal nature of this act.

These points of concern with the use of Rozol for BTPD control were realized as a result of an incident that occurred on the Rosebud Reservation in South Dakota during April 2005. Although it is not legal to use Rozol for the control of BTPDs in that state, a commercial source provided the Rosebud Tribe 600 pounds of Rozol-treated bait free of charge to undertake a "pilot program" for the control of BTPDs. A considerable amount of treated bait was observed on the ground by Service law enforcement agents and biologists during site visits following the Rozol application. Numerous dead and dying BTPDs were also observed aboveground during these site visits. It was noted that many of the carcasses had been scavenged upon. After the Tribe was informed that it had performed an illegal act, the Tribe was directed by EPA to remove and properly dispose of the BTPD carcasses. The Tribe complied with EPA's directive and removed approximately 300 to 400 BTPD carcasses from the surface of the BTPD colony area. Based on this incident, it has been estimated that spring Rozol applications could leave 20 percent or more of the BTPDs in a colony aboveground and available to predators and scavengers.

We recognize that the Rozol label for BTPD use in Kansas requires the applicator to re-visit the site and dispose of carcasses found aboveground. However, based on the experience in South Dakota, this turned into a significant burden. We are concerned that the label will not be properly followed given the amount of time and labor involved in re-visiting treated BTPD colonies multiple times plus picking up and properly disposing carcasses. If that effort is not expended, then those Rozol-killed carcasses are left for other animals, especially scavengers, to consume, leading to a potential for secondary poisoning.

Consequently, while the in-burrow application of Rozol may reduce exposure to grain-eating birds, we have not seen data that demonstrate this application method minimizes the exposure to other nontarget species. Thus, concerns about Rozol's toxicity to nontarget wildlife species, as discussed in number 2 above, should be resolved prior to the approval of this proposed 24(c) application for Rozol to control BTPDs.

4. Rozol has not been adequately proven to be an effective control for BTPD.

EPA has a minimum efficacy criterion of 70 percent activity reduction (EPA 2004b). We have only seen unpublished efficacy information on BTPD control by Rozol from research conducted by Dr. Charles Lee with Kansas State University. A 2002 study by Dr. Lee resulted in a Rozol efficacy of 68 percent for BTPD control. Dr. Lee also presented data from a 2004 study that produced an 87 percent mean efficacy rate for controlling BTPDs with Rozol. All of these studies were in-burrow applications of Rozol-treated bait. The amount of bait applied to each burrow in the 2002 study is unknown; however, the 2004 study applied ¼ cup (53 to 54 grams) to each burrow.

In 2004, the Kansas Department of Agriculture approved a 24(c) permit label for Rozol to be used as a BTPD bait (EPA SLN No. KS-040004). The Kansas Rozol label is identical to the proposed Rozol label submitted to the Nebraska Department of Agriculture for use in Nebraska to control BTPDs. During July 2004, EPA produced an unpublished report (EPA 2004b) that reviewed the efficacy of the Kansas Rozol product (KS-040004). In this report, field trial data from Dr. Lee that was submitted to EPA is summarized and assessed (EPA 2004b). The field trials were conducted in 2002 and 2003. The 2002 data is probably from the same 2002 study mentioned in the preceding paragraph. However, the 2003 data appears to be from an additional study. The EPA efficacy review document (EPA 2004b) summarizes the 2003 data and provides two efficacy rates of 61 percent for three baited BTPD colonies and 53 percent for seven baited BTPD colonies (with a mean efficacy rate of 57 percent for all ten colonies). The amount of Rozol-treated bait applied in each burrow was ¼ cup.

All of the studies conducted by Dr. Lee have determined efficacy of Rozol by a "plugged burrow" methodology. This method assumes that the number of plugged burrows that are opened or unplugged is indicative of prairie dog activity and can be correlated to the number of BTPDs in a colony. Thus, a reduction in burrow activity is considered to be indicative of a reduction in the BTPD colony. However, this method has received criticism for its assumption. The EPA efficacy review document mentions some concerns with this method due to plugged burrows not being opened by BTPDs immediately (EPA 2004b). For example, BTPDs have been reported to stay underground for several days during severe weather (Hyngstrom and Virchow 1994 as cited in EPA 2004b). Sullins (1982) conducted as study using in-burrow application of strychnine to control BTPDs in Montana. Efficacy was determined by two different methods, the plugged-burrow method and a visual observation method. Sullins (1982) provided the following discussion on the two methods:

> "Although well used burrows were selected for plugging, many burrows (even on the control plot) were never reopened once they were plugged. Other small rodents inhabiting prairie dog burrows may have also affected the plugged hole census by

> removing the plugs. In the opinion of this investigator, visual observations gave much more reliable efficacy results in this study."

In summary, the Service is concerned that the efficacy of Rozol for controlling BPTDs has not been adequately established since several studies by Dr. Lee have efficacy rates that do not meet EPA's minimum efficacy criterion. Further, there is a discrepancy between Dr. Lee's 2003 and 2004 studies. Both of these studies applied ¼ cup of Rozol-treated bait per burrow, yet the resulting mean efficacy was 57 percent for 2003 compared to 87 percent for 2004. Finally, we have concerns about the methodology used to determine efficacy in Dr. Lee's studies. Our concerns have been re-iterated and recognized in the scientific community (Sullins 1982). Also, we do not believe that the proposed 24(c) permit application to use Rozol for controlling BTPDs should be considered until the true efficacy for BTPD control can be adequately determined. Therefore, the Service respectively requests that the Nebraska Department of Agriculture disapprove the 24(c) application to use Rozol for BTPD control.

