



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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Dear Mr. Thabault,

This letter transmits U.S. Environmental Protection Agency's (EPA) comments on the U.S. Fish and Wildlife Service (FWS) January 16, 2012, Draft Biological Opinion (BiOp) relative to the potential effects from the application of Rozol® Prairie Dog Bait (EPA Reg. No. 7173-286) for Black-tailed Prairie Dog (*Cynomys ludovicianus*) control to the following federally listed threatened or endangered species: American Burying Beetle (*Nicrophorus americanus*), Black-capped Vireo (*Vireo atricapilla*), Black-footed Ferret (*Mustela nigripes*), Canada Lynx (*Lynx Canadensis*), Chiricahua Leopard Frog (*Lithobates [Rana] chiricahuensis*), Eskimo Curlew (*Numenius borealis*), Golden-cheeked Warbler (*Dendroica chrysoparia*), Gray Wolf (*Canis lupus*), Grizzly Bear (*Ursus arctos horribilis*), Gulf Coast Jaguarundi (*Herpailurus (=Felis) yagouaroundi cacomitli*), Jaguar (*Panthera onca*), Mexican Spotted Owl (*Strix occidentalis lucida*), New Mexican Ridge-nosed Rattlesnake (*Crotalus willardi obscurus*), Northern Aplomado Falcon (*Falco femoralis septentrionalis*), Ocelot (*Leoardys pardalis*), Piping Plover (*Charadrius melodus*), Preble's Meadow Jumping Mouse (*Zapus hudsonius preblei*), and Whooping Crane (*Crus americana*). Throughout these comments, Rozol will be used to refer to the specific product Rozol® Prairie Dog Bait (EPA Reg. No. 7173-286). EPA appreciates the communication with FWS regarding this draft BiOp and anticipates continued communication as the BiOp is finalized. EPAs comments on the draft BiOp are included in the Attachment and are organized in the following sections:

- EPA Comments on Conservation Measures
- EPA Comments on Draft Reasonable and Prudent Measures
- EPA Comments on Scope of the Draft BiOp
- EPA Comments on Label Directions and Off-label Uses
- EPA Comments on Potential Exposure for Secondary Toxicity
- EPA Comments on Toxicity, Risk Estimation, and Risk Characterization
- EPA Comments on Incidents, and
- Other EPA Comments.

EPA makes draft BiOps available through the EPA web site (<http://www.epa.gov/oppfead1/endanger/>) and the public docket for purposes of obtaining comments on draft Reasonable and Prudent Measures and Alternatives. EPA has made clear on its web site and in the docket that any comments on other aspects of the draft BiOp submitted to EPA will be provided to FWS for consideration during development of the final BiOp. I appreciate your consideration of the comments EPA has received in the public docket related to this Draft BiOp (Docket No. EPA-HQ-OPP-2011-0909). This would include all comments with a posting date since January 17, 2012 (the date on which EPA posted the Draft BiOp to the Docket). For your convenience in retrieving these public comments, the docket may be accessed at:

<http://www.regulations.gov/#!docketDetail:dct=FR%252BPR%252BN%252BO%252BSR%252BPS;rpp=25;po=0;D=EPA-HQ-OPP-2011-0909>. An attachment (Excel spreadsheet, created using the 'export' function on the docket webpage) is provided that contains hyperlinks to each of the individual comments as well as to all the supporting material that was posted to the docket.

We look forward to continued collaboration with FWS in achieving a successful formal Section 7 consultation which will result in a final BiOp in 30 days that contains reasonable protections for listed species that co-occur in the area of Rozol use to control black-tailed prairie dogs. Please do not hesitate to contact me at (703)-305-7090 if you have any questions.

Sincerely,



Steven Bradbury, Ph.D., Director
Office of Pesticide Programs

Attachments

cc: David Berol
Donald Brady
Mark Dyner
Catherine Eiden
John Hebert
Richard Keigwin
Meredith Laws
Anita Pease
Lois Rossi

Attachment 1: EPA Comments on the FWS Draft BiOp for Rozol (dated January 16, 2012)

EPA Comments on the Conservation Measures

Black-footed Ferret Conservation Measure. EPA received from FWS the Geographic Information System (GIS) shapefiles for the current 13 black-footed ferret reintroduction areas. EPA requests that the delivery of GIS shapefiles for future black-footed ferret release sites be provided to the EPA in a timely manner. Timely delivery of these shapefiles is important as EPA requires approximately eight months before new maps in the Endangered Species Protection Bulletins (hereafter referred to as Bulletins) can be officially implemented via the EPA County Bulletin website (*Bulletins Live!*). Once the Bulletins are implemented in *Bulletins Live!*, they become an enforceable part of the pesticide label. Eight months from receipt of the shapefiles to implementation in *Bulletins Live!* provides for approximately two months for public comment and revisions, as well as six months for the regulated community to plan for upcoming pesticide applications. These timelines are described in the Bulletins implementation documentation (<http://www.epa.gov/fedrgstr/EPA-PEST/2005/November/Day-02/p21838.htm>).

