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February 17, 2011

Michael H. Simpson
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DELIVERED BY COURIER

Regional Hearing Clerk (E-19J)
U.S. EPA, Region 5
77 West Jackson Boulevard
Chicago, IL 60604

Dear Regional Hearing Clerk:

Re: *In the Matter of Liphatech, Inc.*
Docket No. FIFRA-05-2010-0016

On behalf of Respondent, Liphatech, Inc., I enclose for filing an original and two copies of Respondent's First Supplemental Prehearing Exchange.

Please file-stamp one of the enclosed copies and kindly return it to me in the enclosed postage prepaid envelope. Thank you for your assistance.

Respectfully submitted,

Michael H Simpson

Michael H. Simpson

REINHART\6083273

Encs.

cc Honorable Susan L. Biro (w/encs., by courier)
Ms. Nidhi K. O'Meara (C-14J) (w/encs., by courier)
Mr. Carl Tanner (w/encs., by courier)

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REGIONAL HEARING CLERK
USEPA
REGION 5

Docket No. FIFRA-05-2010-0016
In the Matter of Liphatech, Inc.

CERTIFICATE OF SERVICE

I, Michael H. Simpson, one of the attorneys for the Respondent, Liphatech, Inc., hereby certify that I delivered one copy of the foregoing Respondent's First Supplemental Prehearing Exchange, to the persons designated below, by depositing it with a commercial delivery service, postage prepaid, at Milwaukee, Wisconsin, in envelopes addressed to:

Honorable Susan L. Biro
Office of the Administrative Law Judges
Franklin Court Building
1099 14th Street, NW, Suite 350
Washington, D.C. 20005; and

Ms. Nidhi K. O'Meara (C-14J)
Office of Regional Counsel
U.S. EPA, Region 5
77 West Jackson Boulevard
Chicago, IL 60604

I further certify that I filed the original and one copy of the Respondent's First Supplemental Prehearing Exchange and the original of this Certificate of Service in the Office of the Regional Hearing Clerk, U.S. EPA, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, by depositing them with a commercial delivery service, postage prepaid, at Milwaukee, Wisconsin, on the date below.

Dated this 17th day of February, 2011.

Michael H. Simpson
One of the Attorneys for Respondent
Liphatech, Inc.

REINHART\6083340LNR:JES 02/17/11

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	**Docket No. FIFRA-05-2010-0016**
	)	
Liphatech, Inc.	)	**Hon. Susan Biro**
Milwaukee, Wisconsin,	)	
	)	
Respondent.	)	
	)	
	)	

RESPONDENT'S FIRST SUPPLEMENTAL PREHEARING EXCHANGE

Respondent, Liphatech, Inc. ("Liphatech"), through its undersigned attorneys, hereby submits Respondent's First Supplemental Prehearing Exchange pursuant to Section 22.19(f) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits ("Consolidated Rules"), codified at 40 C.F.R. § 22.19(f).

I. Legal Standard

The Consolidated Rules provide:

> (f) *Supplementing prior exchanges*. A party who has made an information exchange under paragraph (a) of this section, or who has exchanged information in response to a request for information or a discovery order pursuant to paragraph (e) of this section, shall promptly supplement or correct the exchange when the party learns that the information exchanged or response provided is incomplete, inaccurate or outdated, and the additional or corrective information has not otherwise been disclosed to the other party pursuant to this section.

40 C.F.R. § 22.19(f).

The information that is submitted as part of Respondent's First Supplemental Prehearing Exchange was either not yet created or not in Respondent's possession at the time Respondent filed its Initial Prehearing Exchange on October 28, 2010. Furthermore,

the information offered by Respondent will provide a more complete and accurate record in this proceeding.

Complainant will not suffer any prejudice as a result of this submission. Because the hearing date in this proceeding has not yet been set, Complainant will have ample opportunity to review the information prior to hearing.

II. Additional Exhibits

Respondent hereby supplements its Initial Prehearing Exchange to add the following exhibits:

RX NO.	Title of Document	Date of Document	Bates No.
89	Letter to Martha Kauffman, Managing Director, Northern Great Plains Program, World Wildlife Fund regarding World Wildlife Fund Petition to the U.S. Environmental Protection Agency for Suspension of Rozol Prairie Dog Bait dated June 5, 2009	November 16, 2010	4277-4304
90	Memorandum by Arnet Jones and Timothy Kiely, Benefits Assessment for Chlorophacinone (Rozol©) Use to Control Black-Tailed Prairie Dogs, DP 374422 (Note: pg. 11 missing in original)	August 3, 2010	4305-4320

III. Conclusion.

Respondent respectfully submits its First Supplemental Prehearing Exchange in accordance with the Consolidated Rules and hereby reserves the right to continue to supplement its Prehearing Exchange in accordance with the Consolidated Rules.

Dated this 17th day of February, 2011.

Respectfully submitted,

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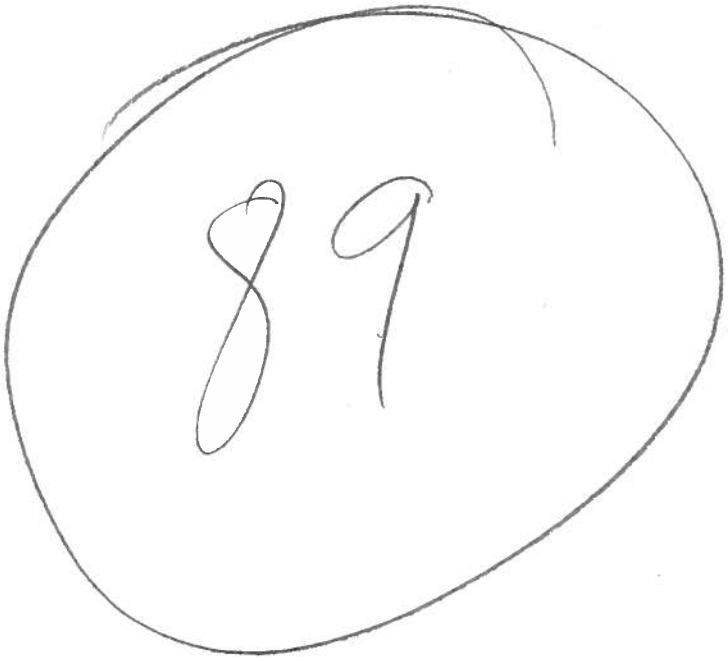
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 16 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Martha Kauffman, Managing Director
Mr. Steve Forrest, Manager of Restoration Science
Northern Great Plains Program
World Wildlife Fund
Post Office Box 7276
Bozeman, MT 59771

Re: World Wildlife Fund Petition to the Environmental Protection Agency for Suspension of Rozol Prairie Dog Bait dated June 5, 2009

Dear Ms. Kauffman and Mr. Forrest:

This is in response to your letter of June 5, 2009 requesting that EPA suspend the registration of the chlorophacinone product, Rozol Prairie Dog Bait (EPA Reg. No. 7173-286), and cancel certain application sites for the product. The Agency has solicited and evaluated public comment on your petition (74 Fed. Reg. 51,601 [Oct. 7, 2009]) and has carefully weighed the available information bearing on your concerns.

In your June 5, letter, you asked EPA to either:

(A) Suspend use of Rozol Prairie Dog Bait. Since the suspension of a registration is an interim remedy that can remain in effect only for the duration of a cancellation proceeding, EPA interprets this as also a request to cancel the registration of Rozol Prairie Dog Bait; or

(B) In the alternative, "rescind the registration of Rozol for those counties where [black-footed] ferrets occur." EPA interprets this as a request to cancel Rozol Prairie Dog Bait to the extent necessary to prevent use in those counties where black-footed ferrets occur;

The Agency agrees with you that this product has a profile of ecological risks that require careful scientific evaluation, and that it is appropriate for the registrant to develop additional data to better characterize those risks. Regarding ecological risks involving species listed under the Endangered Species Act, we have also initiated formal consultation with the U.S. Fish and Wildlife Service (USFWS). (Ref. #1, available at http://www.epa.gov/oppfead1/endanger/litstatus/effects/). In this regard, we agree that Rozol

Prairie Dog Bait's potential to affect the black-footed ferret, and other listed species, must be properly evaluated to meet the FIFRA registration standard. However, in consideration of the risk mitigation measures already mandated for this product (including several recent amendments to the product label), the benefits that accrue from the current availability of this product, the pending consultation with USFWS, with the potential (after conclusion of consultation) to obtain further mitigation through voluntary label amendments, we do not believe that the immediate initiation of cancellation or suspension proceedings for Rozol Prairie Dog Bait is warranted. We will review the Service's biological opinion when it is available and determine, in light of that opinion, whether further mitigation is necessary to adequately address risks to such listed species.

In addition, EPA has taken or anticipates a number of related actions pertinent to your petition. The Agency:

- Is working toward the goal of entering a Memorandum of Understanding with the USFWS, consistent with Executive Order 13,186, regarding conservation of migratory birds. We are currently engaged in dialogue and background research preliminary to that goal.

- Has approved revisions to the product label which increase the carcass search requirements, limit the use season to October 1 – March 15, and incorporate more appropriate directions for carcass disposal;

- Intends to review the U.S. Department of Agriculture's (USDA) National Wildlife Research Center's study on retention of chlorophacinone in the tissues of the black-tailed prairie dogs, when such study becomes available;

- Intends to require the submission, under its FIFRA § 3(c)(2)(B) data call-in authority, of a carcass search efficiency study to determine the degree to which prairie dog carcasses are recoverable. This will provide additional information on the potential for secondary poisoning and better inform labeling mitigation statements..

- Will review the avian reproduction study currently required as a condition of registration, and intends to require the submission (pursuant to FIFRA § 3(c)(2)(B)), of a second avian reproduction study

The attachment to this letter responds to the issues raised in your petition, and describes the Agency's risk-benefit analysis in detail.

Sincerely,

Steven Bradbury, PhD., Director
Office of Pesticide Programs

enc: 9/10/10 revised label

Attachment:
Detailed Response to World Wildlife Fund Petition to the Environmental Protection Agency for Suspension of Rozol Prairie Dog Bait, Dated June 5, 2009

I. LEGAL FRAMEWORK

A. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Standard for Registration, Reregistration, and Registration Review

EPA regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The principal purpose of FIFRA is to regulate the sale, distribution and use of pesticides (through the registration process) in order to protect human health and the environment from unreasonable adverse effects associated with pesticides. See generally FIFRA section 3. Under FIFRA section 3, EPA registers a pesticide only after conducting an extensive scientific review of the risks, and when appropriate, benefits of the proposed use of the pesticide to determine whether the use of the pesticide causes "unreasonable adverse effects" to human health or the environment. FIFRA § 3(c)(5). To meet this standard, the pesticide must not pose "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." FIFRA § 2(bb)

In order to remain registered, a pesticide must be found to continue to meet this risk-benefit standard. The risk-benefit balance may be reassessed at any time or during a scheduled reassessment such as the reregistration or registration review of the pesticide's active ingredient. EPA is authorized to cancel pesticide registrations that do not comply with this standard and, in certain circumstances, to suspend those registrations pending the completion of cancellation proceedings. See FIFRA §§ 2(bb), 3(c)(5), 4(g), 6(b)(c).

Review of a pesticide under this risk-benefit standard is not simply a matter of determining whether there are risks of concern, but rather whether those risks are reasonable in comparison to the anticipated benefits of the pesticide use. First, EPA typically determines whether a particular use of a pesticide poses a meaningful risk (often referred to as a "risk of concern"). If the use does pose a risk of concern, EPA determines whether that risk may be reduced below the level of concern, for example, through changes to the terms and conditions of the registration. Where there are risks of concern, EPA will assess the anticipated benefits of the pesticide use and evaluate the impacts of new conditions or restrictions on users of the pesticide such as agricultural producers.[1] EPA will allow a pesticide to remain registered only where the anticipated benefits outweigh the risks of concern (taking into account any practicable risk reduction measures acceptable to the registrant).[2] If the Agency determines that the risks

[1] EPA also evaluates benefits in certain circumstances where there are no risks of concern (i.e., in the case of public health pesticides). Rozol Prairie Dog Bait is a public health pesticide, since prairie dogs are hosts for fleas that can carry plague.

[2] Note, however, that dietary risks are regulated under section 408 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 346a), which prohibits any pesticide chemical residue unless it is "safe". See generally § 408(b)(2).

associated with a pesticide are disproportionate to the anticipated benefits, the Agency will encourage the registrant to seek voluntary amendments to the terms and conditions of registration. If the registrant fails to make necessary changes voluntarily, the Agency will initiate appropriate regulatory action (such as cancellation under FIFRA section 6).

