

---

---

# UNTESTED PESTICIDE MITIGATION REQUIREMENTS: ECOLOGICAL, AGRICULTURAL, AND LEGAL IMPLICATIONS

*Nimish B. Vyas\**

I.	Introduction.....	335
II.	Pesticide Label Mitigation Statements.....	336
III.	Example: Rozol .....	337
IV.	Conclusion .....	347

## I. INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes the United States Environmental Protection Agency (EPA) to register pesticides for “distribution, sale, and use” in the United States.<sup>1</sup> The objective of the registration process is to certify that a pesticide’s use will not pose an “unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits.”<sup>2</sup> The decision to grant registration to a pesticide is predicated on a risk-benefit analysis where some level of risk from the pesticide’s use is acceptable, in relation to its benefit, as long as the pesticide is used as directed.<sup>3</sup> The directions for a pesticide’s proper use and safety are relayed to the pesticide user via the pesticide’s label.<sup>4</sup> Every pesticide sold in the United States must have an EPA-approved label on its container, and all pesticide

---

\* Research biologist, U.S. Geological Survey, Patuxent Wildlife Research Center. I am indebted to Scott Larson and Matt Schwartz, U.S. Fish and Wildlife Service; Dr. Cynthia Palmer, American Bird Conservancy; and Jason Rylander, Defenders of Wildlife, for their valuable assistance on the manuscript. I also thank the Journal’s anonymous reviewers for their comments.

1. 7 U.S.C. §§ 136–136y (2006); *see also Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)*, U.S. ENVTL. PROT. AGENCY, <http://www.epa.gov/agriculture/lfra.html> (last updated June 27, 2012).

2. 7 U.S.C. §§ 136(bb), 136a(a); *see also Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)*, *supra* note 1.

3. 7 U.S.C. §§ 136(bb), 136a(c)(5), 136a(d); *see also Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)*, *supra* note 1.

4. 40 C.F.R. §§ 156.10(a)(1)(viii), (i)(1)(i) (2012); *see also FRED WHITFORD ET AL., PURDUE UNIV. COOP. EXTENSION SERV., PPP-24, PESTICIDES AND THE LABEL 19* (Arlene Blessing et al. eds. 2004), *available at* <http://www.ppp.purdue.edu/Pubs/ppp-24/ppp24pg19-28.html#pesticide>.

labels include the statement “[i]t is a violation of Federal law to use this product in a manner inconsistent with its labeling.”<sup>5</sup> The term “use” in the above statement encompasses pesticide “storage, transportation, handling, pre-application activities, mixing and loading, worker notification and worker protection, application, post-application activities, and disposal.”<sup>6</sup> The statement on the label consequently charges the pesticide user with the legal responsibility to follow the label.<sup>7</sup>

## II. PESTICIDE LABEL MITIGATION STATEMENTS

A pesticide label’s life cycle begins as a proposed label prepared by the pesticide registrant (e.g., the manufacturer).<sup>8</sup> The proposed label is then reviewed by the EPA to ensure that the final label comports to FIFRA’s language and format requirements.<sup>9</sup> At this stage, given that FIFRA is a risk-benefit statute, if a pesticide’s risks appear to outweigh its benefits, the pesticide label may be amended so as to include mitigation measures that could reduce the risks such that they no longer outweigh the benefits.<sup>10</sup> A hypothetical example: if a pesticide that is toxic to birds is applied on the ground surface, it will be readily available to birds, but if the application method of the same pesticide were to be changed so that it would now have to be applied underground (assuming the pest is controlled), its availability to birds would be reduced. The risks to birds would outweigh the pesticide’s benefit for the ground surface application, but the change on the label to underground application would mitigate for the high risk despite the pesticide’s inherent toxicity. Hence, mitigation requirements are im-

---

5. 40 C.F.R. §§ 156.10(a)(1)(viii), (i)(2)(ii); see 7 U.S.C. §§ 136(p), (u) (providing statutory definitions for “label” and “pesticide”).

6. *Pesticide Registration (PR) Notice 2000-5: Guidance for Mandatory and Advisory Labeling Statements*, U.S. ENVTL. PROT. AGENCY (2000), available at [http://www.epa.gov/PR\\_Notices/pr2000-5.htm](http://www.epa.gov/PR_Notices/pr2000-5.htm) (last updated May 9, 2012); see 7 U.S.C. § 136(ee) (defining the phrase “to use any registered pesticide in a manner inconsistent with its labeling”); see also WHITFORD ET AL., *supra* note 4, at 19.

7. WHITFORD ET AL., *supra* note 4, at 19.

8. 7 U.S.C. § 136a(c)(1); 40 C.F.R. § 152.50(e); see also *Electronic Submissions (via formatted CD/DVD) to the Pesticide Program*, U.S. ENVTL. PROT. AGENCY, (Mar. 2012), <http://www.epa.gov/pesticides/regulating/registering/submissions/> (last updated May 9, 2012) (providing application instructions for pesticide manufacturers).

9. 7 U.S.C. § 136a(c)(3); *Electronic Submissions (via formatted CD/DVD) to the Pesticide Program*, *supra* note 8; *Label Review Manual – Table of Contents*, U.S. ENVTL. PROT. AGENCY, available at <http://www.epa.gov/oppfead1/labeling/lrm/> (last updated July 24, 2013).