Grizzly Bear Conservation Measure: The draft BiOp states that the application period for Rozol shall be restricted to December 1 to March 1 in areas where the range of the grizzly bear overlaps with the range of the black-tailed prairie dog. Previous agreements made between FWS, Liphatech, and EPA resulted in a Conservation Measure for the grizzly bear with an application period for Rozol from December 1 to March 15 in areas where the range of the grizzly bear overlaps with the range of the black-tailed prairie dog (December 13, 2011 letter from EPA to FWS and Liphatech, Docket IDs EPA-HQ-OPP-2011-0909-0033). If this is a typographical error, EPA requests that in the final BiOp this Conservation Measure be written to reflect the previously agreed upon application window (December 1 to March 15) within the grizzly bear range. If FWS has become aware of new information that supports a shorter application window (December 1 to March 1), FWS is requested to share that information with EPA.

Preble's Meadow Jumping Mouse Conservation Measure: EPA noted an inconsistency between the GIS shapefiles provided by FWS and the geographic areas for timing prohibitions specified in the draft BiOp. Conservation measures related to Rozol timing prohibitions for the Preble's meadow jumping mouse in the draft BiOp (page 8) include the following seven counties in Colorado: Boulder, Douglas, El Paso, Elbert, Jefferson, Larimer, and Weld. The species description in the draft BiOp (page 40) indicates that the known distribution of the Preble's meadow jumping mouse in Colorado includes Boulder, Douglas, El Paso, Elbert, Jefferson, Larimer, Teller, and Weld counties. EPA assumes that FWS intended to list Teller County, Colorado in the Conservation Measure for Preble's meadow jumping mouse on page 8 of the draft BiOp, and is including pesticide use limitations within Teller County as part of the County Bulletins for the Preble's Meadow Jumping Mouse.

The GIS shapefiles provided by FWS also included areas in Goshen County, Wyoming, and areas in the following Colorado counties: Adams, Arapahoe, Clear Creek,

Gilpin, Grand, Jackson, Lincoln, and Park. These counties are not specifically named in the draft BiOp as counties where the Preble's meadow jumping mouse is found; therefore, EPA plans to exclude these counties from the Bulletins. Please provide comments if EPA's conclusion regarding the counties that should be included in the maps is incorrect.

EPA Comments on Draft Reasonable and Prudent Measures

EPA's comments on RPMs are reflective of oral agreements, as appropriate, based on a February 2, 2012 meeting between EPA, FWS, and Liphatech. Comments on the RPMs are subdivided into the following categories:

- Establishment and modification of Bulletins,
- Draft reporting requirements,
- Draft RPMs to be reclassified as Conservation Recommendations, and
- Draft outreach-related activities.

Establishment and modification of Bulletins

- **Black-footed ferret (BFF) RPM 1:** *EPA will ensure Rozol will not be used in current and future ferret reintroduction areas.*
In the event that Bulletins are necessary to cover the geographic range of future ferret reintroduction areas, EPA intends to modify the Bulletins as appropriate. EPA requests that the delivery of GIS shapefiles for future black-footed ferret release sites be provided to the EPA in a timely manner. Timely delivery of these shapefiles is important as EPA requires approximately eight months before the these new maps in the Bulletins can be officially implemented via *Bulletins Live!*. Once the Bulletins are implemented in *Bulletins Live!*, they become an enforceable part of the pesticide label. The approximate eight months from receipt of the shapefiles to implementation in *Bulletins Live!* provides two months for public comment and revisions, as well as six months for the regulated community to plan for upcoming pesticide applications. The RPM's terms and conditions should be modified to expressly accommodate this implementation time, starting from when EPA receives an updated shapefile.
- **BFF RPM 5.** *The EPA will ensure that if a previously unknown wild ferret population is discovered, Rozol will not be used on that population.*
EPA intends to modify the Bulletins to reflect identification of wild ferret populations, should they be discovered. EPA requests that the delivery of GIS shapefiles for wild ferret population sites be provided to the EPA in a timely manner. Timely delivery of these shapefiles is important as EPA requires at least eight months before the these new maps in the Bulletins can be officially implemented via *Bulletins Live!*. Once the Bulletins are implemented in *Bulletins Live!*, they become an enforceable part of the pesticide label. The minimum of eight months from receipt of the shapefiles to implementation in *Bulletins Live!* provides two months for public comment and revisions, as well as six months for the regulated community to plan for upcoming pesticide applications. The RPM's

terms and conditions should be modified to expressly accommodate this implementation time, starting from when EPA receives an updated shapefile.

