UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

REPLY TO THE ATTENTION OF:
C-14J

*Via UPS Overnight Delivery*

June 15, 2012

Honorable Susan L. Biro
Office of Administrative Law Judges
U.S. Environmental Protection Agency
Mail Code 1900L
1099 14th Street, NW, Suite 350
Franklin Court
Washington, D.C. 20005

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

Dear Chief Judge Biro:

Enclosed please a copy of *Complainant's Post-Hearing Brief*, which was filed on June 15, 2012, in the above referenced-matter.

Sincerely,

Erik H. Olson
Associate Regional Counsel

Enclosure

cc: Mr. Mark A. Cameli
Reinhart Boerner Van Deuren s.c
1000 North Water Street, Suite 1700
Milwaukee, WI 53202
(*via UPS overnight delovery*)

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**BEFORE THE ADMINISTRATOR**

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| **IN THE MATTER OF:** | ) | |
| | ) | |
| **Liphatech, Inc.** | ) | Docket No. FIFRA-05-2010-0016 |
| **Milwaukee, Wisconsin** | ) | |
| | ) | |
| **Respondent.** | ) | |
| | ) | |

# COMPLAINANT'S POST HEARING BRIEF

## TABLE OF CONTENTS

## TABLE OF AUTHORITIES

### US SUPREME COURT CASES:



### FEDERAL APPEALS AND DISTRICT COURT CASES:



### ADMINISTRATIVE DECISIONS:

**STATUTES:**



**ADMINISTRATIVE REGULATIONS:**

**OTHER AUTHORITY:**

In accordance with the Chief Judge's April 18, 2012 Order Scheduling Post-Hearing Briefs, the United States Environmental Protection Agency, Region 5 ("Complainant" or "EPA"), through its undersigned attorneys, files the instant Complainant's Post-Hearing Brief, pursuant to Section 22.26 of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation, Termination or Suspension of Permits ("Consolidated Rules"), 40 C.F.R. § 22.26. For the reasons explained below, Complainant respectfully requests that the Chief Judge enter an initial decision finding Liphatech, Inc. ("Respondent") liable for the alleged violations of Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136-136y ("FIFRA" or the "Act") and imposing a penalty of $2,891,200 for these violations.

## I. STATUTORY AND REGULATORY BACKGROUND

"FIFRA is a federal statute regulating the manufacture, distribution or sale, and use of pesticides in the United States by means of a national registration system." *In re Tifa Ltd.*, 9 E.A.D. 145, 147 (EAB 2000). Because it is a remedial statute, it "should be construed liberally to effectuate its purposes." *In re Sporicidin Int'l*, 3 E.A.D. 589, 604 (CJO 1991). As the EAB has noted, "consumer protection from false and/or misleading claims is one of the longstanding goals of FIFRA." *In re Microban Prods. Co.*, 11 E.A.D. 425, 447 (EAB 2004) ("*Microban II*").

Pesticides registered under FIFRA can be classified as either general use or restricted use. 7 U.S.C. § 136a(d)(1). Pesticides are classified as restricted use "[i]f the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment." *Id.* §

136a(d)(1)(C). When a pesticide is classified as restricted use, the pesticide can only be sold to and applied by a certified applicator or someone acting under the certified applicator's direct supervision. *Id.* § 136a(d)(1)(C)(ii).

FIFRA § 12(a)(2)(E) makes it unlawful for any registrant to advertise for a restricted use pesticide without giving the classification of the product. *Id.* § 136j(a)(2)(E). EPA has interpreted this prohibition as applying to "all advertisements of the product, including, but not limited, to: (1) Brochures, pamphlets, circulars and similar material offered to purchasers at the point of sale or by direct mail. (2) Newspapers, magazines, newsletters and other material in circulation or available to the public. (3) Broadcast media such as radio and television. . . ." 40 C.F.R. § 152.168(b)(1)-(3). For printed advertisements, the disclosure requirement for restricted use pesticides can be satisfied "by inclusion of the statement 'Restricted Use Pesticide,' or the terms of restriction." *Id.* § 152.168(c). Similarly, for broadcast advertisements, the disclosure requirement can be satisfied by "the spoken words 'Restricted use pesticide,' or a statement of the terms of restriction." *Id.*