10. See *Pesticide Reregistration Facts*, U.S. ENVTL. PROT. AGENCY (Aug. 2008), [http://www.epa.gov/oppsrrd1/reregistration\\_facts.htm](http://www.epa.gov/oppsrrd1/reregistration_facts.htm) (last updated May 9, 2012) (discussing the EPA’s development of risk mitigation measures as part of the product reregistration program).

portant because they can reduce the risks of a pesticide in relation to its benefits and enable, or continue, the pesticide's registration.<sup>11</sup>

Risk mitigation statements on a pesticide label can encompass requirements such as restrictions on the pesticide's purchase (e.g., designating a pesticide as a restricted use pesticide so that only certified applicators can buy the product); restrictions on applications near sensitive areas (e.g., establishing buffer zones around wetlands or endangered species habitat); restrictions on application rates, methods, and practices; and requirements for personal protection (e.g., use of respirators).<sup>12</sup> Since the mitigation measures included on a pesticide label are legally enforceable,<sup>13</sup> the mandates need to be effective and achievable. In general, mitigation measures can reduce risk; many mitigation measures can be executed easily and effectively (e.g. wearing a respirator or avoiding applications on windy days to prevent pesticide drift). However, novel mitigation measures need to be assessed for their feasibility in addition to their efficacy. A novel, untested, but well-intentioned mitigation mandate, while effective in theory, may be considered too burdensome or may be unattainable under operational settings. Consequently, the mitigation action may not be implemented by pesticide users, resulting in label violation and unreasonable risks to the environment.

### III. EXAMPLE: ROZOL

One such case is the mandatory mitigation statement on the pesticide label for the rodenticide, Rozol Prairie Dog Bait (Rozol).<sup>14</sup> In 2009, the EPA granted Rozol Section 3 registration for controlling black-tailed prairie dogs (BTPDs), in ten states: Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming.<sup>15</sup> The Rozol product is comprised of wheat seeds that are treated with the rodenticide active

---

11. See, e.g., OFFICE OF PESTICIDE PROGRAMS, U.S. ENVTL. PROT. AGENCY, INTERIM REREGISTRATION ELIGIBILITY DECISION FOR DIAZINON 40 (2003), available at [http://www.epa.gov/oppsrrd1/REDS/diazinon\\_red.pdf](http://www.epa.gov/oppsrrd1/REDS/diazinon_red.pdf).

12. See, e.g., *id.* at 41–42 (listing examples of reasonable mitigation measures for diazinon); see also, e.g., WHITFORD ET AL., *supra* note 4, at 21–23.

13. *Pesticide Label Review Training*, U.S. ENVTL. PROT. AGENCY, <http://epa.gov/pesticides/regulating/labels/pest-label-training/> (last updated May 9, 2012).

14. See OFFICE OF PESTICIDE PROGRAMS, U.S. ENVTL. PROT. AGENCY, NOTICE OF PESTICIDE REGISTRATION: ROZOL PRAIRIE DOG BAIT (2009) [hereinafter NOTICE OF PESTICIDE REGISTRATION], available at [http://www.epa.gov/pesticides/chem\\_search/ppls/007173-00286-20090513.pdf](http://www.epa.gov/pesticides/chem_search/ppls/007173-00286-20090513.pdf) (detailing follow-up mitigation requirements under the label's directions for use).

15. *Id.* at 1, 4; U.S. FISH & WILDLIFE SERV., U.S. DEP'T OF INTERIOR, FINAL BIOLOGICAL OPINION FOR ROZOL USE ON BLACK-TAILED PRAIRIE DOGS REGISTERED UNDER SECTION 3 OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT at 2 (2012) [hereinafter FINAL BIOLOGICAL OPINION], available at <http://www.epa.gov/espp/2012/borozol-final.pdf>.

ingredient, chlorophacinone, and it is colored bright green.<sup>16</sup> Chlorophacinone is a first generation anticoagulant rodenticide, and it disrupts blood clotting, subsequently causing hemorrhaging and death.<sup>17</sup> Black-tailed prairie dogs are highly social, colonial, diurnal, burrowing rodents in the squirrel family who bear a dual designation as an agricultural pest and an ecological keystone species.<sup>18</sup> Many in the agricultural community consider BTPDs to be a major pest, arguing that they damage crops, compete with livestock for forage, and that their burrows drain fields of water and create a hazard to livestock and farm equipment.<sup>19</sup> Consequently, BTPDs have been subjected to eradication since the early 1900s.<sup>20</sup> These eradications continue today, oftentimes promoted and conducted by county, state, and federal agencies.<sup>21</sup> On the flip side, BTPDs are considered to be a keystone species in the prairie ecosystem because they influence the prairie habitat's structure, function, and composition.<sup>22</sup> As a result, invertebrates<sup>23</sup> and more than 200 vertebrate species have been cited as associated with BTPD colonies

---

16. Nimish B. Vyas, et al., *Chlorophacinone Residues in Mammalian Prey at a Black-Tailed Prairie Dog Colony*, 31 ENVTL. TOXICOLOGY & CHEMISTRY 2513, 2513 (2012) [hereinafter Vyas et al., *Chlorophacinone Residues*].

17. *Id.* (citing Alain F. Pelfrene, *Rodenticides*, in HANDBOOK OF PESTICIDE TOXICOLOGY: AGENTS 1793, 1820 (Robert Krieger et al. eds., 2d ed. 2001)).

18. *See e.g.*, Charles Lee et al., *In-Burrow Application of Rozol to Manage Black-Tailed Prairie Dogs*, 11TH WILDLIFE DAMAGE MGMT. CONF. 349 (2005), [http://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1126&context=icwdm\\_wdmconfproc](http://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1126&context=icwdm_wdmconfproc); Brian J. Miller et al., *Prairie Dogs: An Ecological Review and Current Biopolitics*, 71 J. WILDLIFE MGMT. 2801 (2007); *12-Month Administrative Finding, Black-tailed Prairie Dog*, U.S. FISH & WILDLIFE SERV. (2000), <http://www.fws.gov/mountain-prairie/species/mammals/btprairiedog/12month2000/chapter2.htm>.

19. Justin D. Derner et al., *Are Livestock Weight Gains Affected By Black-Tailed Prairie Dogs?*, 4 FRONTIERS ECOLOGY & ENV'T 459, 459 (2006); Berton Lee Lamb et al., *Attitudes and Perceptions About Prairie Dogs*, in CONSERVATION OF THE BLACK-TAILED PRAIRIE DOG: SAVING NORTH AMERICA'S WESTERN GRASSLANDS 108, 108-10 (John L. Hoogland ed., 2006) (citations omitted).