- **Northern Aplomado Falcon (NAF) RPM 3.** *Within the range of the northern aplomado falcon, maintain the EPA County Bulletin website so that a current listing of counties with habitat for northern aplomado falcons is available to the public.*

EPA intends to modify the Bulletins to include identification of counties containing habitat for the NAF. EPA requests that the delivery of the county GIS shapefile be provided to the EPA in a timely manner. Timely delivery of these shapefiles is important as EPA requires approximately eight months before the these new maps in the Bulletins can be officially implemented via *Bulletins Live!*. Once the Bulletins are implemented in *Bulletins Live!*, they become an enforceable part of the pesticide label. Approximately eight months from receipt of the shapefiles to implementation in *Bulletins Live!* provides two months for public comment and revisions, as well as six months for the regulated community to plan for upcoming pesticide applications. The RPM's terms and conditions should be modified to expressly accommodate this implementation time, starting from when EPA receives an updated shapefile. As the start of the 2012 Rozol use season is less than eight months away, it is not possible for this RPM to be implemented at the beginning of the 2012 Rozol use season.

Draft reporting requirements

- **BFF RPM 2.** *If an applicator or the EPA becomes aware that a ferret is known to occupy a black-tailed prairie dog colony outside of a reintroduction area, Rozol cannot be used on that colony until the ferret or ferrets have been relocated. The reintroduction site manager should be contacted.*

EPA intends to modify the labels to state that knowledge of ferrets occupying areas outside of a reintroduction area must be reported to the National Black-Footed Ferret Coordinator (contact information to be provided on label). As orally agreed to by FWS, the National Black-Footed Ferret Coordinator will be responsible for communicating any spatial and/or temporal prohibitions of Rozol use to applicators and stakeholders within the affected area (likely a period of three weeks). In addition, FWS has orally agreed to trap and relocate ferrets found outside of the reintroduction areas. The RPM's terms and conditions should be modified to reflect that this is an appropriate implementation.

- **BFF RPM 3:** *The EPA or an applicator must notify the Service if ferrets or carcasses thereof are found during any Rozol use related activities.*
- **NAF RPM 1:** *Notify the Service if northern aplomado falcons or carcasses thereof are found during any Rozol use activities.*

The EPA intends to modify existing labels to ensure that any incidents involving the BFF and NAF are collected and reported to the EPA. EPA will then provide Rozol incident reports to FWS. EPA also intends to modify Rozol labels to direct applicators to contact FWS if live BFF or NAF are observed during Rozol use activities. The RPM's terms and conditions should be modified to reflect that this is an appropriate implementation.

- **GW (Grey wolf) RPM 1:** *The EPA shall report, or require applicators to report, all sickened, dying, or dead gray wolves (regardless of their status under the ESA) poisoned as a result of Rozol use on black-tailed prairie dog colonies.* The EPA intends to modify existing labels to ensure that incidents involving the GW are collected and reported to the EPA. EPA will then provide Rozol incident reports to FWS. The RPM's terms and conditions should be modified to reflect that this is an appropriate implementation.
- **BFF RPM 4:** *The EPA in cooperation with Liphatech shall develop and maintain a system to track Rozol used for black-tailed prairie dog control and report to the Service the amounts sold/used in each of the ten states.*
- **NAF RPM 2.** *Maintain a system to track Rozol used for black-tailed prairie dog control and report to the Service the amounts sold/used in each of the ten states.* In the final BiOp, BFF RPM 4 and NAF RPM 2 should be modified to state that EPA will provide FWS staff with FIFRA Confidential Business Information (CBI) clearance the total annual Rozol production information. The final BiOp should state that this is a time limited requirement and that data will only be provided for three years. The RPM's terms and conditions should be modified to reflect that this is an appropriate implementation.