B. FIFRA Cancellation and Suspension

In the absence of voluntary action from a registrant to cancel a pesticide, if EPA determines cancellation is warranted, it must do so in accordance with the process set forth in FIFRA section 6(b) and EPA's regulations at 40 CFR part 164. The standard for cancellation is the same as the criteria for registration: section 6(b) of FIFRA allows EPA to initiate action to cancel pesticide registrations if the Administrator determines that use of the pesticide may generally cause unreasonable adverse effects on the environment (a term defined in section 2(bb) of FIFRA). Any adversely affected person can request a hearing on whether the standard for cancellation is met; registrations generally remain in effect until the conclusion of any cancellation proceeding.

Section 6(c) of FIFRA allows the Administrator to suspend a pesticide registration if the Administrator determines that action is necessary to prevent an "imminent hazard" (a term defined in section 2(1) of FIFRA) during the time required to complete a cancellation proceeding. Suspension under FIFRA section 6(c) is an interim remedy that can remain in effect only for the duration of a cancellation proceeding; if the Administrator determines that cancellation is not appropriate, suspension is no longer an available option under FIFRA section 6.

C. Endangered Species Act

Under the Endangered Species Act (ESA) of 1973, as amended, all federal agencies have the responsibility to ensure that any action authorized, funded or carried out by that agency is not likely to jeopardize the continued existence of any federally listed endangered or threatened species or result in the destruction or adverse modification of critical habitat. EPA is the federal agency authorized to regulate pesticide use through administration of FIFRA. Under the ESA, EPA must ensure that its activities in administering FIFRA are not likely to jeopardize the continued existence of any federally listed, threatened or endangered species.

Regulations of the USFWS and the National Marine Fisheries Service (collectively, "the Services") implementing Section 7 of the ESA require the federal "action" agencies to initiate "consultation" with the appropriate Service (in this particular case, USFWS) on certain actions that "may affect" listed species or designate critical habitat. For its part, USFWS concludes the consultation by issuing a Biological Opinion (BO) that addresses the agency action. In the BO, USFWS determines whether the proposed action is likely to jeopardize the continued existence of the listed species in question. If USFWS determines that a proposed action is likely to jeopardize the continued existence of the species, it must provide the federal agency with any available reasonable and prudent alternatives that the Service determines will preclude likely jeopardy yet still allow the proposed action to continue.

If the federal agency action may result in the taking of individuals of a listed species, the action is permitted only under an "incidental take statement" issued by one of the Services which specifies the legal terms and conditions (known as reasonable and prudent measures or RPMs) under which any incidental take of individual members of a species is permitted.

D. Executive Order 13,186

Executive Order 13,186, regarding the responsibilities of Federal agencies to protect migratory birds, directs each Federal agency taking actions that have, or are likely to have, a measureable negative effect on migratory bird populations to develop and implement a Memorandum of Understanding (MOU) with USFWS to promote the conservation of migratory bird populations.

The executive order calls for the MOU to incorporate a number of agency commitments, which are to be implemented to the extent permitted by law, consistent with appropriations and budgetary constraints, and in harmony with agency mission. The commitments include: (1) integrating bird conservation principles, measures, and practices into agency activities and (2) avoiding or minimizing, to the extent practicable, adverse impacts on migratory bird resources when conducting agency actions.

II. BACKGROUND

A. Rozol Prairie Dog Bait – State and Federal Registrations

The active ingredient in Rozol Prairie Dog Bait is chlorophacinone. Chlorophacinone (2-[(p-chlorophenyl)phenylacetyl)] 1,3-indandione) is a vertebrate control agent used to control a variety of vertebrate pests. It is a "first generation" anticoagulant—several feedings are usually required to reach a lethal dose, with death occurring 3 to 5 days after consumption of the lethal dose. Rodenticide bait products containing chlorophacinone are registered for use for the control of rodents in and around buildings, households and domestic dwellings, uncultivated agricultural and non-agricultural areas, commercial transportation facilities; industrial areas, and food processing, handling, and storage areas and facilities. While bait products intended for use against commensal rats and mice are generally approved for as frequent application as needed, most products intended for field uses have a limited application frequency. Both general use and restricted use chlorophacinone products are currently registered by EPA.

Under the authority of FIFRA section 24(c), states have the authority to register additional uses for a federally registered pesticide. Those registrations are solely for distribution and use within the state for which it was registered to meet a "Special Local Need (SLN)". Between 2004 and mid-January 2008, EPA received notice of eight SLN registrations issued by six State Lead Agencies for chlorophacinone bait manufactured by LiphaTech and targeting black-tailed prairie dogs on rangeland and non-crop areas. Kansas and Wyoming each issued two 24(c) registrations. Kansas issued an SLN in 2004 and replaced it with a second SLN in

2007; Wyoming issued an SLN in 2006, replacing it in 2007. The other 4 SLNs were issued by Nebraska and Colorado in 2006, Texas in 2007 and Oklahoma in 2008.

On January 30, 2008, LiphaTech submitted to EPA an application for federal registration under FIFRA Section 3 for the chlorophacinone product "Rozol Prairie Dog Bait" for control of black-tailed prairie dogs for use only in Arizona, Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming. EPA granted this registration in May 2009 for the states noted above, except Arizona. On June 11, 2009, EPA received LiphaTech's request for voluntary cancellation of the earlier state-issued SLN registrations. EPA published a notice of request for voluntary cancellation for these registrations on February 2, 2010, and cancelled them on October 1, 2010 (notice of the cancellations was published in the *Federal Register* on October 14, 2010). Use of Rozol Prairie Dog Bait is currently authorized based on the federally-issued registration, EPA Reg. No. 7173-286.

B. Biological Opinion, Chlorophacinone Endangered Species Concerns

USFWS addressed chlorophacinone in its Biological Opinion of March 1993 (Ref. #2). That Opinion considered chlorophacinone use for control of Norway rats, roof rats, and house mice in and around homes, industrial, and agricultural buildings; pocket gophers in underground runways; mice and voles in Idaho and Delaware; orchard mice in Delaware, Connecticut, and Arizona; deer mice in noncrop areas of Florida; ground squirrels in Arizona; deer mice, house mice, and pocket gophers in California; and indoor control of bats. The USFWS made "jeopardy" or "no jeopardy" determinations for 28 listed species that chlorophacinone may affect. Other listed species were considered either not at risk of exposure or not likely to be affected.

C. Reregistration Determination

In 1998, EPA completed its reregistration eligibility decision of the rodenticides brodifacoum, bromadiolone, chlorophacinone, diphacinone and its sodium salt, bromethalin, and pival and its sodium salt. This decision is referred to as the Reregistration Eligibility Decision (RED) for the Rodenticide Cluster (Ref. #3). It included a comprehensive reassessment of the required target data and the use patterns currently registered at that time.

EPA determined that all uses of chlorophacinone were eligible for reregistration, with the exception of certain field bait uses, provided that certain risk mitigation measures were adopted. Field-bait uses containing 0.005% chlorophacinone were eligible for reregistration but field-bait uses containing more than 0.005% chlorophacinone were determined to be ineligible for reregistration. Field tests adequately demonstrated that products with lower-concentrations of these active ingredients were sufficiently efficacious for target pest species, and that the uses with higher concentrations have the potential to cause unnecessary secondary poisonings to avian and mammalian predators and scavengers.

D. Comparative Ecological Risk Assessment for Nine Rodenticides

Following the issuance of the Rodenticide Cluster RED, EPA developed a Comparative Ecological Risk Assessment for nine rodenticides to further evaluate the potential for rodenticide bait products to pose ecological risks to non-target birds and mammals (Ref. #4). The nine rodenticides included in the comparative ecological assessment are those addressed in the rodenticide REDs: brodifacoum, bromadiolone, bromethalin, chlorophacinone, diphacinone, and zinc phosphide, as well as three other rodenticides (warfarin, difethialone, and cholecalciferol).

The comparative ecological risk assessment concluded that each of the rodenticide active ingredients poses significant risks to non-target wildlife when applied as grain-based bait products. The risks to wildlife are from primary exposure (direct consumption of rodenticide bait) to all rodenticides and secondary exposure (consumption of pesticide-bearing rodents by predators or scavengers) to anticoagulant rodenticides. Secondary exposure to the second-generation anticoagulants is particularly problematic due to these compounds' high toxicity and long persistence in body tissues (e.g., liver retention half-lives of greater than 300 days). The second-generation anticoagulants are designed to deliver a lethal dose in a single night's feeding, but since time to death is 5-7 days, the target rodent can feed multiple times before death, leading to a carcass containing residues that may be many times the rodent's lethal dose. Additionally, the extended persistence of second-generation anticoagulants in the body of a predator or scavenger can result in adverse effects from additive exposures through multiple feedings that are separated by days or weeks.

E. Request for Comment on the World Wildlife Fund (WWF) Petition

On October 7, 2009, EPA published a notice of the Petition in the Federal Register (Ref. #5) soliciting comment from interested persons. Approximately 64 comments were received in support of the petition to suspend the Rozol registration. Additionally, a public letter writing campaign supporting the suspension included more than 55,000 submissions. Commenters opposed to the suspension of Rozol totaled approximately 85 submittals. Comments on both sides were received from state and local government entities, non-governmental organizations and the general public.

III. PETITION RESPONSE

Petitioners express concern over the potential for secondary exposure and toxicity that Rozol Prairie Dog Bait may have to non-target species, particularly to the endangered black-footed ferret and migratory birds.

EPA has grouped and responded to the Petitioners' assertions as follows:

A. Petitioners Express Concern Regarding Potential for Secondary Poisoning of Non-Target Avian and Mammalian Predators and Scavengers.

B. Petitioners Assert Rozol Prairie Dog Bait Should Not Be Available For Use Until An Avian Reproduction Study Has Been Completed
C. Petitioners Assert Rozol Prairie Dog Bait is an Inhumane Method of Controlling Black-Tailed Prairie Dogs.
D. Petitioners Assert Alternative Products are Available for Black-Tailed Prairie Dog Control That Result in Less Ecological Risk.
E. Petitioners Assert That Rozol Prairie Dog Bait Was Not Registered In Compliance With EPA's "Legal and Policy Mandates."

Addressing each assertion, EPA provides:

1) A summary of the Petitioners' assertion,
2) An overview of substantive comments related to the assertion received during the comment period
3) EPA's response to Petitioners' assertion and significant related comments.

A. Petitioners Express Concern Regarding Potential for Secondary Poisoning of Non-Target Avian and Mammalian Predators and Scavengers.

1. Petitioners' Claims

Petitioners attribute Rozol's slow acting nature as a factor in exposure to non-target predators, maintaining that while above ground, poisoned prairie dogs and other prey items continue to move back and forth between burrows, thus remaining exposed to non-target predators for a period of weeks. In support, Petitioners refer to anecdotal evidence from Kansas that dead hawks had been found by landowners after Rozol was applied to black-tailed prairie dog colonies. Petitioners contend that the potential for poisoned black-tailed prairie dogs and other prey to die aboveground is a basis for concern that scavengers will consume these carcasses and become exposed to Rozol.

Petitioners voice concern regarding possible secondary impacts on predators, specifically the black-footed ferret. Petitioners' noted the death of "...badgers in Kansas after Rozol was used on prairie dogs there" and submitted two necropsy reports for badger carcasses collected in Kansas in 2006 and 2009. Petitioners also refer to anecdotal evidence from Kansas regarding additional animals such as coyotes and swift foxes that had been found dead following a Rozol application.

Additionally, Petitioners point to a 2006 USFWS letter to the EPA which cited the EPA's Risk Assessment, "*Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: A Comparative Approach.*" (Ref. #6) In this risk assessment, primary and secondary risks of nine rodenticides (including chlorophacinone) were compared and determined inconclusive because:

- toxicity data were missing
- exposure differences were not taken into consideration

- sublethal effects, such as effects on reproduction, were not taken into consideration
- bioaccumulation of chlorophacinone due to repeated exposure to sublethal levels was not considered.

Petitioners believe additional studies that examine secondary toxicity from consumption of poisoned prairie dogs must be completed.

Petitioners note much concern about the secondary impacts of Rozol on non-target endangered species such as the American burying beetle, Aplomado falcon, and, in particular, the black-footed ferret.

2. Public Comments

a. Comments in Support of the Petition to Suspend Registration

Multiple commenters expressed concern about the effects of rodenticides on raptors and mammals who scavenge or prey on prairie dogs. They noted that in 2005, illegal Rozol use in South Dakota on a prairie dog colony resulted in extensive numbers of dead and dying prairie dogs above ground which had been widely scavenged by other wildlife. They also state that mortality from secondary poisoning due to Rozol application in prairie dog towns has been documented in a badger collected in Kansas in 2006. This documentation of the badger poisoning was submitted to the record. Commenters also stated that because prairie dogs may consume much more than a lethal dose, they may be carrying in their system a "super dose" of chlorophacinone, which can result in secondary poisonings.