20. *See, e.g.*, Valerie A. Barko, *History of Policies Concerning the Black-tailed Prairie Dog: A Review*, 77 PROC. OKLA. ACAD. SCI. 27, 28 (1997).

21. *See e.g.*, KAN. STAT. ANN. § 80-1202 (1997) ("township trustees . . . may enter upon the [private] lands so infested [by prairie dogs] . . . and make diligent efforts to exterminate all prairie dogs thereon."); *see also* Barko, *supra* note 20, at 28 (citing Brian Miller et al., *The Prairie Dog and Biotic Diversity*, 8 CONSERVATION BIOLOGY 677, 678 (1994)); DANIEL W. MULHERN & CRAIG J. KNOWLES, USDA FOREST SERV., BLACK-TAILED PRAIRIE DOG STATUS AND FUTURE CONSERVATION PLANNING, CONSERVING BIODIVERSITY ON NATIVE RANGELANDS: SYMPOSIUM PROCEEDINGS 19, 20 (1997), available at [http://www.fs.fed.us/rm/pubs\\_rm/rm\\_gtr298.pdf](http://www.fs.fed.us/rm/pubs_rm/rm_gtr298.pdf).

22. *See generally* Natasha B. Kotliar et al., *A Critical Review of Assumptions About the Prairie Dogs as a Keystone Species*, 24 ENVTL. MGMT. 177 (1999) (analyzing the BTPD's role as a keystone species through a review of previous scientific literature on the topic).

23. *See generally* Jon C. Sharps & Daniel W. Uresk, *Ecological Review of Black-Tailed Prairie Dogs and Associated Species in Western South Dakota*, 50 GREAT BASIN NATURALIST 339, 341 (1990) (providing a summary of literature identifying invertebrates in prairie dog colonies).

throughout the year.<sup>24</sup> These animals use the BTPD burrows for shelter and nesting, use the BTPD-manicured vegetation as forage and habitat for nesting, and use BTPDs and other animals that are attracted to the colonies as prey.<sup>25</sup> Several of these species, such as the swift fox, the federally endangered black-footed ferret,<sup>26</sup> and several bird species protected under the Migratory Bird Treaty Act and listed as the U.S. Fish and Wildlife Service's (FWS) Birds for Conservation Concern, including the mountain plover, burrowing owl, golden eagle, and ferruginous hawk,<sup>27</sup> are dependent on BTPDs.<sup>28</sup>

The EPA classifies Rozol's active ingredient, chlorophacinone, as "very highly toxic" for mammals, but only as "moderately toxic" for birds.<sup>29</sup> Studies, however, have recently demonstrated that first generation anticoagulant rodenticides are significantly more toxic to birds than the EPA's "moderately toxic" classification.<sup>30</sup> Since chlorophacinone does not discriminate between BTPDs and other wildlife species, non-target wildlife can also be killed at Rozol-treated BTPD colonies.<sup>31</sup> Seed-eating species (e.g., small mammals, game birds, song-

24. Kotliar et al., *supra* note 22, at 180, 183 (acknowledging the importance of prairie dogs despite the conclusion that "the prairie dog's influence on vertebrate species richness may be lower than frequently asserted," and that further research is necessary).

25. *See generally* Kotliar et al., *supra* note 22.

26. *Black-Footed Ferret*, U.S. FISH & WILDLIFE SERV., <http://www.fws.gov/mountain-prairie/species/mammals/blackfootedferret/> (last updated Apr. 24, 2013) (stating that on March 11, 1967, the black-footed ferret was listed as endangered range-wide).

27. The mountain plover, burrowing owl, golden eagle, and ferruginous hawk were listed on the U.S. Fish and Wildlife Service's Birds for Conservation Concern list in 2008. U.S. DIV. OF MIGRATORY BIRD MGMT., U.S. FISH & WILDLIFE SERV., BIRDS OF CONSERVATION CONCERN 2008 at 25, 27, 32 (2008), available at <http://www.fws.gov/migratorybirds/NewReports/Publications/SpecialTopics/BCC2008.BCC2008.pdf>. They are also protected species under the Migratory Bird Treaty Act. *See* Migratory Bird Treaty Act, 16 U.S.C. §§ 703–712 (2006); *see also* 50 C.F.R. § 10.13 (2012). Golden eagles are also protected by the Bald and Golden Eagle Protection Act. *See* Bald and Golden Eagle Protection Act, 16 U.S.C. § 668(a) (2006); 50 C.F.R. pt. 22.

28. Kotliar et al., *supra* note 22, at 183; *see* David L. Plumpton & David E. Andersen, *Habitat Use and Time Budgeting by Wintering Ferruginous Hawks*, 99 CONDOR 888, 888 (1997); *see also* DAVID A. WEBER, WINTER RAPTOR USE OF PRAIRIE DOG TOWNS IN THE DENVER, COLORADO VICINITY 195, 196 (2004), available at <http://www.cals.arizona.edu/pubs/adjunct/snr0704/snr07042p.pdf>.

29. ANDREW SHELBY ET AL., U.S. ENVTL. PROT. AGENCY, RISKS OF CHLOROPHACINONE USE ON BLACK TAILED PRAIRIE DOGS TO FEDERALLY ENDANGERED AND THREATENED SPECIES 71–73 (2010), available at <http://www.epa.gov/espp/litstatus/effects/chlorophacinone/assessment.pdf>.