Draft RPMs to be Reclassified as Conservation Recommendations

- **BFF RPM 6.** *The EPA shall initiate or require studies to evaluate secondary toxicity of the EPA registered prairie dog rodenticides to ferrets.*
- **BFF RPM 7.** *The EPA shall initiate or require studies to demonstrate whether the label requirements that are intended to prevent secondary poisoning of non-target animals is preventing routes of secondary exposure.*
- **GW RPM 2.** *The EPA shall develop means to reduce the amount of Rozol-poisoned black-tailed prairie dogs and non-target species available for gray wolf consumption.*
- **NAF RPM 5.** *Contribute to efforts to re-establish the northern aplomado falcon within its range in the U.S.*

On February 2, 2012, EPA, FWS, and Liphatech orally agreed three draft RPMs (BFF RPM 6, BFF RPM 7, and NAF RPM 5) should be considered Conservation Recommendations rather than Reasonable and Prudent Measures. EPA believes this agreement is appropriate and that the final BiOp should be revised accordingly.

In addition, EPA requests that when moving the draft BFF RPM 6 to a Conservation Recommendation, the scope be changed to reflect evaluation of secondary toxicity of Rozol, rather than evaluation of secondary toxicity of "registered prairie dog rodenticides" as the BiOp should only address the proposed action.

EPA also requests that draft GW RPM 2 be considered a Conservation Recommendation.

The Service consultation regulations and the draft BiOp defines RPMs to "include actions that occur within the action area, involve only minor changes to

the project.....should minimize the impacts of incidental take.....are consistent with the proposed action's basic design, location, scope, duration and timing" (page 59 of the draft BiOp). EPA's concerns regarding these four proposed RPMs is that these RPMs do not involve *minor* changes and that these RPMs would not directly function to minimize impacts of incidental take. For the proposed BFF RPMs, it is unclear how requirements aimed at improving understanding of toxicity and estimating likelihood (or reduction in the likelihood) of secondary exposure occurrences would directly impact the minimization of incidental take. In addition, the BFF RPMs 6 and 7 and GW RPM 2 are similar to the draft Conservation Recommendations for the NAF (page 99-100). Finally, for NAF RPM 5, the proposed requirements address recovery and re-introduction of the NAF, rather than minimization of incidental take.

Draft outreach-related activities

- **NAF RPM 4.** *Within the range of the northern aplomado falcon, inform public users about the risks of Rozol to non-target organisms and how risks can be minimized.*

Regarding outreach-related activities, it was orally agreed on February 2, 2012, that FWS would allow EPA flexibility in implementing this RPM. For example, EPA could include content provided by FWS on its Endangered Species website (<http://www.epa.gov/espp/>) as a substitute for the brochure discussed in the implementation steps for NAF RPM 4. Any Web content provided by FWS would need to be reviewed following EPA's standard processes. In addition, this information could also be electronically provided to states that include NAF range to for their use and dissemination during certified applicator training. The RPM's terms and conditions should be modified to reflect that this is an appropriate implementation.

EPA Comments on Scope of the Draft BiOp

Page 11, 2nd paragraph. *Chlorophacinone and diphacinone are the only indandione active ingredient rodenticides currently registered for use in the United States. Both have been registered for use to control black-tailed prairie dogs under FIFRA section 24(c) for Special Local Needs and Rozol has been registered under FIFRA section 3.*

EPA Comment: There are no current registrations in the United States for diphacinone use on black-tailed prairie dogs.

Page 30, 3rd paragraph: *If EPA chooses to continue registration of Rozol and other anticoagulants for use on prairie dogs, it should first develop alternative testing protocols to evaluate their toxicity to non-target species.*

EPA comment: This draft BiOp should address concerns only regarding Rozol use, the federal action which is the subject of this consultation. Inclusion in the BiOp Conservation Measures or Reasonable and Prudent Measures for other chemicals falls outside the scope of the consultation and therefore is not appropriate.

EPA Comments on Label Directions and Off-label Uses

Page 2, third point in time line: *1990's Rozol Pocket Gopher Bait made with chlorophacinone is used off-label on prairie dogs with the EPA's authorization and begins to generate interest as a prairie dog rodenticide (Lee et al. 2005).*

Page 63, 1st paragraph: *... used under Special Local Needs labels for black-tailed prairie dog control since 2004 and as early as 1991 under a pocket gopher formulation (Lee et al. 2005).*

EPA Comment: Chlorophacinone was first approved for use on prairie dogs as a Section 24c registration (Special Local Needs) in Kansas on April 1, 2004. This label (KS-040004) was valid from April 1, 2004, to April 1, 2009. EPA does not have any record of authorization to use Rozol Pocket Gopher Bait in black-tailed prairie dog burrows. Therefore, the use described in Lee *et al.* (2005) was inconsistent with the labeling of EPA-approved products and constituted an illegal use of the pesticide.