According to USFWS, there is anecdotal evidence that chlorophacinone concentrations in prairie dogs are higher than in other rodent species treated with the substance. Also, they state that prairie dogs have a larger body size, compared to other rodents, leading to higher secondary exposures than in other use scenarios.

USFWS contends, in a 5-year review of the black-footed ferret, that poisoning of prairie dogs is a major factor in the decline of ferrets, due both to decreases in the prairie dog population and due to inadvertent secondary poisoning of ferrets.

Commenters believe impacts to migratory birds from Rozol are of concern, reporting that raptor carcasses have been found in areas treated with anticoagulants, and that a bald eagle was recently killed from Rozol exposure in Nebraska (Ref. #7). They also note a study (Ref. #8) which found ferruginous hawks are closely linked to prairie dogs and occur in higher numbers in areas of high prairie dog concentrations.

Commenters report that there may be significant underreporting of secondary exposures to migratory birds following use of Rozol. They assert this is because it is difficult to verify impacts in the field to non-target species, which can travel long distances between the time of ingestion of the poison and death. They believe there may be underreporting of impacts to other non-target species, due to 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 (Refs. #9-11).

Commenters state that Rozol is less efficacious than other readily available products, due to the need for multiple feedings and possible follow up treatments. They believe the expense of multiple return trips to collect dead and dying prairie dogs outweighs any perceived savings from the need to only place bait once with Rozol versus a need to pre-bait with zinc phosphide (Ref. #12). They also cite a March 2006 report from Kansas State University Agricultural Extension (Ref. #13) which reportedly established that Rozol is not the least expensive of the registered toxicants available.

Commenters imply that the risk of secondary poisoning is avoided with the use of non-pesticidal techniques for prairie dog control. The HSUS commented that there are a number of non-pesticidal control techniques for prairie dog control such as tall-grass buffer zones and relocation. (Ref. #14)

b. Comments Objecting to Suspension of the Registration

The product registrant, LiphaTech, claims that under real-world conditions the risk of secondary poisoning from chlorophacinone is low because it is metabolized quickly (Ref. #15). LiphaTech references a California Department of Food and Agriculture assessment and says California has been actively monitoring wildlife for rodenticide poisoning and has found very few problems. LiphaTech states that California finds "very few problems" with primary and secondary hazards due to chlorophacinone use. LiphaTech also cites broadcast uses in Washington and Oregon and says there are few non-target issues there (Ref. #16).

LiphaTech believes that some of the secondary hazard studies represent severe "worst case" scenarios, which result in over-estimation of hazard (Ref. #17). They point to the limitations of the secondary hazard studies, namely, the summing of study results with dissimilar study methods. LiphaTech believes the dosing of rodents in the secondary hazard studies is highly unlikely to occur in the wild (Ref. #18).

LiphaTech asserts that there is a flaw in the comparative summary analysis of rodenticides (referring to Ref. #4). LiphaTech disagrees that it was appropriate for the second generation anticoagulants brodifacoum, bromadiolone and difethialone to be assigned lower summary risk values than chlorophacinone for mammals (Ref. #18).

LiphaTech indicates that it sponsored a study to look at impacts to the American Burying Beetle. LiphaTech indicates that the study found no adverse effects (Ref. #19).

Correspondence from LiphaTech dated January 20, 2006 claims that the black-footed ferret is not in Nebraska. (Ref. #15)

LiphaTech takes issue with the EPA's November 6, 2008 ecological risk assessment which states; "However, this label targets the major food source of the black-footed ferret within

much of its entire historic range, making re-colonization and recovery unlikely" (Ref. #20, referring to Ref. #19). LiphaTech claims the label for Rozol prohibits use in areas where the black-footed ferret occurs, and that EPA's statement therefore has no basis in fact.

Regarding secondary hazard to birds, LiphaTech asserts that the data clearly do not show it to be significant or even considerable (Ref. #17). LiphaTech refers to 12 avian hazard studies in which no birds died from exposure to Rozol. They note that the data show that secondary risk to birds can be minimized by proper carcass retrieval/disposal as required by the label.

LiphaTech claims that EPA's review about risks is not supported by real-world experience and that though some animals poisoned will move off site before dying many will remain onsite (Ref. #17). LiphaTech claims after poisoning "animals feel sick and usually move to the comfort of their burrow before death" (Ref. #15). LiphaTech refers to their "field efficacy" study in which they baited more than 11,000 prairie dog burrows and recovered only 9 carcasses. They state that there is no equivalent quantitative information on zinc phosphide applications (Ref. #19).

LiphaTech believes the benefits of Rozol outweigh any risks of secondary poisoning because the alternative bait (zinc phosphide) is labor intensive, sensitive to weather (degraded by moisture), and doesn't always give adequate control (Ref. #19).

3. EPA Response

EPA agrees that secondary exposure via chlorophacinone residues in carcasses and/or prey items represents a risk of concern that requires sound characterization. (See Refs. #21, 22, 23).

Exposure through this pathway remains a concern, despite the rate at which chlorophacinone is metabolized in mammals. Data indicate that average whole body chlorophacinone residue concentrations can be as high as 2.24 ppm in black-tailed prairie dog carcasses. Additionally, there is a high likelihood that an animal will be consumed as prey while the poison is taking effect. To ensure that its analysis is protective, the Agency believes that it is appropriate to consider whole body residue concentration of 2.24 ppm and to consider potential predation of intoxicated prairie dogs. The Agency consistently assesses at the maximum potential exposure levels and most sensitive toxicity endpoints (Ref. #24). This residue concentration is above the average whole body concentrations for which data is available, however, it is a concentration that has been demonstrated to occur, and use of this figure in risk management is reasonably protective of listed species.

An EPA review of the LiphaTech study "Determination of Chlorophacinone Residues in Prairie Dog Whole Body and Liver Tissue" concluded that some progress was made toward addressing secondary exposure to predators and scavengers but carcass handling methods were not described and chemical degradation is suspected in some samples. Additional studies are needed to further assess primary non-target exposure and quantify secondary exposure (Ref. #25).

EPA notes that USFWS has commissioned a study with the United States Department of Agriculture's National Wildlife Research Center to evaluate the retention time of chlorophacinone in the tissues of black-tailed prairie dogs exposed to Rozol bait. This study is currently ongoing. EPA intends to review the results of the study when it is completed.

The Agency acknowledges that other field uses of chlorophacinone exist and acknowledges the data supporting those uses. However, these use patterns and data are not sufficient to characterize the risks specific to use on black-tailed prairie dogs. For instance, the peak whole body residue concentration for black-tailed prairie dogs appears to be significantly higher than the peak whole body residue concentration for ground squirrels fed bait with the same concentration. Though this distinction is based on limited data, the finding coincides with anecdotal evidence cited by Defenders of Wildlife and USFWS that chlorophacinone concentrations in prairie dogs are higher than in other rodent species. Some field uses for pests such as pocket gophers, ground squirrels or voles have had significant incidents associated with them; chiefly among them is the take of four endangered San Joaquin Kit Foxes due to chlorophacinone poisoning. However, these incidents all involved above-ground applications of chlorophacinone. The four kit foxes died, presumably of primary exposure, by ingesting grain that had been treated with chlorophacinone. The registrant is correct in noting that no incidents have been reported for field uses of chlorophacinone in Washington and Oregon, states in which large amounts of chlorophacinone are used against voles and other rodents that are serious pests in "grass grown for seed" and other grown for seed commodities. However, the lack of reported incidents from field uses on other target species, in other locations, does not negate the potential non-target risk from use of the product against black-tailed prairie dogs, in the locations where black-tailed prairie dogs are found.

While LiphaTech asserts that the chlorophacinone concentrations in rodents in the secondary hazard studies are highly unlikely to occur in the wild, EPA believes that those levels are reasonable assumptions for a protective risk assessment. In actual use, the Rozol prairie dog bait is expected to dominate feeding activity of granivores for the period of time that it is available. It would not be unrealistic for a prairie dog or non-target granivore to feed on Rozol bait exclusively until it succumbs to anticoagulant poisoning.

The Agency finds potential for significant impacts to predators and scavengers due to secondary exposure to chlorophacinone from its use on black-tailed prairie dogs. Incidents involving two badgers, two turkeys and a bald eagle have been attributed to this use under section 24(c) labels. These incidents are noteworthy and the Agency agrees with USFWS, the Western Association of Fish and Wildlife Agencies, and Defenders of Wildlife that there may be significant underreporting of secondary exposures to migratory birds following use of Rozol. We think it is unlikely that the available incident data are complete, due to the slow acting nature of anticoagulant poisoning. Furthermore, EPA is not aware of an acceptable study on black-tailed prairie dogs that demonstrates, as LiphaTech suggests, that after poisoning "animals feel sick and usually move to the comfort of their burrow before death." The LiphaTech study "Field Efficacy and Hazards of Rozol Bait for Controlling Black-Tailed Prairie Dogs" included attempts at determining carcass availability to predators and scavengers. Due to the infrequency of carcass searches as well as narrow search ranges, EPA determined the study to be invalid (Ref. #25).

Because the Agency is unaware of reliable data indicating the frequency with which poisoned non-target animals will remain on site versus migrating off site, we presume that many more incidents are occurring than are documented, based on the slow-acting nature of chlorophacinone and the established mobility of non-target predators. Finally, EPA notes an instance of illegal use of chlorophacinone on the Rosebud Reservation in South Dakota in 2005 involving Rozol Pocket Gopher Bait used in a broadcast application to the surface with many prairie dogs being found dead and dying above ground. These prairie dogs were reportedly widely scavenged by other wildlife. While the Agency does not believe this misuse incident, standing in isolation, would appropriately serve as an adequate basis for assessing risk from the approved uses of chlorophacinone, the information nevertheless contributes to a characterization of potential risk to non-target predators and scavengers.

Notwithstanding current product labeling, which requires users to contact USFWS before using the product (but does not automatically prohibit product use) within prairie dog towns in the range of the black-footed ferret, the Agency believes there is factual basis to postulate the existence of risks involving the federally endangered black-footed ferret. This is because prairie dogs are the major food source of the black-footed ferret and the black-tailed prairie dog, in turn, is the target organism for Rozol Prairie Dog Bait. The USFWS found in a 5-year review of the black footed ferret that the poisoning of prairie dogs is a major cause for decline of the species. It is due, in part, to this evaluation that EPA has initiated formal consultation under the ESA.

Concerning limitations to the weight-of-evidence approach taken in "Potential Risks of Nine Rodenticides to Birds and Non-target Mammals: a Comparative Approach" (Ref. #4) cited by LiphaTech, any such issue is not relevant to whether or not chlorophacinone poses a risk of secondary toxicity to non-target organisms. The alternative pesticides currently available are not second-generation anticoagulants so a comparison to second generation compounds is not pertinent.

EPA disagrees with LiphaTech's claim (stated in their correspondence of January 20, 2006, Ref. #15) that the black-footed ferret is not in Nebraska. EPA's current information from the USFWS indicates that the range of the black-footed ferret extends into Nebraska.

Regarding potential impacts to migratory birds, EPA notes that in tests in which poisoned prey were offered to captive avian predators, some of the birds displayed signs of intoxication (external bleeding, internal hematoma, increase blood coagulation time). While the tests resulted in no deaths, EPA concludes that these studies showed significant sublethal effects (Ref. #23).

LiphaTech expressed surprise that EPA noted potential risk to reptiles, however, it is scientifically appropriate and consistent with EPA's policy to use avian toxicity data as a surrogate for reptile toxicity (Ref. #24).

Regarding LiphaTech's study relating to the endangered American Burying Beetle, the study has been reviewed and is discussed in EPA's September 29, 2010 document: "Risks of Chlorophacinone Use on Black Tailed Prairie Dogs to Federally Endangered and Threatened Species."(Ref. #21) While the study showed that adult burying beetle survival and fecundity is

not affected at environmentally relevant residue levels, it also showed that larvae brooding on chlorophacinone residues have reduced survival.

In reference to the use of non-pesticidal controls to avoid the risk of secondary poisoning posed by Rozol, EPA notes that it does not require submission of data on alternative methods of control of target pests. EPA understands that habitat modification may not provide sufficient remedy to a pest situation and that pesticides provide an additional necessary tool for pest management.