30. Barnett A. Rattner et al., *Assessment of Toxicity and Potential Risk of the Anticoagulant Rodenticide Diphacinone Using Eastern Screech-Owls (Megascops asio)*, 21 ECOTOXICOLOGY 832, 832, 844 (2012); *see also* Nimish B. Vyas & Barnett A. Rattner, *Critique on the Use of the Standardized Avian Acute Oral Toxicity Test for First Generation Anticoagulant Rodenticides*, 18 HUM. & ECOLOGICAL RISK ASSESSMENT 1069, 1074 (2012).

31. NIMISH B. VYAS, PATUXENT WILDLIFE RES. CENT., U.S. GEOLOGICAL SURV., ANNUAL REPORT 2010: CHARACTERIZATION OF AVIAN HAZARDS FOLLOWING CHLOROPHACINONE

birds) are attracted to the grain (winter wheat) bait of Rozol and can be poisoned by directly consuming the Rozol bait, whereas predatory and scavenger species (e.g., hawks, eagles, vultures) are poisoned by feeding on poisoned prey.<sup>32</sup> Rozol is registered for use only from October 1 to March 15 of the following year;<sup>33</sup> therefore, the grain bait and the dead and dying animals at poisoned BTPD colonies become an attractive concentrated food source for wildlife when other items are scarce during the winter months.<sup>34</sup>

Because of environmentalists' and the FWS's concerns about the high potential for non-target wildlife poisoning,<sup>35</sup> the Rozol Prairie Dog Bait Section 3 registration label has undergone several modifications and iterations to mitigate for ecological risks.<sup>36</sup> The 2009 label was registered on May 13, 2009; the 2010 amended label was registered on September 10, 2010; and the 2012 amended label was registered on August 8, 2012.<sup>37</sup> But all three versions contain a mandatory mitigation requirement that, after Rozol application, the applicator must conduct multiple follow-up visits to the treated colony to remove dead and dying BTPDs and Rozol on the ground surface in order to reduce the risks to non-target

---

(ROZOL®) USE FOR PRAIRIE DOG CONTROL 4 (2010) [hereinafter VYAS, ANNUAL REPORT], available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0909-0030>.

32. See *id.* at 15; see also Nimish B. Vyas et al., *Evidence of Songbird Intoxication from Rozol® Application at a Black-Tailed Prairie Dog Colony*, 4 J. FISH & WILDLIFE MGMT. 97, 97 (2013).

33. OFF. OF CHEMICAL SAFETY & POLLUTION PREVENTION, U.S. ENVTL. PROT. AGENCY, AMENDED LABEL AS REQUIRED BY THE FINAL BIOLOGICAL OPINION FOR ROZOL USE ON BLACK-TAILED PRAIRIE DOGS REGISTERED UNDER SECTION 3 OF FIFRA: ROZOL PRAIRIE DOG BAIT 3 (2012) [hereinafter AMENDED LABEL], available at [http://www.epa.gov/pesticides/chem\\_search/ppls/007173-00286-20120808.pdf](http://www.epa.gov/pesticides/chem_search/ppls/007173-00286-20120808.pdf).

34. VYAS, ANNUAL REPORT, *supra* note 31 at 11, 15.

35. See, e.g., Memorandum Opinion at 37, *Defenders of Wildlife v. Jackson*, No. 1:09-CV-01814-ESH (D.D.C. June 14, 2011). The United States District Court for the District of Columbia stated that “the [Natural Resources Defense Council] is therefore entitled to a declaratory judgment that the [EPA] violated the [Endangered Species Act] by registering Rozol without first consulting with the FWS.” *Id.* The court imposed an injunction to temporarily prohibit Rozol's sale and use in Montana, New Mexico, North Dakota, and South Dakota, pending the completion of the FWS's Biological Opinion on the risks to endangered species and the formal EPA-FWS consultation process. Order on Remedy at 2–5, *Defenders of Wildlife v. Jackson*, No. 1:09-CV-01814-ESH (D.D.C. July 27, 2011).

36. FINAL BIOLOGICAL OPINION, *supra* note 15, at 4–7 (providing a history of major actions taken by environmentalists, the FWS, and the EPA regarding Rozol use and the label).

37. NOTICE OF PESTICIDE REGISTRATION, *supra* note 14; OFF. OF PREVENTION, PESTICIDES & TOXIC SUBSTANCES, U.S. ENVTL. PROT. AGENCY, LABELING AMENDMENT; REVISED DIRECTIONS FOR USE: ROZOL PRAIRIE DOG BAIT (2010) [hereinafter LABELING AMENDMENT], available at [http://www.epa.gov/pesticides/chem\\_search/ppls/007173-00286-20100910.pdf](http://www.epa.gov/pesticides/chem_search/ppls/007173-00286-20100910.pdf); AMENDED LABEL, *supra* note 33.

wildlife.<sup>38</sup> The multiple follow-up visits requirement is the mitigation linchpin of the Rozol label. The 2009 label stated:

The applicator must return to the site with[in] 5 to 10 days after bait application to collect and properly dispose of any bait or dead or dying prairie dogs that may have come to the surface . . . The applicator must also return to the site 14 to 21 days after bait application to collect and properly dispose of any additional bait or dead or dying prairie dogs that may have come to the surface.<sup>39</sup>

The 2010 label and the current 2012 label modified the timing and increased the number of post-application follow-up visits to further reduce ecological risks:

The applicator must return to the site within 4 days after bait application, and at 1 to 2 day intervals, to collect and properly dispose of any bait or dead or dying prairie dogs found on the surface . . . Continue to collect and dispose of dead or dying prairie dogs and search for nontarget animals for at least two weeks, but longer if carcasses are still being found at that time.<sup>40</sup>

The multiple follow-up visits requirement would be expected to reduce risks to non-target wildlife by removing the sources of poisoning (above-ground bait and poisoned animals). However, the multiple follow-up visits mitigation requirement is novel (specifically tailored to reduce Rozol Prairie Dog Bait's risks to non-target wildlife) and untested with respect to its practicality for implementation.