Under FIFRA § 3(c)(1)(C), "any applicant wishing to register a pesticide must file a statement that includes 'a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use.'" *In re Antkiewicz*, 8 E.A.D. 218, 234-35 (EAB 1999) (citing 7 U.S.C. § 136a(c)(1)(C)). FIFRA § 12(a)(1)(B) makes it unlawful for any person to distribute or sell a registered pesticide "if any claims made for it as part of its distribution or sale substantially differ from any claims made for it as part of the statement required in connection with its registration under [FIFRA § 3, 7 U.S.C. § 136a]." 7 U.S.C. § 136j(a)(1)(B). "To distribute or sell" is defined by FIFRA as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or

receive and (having so received) deliver or offer to deliver." 7 U.S.C. § 136(gg). FIFRA § 2(gg)'s implementing regulation, codified at 40 C.F.R. § 152.3, provides that the definition of "distribute or sell" includes grammatical variations of these words, such as distribution, sale, shipped, held for distribution, released for shipment, or offered for sale. EPA has interpreted "offer for sale" in the context of FIFRA § 12(a)(1)(B) "as extending to advertisements in any advertising medium to which pesticide users or the general public have access." 40 C.F.R. § 168.22(a).

FIFRA § 14(a)(1) authorizes EPA to assess civil penalties for any violations of the Act. 7 U.S.C. § 136*l*(a)(1). For violations of FIFRA occurring after March 15, 2004 through January 12, 2009, EPA may assess up to $6,500 for each offense. 40 C.F.R. §§ 19.2, 19.4. For violations occurring after January 12, 2009, EPA may assess up to $7,500 for each offense. 40 C.F.R. § 19.4. When determining the amount of a penalty, FIFRA requires EPA to "consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. 7 U.S.C. § 136*l*(a)(4).

## II. RELEVANT PROCEDURAL BACKGROUND

On May 11, 2010, Complainant filed a civil administrative complaint against Respondent. On January 6, 2011, Complainant filed its First Amended Complaint ("Complaint"), in which Complainant narrowed the issues by eliminating an alternative basis for pleading a number of counts and reducing the proposed penalty.[1] The Complaint alleged that Respondent violated FIFRA by: 1) advertising Rozol, a restricted use pesticide, without giving its classification as required by FIFRA § 12(a)(2)(E), 7 U.S.C. § 136j(a)(2)(E); and by 2) distributing or selling Rozol using claims made for it as a part of its distribution or sale that

[1] On December 29, 2010, the Presiding Officer granted Complainant's Motion for Leave to Amend Complaint to Reduce Penalty and Complainant's Motion for Leave to Amend the Complaint.

substantially differed from any claims made for it as part of the statement required under FIFRA § 3 in violation of FIFRA § 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B). In the Complaint, EPA proposed a civil administrative penalty of $2,891,200. Respondent filed an Answer to the Complaint on February 4, 2011.

Subsequently, the parties filed competing motions for accelerated decision on all of the counts alleged in the Complaint. On May 6, 2011, the Chief Judge issued an Order on Motions for Accelerated Decision Regarding Alleged Violations of FIFRA § 12(a)(2)(E), pursuant to which Respondent was found liable for Counts 1 through 2,140 of the Complaint. On June 24, 2011, the Chief Judge issued an Order on Motions for Accelerated Decision Regarding Alleged Violations of FIFRA § 12(a)(1)(B), denying Complainant's motions for accelerated decision on liability for the remaining counts of the Complaint, Counts 2,141 through 2,231. Therefore, Respondent has been found liable for the violations alleged in Counts 1 through 2,140 of the Complaint, but Respondent's liability for the violations in counts 2,141 through 2,231 of the Complaint must be determined. In addition, the appropriate penalty for the Respondent's violations of FIFRA must also be determined.

## III. RELEVANT FACTUAL BACKGROUND

The basic facts of this case are, for the most part, undisputed. Respondent is a Wisconsin corporation that claims to be "the world's leading developer of rodent control products." (*See, e.g.,* CX14a, EPA180). Among other pesticide registrations, Respondent holds registrations for two pesticides that are at issue in this case: (1) Rozol Pocket Gopher Bait, and (2) Rozol Prairie Dog Bait.[2] Both of these pesticides are currently registered under the authority of FIFRA § 3.