B. Petitioners Assert Rozol Prairie Dog Bait Should Not Be Available For Use Until Avian Reproduction Study Has Been Completed.

1. Petitioners' claims

Rozol Prairie Dog Bait was conditionally registered in accordance with FIFRA Section 3(c)(7)(A) provided that LiphaTech submits an Avian Reproduction Study within three (3) years of the date of registration. The due date of the study has since been extended to October 29, 2012, after EPA evaluated additional existing data identified by LiphaTech and determined (by letter on October 29, 2009, Ref. #26) that the submitted data do not satisfy the condition to submit an Avian Reproduction Study. Petitioners note that LiphaTech has not submitted this study and assert this study should be completed before Rozol is approved for use on black-tailed prairie dogs.

2. Public Comments

One commenter pointed out an EPA statement in the October 29, 2009 letter (Ref. #27). The EPA statement was that the Rozol registrant had not timely submitted voluntary cancellation requests for its SLNs and committed to a three-year Avian Reproduction study. The commenter believes this should be grounds for cancellation.

3. EPA Response

EPA has since determined that LiphaTech had, in fact, requested voluntary cancellation of its SLNs within 30 days of the registration date. The contrary statement in EPA's October 29, 2009 letter was erroneous.

LiphaTech responded to the avian reproduction study requirement by requesting a waiver based on their citation of two studies on the Japanese quail that it believed could be used to fulfill this requirement. These studies had not been reviewed at the time of registration and the lack of avian reproduction data was cited as a data gap. Thus, EPA required an avian reproduction study as a condition of the product registration. EPA has since determined that the submitted studies do not provide sufficient data to adequately quantify potential reproductive impairment in birds. (Ref. #28) Subsequently, LiphaTech timely committed to conduct an avian reproduction study pursuant to OPP Guideline 850.2300 and submit the study to EPA within 3 years of EPA's

October 29, 2009 letter (which notified LiphaTech that the existing studies in question were insufficient).

The requirement for the avian reproduction data is consistent with the data requirements for non-target organisms at 40 CFR 158.630. It is not specifically associated with the use on any particular target pest and so is not required solely in support of the registration for black-tailed prairie dogs. Rather, avian reproduction data is a generic data requirement for field-use registrations targeting pests outdoors. Rozol Prairie Dog Bait does not introduce any new avian reproduction issues that are distinguishable from registered formulations of chlorophacinone used for other target pests such as voles and pocket gophers.

Since issuing its October 29, 2009 letter to LiphaTech, EPA has determined that the appropriate data requirement for this product is two avian reproduction studies, one with waterfowl and another on an upland game bird species. See 40 CFR 158.630(e)(4). Therefore, EPA will issue a data call-in for a second avian reproduction study, pursuant to FIFRA § 3(c)(2)(B), to ensure that data are available for both waterfowl and an upland game bird species.

C. Petitioners Assert Rozol Prairie Dog Bait is an Inhumane Method of Controlling Black-Tailed Prairie Dogs.

1. Petitioners' Claims

As described by the Petitioner, "...the poisoned animals over a period of weeks, lose bodily fluids, mainly blood, through various orifices. In the final days or hours of exposure, the animal's skin membranes may also rupture, leading to fluid loss directly through body areas where no vents would otherwise exist." As a result of chlorophacinone's slow acting nature, poisoned prairie dogs remain active for a period of time, while they slowly become debilitated before fully succumbing to the rodenticide's effects. Petitioners believe this is an inhumane method of controlling black-tailed prairie dogs.

2. Public Comments

In their letter dated December 7, 2009, and in comments delivered in person, the Humane Society of the United States (HSUS) provided input pertaining to the humaneness of using Rozol, zinc phosphide, and other lethal methods to control prairie dogs. With respect to Rozol, HSUS supports and agrees with the Petitioners' view (Ref. #14 and #29). HSUS also stated that Rozol, along with other anticoagulants, are inhumane to any animal that consumes them; any animal that dies from ingestion of an anticoagulant suffers inhumanely, experiencing moderate to severe pain and distress for an average of one to three days before death. HSUS further asserted that animals suffering from sublethal effects also experience pain and suffering. Finally, HSUS asserted that zinc phosphide poisoning is also painful, and expressed the overall view that prairie dogs should not be controlled using lethal methods

The South Dakota Chapter of The Wildlife Society (SDTWS) cites the lengthy period of morbidity before death as inhumane and listed this as a reason for Rozol's registration to be

rescinded. Additionally, the People for the Ethical Treatment of Animals (PETA) expressed similar feelings as those of the HSUS stating, "The willful infliction of such unimaginably horrific suffering...must surely fall well outside any EPA goals for humane treatment of wildlife (Ref. #30 and #31."

3. EPA Response

EPA respects the commenters' concerns and acknowledges that the use of rodenticides results in the killing of mammals. While EPA is concerned about harm to all organisms, we recognize that pesticides, by their very nature, frequently result in the mortality of the target pest. Our charge is to evaluate pesticides and make risk-benefit decisions regarding unreasonable adverse effects on the environment. EPA supports the use of integrated pest management (IPM) and non-chemical control methods. Thus, we encourage persons affected by prairie dog populations to consider whether non-lethal control measures (e.g. encouragement of taller vegetation, addition of visual barriers, live traps and relocation) are sufficient to manage populations in their particular circumstances. Ranchers and farmers have indicated that they prefer not to use lethal baits due to the cost and labor intensity (Rozol must be hand-applied down each burrow). Rodenticides are thus considered to be an additional tool in the IPM toolbox and not necessarily the first and only step in a control program. Furthermore, Rozol has a limited availability since the use season is restricted to one or two applications during the winter months between October 1 and March 15.

The agency notes that there is a long history of use of anticoagulant pesticides to control rodent pests. Anticoagulants such as chlorophacinone have been registered in the U.S. for over 30 years. Chlorophacinone is registered for use against rodents such as rats, mice, voles, ground squirrels, chipmunks, muskrats and pocket gophers. Since black-tailed prairie dogs are also rodents, EPA does not regard the use of an anticoagulant to control black-tailed prairie dogs as presenting, in this respect, any significant new concerns.

D. Petitioners Assert Alternative Products are Available for Black-Tailed Prairie Dog Control That Result in Less Ecological Risk.

1. Petitioners' Claims

The petitioner notes the availability of alternative products, containing zinc phosphide, to control prairie dogs. The petitioner states that prairie dogs that have ingested Rozol can survive for "weeks" (and be available to predation), while zinc phosphide will kill prairie dogs in "hours". Thus, according to the petitioner, chlorophacinone (as compared to zinc phosphide) has a longer period in which a dying prairie dog is disoriented and in distress, making it more of a target for secondary predation.

2. Public Comments

Public comments (Refs. #10, #11, and #32) asserted the following:

- Compared to zinc phosphide, with chlorophacinone there is a longer period in which a dying prairie dog is disoriented and in distress, making it a target for secondary predation
- Chlorophacinone is more persistent in body tissues than zinc phosphide, leading to a higher risk of secondary poisoning. Recent studies (Refs. #4 and 33) indicate that anticoagulants pose a greater risk of secondary poisoning than zinc phosphide

LiphaTech asserts that Rozol is safer for non-target birds and mammals than Zinc Phosphide, because the LD50 dose for chlorophacinone is much larger than the LD50 dose for Zinc Phosphide (Ref. #15). LiphaTech also notes that while zinc phosphide is broadcast on the ground surface, chlorophacinone is placed 6 inches into burrow openings when used to control prairie dogs.

The Wildlife Society claims that Rozol is less efficacious than other readily available products (e.g., zinc phosphide) due to the need for multiple feedings and possible follow up treatments. (Ref. #12). While chlorophacinone use avoids the need to pre-bait (as is required with zinc phosphide), they believe that the expense of multiple return trips to collect dead and dying prairie dogs outweighs any perceived savings from this distinction.

The Nebraska Farm Bureau Federation commented (Ref. #34) that the Nebraska SLN registration for Rozol Prairie Dog Bait (issued in February, 2006) was in place until March of 2009. Under the SLN registration, the Nebraska Department of Agriculture (NDA) required significant monitoring activity for Rozol use and application. As part of this effort, the NDA also conducted significant monitoring of Rozol at application sites. The results of the NDA monitoring reported Rozol to be a highly effective prairie dog control product with "virtually no risk to non-targeted species." The Kansas Decatur Animal Control and Decatur County Commissioners reported (Ref. #35) that fewer non target animals access chlorophacinone than zinc phosphide because chlorophacinone is placed in the burrow of active black-tailed prairie dogs. Zinc phosphide is placed above ground where it is accessible by all who travel through the treated site; this is open to any seed eating bird that travels through as well as any forage eating mammal. NDA notes that they have witnessed a few dead meadow larks as well as cottontail rabbits on these sites and have seen just a few prairie dogs that were on the ground. On chlorophacinone sites that were treated, only one prairie dog was found, which was buried on site. They have not seen any predators feeding on sites treated although they noted seeing where some digging was done (the hole was not over 6-8 inches below the surface). They conclude that if the label is followed chlorophacinone is as safe as or safer to use than zinc phosphide.

The Colorado Department of Agriculture suggested (Ref. #36) that EPA's assessment, "Potential Risks of Nine Rodenticides to Birds and Non-target Mammals: A Comparative Approach" indicates that zinc phosphide is higher risk than chlorophacinone for use on black-tailed prairie dogs.

3. EPA Response

Both zinc phosphide and chlorophacinone rodenticides may adversely affect non-target organisms. EPA notes that zinc phosphide use is associated with a large number of non-target animal exposures and deaths. Currently there are fewer reported chlorophacinone non-target incidents than reported zinc phosphide incidents. The types of risk to non-target animals from zinc phosphide and chlorophacinone are very distinct. EPA does not claim zinc phosphide is safer than chlorophacinone for use on black-tailed prairie dogs—rather that risks of both pesticides need to be fully characterized for this use. Mortality from zinc phosphide poisoning is rapid and can occur just over an hour after ingestion. Given this, animal carcasses poisoned by zinc phosphide can be found in obvious places because the animal does not necessarily have time to find a concealed place to die. Chlorophacinone poisoning occurs over a period of days potentially allowing the animal to find a less obvious place to expire, below ground or above ground, making it both less available for predation and scavenging and more difficult for applicators to find when searching for carcasses. However, EPA is not aware of an acceptable study to substantiate such a conclusion about carcass availability. Thus, the currently available data are insufficient to establish, among pesticides used to control black-tailed prairie dogs, whether zinc phosphide use entails less risk to the environment than chlorophacinone use. For the relative benefits of chlorophacinone for black-tailed prairie dogs, refer to Section F.

EPA's "Zinc Phosphide Reregistration Eligibility Document" (Ref. #37) stated that the use of zinc phosphide presents a hazard to non-target wildlife. The RED reported that zinc phosphide is highly toxic to birds on an acute basis and highly to very highly toxic to small mammals. Because zinc phosphide bait for black-tailed prairie dogs is applied on the surface of the ground, on top of and around the burrow, non-target granivores may be exposed. The RED noted that mortality of non-target rodents during the management of prairie dog and ground squirrel colonies from zinc phosphide applications was documented. Baiting in orchards produced mortality in rabbits, gallinaceous birds, and grain-eating passerine birds. Six birds of a group of 24 found dead in a sugarcane field that was treated with zinc phosphide were found to have eaten the bait. Mortality from zinc phosphide applications also was documented for deer, chickens, upland game birds, waterfowl, and aquatic invertebrates in Hawaii. Canada geese were killed in baited alfalfa enclosures.

EPA has received information from states such as Michigan where wild turkeys, ring-necked pheasants, black and gray squirrels, Canada geese, and possibly white-tailed deer have died from zinc phosphide poisoning. Wild turkeys were apparently the most seriously affected Incidents were also documented in Logan, Kansas where 42 turkeys died from zinc phosphide poisoning. If non-target wildlife feeds on zinc phosphide bait, they will most likely be killed. Because of this risk, the label requires any spilled or unused bait to be buried.

The zinc phosphide bait products are classified as Restricted Use because of their inhalation risk to humans, and also because of their hazard to non-target species. Although only one application is permitted in a use season, the use season is 3 months longer than that for Rozol. Zinc phosphide may be applied from July through February, covering mid- to late summer when many animals are active.