Recent evidence indicates that the pesticide users consider the mitigation measures onerous and unrealistic; therefore, in practice, risk reduction is unlikely to be achieved. In the summer of 2010, EPA officials discussed the impact of increasing follow-up requirements on the user community with state personnel from the North Dakota and South Dakota Departments of Agriculture, North Dakota Game and Fish Department, North Dakota State University Extension Service, Standing Rock Sioux Tribe members, wildlife officials, landowners, a commercial applicator, and the FWS.<sup>41</sup> While there is disagreement as to how

---

38. NOTICE OF PESTICIDE REGISTRATION, *supra* note 14, at 4–5; LABELING AMENDMENT, *supra* note 37, at 2; AMENDED LABEL, *supra* note 33, at 3.

39. NOTICE OF PESTICIDE REGISTRATION, *supra* note 14, at 4–5.

40. LABELING AMENDMENT, *supra* note 37, at 2; *see also* AMENDED LABEL, *supra* note 33, at 4.

41. Letter from Jim Gray, Pesticide & Fertilizer Div. Dir., N.D. Dep't of Agric., to U.S. Env'tl. Prot. Agency (Feb. 15, 2012), *available at* <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0909-0119> (citing U.S. FISH & WILDLIFE SERV., U.S. DEP'T OF INTERIOR, DRAFT BIOLOGICAL OPINION FOR ROZOL USE ON BLACK-TAILED PRAIRIE DOGS REGISTERED UNDER SECTION 3 OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT 17 (2012), *available at* <http://www.epa.gov/espp/rozol-draft-memo.pdf>).

the attendees responded to the additional requirements, FWS personnel present at the meeting observed that several of the meeting attendees voiced their concerns regarding the 2009 Rozol label's multiple follow-up visits requirement.<sup>42</sup> The FWS also observed that the attendees considered the multiple follow-up visits and the carcass disposal requirements on the then-active 2009 label to be already laborious and unrealistic, and that the attendees said they did not have the time, resources, or interest to conduct the follow-up visits.<sup>43</sup> Since the attendees admitted to non-compliance with the less stringent follow-up requirements on the 2009 label (as few as two required follow-up visits over a three-week period),<sup>44</sup> they appeared indifferent to the more demanding multiple follow-up visits requirements of the new 2010 Rozol label (eleven follow-up visits over the three-week period).<sup>45</sup>

From the Rozol-users' perspective, the mitigation requirements to return to the application site and to collect and dispose of bait or dead and dying prairie dogs on the ground surface in order to minimize harm to non-target wildlife are idealistic.<sup>46</sup> To properly conduct searches and to collect and dispose of dead animals at each colony is time and labor intensive. The 2009 and 2010 Rozol labels lacked sufficient guidance on how to conduct the follow-up visit.<sup>47</sup> Therefore, it

---

42. Letter from Scott Larson, Field Supervisor, Fish & Wildlife Serv., to Dr. Debbie Edwards, U.S. Env'tl. Prot. Agency (Sept. 17, 2010), *available at* <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2010-0584-0005>.

43. *Id.*

44. Interviews with U.S. Fish & Wildlife Serv. attendees: Bill Bicknell, Biologist, Fish & Wildlife Serv.; Scott Larson, Field Supervisor, Fish & Wildlife Serv.; Micah Reuber, Former Biologist, Fish & Wildlife Serv.; Jeff Towner, Field Supervisor, Fish & Wildlife Serv. (Nov. 15–19, 2012).

45. In 2010 and 2011, I conducted a field study funded by the FWS to monitor Rozol's effects on non-target wildlife at several Rozol-treated BTPD colonies on private lands in Colorado. Whereas the objective of my study was to collect data on wildlife, my personal observations further support the users' disinterest in conducting follow-up visits. I serendipitously visited four Rozol-treated colonies over a three week period post-Rozol application but found no evidence of effective follow-up visits. The Rozol label's mitigation statement requires that the applicator must remove wildlife carcasses and any Rozol remaining on the surface during the follow-up visits. I found dead non-target mammalian wildlife above ground and observed Rozol on the ground surface during every visit at all colonies. For example, at one of the treated colonies, I observed the same Rozol-killed cottontail rabbit (the rabbit exhibited external bleeding which is a typical sign of anticoagulant rodenticide poisoning) during two of my visits (about fourteen days and twenty-one days after application). During my second visit, I observed a red-tailed hawk standing on the ground near the rabbit (presumably preparing to scavenge the rabbit) and when flushed twice by my presence, the hawk returned to the rabbit each time. This is an example of the lack of follow-up visits to remove poisoned carcasses and how it can lead to poisoning of predatory species.

46. *See* Interviews with U.S. Fish & Wildlife Serv. attendees, *supra* note 44.

47. *Compare* NOTICE OF PESTICIDE REGISTRATION, *supra* note 14, at 4–5, *and* LABELING AMENDMENT, *supra* note 37, at 2 (both detailing the time of day for carcass collection and proper



was not uncommon for applicators to hand-off the responsibility for conducting the follow-up activities to the landowner or to simply drive past the treated BTPD colony and consider it a follow-up visit.<sup>48</sup> In the absence of specific directions for conducting the follow-up visits, the above alternate methods were considered sufficient by some applicators,<sup>49</sup> though it can be reasonably argued that this is far from the label's intent for requiring the follow-up visits. The 2012 iteration of the Rozol label does provide some guidance on conducting follow-up visits.<sup>50</sup> The label states:

Carcass searches must be performed using a line-transect method that completely covers the baited area. Transect center lines must be not more than 200 feet (about 60 meters) apart, and should be considerably less if searches are conducted in more densely vegetated sites. Transect lines may be traveled on foot or by vehicle at a rate not to exceed 4 mph.<sup>51</sup>

Assuming a 100-acre colony (approximately forty and one-half hectares) is treated with Rozol, it would take the searcher a minimum of approximately one hour by vehicle and approximately one and a half hours on foot per visit, in addition to the time to collect and properly dispose of poisoned animals. Furthermore, adverse effects to BTPDs and non-target wildlife can continue for at least twenty-nine days after Rozol application.<sup>52</sup> Therefore, the 2010 and 2012 Rozol label requirements could result in around fifteen follow-up visits per colony over a period of about a month.<sup>53</sup> If commercial and government applicators follow the mitigation requirements, the time required to conduct the follow-up visits per treated colony would force them to limit the number of BTPD colonies they can treat during the application season. For non-commercial individual applicators, the short daylight hours and cold weather in winter could also prevent the required multiple follow-up visits. Furthermore, BTPDs garner considerable con-

---

burial depth), with AMENDED LABEL, *supra* note 33, at 3 (adding instructions on the proper method for conducting carcass searches).