[2] Unless otherwise, noted Complainant will use the following abbreviations throughout this brief. Complainant will use "Rozol Prairie Dog Bait" to refer generally to Rozol Prairie Dog Bait (EPA Reg. No. 7173-286), a pesticide registered under FIFRA § 3 (CX27), as well as the supplemental Special Local Needs registrations under FIFRA § 24(c). (CX2-CX7). Complainant will use "Rozol Pocket Gopher Bait" to refer to the Rozol Pocket Gopher Bait II

(CX1; CX27). Rozol Pocket Gopher Bait is registered under FIFRA § 3 for use on pocket gophers. (CX1, EPA3). Rozol Pocket Gopher Bait is classified as a restricted use pesticide "due to hazard to nontarget organisms." (*Id.*) As a result of its classification as a restricted use pesticide, Rozol Pocket Gopher Bait can only be sold to and used by a certified applicator or persons under their direct supervision and only for those uses covered by the certified applicator's certification. (*Id.*)

Rozol Prairie Dog Bait was initially registered in the states of Kansas, Nebraska, Wyoming, Colorado, Texas, and Oklahoma under FIFRA § 24(c) to control black-tailed prairie dogs under supplemental "Special Local Needs" ("SLN") labels. (CX 2-7; *see also* RX 4-9). During the time period relevant to this case, the supplemental SLN labels for Rozol Prairie Dog Bait expressly incorporated "all applicable directions, restrictions and precautions on the label for" Rozol Pocket Gopher Bait and required that the user have both the SLN label for Rozol Prairie Dog Bait and the label for Rozol Pocket Gopher Bait in his or her possession at the time of application. (CX2, EPA24; CX3, EPA32; CX4, EPA42; CX5, EPA50; CX6, EPA52; CX7, EPA57). All of the supplemental SLN labels stated that Rozol Prairie Dog Bait is classified as a restricted use pesticide "due to potential secondary toxicity to nontarget organisms." (*Id.*) Furthermore, all of the supplemental SLN labels stated that Rozol Prairie Dog Bait could only be sold to and used by a certified applicator or persons under their direct supervision and only for those uses covered by the certified applicator's certification. (*Id.*)

On May 13, 2009, Rozol Prairie Dog Bait was registered under FIFRA § 3, and its registration was conditioned on, among other things, the requirement that Respondent voluntarily cancel the SLN registrations in the six different states. (CX27, EPA504). On February 2, 2010,

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(Alternative Name: Rozol Pocket Gopher Bait Burrow Builder Formula) (EPA Reg. No. 7173-244). Finally, Complainant will use "Rozol" to refer to "Rozol Pocket Gopher Bait" and "Rozol Prairie Dog Bait," collectively.

EPA announced its receipt of applications by Respondent to cancel the SLN registrations for Rozol Pocket Gopher Bait. (CX 108, EPA2511-13). The label for the FIFRA § 3 registration for Rozol Prairie Dog Bait states that it is classified as a restricted use pesticide "due to hazard to nontarget organisms." (CX27, EPA509). Like the accepted label for Rozol Pocket Gopher Bait, the label for the FIFRA § 3 registration for Rozol Prairie Dog Bait provides that, as a result of its classification as a restricted use pesticide, it can only be sold to and used by a certified applicator or persons under their direct supervision and only for those uses covered by the certified applicator's certification. (*Id.*)

After obtaining the supplemental SLN registrations for Rozol, but prior to obtaining the registration for Rozol Prairie Dog Bait under FIFRA § 3, Respondent began a large-scale advertising campaign, which included advertisements broadcast by radio, disseminated in print, disseminated through direct mail packages, and advertisements posted on its website. (*See* Schmit Tr.[3] at 11:3-5 ("We generally – the marketing people – once a product is federally registered they want to sell it."). Four separate versions of Respondent's radio advertisements were broadcast on 2,117 separate occasions from at least September 26, 2007 to April 26, 2008. (CX42, EPA860-61; CX43, EPA862-63; CX44, EPA864-65; CX45, EPA866-67). Respondent contracted with the following radio stations or radio station conglomerates for the broadcast of one or more of the different versions of its radio advertisements for Rozol:

(1) Golden Plains AG Network, 120 broadcasts, from October 8, 2007 to December 21, 2007 (CX14a, EPA331-33);