There is also some risk of secondary poisoning from zinc phosphide. The zinc phosphide RED states that if a target animal eats the toxicant and is subsequently eaten by a predator or a

scavenger, secondary poisoning may occur to the predator or scavenger. The RED cited a study in which Siberian ferrets showed non-lethal acute intoxication following secondary zinc phosphide poisoning. The risk of secondary poisoning is low because zinc phosphide does not accumulate in the tissues of the target animal. The primary source of zinc phosphide to a carnivorous or scavenging animal is the digestive tract of the target animal, where un-reacted zinc phosphide may remain. Most animals, when given a choice, refuse to eat the digestive tract of poisoned animals. The RED, however, cited a study in which the authors stated "Many cases of secondary poisoning have involved cats and dogs, possibly because these species have been noted to consume stomach contents of poisoned animals in laboratory studies, whereas wild carnivores tend to avoid consuming the GI tract."

EPA concluded in the RED that predators or scavengers who eat a target animal that has been killed by zinc phosphide will not be killed. They may become ill, listless, and regurgitate. However, EPA has determined that secondary poisoning from zinc phosphide cannot be completely dismissed. The labels for zinc phosphide baits include the warning "Dogs and other predatory and scavenging mammals might be poisoned if they feed upon animals that have eaten this bait."

The Colorado Department of Agriculture is correct in some regard in noting that EPA's 2004 assessment, "Potential Risks of Nine Rodenticides to Birds and Non-target Mammals: A Comparative Approach" indicates that zinc phosphide is higher risk than chlorophacinone for use on black-tailed prairie dogs. The assessment states that:

– Brodifacoum and difethialone stand out as the two rodenticides posing the greatest potential overall risk to birds and non-target mammals, followed by bromadiolone and diphacinone. Zinc phosphide also ranked high for overall risk based on the comparative analysis modeling, primarily because of high potential primary risks.

– Brodifacoum, difethialone, and zinc phosphide pose the greatest potential primary risks to birds that eat bait. A single zinc phosphide or brodifacoum bait pellet provides more than an LD50 dose for a small bird. In contrast, a small bird would need to eat more than twice its body weight in bait pellets to ingest a comparable dose of a first-generation anticoagulant in a single feeding.

Rozol Prairie Dog Bait is registered for black-tailed prairie dogs only. Zinc phosphide baits are registered for black-tailed, white-tailed, and Gunnison's prairie dogs. Because zinc phosphide is registered in more states, against more target species, and for a longer use season, the opportunity for non-target exposure is expected to be greater than for Rozol.

E. Petitioners Assert That Rozol Prairie Dog Bait Was Not Registered In Compliance With EPA's "Legal and Policy Mandates."

1. Petitioners' Claims

Petitioners note that, at the time of the petition, EPA had not initiated formal consultation with the United States Fish and Wildlife Service (USFWS), under the Endangered Species Act, regarding the registration of Rozol Prairie Dog Bait. Petitioners also note that EPA has not entered an MOU with USFWS to implement Executive Order 13,186 and promote the conservation of migratory bird populations. Petitioners urge EPA to conduct the consultation and enter such an MOU. Petitioners further urge EPA to suspend the registration of Rozol Prairie Dog Bait until these steps have been taken.

2. Public Comments

Comments from numerous stakeholders urged EPA to promptly conduct appropriate Endangered Species Act consultation with USFWS. LiphaTech commented that "there is no need for this process to affect the registration status of Rozol Prairie Dog Bait," whereas other commenters contended that EPA should first withdraw or rescind the registration of this product, pending the outcome of the consultation process.

Comments from numerous stakeholders urged EPA to promptly enter an MOU consistent with Executive Order 13,186.

3. EPA Response

EPA recognizes its substantive and procedural duties, under section 7(a)(2) of the Endangered Species Act, to ensure that its actions are not likely to jeopardize the continued existence of any federally listed endangered or threatened species or result in the destruction or adverse modification of critical habitat. EPA has initiated formal consultation with the USFWS regarding the registration of Rozol Prairie Dog Bait.

EPA also acknowledges petitioners' concerns for the protection of migratory bird populations. EPA is actively engaged in developing a Memorandum of Understanding (MOU) with USFWS, to describe our collaborative approach to promoting the conservation of migratory bird populations. In response to Executive Order 13,186, Steve Owens, the Assistant Administrator for EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) attended the first meeting of the Council for the Conservation of Migratory Birds on December 3, 2009. Since then, EPA's Office of Pesticide Programs (OPP) has taken the lead in this process. OPP staff have been regularly attending Council staff meetings, improving our understanding of bird conservation issues and contributing ideas for best management practices related to bird conservation. OPP staff are currently conducting the background research necessary for the development of an MOU with the USFWS. However, since the finalization of an MOU necessarily depends on the mutual agreement of EPA and USFWS, EPA cannot make a unilateral commitment to enter such an agreement.

The procedural circumstances described by the petitioner (relating to the status of consultation under the Endangered Species Act and the current absence of an EPA-USFWS MOU under Executive Order 13,186) do not establish a basis for suspension under FIFRA. Suspension addresses circumstances in which not only are cancellation proceedings warranted but further immediate action is also necessary to prevent an imminent hazard during the time

required for such cancellation proceedings. See FIFRA § 6(c)(1). "Imminent hazard" is defined in section 2(l) of FIFRA to cover circumstances where continued use of a pesticide: (1) would likely result in an unreasonable adverse effect on the environment within the time required for a cancellation proceeding; or (2) will involve unreasonable hazard to the survival of a species listed as threatened or endangered under the Endangered Species Act. These standards turn on EPA's substantive judgment as to the potential effects of a pesticide, not on the procedural status of consultation or coordination pursuant to other laws or executive orders.

EPA does not believe that the procedural circumstances noted by petitioners (i.e., that EPA has not completed an endangered species consultation for Rozol Prairie Dog Bait, or developed an MOU under Executive Order 13,186) themselves establish the existence of an "imminent hazard," as that term is defined under FIFRA. Furthermore, petitioners do not expressly assert that the use of Rozol Prairie Dog Bait poses an imminent hazard.

F. FIFRA Risk Management Determination

EPA received the application for registration of Rozol Prairie Dog Bait under FIFRA Section 3 in February 2008. Prior to EPA's receipt of the Section 3 application, six State Lead Agencies had registered Rozol Prairie Dog Bait under FIFRA section 24(c): Colorado, Kansas, Nebraska, Oklahoma, Texas and Wyoming.

That six states issued SLN registrations targeting the black-tailed prairie dog indicated the existence of an interregional pest problem. Ten states are known to be inhabited by the black-tailed prairie dog, which is the most common and widespread of five prairie dog species endemic in North America.

EPA believes that as a black-tailed prairie dog population increases (as measured by the proportion of the area the colony covers), they may begin to compete with livestock for forage and may significantly reduce weight gain and thus livestock health and productivity. EPA analyzed the impact of prairie dog competition on livestock revenue per head and considered ranchers' reports that black-tailed prairie dogs are capable of rendering large areas of land unsuitable for cattle grazing. (Refs. #38, 42) The analysis suggests that, as prairie dog density increases or as a colony expands, livestock producers will face increasing competition and will, at some point, decide to take action. This point will depend on highly localized factors, including pasture productivity, forage composition, and the expansion rate of the colony, and larger economic factors such as cattle prices, input costs, and control costs , as well as the producer's perception of damage caused by the prairie dog. Economic data presented in the analysis indicates that when 60% of pasture is colonized by prairie dogs, the loss in net operating revenue compared to un-colonized pastures reaches nearly 30%.

Both non-lethal and lethal control measures are available for control of black-tailed prairie dogs. Non-lethal approaches are limited to pasture management, use of visual barriers, and live trapping. Since prairie dogs prefer short vegetation, any pasture management practice that encourages taller vegetation may discourage prairie dogs from expanding into new areas,

and may even force a town to relocate. Conversely, since prairie dogs avoid tall vegetation, overgrazed pastures are favorable for town establishment and expansion.

In general, these practices have had limited application in grazing operations in the past. Construction of visual barriers, (fences, hay bales, etc., to block the prairie dog's view) has also been tried in the past with little success, in part because of the high construction and maintenance cost. Trapping using leg-hold or body traps is labor-intensive and expensive, and may only be applicable to small areas. None of these approaches have been shown to be cost-effective, although trapping and relocating is possible with small populations and when volunteer groups contribute labor to relocating the prairie dogs, and when there are suitable areas available for relocation. There may be other restrictions that vary by state.

Poison baits are the most common control method when significant population reductions are needed. While other lethal measures are available (e.g., shooting or fumigating), they are typically impractical as a long-term management strategy, generally because they are labor-intensive or prohibitively expensive.

Zinc phosphide bait presents higher risk to applicators than chlorophacinone bait. Acute toxicology data of these formulations places zinc phosphide bait products in Toxicity Category II, which means they are more toxic to humans than Rozol Prairie Dog Bait, which is in Toxicity Category III. Thus, zinc phosphide baits are labeled with the signal word "Warning" while Rozol is labeled with the signal word "Caution."

The labels of the zinc phosphide products both state: "May be fatal if inhaled." Due to this very serious risk to the applicator, these products require the use of a respirator. The labeling also states "Harmful if absorbed through the skin or swallowed. Causes eye irritation." The toxicity profile of these formulations as communicated through the Precautionary Statements and First Aid sections of the labels is much more severe for the zinc phosphide products than for Rozol, indicating that these products are much riskier to handle and apply. While both zinc phosphide and Rozol are classified as Restricted Use (RU), the RU statement for the zinc phosphide products states: "Restricted Use Pesticide Due to Inhalation Hazards to Humans and Hazards to Non-target Species." The RU statement for Rozol is "Restricted Use Pesticide Due to Hazard to Non-target Organisms."

The State Lead Agencies and others have reported to EPA that zinc phosphide baits are not always efficacious. In making their determination of a Special Local Need in 2006, the Colorado Department of Agriculture (CDA) noted that in order to obtain good control, prairie dogs must be conditioned to accept the bait by prebaiting since bait aversion can develop. CDA also listed the following limitations of zinc phosphide, compared to chlorophacinone (Ref. #36):

- Applicators may not have the skill to evaluate acceptance of grain during pre-baiting. If they are not accepting the grain during prebaiting, then application of the bait will be ineffective
- Prairie dogs that take a sub-lethal dose will develop bait avoidance, due to the rapid onset of symptoms
- Zinc phosphide will degrade rapidly under wet and snowy conditions

- Zinc phosphide can only be used one time per year
- Zinc phosphide can only be applied to rangeland grasses with less than 50% ground cover. This limits the use of zinc phosphide in areas that have more abundant vegetation.

Aluminum phosphide is used to kill prairie dogs through fumigation. It is activated by moisture in the air and releases phosphine gas. It is extremely dangerous for applicators and bystanders, with a number of fatalities associated with several of the products.

EPA concurred that a Special Local Need existed for those States which issued 24(c) registrations for Rozol based on the fact that only one other bait existed, zinc phosphide, and that its efficacy was inconsistent, especially due to the potential problem with bait acceptance.

EPA understands that when an applicator chooses bait from an economic standpoint, they may prefer Rozol even though it costs more than the zinc phosphide products. Eliminating the skilled labor requirement for prebaiting with zinc phosphide is apparently a relevant factor for such applicators. Prebaiting necessitates observation to ensure that the black-tailed prairie dogs consume the untreated oats. At least one zinc phosphide product suggests scattering several different types of grains in a few places to determine whether prairie dogs are accepting grains and which they prefer. Application sites must be examined to determine when all or most of prebait has been taken, prior to applying the zinc phosphide. Thus, the prebaiting requirement may be time consuming and labor intensive. Additionally, multiple trips through a colony can make prairie dogs wary and reduce the acceptance of the baits.

A commenter (Ref. #11) suggested that the apparent willingness of applicators to pay a premium to avoid the pre-baiting labor requirements associated with zinc phosphide is indicative that such applicators will not likely comply with the carcass search requirements on the Rozol Prairie Dog Bait label. But EPA does not believe that this theory represents evidence of a widespread and commonly recognized practice of disregarding carcass search requirements. Applicators may have a variety of reasons to prefer one prairie dog control product over another. As described above, these may relate to applicator skills, the timing and location of desired application, and the conditions under which application will occur. Furthermore, EPA does not believe there is a sufficient factual basis to presume that the carcass-search requirements of Rozol Prairie Dog Bait are so onerous as to render the product unmarketable if used as directed by the label. EPA's communications with ranchers and farmers on tribal and private lands have not led us to conclude that applicators will disregard the carcass search requirements (Ref #39). In fact, we understand ranchers tend to look for "success" of the Rozol baiting program and monitor the application area to ensure that the bait has been consumed and the population affected through observed decline in prairie dog activity. Additionally, state pesticide lead agencies are charged with enforcement of label requirements such as carcass searches. For example, the Nebraska Department of Agriculture required those using Rozol under the SLN to complete significant monitoring activities when applying the product and afterwards (Ref #40) The South Dakota Department of Agriculture stated that they plan to reprioritize inspection resources to monitor compliance with the label requirements of Rozol (Ref #41). For the above reasons, EPA believes it is appropriate to base its risk management determination on product use that complies with the product label requirements.