48. Interview with Fred Raish, Supervisor, Yuma Cnty. Pest Control Dist., in Yuma, Colo. (Jan. 2010).

49. *See id.*

50. *See* AMENDED LABEL, *supra* note 33, at 3.

51. *Id.* The maximum spacing of 200 feet between search transects has not been tested in the field to determine its effectiveness for detecting BTPD and non-target wildlife carcasses at BTPD colonies. The 2009 and 2010 Rozol labels did not provide guidance on how to conduct follow-up searches, and therefore driving past the colony has been considered a follow-up visit by some applicators. Carcass recovery success depends on the transect spacing; the size, shape, color of animal; the vegetation and terrain; and the searcher's abilities.

52. Vyas et al., *Chlorophacinone Residues*, *supra* note 16, at 2513–14.

53. *See, e.g., id.* at 2513–14 (providing an example of a twelve-day search over a twenty-nine day period at one colony).

tempt in agricultural communities, making it more difficult for Rozol users to be motivated to expend the additional effort retrieving prairie dogs once they have been poisoned.<sup>54</sup>

Recognizing that the multiple follow-up visits requirement can discourage buyers, Rozol advertisements have avoided mentioning the multiple follow-up visits mandate. Instead, the advertisements have promoted their product as “less work” at a lower cost in comparison to the competitor rodenticide zinc phosphide because the latter requires the applicator to pre-bait each BTPD mound with un-poisoned grain to accustom the BTPDs to accept the zinc phosphide-treated grain.<sup>55</sup> Rozol advertisements, therefore, have touted Rozol’s cost effectiveness because it does not require pre-baiting, but the advertisements fail to mention the costs associated with conducting the follow-up visits.<sup>56</sup> The EPA filed a complaint against Rozol’s manufacturer stating that its advertising claims were false and misleading.<sup>57</sup>

Based on the FWS’s observations at the meeting with the EPA and Rozol users in North Dakota, the author’s personal experience while conducting the field study, the logistics of conducting the multiple follow-up visits, and the Rozol advertisements, it would not be unreasonable to presume that there appears to be little cultural interest in conducting effective searches for dead BTPDs.

---

54. See generally, Donna Lybecker et al., *Public Attitudes and Knowledge of the Black-tailed Prairie Dog: A Common and Controversial Species*, 52 *BIOSCI.* 607, 609 (2002); see also Berton Lee Lamb & Kurt Cline, *Public Knowledge and Perceptions of Black-Tailed Prairie Dogs*, 8 *HUM. DIMENSIONS WILDLIFE* 127, 130 (2003); Berton Lee Lamb et al., *Attitudes And Perceptions About Prairie Dogs*, in *CONSERVATION OF THE BLACK-TAILED PRAIRIE DOG: SAVING NORTH AMERICA’S WESTERN GRASSLANDS* 108 (John Hoogland ed., 2006).

55. LIPHATECH, *CONTR. RANGE RODENTS* (2009) (brochure for Rozol published by the manufacturer, Liphatech); see OFF. OF PESTICIDE PROGRAMS, U.S. ENVTL. PROT. AGENCY, NOTICE OF REREGISTRATION AND AMENDED LABEL FOR ZINC PHOSPHIDE PRAIRIE DOG BAIT 3 (2011), available at [http://www.epa.gov/pesticides/chem\\_search/ppls/013808-00006-20111121.pdf](http://www.epa.gov/pesticides/chem_search/ppls/013808-00006-20111121.pdf).

56. See Letter from Bob Lanka, President, The Wildlife Soc’y: Cent. Mountains & Plains Sec., to Dr. Debbie Edwards, U.S. Env’tl. Prot. Agency (Aug. 17, 2009), available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0684-0012>.

57. On May 14, 2010, the U.S. Env’tl. Prot. Agency Region 5 filed a civil administrative complaint against [Rozol’s manufacturer] Liphatech, Inc. (Respondent or Liphatech) that alleged Liphatech violated the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The complaint alleged, inter alia, that Respondent violated Section 12(a)(1)(B) of FIFRA (7 U.S.C. § 136j(a)(1)(B) (2006)) and, additionally or in the alternative, Section 12(a)(1)(E) of FIFRA (7 U.S.C. § 136j(a)(1)(E)). The claim alleged false and misleading branding under 40 C.F.R. 156.10(a)(5) (2006). See Complaint at 81-107, *In the Matter of Liphatech, Inc.*, No. FIFRA-05-2010-0016 (2010), available at <http://yosemite.epa.gov/OA/RHC/EPAAdmin.nsf/Filings/DF58772C3E125BEE85257724001B8F73?OpenDocument>.

