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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