Since Rozol Prairie Dog Bait was registered in May, 2009, EPA has learned from applicators that while they want to have the tool available, applications of bait are very expensive and the decision to use them is not made casually. In addition to the cost of the baits, a certified applicator must be hired to apply Rozol (except where the rancher or an employee is certified). For this reason, lethal baits are not applied on a continuing and unending basis. It generally is not necessary for ranchers to use lethal methods annually. Instead, to prevent repopulation, experts recommend that lethal treatments be used in 3- to 5- year intervals (Ref. #42)

EPA has recently approved an application by LiphaTech to modify the label for Rozol in certain ways that contribute to the mitigation of ecological risk from this product (an updated copy of the product label incorporating these changes is attached to this response):

- The use season has been revised to a final end point of March 15 regardless of spring green-up.
- The frequency of mandatory carcass searches has been significantly increased, and the initial search must now occur within four days of application.
- Carcass disposal language now accommodates circumstances in which burial is impracticable (such as when the ground is frozen), to ensure proper disposal even in such circumstances.

EPA's risk management conclusion is that while the use of this product presents ecological risks of concern, given the benefits of the product the immediate initiation of cancellation or suspension proceedings for Rozol Prairie Dog Bait, while consultation with USFWS is ongoing, is not warranted. Upon completion of consultation with USFWS, EPA will determine whether further mitigation is necessary to adequately address risks to listed species. In reaching this conclusion, EPA is mindful:

- that the colonization of available grazing land by prairie dogs can lead to significant revenue reductions among livestock producers;
- that the alternatives to poison bait and fumigation have not been demonstrated to effect significant reductions in prairie dog populations;
- that chlorophacinone bait presents fewer safety issues for the applicator than zinc phosphide bait or aluminum phosphide fumigant;
- that in certain circumstances chlorophacinone bait is more effective or more expedient to apply than the available alternatives; and
- zinc phosphide demonstrates high potential for primary risks with a number of nontarget incidents associated with its use

In reaching its risk management conclusion, EPA found the following mitigation factors to be particularly pertinent:

- The product's Restricted Use classification. Only certified applicators may purchase Rozol, and these sales are tracked. Rozol must be applied by them or under their supervision. Thus, only a limited set of individuals with knowledge of product labeling and the habits of the target species have access to Rozol.

- Use is limited to one or two applications in the period between October 1 and March 15 of the following year. This is when prairie dogs reside primarily underground and surface activity is at a seasonal low.
- Application is below ground only, into the burrow.
- Post-use carcass searches are required. Any prairie dogs that may die above ground must be disposed of according to the label (buried if practical or disposed of by other methods that insure the carcasses are inaccessible to scavengers). A commenter expressed concern about the potential for scavengers to subsequently excavate buried carcasses (Ref. #43). EPA nevertheless expects burial to reduce the risk of secondary exposure to scavengers. The product label states that carcasses must be buried at least 18 inches below the surface or in inactive burrows. The label requires covering and packing the hole with soil. It also recommends that the applicators do carcass collections in late afternoon near sundown to reduce the potential of nocturnal animals finding carcasses.

EPA shares petitioners' particular concern about potential risks to the black-footed ferret, a federally-listed endangered species. Risks to the ferret are of particular concern because the ferret preys almost exclusively on the black-tailed prairie dog, and uses the black-tailed prairie dogs' burrows as habitat. (Ref. #21). EPA agrees that these risks must be addressed in a manner that meets FIFRA's standard for registration. However, EPA does not believe that an immediate grant of the relief petitioners have requested (cancellation action to prevent use in those counties where black-footed ferrets occur), in advance of the conclusion of consultation with USFWS, is warranted. EPA reaches this conclusion, in part, based on the existing mitigation measures and benefits associated with Rozol Prairie Dog Bait, listed above. EPA also recognizes that its receipt of USFWS' biological opinion will be critical to conducting a full evaluation of the risks and, to the extent additional mitigation is warranted, whether actions other than the county-by-county off-labeling (and potentially inconsistent with such off-labeling) might reduce risk to the black-footed ferret more effectively or with less loss of product benefits.

EPA may update its conclusions based on its review of additional relevant information, such as the following:

- The biological opinion of USFWS, concluding consultation under Section 7 of the Endangered Species Act.
- The results of the upcoming USDA chlorophacinone tissue retention study
- The results of the carcass search efficiency study (which EPA is requiring pursuant to FIFRA § 3(c)(2)(B))
- The results of two avian reproduction studies
- Any FIFRA § 6(a)(2) incident reports submitted in connection with the product

IV. ACTION ON PETITION

For the reasons set forth in the attached response, the petition is PARTIALLY DENIED. EPA does not believe that immediate action to suspend or cancel the registration, while consultation with USFWS is ongoing, is warranted. However, EPA has determined that further data (results

of a carcass search efficiency study and a second avian reproduction study) are required to maintain the registration in effect, and intends to require the submission of those data pursuant to FIFRA § 3(c)(2)(B).

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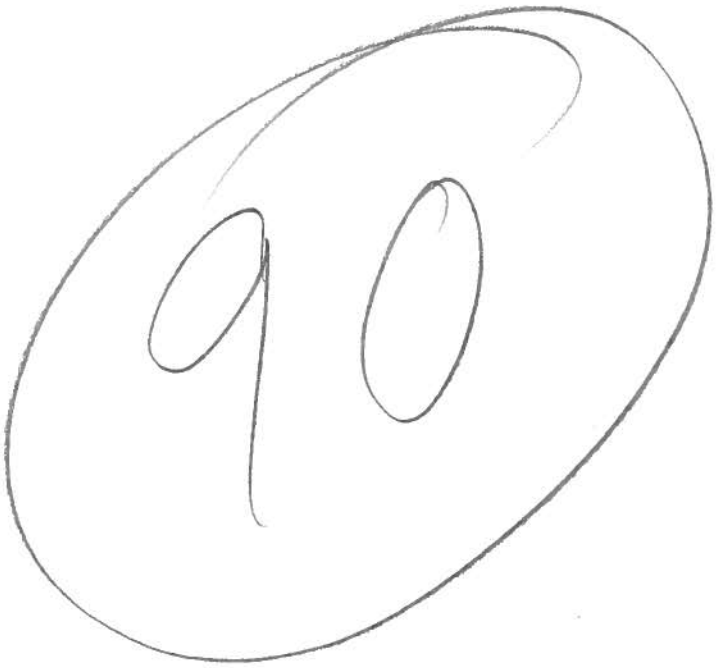
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

AUG 0 3 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Benefits Assessment for Chlorophacinone (Rozol®) Use to Control Black-Tailed Prairie Dogs, DP 374422

FROM: Angel Chiri, Entomologist
Colwell Cook, Entomologist
Biological Analysis Branch

T J Wyatt, Senior Economist
Elizabeth Hill, Economist 7/28/10
Economic Analysis Branch
Biological and Economic Analysis Division (7503P)

THRU: Arnet Jones, Chief for Arnet Jones 3 Aug 2010
Biological Analysis Branch

Timothy Kiely, Chief For Timothy Kiely
Economic Analysis Branch
Biological and Economic Analysis Division (7503P)

TO: Jennifer Gaines, Risk Manager Reviewer
John Hebert, Risk Manager
Meredith Laws, Chief
Insecticide and Rodenticide Branch
Registration Division (7505P)

Product Review Panel Date: June 9, 2010

Summary

In 2009, the U.S. EPA Office of Pesticide Programs (OPP) registered chlorophacinone as a poison bait for use against black-tailed prairie dogs under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This registration is intended to replace state

registrations in Nebraska, Kansas, Colorado, Texas, Wyoming, and Oklahoma under Section 24(c) of FIFRA for special local needs and to provide consistency in use directions. The federal registration has been contested by several stakeholder groups, including a petition filed by the World Wildlife Fund (WWF) requesting that the registration be rescinded over concerns regarding secondary impacts on non-target species. This document reviews information received as part of the public comment period on the petition, as well as other literature, to assess the extent to which chlorophacinone provides benefits, especially to livestock producers, beyond that provided by other available control measures, primarily zinc phosphide.

The principal benefit of chlorophacinone bait to users is a substantial reduction in the time and labor required for effective use. Chlorophacinone is unlikely to result in bait aversion and does not require prebaiting. Bait aversion occurs in relatively fast acting poisons, like zinc phosphide, when prairie dogs ingest a sub-lethal dose, become ill, and consequently refuse to consume more of the baited material. As a result, the level of control is reduced. This leaves a population that can quickly return to levels that directly compete with livestock production. Bait aversion can be avoided with proper prebaiting, but prebaiting, like baiting itself, is labor intensive and requires a certain level of skill. Further, multiple trips through a colony can make prairie dogs wary and reduce the performance of baits. Further, zinc phosphide converts to phosphine gas when exposed to moisture, reducing it effectiveness in damp conditions and when precipitation occurs.

A secondary benefit of chlorophacinone is that post-application requirements for disposal of dead prairie dogs and remaining bait are more flexible than those for zinc phosphide and could permit livestock producers to incorporate follow up searches for carcasses and remaining bait with general checks on livestock. One disadvantage of chlorophacinone, however, may be the higher chemical cost, although the savings in labor may result in similar overall application costs with zinc phosphide.

Background/Purpose

Six states, Nebraska, Kansas, Colorado, Texas, Wyoming, and Oklahoma, registered chlorphacinone bait for use against prairie dogs between 2004 and 2008. A Section 3 registration of prairie dog bait containing chlorophacinone (Rozol©) was approved by the Office of Pesticide Programs of the EPA on May 13, 2009. On June 5, 2009, the World Wildlife Fund (WWF) filed a petition requesting that EPA suspend the registration of Rozol© prairie dog bait over potential effects on non-target species, including endangered species and migratory birds. On July 10, 2009 a lawsuit was filed by Defenders of Wildlife and Audobon of Kansas against EPA for violating Federal laws, including the Migratory Bird Treaty Act, the Endangered Species Act, and the Bald and Gold Eagle Protection Act, with the registration of Rozol for prairie dogs.

This analysis, prepared in support of the Agency's response to the WWF petition, examines the role of chlorophacinone bait in the control of the black-tailed prairie dog, *Cynomys ludovicianus*. BEAD recognizes that many individuals and groups consider prairie dogs to be a keystone species with a unique role in the ecosystem, while others consider prairie dogs to be pests that need to be controlled or managed.

Depending on the location, large populations, town-building habits, and burrowing activities of prairie dogs may conflict with human interests, especially ranching and agricultural activities. As is often the case with many other animal and plant "pests," the pest status of an organism can be highly variable. A ground cover plant, for instance, may be a beneficial ornamental that helps to protect the soil and prevent erosion in some situations. The same plant, if allowed to grow and expand unchecked, becomes a "weed" as it invades adjacent areas, outcompeting and choking other plant species. In this regard, prairie dogs become pests when they begin to compete with human interests and their activities result in some form of economic damage.

There is also concern that black-tailed prairie dogs could be vectors of zoonotic diseases, including tularemia (Avashia, *et al.*, 2004), monkeypox (Bernard and Anderson, 2006), and plague (CDC 1997; Reynolds, 2006). None of the diseases are unique to prairie dogs and most cases of transmission are from wild-caught prairie dogs sold for the commercial exotic pet trade (Aveshia, *et al.*, 2004; Bernard and Anderson, 2006). The plague bacterium, *Yersinia pestis*, is usually transmitted by bites from infected fleas. Many mammals can harbor the disease, including prairie dogs (CDC, 1997; Reynolds, 2006; FWS, 1999). Plague epizootics cause nearly 100% mortality in affected prairie dog colonies in 3-4 days (Barnes, 1993). However, few cases of plague in humans are attributable to prairie dogs, and most of those are through cats and dogs picking up the fleas and bringing them home (Azad, *et al.*, 2004; FWS, 1999; CDC 1997, Reynolds, 2006). Therefore, BEAD concludes that prairie dog control, by any means, would not provide substantial benefits through a reduction in vector borne disease.

This assessment briefly discusses the potential for conflict between prairie dogs and livestock production and methods of prairie dog control, and concludes that there are situations where prairie dog control is valuable. Following this is a qualitative assessment of the benefits of chlorophacinone in light of the availability of other control measures, especially zinc phosphide bait an alternative poison.