Page 14, 1st paragraph: *Bait spilled by applicators or not entirely placed in burrows can be difficult and time consuming to collect.*

Page 16, 5th paragraph: *Even though the current label requires collection and disposal of live prairie dogs, we have encountered applicators who indicate that this is not readily accomplished.*

Page 18, 2nd paragraph: *Pamphlets produced by Liphatech indicate that little effort is needed to meet the Rozol label requirement for carcass searches and disposal of prairie dogs carcasses (Bruesch 2009, Liphatech 2009).*

Page 29, 3rd bullet: *Label requirements aimed at reducing non-target species exposure based on return site visits for weeks after the application to pick up dead and dying prairie dogs and bait are impractical, and not effective at protecting non-target species that may dig up carcasses or feed on poisoned prey during periods between required carcass searches.*

EPA comment: The Rozol label requires the applicator to collect and dispose of any bait found on the ground surface when returning to the site to collect and dispose of dead and dying prairie dogs. The label requires that the applicator must return to the site within 4 days after application and every 1 to 2 days for at least two weeks and longer if carcasses are still being found. It is illegal and a misuse of the product to use it in a manner that is inconsistent with its labeling. Ecological risk assessments conducted by EPA's Environmental Fate and Effects Division (EFED) are conducted based on label language as the legally allowable methods for use. Marketing pamphlets do not absolve the user from the legal requirement to use Rozol consistent with its labeling.

FWS has not demonstrated in the draft BiOp that the return site visits, as required by the label, are 'impractical.' Carcass search and collection as defined by the label will reduce the risk to non-target carnivores and scavengers. The label requires that carcasses be buried at least 18" deep or disposed of using other approved measures (if digging a hole is not possible). EPA is not aware of any instances of non-target animals digging up a properly buried carcass for consumption.

Page 17, 1st paragraph: *Although the Rozol label requires the search and removal of dead and dying prairie dogs following application, the limited information on applicator*

behavior indicates that few if any moribund or dead prairie dogs found on the surface are collected and disposed of in a manner that substantially reduces secondary exposure (Service 2010a, Tosh et al. 2011).

Page 18, 1st paragraph: *A recent on-farm survey on anticoagulant use in Northern Ireland found that applicators seldom followed best practice guidelines designed to maximize efficacy and reduce risk of non-target species exposure. They found that applicators almost never searched for and removed poisoned carcasses and many baited for prolonged periods or permanently.*

EPA comment: It is illegal and a misuse of the product to use it in a manner that is inconsistent with its labeling. Tosh *et al.* (2011) does not discuss prairie dog control, but rather summarizes a survey of farmers in Northern Ireland and their rodenticide use practices. It is unlikely that the survey from Northern Ireland, which mentions baiting as part of the application method, is representative of the Rozol use pattern assessed in this BiOp. It is also unclear whether the label for these anticoagulant use patterns specifies search and removal of carcasses, similar to the U.S. label for Rozol.

Page 17, 1st paragraph: *During a prairie dog meeting in 2010 attended by the EPA and hosted by the North Dakota Department of Agriculture and Standing Rock Sioux Indian Reservation, ranchers and professional pesticide applicators indicated that they do not have the time, resources or inclination to conduct multiple return visits to a Rozol treated prairie dog colony to collect dead and dying prairie dogs, and that current label requirements for two return visits to treated prairie dog towns were unrealistic and impractical.... Of particular note from that meeting was that none of the attendees had ever picked up and disposed of live prairie dogs or their carcasses after Rozol application. The Montana Department of Agriculture also questioned the practicality of the Rozol label, especially the retrieval of live prairie dogs, and expressed their belief that most applicators will have difficulty with strict adherence to the label (de Young 2009).*

EPA Comment: This town-hall type meeting was attended by members of the EPA, FWS, tribal members, ranchers from North and South Dakota, as well as staff from the North and South Dakota Departments of Agriculture. At the time of this meeting, Rozol was not registered for use in South Dakota and it had only been registered for one year in North Dakota. The draft BiOp should include information concerning the timing of the meeting in relationship to the approval of Rozol use in order to provide appropriate context for the statement that "...none of the attendees had ever picked up and disposed of live prairie dogs or their carcasses after Rozol application." EPA thinks it is likely that few, if any, attendees had applied Rozol in prairie dog towns.

EPA Comments on Potential Exposure for Secondary Toxicity

Page 23, paragraph 2: *The highest liver known chlorophacinone concentration in a black-tailed prairie dog is 8.4 µg/g ww in a black-tailed prairie dog that consumed 52.8 grams of Rozol and was euthanized two days later (Witmer 2011).*

EPA comment: EPA encourages submission of Witmer (2011) for review and inclusion in future risk assessments.