Conservationists, too, are concerned with the label's linchpin mitigation requirement because it can be difficult to satisfy.<sup>58</sup> Their concern is raised because of two issues in relation to FIFRA: risk and harm.<sup>59</sup> Risk is the probability that harm (e.g., mortality) will be inflicted on a free-ranging animal, whereas harm is the actual adverse effect (e.g., mortality) itself. The objective of an ecological risk assessment is, therefore, to predict a pesticide's harm to free-ranging wildlife.<sup>60</sup> However, since risk assessment is a mathematical modeling endeavor, the input data can temper the results. As mentioned earlier in the hypothetical example (risk to birds is minimized if the pesticide is not available on the ground surface), risk assessment's output can be modulated by changing the parameters of pesticide exposure.<sup>61</sup> Similarly, in the case of Rozol, the mitigation requirement of conducting multiple follow-up visits to remove poisoned animals would reduce the risks to scavengers and predators, but only if the label's mitigation requirements are meticulously followed as intended by the label. FIFRA places considerable importance on a pesticide's risk characterization by requiring it to be weighed against the pesticide's benefit.<sup>62</sup> A registration of a pesticide or its continued use is contingent on determining if its risk (after adjusting for the mandatory mitigation statements on the label) is acceptable when compared to its benefit.<sup>63</sup> The risk-benefit comparison assumes that the label can and will be followed as directed. The validity of the registration decision, therefore, rests on the implementation of the mitigation requirements in the field. Mitigation requirements considered burdensome, and thus not followed by the pesticide users,

58. See, e.g., Memorandum Opinion, *supra* note 35; Order on Remedy, *supra* note 35.

59. See *Ecological Committee on FIFRA Risk Assessment Methods (ECOFRAM) Terrestrial Work Group Report: I. Introduction and Problem Formulation*, U.S. ENVTL. PROT. AGENCY, <http://www.epa.gov/oppefed1/ecorisk/introduction.htm> (last updated May 9, 2012) (discussing use of risk assessments as required under FIFRA); see also *Guidance for using Incident Data in Evaluating Listed and Non-Listed Species under Registration Review*, U.S. ENVTL. PROT. AGENCY (Oct. 2011), [http://www.epa.gov/pesticides/science/efed/policy\\_guidance/team\\_authors/endangered\\_species\\_reregistration\\_workgroup/esa\\_incident\\_guidance.htm#addressing](http://www.epa.gov/pesticides/science/efed/policy_guidance/team_authors/endangered_species_reregistration_workgroup/esa_incident_guidance.htm#addressing) (last updated May 9, 2012) (discussing requirements for collecting adverse effects data under FIFRA).

60. See *Ecological Risk Assessment*, U.S. ENVTL. PROT. AGENCY, [http://www.epa.gov/risk\\_assessment/ecological-risk.htm](http://www.epa.gov/risk_assessment/ecological-risk.htm) (last visited Aug. 25, 2013).

61. See Nimish B. Vyas et al., *Field Evaluation of an Avian Risk Assessment Model*, 25 ENVTL. TOXICOLOGY & CHEMISTRY 1762, 1767–70 (2006) (discussing the difference in results of risk assessments conducted in laboratory and field settings).

62. See *EPA Determines That Chlorfenapyr Does Not Meet the Requirements for Registration; American Cyanamid Withdraws Application*, U.S. ENVTL. PROT. AGENCY, <http://www.epa.gov/opprd001/chlorfenapyr/> (last updated May 9, 2012) (providing an example of the importance of risk characterization). EPA determined that the pesticide chlorfenapyr did not qualify for Section 3 Registration for use on cotton because the risks to birds greatly outweighed the economic benefits of the pesticide. *Id.*

63. See 7 U.S.C. § 136a(c)(5)–(6) (2006).

not only fail to reduce risk, but also undermine the comparison of the risks and benefits of a pesticide.

Harm is the actual negative effect of pesticide use; therefore, adverse effects need to be documented in the field under operational conditions. The key to gathering evidence on the hazards of Rozol lies in conducting effective multiple follow-up visits. If the follow-up visits are not conducted, evidence of Rozol's hazard is lost. Determination of Rozol's hazards in the field is restricted by two factors. First, Rozol is typically used on privately owned farms, pastures, and ranches where monitoring by individuals other than the applicators and landowners is not likely to occur. Second, effective follow-up visits by the users lack efficiency. Despite these limitations, non-target wildlife mortalities have been documented following operational applications of Rozol at BTPD colonies, and include two bald eagles, one ferruginous hawk, one great horned owl, two wild turkeys, one western meadowlark, two thirteen-lined ground squirrels, and two American badgers.<sup>64</sup> While the list of affected non-target species and individuals is short, it nevertheless provides an invaluable window into Rozol's hazards. The evidence shows that Rozol's use does result in wildlife mortalities. It is therefore reasonable to conclude that the adverse effects of Rozol are not limited to the animals listed above but that these mortalities represent the tip of the iceberg.<sup>65</sup>

Adverse effects data is of importance when considering the fate of a registered pesticide. According to FIFRA:

If it appears to the [EPA] Administrator that a pesticide . . . when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of the Administrator's intent either—(1) to cancel its registration . . . or (2) to hold a hearing to determine whether or not its registration should be canceled . . .<sup>66</sup>

Furthermore, in *Ciba-Geigy Corporation v. U.S. Environmental Protection Agency*, the Fifth Circuit asserted that “FIFRA gives the [EPA] Administrator sufficient discretion to determine that recurring bird kills, even if they do not significantly reduce bird population, are themselves an unreasonable environ-

---

64. VYAS, ANNUAL REPORT, *supra* note 31, at 12; FINAL BIOLOGICAL OPINION, *supra* note 15 at 22, 29; Vyas et al., *Chlorophacinone Residues*, *supra* note 16, at 2514; Mark G. Ruder et al., *Intoxication of Nontarget Wildlife with Rodenticides in Northwestern Kansas*, 47 J. WILDLIFE DISEASES 212, 212 (2011).

65. See generally Nimish B. Vyas, *Factors Influencing Estimation of Pesticide-Related Wildlife Mortality*, 15 TOXICOLOGY & INDUS. HEALTH 186 (1999) (discussing problems affecting accuracy in mortality reporting).