Black-Tailed Prairie Dogs Biology

The black-tailed prairie dog is the most common and widespread of five prairie dog species endemic to North America. Black-tailed prairie dogs are social rodents that currently inhabit approximately 1.2 million acres (Henderson, 1979), primarily in the short grass and mixed-grass prairies of the Great Plains states of Montana, North Dakota, South Dakota, Wyoming, Nebraska, Colorado, Kansas, Oklahoma, New Mexico, and Texas.

Black-tailed prairie dogs are burrowing rodents related to ground squirrels. They weigh about 2-3 lb, feed primarily on grasses and herbaceous plants, and have a single generation per year. Individual colonies, or towns, may occupy from one to several thousand acres (May, 2001), with a density of around 30 individuals per acre (see Miller, 2007). Prairie dogs prefer grazing on short vegetation and modify the ecosystem by encouraging the growth of certain plants, while reducing the growth of grasses, which affects the species composition and abundance of other rodents and birds in the area (Agnew, *et al.*, 1986; Sharps and Uresk, 1990). Prairie dogs are considered an ecological "keystone species," as many wildlife species depend on the habitat created by their foraging and burrowing activities (May, 2001; Sharps and Uresk, 1990).

Prairie Dogs – Livestock Interaction

Prairie dogs seem to benefit from grazing by domesticated livestock and bison. Grazing helps to keep grasses lower, affording the prairie dogs better views of approaching predators (Breland, *et al.*, undated). Grazing by cattle and sheep has been proposed as a method of improving prairie dog habitat in Utah (Elmore and Messmer, 2006) and exclusion of cattle or reduced stocking rates may be a means of regulating prairie dog populations (Uresk *et al.*, 1981).

There is variability in the reported dietary overlap and forage consumption equivalence for black-tailed prairie dogs and cattle. Depending on their abundance, prairie dogs can compete for forage with other grazing mammals, including cattle. Dietary overlap between prairie dogs and cattle has been estimated to be between 60 and 76% (see Krausman, 1996).

Overall, there are competing effects from prairie dog browsing on forage availability. Prairie dogs consume grasses, which would otherwise be available to cattle, but this may stimulate additional growth resulting in higher quality forage (Breland *et al.*, undated; O'Meila *et al.*, 1982). This is less likely to occur in more arid conditions. Moreover, as time passes, prairie dogs alter the balance of species within the colony area away from grasses towards forbs, which tend to be less palatable for domesticated livestock (Breland, *et al.*, undated). However, Breland, *et al.* (undated) state that bison grazing on prairie dog colonies have a nutritional advantage over those grazing on undisturbed prairie and that antelope and elk also seem to show a preference for grazing in and around prairie dog colonies. Collins *et al.* (1984) found no statistical difference in total forage production between ungrazed areas and areas grazed by prairie dogs, but that usable cattle forage decreases by 51 kg/ha in areas grazed by prairie dogs. Another rodent with somewhat similar characteristics, Richardson's ground squirrel, was estimated to reduce alfalfa production by 31% on average (Johnson-Nistler *et al.*, 2005), but this likely far exceeds damage to pasture production that is characterized by multiple forage species. Johnston-Nistler *et al.* found that producers tended to slightly underestimate the extent of losses attributable to damage from ground squirrels.

The overall impact of prairie dogs on domestic livestock production appears to vary by situation, with factors such as rainfall and grass type playing an important role. O'Meila, *et al.* (1982) found that steers grazed on pastures in Oklahoma with prairie dogs gained less weight than those grazed on pastures without prairie dog competition. However, the difference was not statistically significant. The authors classified the area as being moderately productive. Uresk and Paulson (1988) found that optimal stocking rates in South Dakota declined as much as 10% as pasture area occupied by prairie dogs increased from 0 to 20%. In a six-year study in Colorado, Derner, *et al.* (2006) found that livestock weight gain, under moderate stocking rates, declined with increasing percentage of pasture colonized by prairie dogs. The relative decline per animal was estimated at about 0.2% for each percentage increase in area colonized and was statistically significant. The study area was short-grass steppe and the authors hypothesized that impacts could be larger in more productive ecosystems since prairie dogs tend to reduce ground cover to the same height regardless of the height of undisturbed grass. It should be noted that Uresk and Paulson (1988) and Derner *et al.* (2006) are among the few studies that relate losses to measures

of prairie dog population, *i.e.*, percent of pasture colonized, instead of simply with and without prairie dogs.

To understand the implications of reduced weight gain, BEAD used a partial budget analysis, based on the data from Derner, *et al.* (2006), which examined a summer stocker operation (Table 1). This type of operation purchases weanling calves in the spring, runs them on pasture for about five months, and sells them as feed steers in the fall. Costs are derived from an enterprise budget for Western Kansas (Dhuyvetter and Langemeier, 2009). Calves in the Derner *et al.* (2006) study averaged 578 pounds (263 kilograms) at the beginning of the season and put on an average of 270 pounds (122.5 kilograms) over the course of the summer. Starting weight and weight gain from Derner *et al.* may be higher than is typical. Dhuyvetter and Langemeier (2009) base their budget on a starting weight of 550-pound calves and a weight gain of 225 pounds. Similarly, a stocker enterprise budget from the Texas High Plains used a starting weight of 500-pound calves and a weight gain of 225 pounds for the season (TCE, 2007). For this analysis, BEAD uses a starting weight of 550 pounds, as in the Kansas budget, with a weight gain of 270 pounds, as in Derner, *et al.* (2006). With prairie dogs colonizing 20% of the pasture, Derner, *et al.* estimate weight gain to be 5.5% less than without prairie dog colonies, or about 255 pounds. If 60% of the pasture is colonized by prairie dogs, estimated weight gain is about 232 pounds, or 13.9% less than on uncolonized pasture.

Derner *et al.* (2006) based the economic impacts on a sales price of $1.10 per pound. The Kansas budget is based on a sales price of just under $1.00 per pound. The National Agricultural Statistics (NASS) report average prices of around $0.95 per pound in 2007 and 2008 (USDA, 2009c) while fall prices in 2009 were only around $0.85 per pound (USDA, 2009b). For this analysis, BEAD uses the NASS annual average of $0.95 per pound. The major expense of a stocker operation is the purchase of calves, which typically are sold at a higher price per pound. Derner *et al.* (2006) did not consider expenditures in their analysis while Dhuyvetter and Langemeier (2009) used a purchase price of $1.17 per pound in their budget. NASS reports the average price of calves over the year to be $1.19 per pound in 2007 and $1.10 per pound in 2008 (USDA, 2009c). Spring calf prices in 2009 were just under $1.10 per pound (USDA, 2009a). BEAD's analysis is based on a price of $1.10 per pound.

Dhuyvetter and Langemeier (2009) estimate operating costs to total $126 per head. However, this estimate includes the cost of summer pasture and labor, both of which BEAD considers owner-supplied. It also includes some interest costs and depreciation, which BEAD typically includes under fixed costs. Fixed costs per head, like fixed costs per acre in crop production, are highly dependent on land tenure and size and diversity of operations. Therefore, BEAD's analyses generally do not include fixed costs, recognizing that we may overestimate producer income and underestimate the impact of pest problems or regulatory changes. As a result of these changes, BEAD estimates operating costs of about $40 per head, including mineral supplements, veterinary supplies, equipment costs and fence repairs. As shown in Table 1, total operating costs are estimated to be around $645 per head. Thus, in the uncolonized pasture, net operating revenue is calculated to be about $134 per head. Given lower weight gain, net operating revenue falls to $119 per head if 20% of the pasture is colonized by prairie dogs, a decrease of over 11%, and to only $97 per head, a loss of more than 27%, if 60% of the pasture is colonized.

Table 1. Impact of Prairie Dog Competition on Livestock Revenue per Head

	Uncolonized Pasture	20% of Pasture Colonized	60% of Pasture Colonized
Sale Weight	820	805	782
Sale Price per pound	$0.95	$0.95	$0.95
Gross Revenue	$779	$765	$743
Expenses			
Stocker Weight	550	550	550
Purchase Price per pound	$1.10	$1.10	$1.10
Stocker Steer	$605	$605	$605
Other Inputs	$40	$40	$40
Total Operating Costs	$645	$645	$645
Net Operating Revenue	$134	$119	$97
Loss in Net Operating Revenue Compared to Uncolonized Pasture		-11.3%	-27.4%

Sources: Derner *et al.* (2006); Dhuyvetter and Langemeier (2009); BEAD calculations

This suggests that, as prairie dog density increases or as a colony expands, livestock producers will face increasing competition and will, at some point, decide to take action. This point will depend on highly localized factors, including pasture productivity, forage composition, and the expansion rate of the colony, and larger economic factors such as cattle prices, input costs, and control costs, as well as the producer's perception of damage caused by the prairie dog.

Prairie Dog Control

Prairie dog control techniques may be classified as nonlethal and lethal. Nonlethal approaches are limited to pasture management, use of visual barriers, and live trapping. Since prairie dogs prefer short vegetation, in part to be able to detect approaching predators and take cover in their burrows, any pasture management practice that encourages taller vegetation may discourage prairie dogs from expanding into new areas, and may even force a town to relocate. Conversely, since prairie dogs avoid tall vegetation, overgrazed pastures are favorable for town establishment and expansion (May, 2001). In general, these practices have limited appeal in grazing operations since excluding cattle and promoting the growth of tall vegetation means foregoing revenue and increasing costs. Construction of visual barriers, such as fences and hay bales, to block the view of prairie dogs has also been tried with little success, in part because of the high construction and maintenance cost. Trapping using leg-hold or body traps is labor-intensive and expensive, and may be only applicable to small areas. None of these approaches have been shown to be cost-effective, although trapping and relocating is possible when populations are small, when groups dedicated to the protection of prairie dogs are involved, and when there are suitable areas available for relocation (Lee, 2006; MDA, 2006).

Lethal methods involve shooting, the use of small explosives, burrow gassing, and the use of toxic baits. Shooting is labor-intensive and impractical as a long-term management strategy. Similarly, the use of burrow fumigants, such as aluminum or magnesium phosphide tablets and

ignitable gas cartridges, is also labor-intensive and expensive. The lethal method that has been most commonly used in the past by ranchers, farmers, and wildlife managers is toxic baits (Plumb and McDonald, undated).

It generally is not necessary for ranchers to use lethal methods annually. Instead, to prevent repopulation, experts recommend that lethal treatments be used in 3- to 5-year intervals (Ursek and Schenbeck, 1985). Although factors such as population pressure and weather play a role in how fast repopulation occurs, the years between treatments may to some extent depend on how the population was initially eradicated. For example, in the case of zinc phosphide, it has been found that completely treating colonies is more effective than partially treating several colonies in keeping population numbers down longer. Furthermore, perimeter treatments are believed to be less effective than placing baits in central areas to colonies or distributing bait in broad bands through the colony (Knowles, 1986).

Use of Toxic Baits for Prairie Dog Control

Currently, two active ingredients, both formulated as bait, are registered for black-tailed prairie dog control: zinc phosphide and chlorophacinone.

Zinc Phosphide

Zinc phosphide was first synthesized in 1740 and first used as a rodenticide in 1911 in Italy (Witmer and Fagerstone, 2003). Although it was first registered in the United States as a rodenticide in 1947, a zinc phosphide prairie dog bait was not developed until the mid-1970s. Zinc phosphide bait is also registered for control of several other rodents, including voles, deer mice, cotton rats, roof rats, Norway rats, kangaroo rats, pocket gophers, and ground squirrels (EPA, 1998a). Once ingested, zinc phosphide reacts with moisture in the gastrointestinal tract to liberate phosphine gas, which is the lethal agent. Death occurs from heart and kidney failure. Zinc phosphide is the rodenticide most commonly used in agriculture. It is available in ready-to-use dry baits (whole-grains and pellets) and as a dry concentrate that is used by applicators to prepare toxic baits. Zinc phosphide bait products contain 2% active ingredient and are classified as Restricted Use Pesticides.

Zinc phosphide bait is often not readily accepted by target rodents, *i.e.*, prairie dogs, because of its odor, taste, and color. Therefore, use requires prebaiting with the bait grain alone 2-3 days before applying the toxic bait, to get the prairie dogs used to feeding on that particular grain. This step improves the chances that prairie dogs will ingest a lethal dose when zinc phosphide bait is deployed before they become ill and cease feeding. If they do not ingest a lethal dose, prairie dogs will develop an aversion to the bait, often referred to as "bait shyness," and will avoid feeding on it in the future. Prebaiting requires some skill and effort. According to South Dakota's guidance, if too little is applied, not enough prairie dogs will become accustomed to the bait and control will suffer, but if too much is applied, it may attract other animals who will then consume the poison bait (Huber, 2008). If the prebait is disturbed by weather events or if the baiting cannot be conducted within 10 days, it is necessary to prebait again to achieve good results (Huber, 2008).