Page 27, 3rd paragraph: *Raptors are believed to be especially susceptible to secondary poisoning from Rozol given the likelihood that they can spot dead or dying black-tailed prairie dogs that are more difficult to see from a ground level perspective (Vyas 2010b) and raptors have been observed to be attracted to Rozol poisoned black-tailed prairie dog colonies (Vyas 2010a).*

EPA comment: Vyas (2010a) does not provide any quantitative data or analysis to support the conclusion that raptors are attracted to Rozol poisoned black-tailed prairie dog colonies. Observation of raptors in treated colonies is not sufficient to conclude that raptors preferentially hunt and feed in treated colonies when compared to untreated colonies.

EPA Comments on Toxicity, Risk Estimation, and Risk Characterization

Page 12, 1st paragraph: *For example, the median Lethal Dose (LD₅₀) from a single exposure of chlorophacinone to Norway rats (*Rattus norvegicus*) is 20.5 micrograms per gram (µg/g), whereas a 5-day daily dose LD₅₀ is 20 times lower at 0.95 µg/g (Jackson and Ashton 1992).*

Page 28, 2nd bullet point: *Chlorophacinone is most toxic when animals are exposed to multiple doses for multiple days. Thus, current required acute standardized toxicity tests for chlorophacinone greatly underestimate risk to non-targets [sic] animals.*

EPA Comment: EPA has reviewed additional data evaluating toxicity of a single acute oral exposure of chlorophacinone to Norway rats (MRID 41875301) that resulted in an LD₅₀ of 6.26 µg/g-bw. This endpoint, when compared to the endpoint of 20.5 µg/g-bw reported in the open literature, suggests that Norway rats exhibit a wide range of sensitivity to chlorophacinone. If the LD₅₀ of 6.26 µg/g-bw was compared to the total dose administered over five days (Jackson and Ashton 1992), the 5-day daily dose LD₅₀ is 6 times lower. While this is not an insignificant difference, it is much more typical of among-test variability in endpoints when testing methodology (e.g., dose administration) is the same among those tests. Jackson and Ashton (1992) do not present details of the laboratory methods and results (e.g., time to mortality, body weights, raw data, feed consumption, sublethal effects, laboratory conditions) which would add to the characterization of the apparent differences in sensitivities. EPA suggests that presenting this single ratio of LD₅₀s without presenting all available data and uncertainties mischaracterizes the level of confidence in the LD₅₀ values.

Toxicity tests using multiple gavage exposures are available for only one species (Norway rat); therefore, the data are insufficient to extrapolate the conclusions to all animals. Use of the dietary LC₅₀ toxicity studies (available for both birds and mammals for chlorophacinone) provides an alternative approach to evaluating toxicity with multiple day exposure periods.

Page 14, 2nd paragraph: *The Rozol application rate of approximately ¼ cup of bait (53 grams) down each active prairie dog burrow may be excessive and likely results in increased risk to non-target species... While that level of dosing likely ensures high levels of death to prairie dogs, it likely also contributes to prairie dogs consuming multiple lethal doses as well*

as providing left-over bait to remain available for non-target species to consume after the prairie dogs have been killed.

Page 29, 2nd bullet: *Based on the label application rate, excessive lethal doses per black-tailed prairie dog are likely applied and result in increased risk to non-target species. In addition to having excess bait available for direct consumption by non-target species, over-application and Rozol's prolonged toxic mode of action result in a high risk of secondary exposure to non-target species, especially those species attracted to poisoned black-tailed prairie dog colonies. A six month application season for Rozol can result in a long duration and increased opportunity for repeated exposure to chlorophacinone and/or diphacinone rodenticides as the species migrates or moves within their territory.*

EPA comment: FWS has presented no empirical evidence to demonstrate that "excessive lethal doses" are applied when the label directions are followed. Even if it was concluded that the point estimate ratio of 20 (single dose LD₅₀ compared to a 5-day daily dose LD₅₀, page 12 of the draft BiOp) presented by FWS was appropriate to extrapolate to the prairie dog LD₅₀, the statement on page 14 of the draft BiOp "53 grams of bait likely provides at least 10 lethal doses," would only be true if the exposed individuals were the most sensitive and if these individuals consumed a sufficient quantity of bait for five consecutive days. The example in this paragraph does not adequately characterize all the exposure and toxicity uncertainties and presents an unduly conservative scenario.

Although the application season is as long as six months depending on the geographic location, the label restricts re-application to the same location to only twice per season. This restriction and label requirements regarding bait clean-up should eliminate the concern for a 'long duration' exposure expressed by FWS.