66. 7 U.S.C. § 136d(b).

mental effect.”<sup>67</sup> The Court also stated that “the Administrator may cancel a registration if it appears to him that the pesticide commonly causes unreasonable risks.”<sup>68</sup> Though it is not known to what degree the multiple visits requirement on the Rozol label, when followed, is effective in reducing hazards to non-target wildlife, ignoring the linchpin requirement for multiple follow-up visits renders the label’s potential protective measures impotent. Risk assessment and adverse effects determination can play an important role in pesticide regulations provided that the conditions on the label are followed.

#### IV. CONCLUSION

The function of a pesticide label is not just to provide information on application rates, times, and methods, but also to provide mitigation procedures to minimize ecological harm.<sup>69</sup> The Rozol example shows that novel, untested mitigation measures need to be “practical and enforceable.”<sup>70</sup> Biological (ecology of non-target wildlife) and non-biological (values, costs, interests, and motives of the Rozol user community) processes affect implementation and effectiveness of mitigation mandates.<sup>71</sup> While it is not possible when approving a pesticide label to know how readily a mitigation measure will be adopted by the users, the Rozol example shows that implementation of even the mandatory label requirements cannot be presumed. Based on the observations by the FWS personnel attending the meeting in North Dakota, the Rozol example is unique in that it brought to light the obstacles of implementing mandatory, untested, novel label statements.<sup>72</sup> The EPA recently registered another first generation anticoagulant rodenticide

---

67. *Ciba-Geigy Corp. v. U.S. Env'tl. Prot. Agency*, 874 F.2d 277, 280 (5th Cir. 1989). The Court reviewed the EPA Administrator’s order to cancel the pesticide diazinon’s registration for use on golf courses and sod farms based on concerns over its adverse effects on birds. *Id.* at 278–80.

68. *Id.* at 279.

69. *See, e.g.*, U.S. ENVTL. PROT. AGENCY, LABEL REVIEW MANUAL—CHAPTER 11: DIRECTIONS FOR USE at 11–19 (last updated July 24, 2013), available at <http://www.epa.gov/oppfead1/labeling/lrm/chap-11.pdf> (discussing the function of label statements in the protection of endangered species).

70. Thomas Thongsinthusak & Joseph P. Frank, *Developing Pesticide Exposure Mitigation Strategies*, in *ASSESSING EXPOSURES AND REDUCING RISKS TO PEOPLE FROM THE USE OF PESTICIDES* 98, 98 (Robert I. Krieger et al. eds., 2007).

71. *See generally* Marc Mangel et al., *Principles for the Conservation of Wild Living Resources*, 6 *ECOLOGICAL APPLICATIONS* 338 (1996) (discussing the need for a balance between the biological and non-biological factors); *see also* W.E. Grant et al., *Quantitative Modeling of Coupled Natural/Human Systems: Simulation of Societal Constraints on Environmental Action Drawing on Luhmann’s Social Theory*, 158 *ECOLOGICAL MODELING* 143 (2002) (discussing the integration of biological and non-biological factors in ecological modeling).

72. *See* Letter from Scott Larson to Dr. Debbie Edwards, *supra* note 42.

product (Kaput-D, active ingredient diphacinone) for prairie dog control.<sup>73</sup> Kaput-D and Rozol target the same user groups and their labels follow the same application method and multiple follow-up visits requirement.<sup>74</sup> Therefore, it is sensible to assume that Kaput-D users may also disregard the multiple follow-up visits mandate. Unpopular mitigation requirements can result in an on-paper risk reduction, but Rozol users remain in jeopardy for not complying with the label,<sup>75</sup> and conservationists remain dissatisfied because of an underestimation of risk and a lack of monitoring for adverse effects.<sup>76</sup> The user community can be vital when developing mitigation requirements because it can provide candid feedback on the likelihood that the mandates will be followed. Surveying the user community, however, can be tricky. For example, during the meeting held in North Dakota in the summer of 2010 to discuss an increase in the number of follow-up visits, even though EPA and FWS personnel were present at the same meeting, they experienced contradictory responses from the meeting attendants.<sup>77</sup>

Courts of law recognize the pesticide label as a legal contract that requires the user to follow the label directions<sup>78</sup> and the EPA maintains that “the label is the law.”<sup>79</sup> The label’s legal obligations bestowed on the user necessitate that the label mandates be achievable.<sup>80</sup> Novel, untested, mandatory mitigation requirements that are considered key for reducing risks need to be confirmed for their practicality and effectiveness to ensure label compliance and minimize ecological hazards.

---

73. U.S. ENVTL. PROT. AGENCY, REGISTRATION DECISION FOR KAPUT-D PRAIRIE DOG BAIT TO CONTROL BLACK-TAILED PRAIRIE DOGS 2 (2012), available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0739-0015>.

74. Compare U.S. ENVTL. PROT. AGENCY, KAPUT-D PRAIRIE DOG BAIT LABEL 2, available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0739-0016> with AMENDED LABEL, *supra* note 33, at 3–4.

75. See 7 U.S.C. § 136j(a)(2)(G) (2006). “[I]t shall be unlawful for any person . . . to use any registered pesticide in a manner inconsistent with its labeling.” *Id.*

76. Letter from Jason C. Rylander, Senior Staff Att’y, Defenders of Wildlife et al., to Lois Rossi, Dir., Office of Pesticide Programs, Registration Div., U.S. Env’tl. Prot. Agency (Sept. 24, 2012), available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0739-0013>.

77. Compare Letter from Jim Gray, *supra* note 41, with Letter from Scott Larson, *supra* note 42, and Interviews with U.S. Fish & Wildlife Serv. attendees, *supra* note 44.

78. WHITFORD ET AL., *supra* note 4, at 19.

79. *Pesticide Label Review Training*, *supra* note 13.

80. See *id.* (stating, “reviewers evaluate labels according to four core principles: clarity, accuracy, consistency with EPA policy, and enforceability”).