Zinc phosphide is an acute poison that kills target rodents as the result of a single feeding. When properly prebaited, zinc phosphide bait generally provides effective control of black-tailed prairie dog populations. Most field efficacy studies show that treatment results in burrow activity reduction in the 85% - 95% range, relative to untreated controls (Holbrook and Timm, 1985; Uresk et al., 1986). In one study, treatment with zinc phosphide bait reduced black-tailed prairie dog colony area expansion to 1%, when compared with a 65% area expansion in untreated colonies (Uresk and Schenbeck, 1987). Efficacy of zinc phosphide is dependent on weather conditions, especially precipitation, because it converts to phosphine gas when moist. In a study on Richardson's ground squirrel, Jonson-Nistler et al. (2005) found an average 58% reduction in numbers following the use of zinc-phosphide, which they blamed in part on a rain-snow event within 24 hours of treatment at one of the study sites.

Zinc phosphide bait is registered for use against black-tailed prairie dogs in rangelands, pasturelands, and reforestation seedling plantations. The bait is applied by hand, at the edge of active mounds, from July through February, when available forage is less and the bait is more likely to be consumed. A single application per year is allowed. The restricted entry interval (REI) is limited to the day of application, although some states may have more restrictive REIs. The label requires the use of protective gear and only applicators are allowed in treated areas. In addition the label does not allow use in areas inhabited by livestock. Furthermore, livestock are not allowed to graze in treated areas for at least as long as bait remains available. Zinc phosphide may not be applied to bare ground, to rangelands with less than 50% ground cover, or where plants are grown for food or feed.

Post-application requirements vary depending on the particular product. Some zinc phosphide labels require that, following application, the treated area be inspected daily, until no bait is left, and all uneaten bait and carcasses be disposed of while other labels require that all spilled or unused bait, as well as animal carcasses, be buried within three days after application.

Collins *et al.* (1984) analyzed the benefits and costs of black-tailed prairie dog control in South Dakota and concluded that poisoning with zinc phosphide was not economically feasibly. The benefits of control were an increase in available cattle forage, which was valued based on the cost of renting an area of land that would produce an equivalent amount of forage. Costs included planning, management, poison, and monitoring. Actual area treated for prairie dogs from 1978 to 1980 was used in the study. In 1979, over 50% of the area treated in 1978 had to be retreated and nearly 20% of the area treated in 1979 was retreated in 1980, suggesting relatively poor efficacy or rapid repopulation. Collins *et al.* assumed that benefits were obtained only if the area did not require retreatment and the authors did not include benefits of preventing further spread of prairie dogs. Even if the area retreated annually was only 5% of the original area, Collins *et al.* estimated it would take more than 20 years to recover the original control costs.

Chlorophacinone

Chlorophacinone is a first-generation anticoagulant that was first registered in 1971. When ingested, anticoagulants inhibit the formation of prothrombin, a key protein in the blood clotting process, resulting in capillary damage and internal bleeding. Prairie dogs die within four to five

days after ingesting the chlorophacinone bait. Bait formulations of chlorophacinone contain 0.005% active ingredient and are registered for control of several small mammals, including commensal rodents (Norway rat, roof rat, house mouse); several native field rodents, including voles, white-footed mice, cotton rats, wood rats, muskrats, ground squirrels, and pocket gophers; jackrabbits (lagomorphs), and moles (insectivores) (EPA, 1998b). Bait products registered for black-tailed prairie dog control are classified as Restricted Use Pesticides.

According to the label, chlorophacinone bait is registered for use in rangelands and noncrop areas. Protective clothing and chemical-resistant gloves are required for the applicator. The bait is applied by hand, at least six inches down into active burrows, at the rate of two ounces per burrow, between October 1 and March 15. Two applications are allowed per year. A second application may be made if prairie dog activity persists several weeks or months after the initial application. Children, persons not involved in the application, pets, and domestic animals are not allowed in areas being treated. Livestock is not allowed to graze in treated areas for at least three days following application. There is no restricted entry interval or area restrictions involving vegetation cover. The poison is slow acting; therefore, the prairie dogs do not connect consumption of the bait to sickness or death, so bait aversion is not a problem; consequently no prebaiting is necessary. The label requires that the applicator return to the treated area within 5-10 days after application to collect and dispose of uneaten bait and dead or dying prairie dogs. A second search is to be made 14-21 days after application. Field disposal requires burial of prairie dogs a minimum of 18 inches deep and packing the hole with dirt.

In terms of efficacy, when applied according to label instructions chlorophacinone bait may reduce prairie dog numbers by about 90% (Lee, 2006). A review by EPA (Jacobs, 2009) of a study conducted by Lee and Hynsgrom (2007) indicates that the efficacy of an in-burrow application of 1/4 cup of chlorophacinone bait resulted in a prairie dog activity reduction in the 85% - 100% range, based on the closed burrows index.

EPA was able to identify only one study with a direct comparison between chlorophacinone and zinc phosphide and it pertained to control of Richardson's ground squirrel, not prairie dogs (Johnson-Nistler *et al.*, 2005). The chlorophacinone treatment reduced ground squirrel populations by 84%, while the zinc phosphide treatment achieved only 58% reduction. However, chlorophacinone bait was applied twice, once at the time of pre-baiting for zinc phosphide and again at the time of the zinc phosphide application. This likely improved the efficacy of chlorophacinone in comparison to a more typical, single application. Further, the average efficacy of zinc phosphide was reduced by rain and snow that followed an application because moisture causes it to convert to phosphine gas. In treatments not compromised by precipitation, zinc phosphide achieved an efficacy rate up to 72% reduction in ground squirrel populations. BEAD notes, however, that measures of product performance in the field must include situations with less than ideal conditions.

Comparison of Chlorophacinone and Zinc Phosphide Bait in Prairie Dog Control

As previously discussed, this assessment focuses on the value of chlorophacinone bait as a black-prairie dog management tool, keeping in mind that zinc phosphide bait, with a similar use pattern, has been in existence in the U.S. since the mid 1970s. This analysis examines if the use of a

chlorophacinone bait offers any unique advantages over zinc phosphide bait when used to control prairie dogs, or if there are special circumstances where treating with chlorophacinone bait would be more useful or convenient than the alternative.

Both bait products are Restricted Use Pesticides, and therefore require that users be certified applicators. The use of the zinc phosphide bait is limited to a single annual application, whereas chlorophacinone bait may be applied a second time, if needed. Prebaiting is required for zinc phosphide bait, but not for chlorophacinone. Using zinc phosphide bait effectively requires applicator skills for accurately judging if prairie dogs are ready to accept the toxic bait after prebaiting period. Prebaiting is a critical and necessary step, not only because it is required by the label, but also because without it, the proportion of target rodents consuming enough bait to ingest a lethal dose would be lower and a second treatment is not allowed. Furthermore, prairie dogs consuming a sub-lethal dose would feel ill, but survive and develop aversion to the bait for as long as they live. Rodents that ingest a sub-lethal dose of chlorophacinone do not develop bait aversion. Finally, zinc phosphide bait may not be applied to bare ground, or to rangelands with less than 50% ground cover, or where plants are grown for food or feed. No such restrictions apply to the use of chlorophacinone bait, which is placed into the burrow.

In response to the petition for cancellation of the chlorophacinone bait, fourteen public comments were submitted by ranchers, farmers, and wildlife managers in support of the continued registration of this product. The main point of the comments may be summarized as follows:

- Both chlorophacinone and zinc phosphide baits are equally effective, but the latter requires prebaiting (one comment).
- Zinc phosphide bait is effective, but less so than chlorophacinone; chlorophacinone provides better control than zinc phosphide (two comments).
- Chlorophacinone bait is useful, effective, or needed to control prairie dog populations; zinc phosphide is not mentioned. (eight comments).
- Chlorophacinone is more economical, does not require prebaiting, and is more cost-effective (two comments)
- Have not used zinc phosphide due to EPA warnings (one comment)

In addition, several comments affirm that the preference for chlorophacinone is because commenters perceive that it poses less risk to humans and/or non-target animals than zinc phosphide.

Based on the field studies and efficacy data reviewed above, BEAD concludes that zinc phosphide and chlorophacinone are similarly effective for managing black-tailed prairie dog populations under ideal conditions. However, chlorophacinone is likely to be more effective than zinc phosphide under a broader set of conditions. Efficacy of zinc phosphide may be reduced by precipitation or damp conditions since moisture causes it to convert to phosphine gas (see Johnson-Nistler, *et al.*, 2005). Further, prebaiting must be done correctly or the odor, color, and taste of zinc phosphide may reduce its acceptance by prairie dogs and may even result in bait avoidance in future periods. That is, the performance of zinc phosphide in providing control of prairie dogs rests critically on successful prebaiting. Therefore, using zinc phosphide bait

Table 2. Comparison of Zinc Phosphide and Chlorophacine Baits

	Zinc Phosphide	Chlorophacinone	Remarks
Use Site	Rangeland, pastureland, reforestation seedlings	Rangeland, noncrop areas	No appreciable difference
	At least 50% ground cover	No restrictions	Chlor. advantage
Application method	By hand, at edge of mound	By hand, in burrow	No appreciable difference
Application period	July – February	October – mid-March	Narrower range for chlor., but slightly longer into spring
Livestock	Grazing not allowed in treated area (indeterminate length of time – as long as bait available)	Grazing not allowed in treated area for at least 3 days	No appreciable difference; application may often occur after stock is taken off summer pasture
Max. # Applications	One	Two	Chlor. better if activity persists
Efficacy	85-95% reduction in activity	85-100% reduction in activity	No appreciable difference, but ZP efficacy can be substantially reduced by damp conditions
Bait Aversion	Possible and potentially last 2-3 years; learned behavior?	None	Aversion reduces product performance of ZP, although can be avoided with proper prebaiting
Follow-up	Daily check until no bait is left; Bury uneaten bait after three days	Two searches, 5-10 days and 14-21 days after application	Chlor. seems to provide more flexibility; more compatible with livestock management practice if stock allowed back onto treated area
Cost	$1.50/acre [1] $1.50-3.00/acre [2]	$2.80-6.00/acre [2]	Very limited information available.

[1] Miller et al. (2007). Assumes 30 burrows/acre. Estimate does not include the cost of labor.

[2] Johnson-Nistler et al. (2005). Cost of chlorphacinone half of that reported to represent a typical, single application. Estimate does not include the cost of labor.

Conclusions

Like any other organism, prairie dogs' status as a beneficial or a pest depends on the situation and their population. Even in livestock production systems, prairie dogs, forage species, and livestock exist in a complex dynamic. At low population levels, prairie dogs may improve forage quality by clipping grasses and promoting new growth. However, as population increases, as measured by proportion of area the colony covers, they may begin to directly compete with livestock for forage and can reduce weight gain, and thus livestock health and productivity. The extent to which prairie dogs are economically damaging depend on a number of factors, including local conditions, such as pasture productivity and forage composition.

A number of control measures are available, including both lethal and non-lethal means. The most cost-effective measure will generally depend on localized conditions, including prairie dog population dynamics such as the growth rate of the colony. Pasture management can slow or deter colony growth; trapping and relocation may be possible with small populations. Lethal measures such as shooting are typically used to slow growth or maintain population levels. Poison baits and fumigations are used when significant population reductions are needed. However, fumigating burrows is generally prohibitively expensive.

In summary, there are currently two poison baits available for prairie dog control: chlorophacinone and zinc phosphide. The principal benefit of chlorophacinone bait, compared to zinc phosphide, is that use is unlikely to result in bait aversion. Bait aversion occurs in relatively fast acting poisons when the prairie dog ingests a sub-lethal dose, becomes ill, and relates the illness to the consumption of the baited material. As a result, it will not consume baited material and the level of control is reduced. This leaves a population that can quickly return to levels that directly compete with livestock production. Bait aversion can be avoided with proper prebaiting, but prebaiting, like baiting itself, is labor intensive and requires a certain level of skill. Further, multiple trips through a colony can make prairie dogs wary and reduce the performance of baits. The efficacy of zinc phosphide can also be reduced under damp conditions because moisture causes it to convert to phosphine gas. However, there is insufficient information to quantitatively estimate comparative performance in the field in terms of additional forage production or livestock productivity.

Post-application requirements for chlorophacinone may also provide more flexibility because daily checks are not required immediately following application. Chemical costs appear to be somewhat higher for chlorophacinone than for zinc phosphide, but the lower labor requirements for chlorophacinone applications may make the two similar in total costs.

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