Page 12, 1st paragraph: *Likewise, a dietary toxicity test that provided a measured diphacinone-treated diet for daily consumption by eastern screech-owls (Megascops asio) found that repeated low-dosage exposure over seven days increased diphacinone toxicity by more than an order of magnitude compared to an acute oral toxicity test (Rattner et al. 2011a; Vyas, personal communication, 2011a).*

EPA Comment: The mode of action of chlorophacinone and diphacinone is similar as these two chemicals belong to the same class; however, the comparison stated above requires additional characterization. This statement compares a "multiple day dietary exposure study" to a "single gavage exposure study" for two different bird species. These differences should be discussed in the BiOp prior to making conclusions regarding toxicity differences.

Page 12, 2nd paragraph: *Mortality from LD50 tests indicate two peaks in the number of black-tailed prairie dog deaths, a larger peak that occurs 9 to 14 days after exposure and a second smaller peak that occurs 17 to 20 days after exposure (Yoder 2008).*

EPA Comment: EPA recently finalized its review of the Yoder (2008) study (MRID 47333601). While the reviewer concurred that there was high variability in time to death (9 to 20 days after dosing), the data presented were not adequate (only 10 individuals at each of five dose levels, no strong dose-response relationship, and distance of two days between the "two peaks" very narrow relative to the width of the time to mortality ranges) to characterize the mortality pattern as having two separate peaks.

Page 21, 1st paragraph: *Given the similarity of chlorophacinone to diphacinone, we conclude that at least raptors (e.g., the northern aplomado falcon), and possibly other groups of species, will exhibit greater sensitivity than can be estimated from existing mallard or northern bobwhite studies.*

EPA comment: While chlorophacinone and diphacinone are similar based on chemical structure and mode of action, similar patterns in differential toxicity to different bird classes (upland game birds compared to raptors) has not been established. Bobwhite quail are not equally sensitive to chlorophacinone (LD₅₀ = 258 mg a.i./kg-bw, MRID 41513101) and diphacinone (LD₅₀ = 1630 mg a.i./kg-bw, MRID 42245201); therefore, it cannot be presumed that the relative sensitivity of bobwhite quail and American kestrels to diphacinone can be applied to the bobwhite quail data for chlorophacinone. EPA recognizes the possibility that raptors may be more sensitive to both indandione rodenticides, but does not have sufficient information to quantify the increased sensitivity.

Page 21, 2nd paragraph: *Furthermore, the LC50-based TRV does not account for potential sub-lethal effects of chlorophacinone that can decrease listed species survival and/or reproduction. Accounting for sub-lethal effects from chlorophacinone exposure such as fatigue, clotting abnormalities, and hemorrhaging is important when evaluating risk to federally listed species.*

EPA Comment: EPA has issued a Data Call-In (DCI) for avian reproduction studies conducted with chlorophacinone and is anticipating their submission. EPA requests FWS provide a threshold of adverse effects for fatigued animals is using the provided parameters. EPA also requests that FWS provide further information on how it is determined whether “fatigue” is chemically-related or caused by other stressors.

EPA Comments on Incidents

Page 13, 3rd paragraph: *Twenty-nine adult domestic pigeons (Columba livia) were poisoned with a 0.005 percent chlorophacinone wheat grain bait after a broadcast application targeted at common voles (Microtus arvalis) (Sarabia et al. 2008).*

EPA Comment: This incident occurred in Spain; the product label with application rates and methods is not available for EPA review and for comparison with application methods on labels registered by the EPA. The article does confirm that non-target mortality may occur after ingestion of chlorophacinone bait; however, it is unclear if the exposure scenario and application rate is comparable to Rozol application methods.

Page 13, 3rd paragraph: *Green droppings from these birds suggest they were consuming bait; an assumption subsequently confirmed by detection of chlorophacinone residues in these droppings (Vyas, personal communication, 2011b).*

EPA comment: EPA encourages submission of these data to EPA for review and for possible use in future risk assessments.

Page 19, 4th paragraph: *A Rozol application in South Dakota on a prairie dog colony in 2005 found approximately 400 to 500 dead and dying prairie dogs on the surface when a 160-acre densely populated prairie dog town was treated with Rozol. At that time, Rozol*

was not authorized for use in South Dakota and a subsequent investigation by EPA ensued but the outcome is not available at this time.

Comment: This is an example of an illegal use as Rozol was not authorized for use in South Dakota in 2005.