5. The Kansas 24(c) SLN permit for the use of Rozol to control BTPD (KS-040004) may not have been properly evaluated and reviewed prior to approval. The existence of this permit should not be used as evidence to support the approval of a similar 24(c) SLN permit in Nebraska.

All of the facts and concerns we have presented thus far in this letter to support the disapproval of the proposed 24(c) SLN permit request in Nebraska also apply to the use of Rozol to control BTPDs in Kansas. Unfortunately, it appears that extenuating circumstances led to the Kansas Department of Agriculture's (KDA) approval of Rozol to control BTPDs. The EPA (2004b) report that addresses the efficacy review of KS-040004 also expresses conclusions and concerns similar to those that we have presented in this letter. Of particular interest is a conclusion in the EPA report that there is not a proven "special local need" for Rozol that cannot be satisfied through the use of existing licensed pesticide products, and a concern about Rozol's true efficacy (EPA 2004b). It appears that EPA allowed Kansas to proceed with the 24(c) permit and label for KS-040004 due to some loopholes and technicality issues. The Service is unaware of the exact reasoning; however, the EPA (2004b) efficacy review report provides some insight. The following statement is included in that EPA report:

> "The rationale by which KS-040004 was considered to be suitable for 'special local needs' labeling supplemental to LiphaTech's Rozol® Pocket Gopher Bait ([EPA Registration Number] 7173-184) is rather thin at present and would become inapplicable if the label for that product is modified as it is expected to be at the time of product reregistration."

The EPA report further states that it does "...not know who in EPA provided KDA with the interpretation of Section 2(ee) [of the Federal Insecticide, Fungicide, and Rodenticide Act] that they opted to use as a basis for proceeding with KS-040004" (EPA 2004b).

Contrary to the decision made by KDA, the South Dakota Department of Agriculture (SDDA) rejected a request in 2005 for a 24(c) SLN registration of Rozol Pocket Gopher Bait® to control BTPDs. The Service was able to obtain a screened copy of the SDDA letter in response to the

24(c) SLN registration request. The following four reasons were provided by SDDA for its rejection or disapproval of the request:

1) Legality. There was no SLN because other federally registered products are available for prairie dog control.
2) Efficacy. It was determined that other, federally registered pesticide products are more effective at controlling BTPDs. Additionally, SDDA concluded that "Rozol requires several feedings, and possibly follow-up treatments, to be effective."
3) Environmental hazards. Rozol presents a "significant secondary poisoning hazard" and, as a result, the site must be monitored for dead BTPDs and carcasses must be collected and disposed of properly.
4) Cost. Based on the cost of labor, number of pre- and post-treatment visits necessary, and the cost of the bait, SDDA estimated "the per acre costs of Rozol treatments to be at least 50% higher than zinc phosphide treatments."

6. In-burrow application and carcass pickup are required label restrictions that are essential to protect wildlife resources. These restrictions would likely negate perceived labor and cost benefits of Rozol.

BTPDs generally have to feed on Rozol-treated bait multiple times before a lethal dose is consumed (EPA 2004a). Additionally, the proposed 24(c) label for Rozol indicates that multiple treatments to all active burrows within the BTPD colony are sometimes necessary to effectively reduce the BTPD population. On the other hand, pesticide products currently registered for BTPD control do not require multiple feedings or multiple treatments of the pesticide to achieve reductions in BTPD populations. Admittedly, zinc phosphide does require pre-baiting with untreated bait prior to application of treated bait (in essence, two visits to the colony to apply bait). However, as mentioned above, Rozol generally requires two treatments with treated bait to achieve high efficacy rates, which also results in two visits to the colony to apply the bait. There are other pesticides, such as aluminum phosphide and gas cartridges, that are available to control BTPDs that do not require two visits to the colony to apply bait.

Due to secondary poisoning concerns, the proposed 24(c) label for Rozol requires that all dead animals found above the ground (following treatment of Rozol) be collected and disposed of properly either off-site or on-site in holes dug at least 18 inches deep. Due to the necessary multiple feedings and the longer time involved for an animal to die from Rozol (because it is an anticoagulant), this will result in numerous visits to the BTPD colony to search for BTPD carcasses. This, in turn, increases the cost of labor to properly apply Rozol to control BTPDs. Labels for some of the other pesticides currently registered for BTPD control do not have specified requirements about collecting and properly disposing of BTPD carcasses.

Additionally, the proposed 24(c) label for Rozol requires that the applicator retrieves and properly disposes of any bait that is spilled aboveground or inside the burrow within 6 inches of the entrance. This requirement has the potential to greatly increase the amount of time needed to properly apply Rozol compared to the amount of time needed to apply some of the other approved pesticide products. This, again, will add to the cost of labor to use Rozol for BTPD control.

Finally, we have been informed that the cost of Rozol bait for control of BTPDs would most likely be similar to the cost of zinc phosphide bait. However, the amount of Rozol-treated bait that is used for each in-burrow application is significantly greater than the amount of zinc phosphide that is used for each application by the outside of a burrow or mound. Specifically, ¼ cup (53 to 54 grams) of Rozol-treated bait is used for each burrow compared to 1 teaspoon (4 grams) of zinc phosphide-treated bait. Regardless of whether the costs of the two baits are similar, the total cost of Rozol bait to treat a given BTPD colony will be much greater than the total cost of zinc phosphide bait.

Based on the concerns that we present in this letter, we request that the Nebraska Department of Agriculture not issue the 24(c) SLN registration for Rozol to control BTPDs in Nebraska. Thank you for providing us the opportunity to provide comments. Questions or need for additional information regarding this matter by members of your staff may be referred to Ms. Christina Lydick within our office at christina_lydick@fws.gov or (308) 382-6468, extension 14.

Sincerely,

John Cochnar
Acting Field Supervisor

Literature Cited

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