Page 27, 2nd paragraph: *More dead raptors were found in that same area of Kansas after Rozol was used to control prairie dogs in 2009 including two more ferruginous hawks and a bald eagle that were found shot and thus not tested for chlorophacinone (Service 2009c). Also in that same area of Kansas, Audubon of Kansas reported that in addition to the raptors provided to Service law enforcement in 2009 they had found an additional 17 dead hawks, mostly ferruginous hawks that were not picked up in the field.*

EPA comment: It is unclear whether these wildlife mortalities are attributed to chlorophacinone or Rozol as no definitive testing for chlorophacinone in body tissues was conducted. This level of uncertainty in characterizing the cause of mortality should be clearly stated in the final BiOp.

Other EPA Comments

Page 9, 4th paragraph and Page 10 (figure): *Range maps from NatureServe for federally listed species and/or their critical habitats were overlaid on that historic black-tailed prairie dog map to determine any overlap which was used in the EPA's BA to inform "May Affect" determinations for federally threatened or endangered species and their critical habitats.*

EPA Comment: The map of the historic black-tailed prairie dog range was obtained from NatureServe. The range maps for the listed species found in EPA's BA did not come from NatureServe but rather from the county-level data available for each species on the U.S. Fish and Wildlife's website (<http://www.fws.gov/endangered/>).

Page 14, 3rd paragraph: *Results from other studies indicate that application rates of less than 53 grams of product per active burrow can be effective at killing black-tailed prairie dogs. Sullins (1990) reported a 96 percent reduction in the visible count of black-tailed prairie dogs after providing 0.01 percent chlorophacinone product in two applications of 9 grams per active burrow for a total of 18 grams within 48 hours.*

EPA comment: The product used in Sullins (1990) has a higher percent active ingredient than Rozol (0.005% a.i.). Assuming 18 grams per burrow of the product used in Sullins (1990), the equivalent amount of Rozol is 36 grams (on a mg chlorophacinone basis) rather than 18 grams as indicated in the draft BiOp. This comparison should be corrected in the BiOp by stating that the 96 percent reduction in visible counts of black-tailed prairie dogs occurred after providing the equivalent of 36 grams of Rozol per active burrow. This is in comparison to the 53 grams of Rozol to be applied in each active burrow based on the label directions.

Page 40, 1st paragraph: *The EPA BA (Appendix A, p.20) erroneously shows the Preble's meadow jumping mouse's range to be throughout all of Wyoming.*

EPA Comment: EPA appreciates the error correction and will ensure that future assessments evaluating the Preble's meadow jumping mouse will use the current range maps.

South Dakota in 2002

Page 11, 2nd paragraph: More detailed reports were found in the same area of Kansas after 2002 were used as control points to 2002 including two more distributions found. A field report that was found that this was tested for distribution (reviewed 2002). Also in the same area of Kansas, Johnson of Kansas reported that in addition to the species provided in Section 4.01, he found an additional 17 other species. Many distributions found that were not picked up in the field. EPA comment: It is unclear whether these wildlife distributions are sufficient to distinguish or record as no definitive testing for this species in each range was conducted. This level of uncertainty in characterizing the range of continuity should be clearly stated in the final BHT.

Other EPA Comments

Page 5, 4th paragraph and Page 10, 11th paragraph: Range maps from Kansas for black-tailed prairie dogs and black-tailed prairie dogs were included on the black-tailed prairie dog map in distribution and range which was used in the EPA's BHT to inform the distribution of black-tailed prairie dogs. EPA comment: The map of the black-tailed prairie dog range was obtained from Kansas. The range maps for the black-tailed prairie dog in EPA's BHT did not come from the same source but rather from the range-level data available for each species on the 1:250,000 and 1:100,000 scale maps (see Appendix A).

Page 14, 3rd paragraph: Results from other studies indicate that application rates of less than 25 grams of product per acre may be effective in killing black-tailed prairie dogs. Solignum (1990) reported a 50 percent reduction in the visible count of black-tailed prairie dogs after applying 0.5 percent chlorpyrifos product in two applications of 25 grams per acre for a total of 50 grams a year for 4 years. EPA comment: The product used in Solignum (1990) has a higher percent active ingredient than Rowl (0.009% a.i.). Assuming 18 grams per gallon of the product used in Solignum (1990), the equivalent amount of Rowl is 36 grams for a 0.5% chlorpyrifos label. In the BHT by stating that the 50 percent reduction in visible counts of black-tailed prairie dogs occurred after providing the equivalent of 36 grams of Rowl per acre, this is in comparison to the 55 grams of Rowl to be applied in each range. This is based on the label direction.

Page 20, 1st paragraph: The EPA BHT Appendix A, 2.10 erroneously shows the Preble's meadow jumping mouse's range as the distribution of 1990.