(2) Western Kansas Broadcast, 229 broadcasts, from January 15, 2008 to March 2,

[3] When referring to the transcript in this brief, Complainant will use the following abbreviations: (1) "Schmit Tr." for the consecutively-paginated transcript of Mr. Thomas Schmit's testimony on February 9 and 10, 2012; (2) "Niess Tr." for the transcript of Ms. Claudia Niess's testimony on February 7, 2012; (3) "Hebert Tr." for the consecutively-paginated transcript of Mr. Hebert's testimony on February 7 and 8, 2012; (4) "Vyas Tr." for the transcript of Dr. Nimish Vyas's testimony on February 8, 2012; and (5) "Steeger Tr." for the transcript of Dr. Thomas Steeger's testimony on February 8, 2012.

2008 (*Id.*, EPA334-45);

(3) High Plains Radio, 1,521 broadcasts, from September 26, 2007 to December 31, 2007 (*Id.*, EPA348-51); and

(4) KGNC-AM and KXGL-FM, 247 broadcasts, from November 12, 2007 to April 26, 2008 (*Id.*, EPA354-60).

These radio "stations were selected by [Respondent's] marketing department based on a location of the target market. Selection was also based on comments from [Respondent's] sales force and customers as to which stations were appropriate for this advertising. Finally, station selection was also influenced by corporate links between stations in different geographic areas, in order to obtain volume discounts offered by related groups of stations." (CX14, EPA149).

Respondent's print advertisements were published in stockmen's and cattlemen's trade journals published from October 2007 to April 2008 that were circulated in six different states in which Respondent had obtained supplemental SLN registrations for Rozol Prairie Dog Bait: Colorado, Kansas, Nebraska, Oklahoma, Texas, and Wyoming. The majority of the print advertisements occupied almost an entire page and included pictures of a prairie dog and a burrow, as well as certain statements. In large font, the print advertisements urged the public to "[p]ut an end to Prairie dog damage with rozol®." (CX 14a, EPA286-EPA328; *see also* CX 14a, EPA330 (classified-type advertisement for Rozol)[4]). Respondent's print advertisements were published in at least 23 separate issues of the following various stockmen's and cattlemen's trade journals:

(1) Colorado Cattlemen's Association, *Cattle Guard*, October 2007 (CX14a, EPA285-88);

(2) Kansas Livestock Association, *Kansas Stockman*, October 2007 through February 2008 (*Id.*, EPA284-93);

[4] A number of Respondent's print advertisements for Rozol that are at issue in this case were published in the weekly issues of the *Wyoming Livestock Roundup* from February 16, 2008 through April 5, 2008. These particular advertisements are small and do not occupy the majority of an entire page of a trade journal. (CX 14a, EPA328-30).

(3) Nebraska Cattlemen Publication, *Nebraska Cattleman*, October 2007 through February 2008 (*Id.*, EPA394-99);

(4) Oklahoma Cowman Publication, *Oklahoma Cowman*, February 2008 (*Id.*, EPA300-01);

(5) The Cattleman Publication, *The Cattleman*, October 2007, November 2007, March 2008, and April 2008 (*Id.*, EPA302-06); and

(6) Wyoming Livestock Publication, *Wyoming Livestock Roundup*, February 16, 2008 through April 5, 2008 (weekly) (*Id.*, EPA328-30).

As Mr. Thomas Schmit, Manager of Regulatory Affairs for Respondent, testified, Respondent's "salespeople are members of th[ese] organizations, they pay dues and they participate in meetings for the purpose of marketing [Respondent's] products." (*Id.* at 67:17-20).

In addition to broadcasting advertisements for Rozol on the radio and publishing print advertisements for Rozol in various stockmen's and cattlemen's journals, Respondent also disseminated print advertisements through direct mail packages. Respondent initially distributed direct mail packages "in a single mailing done in November of 2007." (CX14a, EPA150). These direct mail packages were distributed in all six of the states in which Respondent had obtained supplemental SLN registrations for Rozol Prairie Dog Bait. (*Id.*) Respondent's initial direct mail packages included a two-page cover letter, a "Black-Tailed Prairie Dog Control – Research Bulletin" ("Research Bulletin"), a copy of the state-specific FIFRA § 24(c) supplemental SLN label, and a brochure entitled "Control Pocket Gophers & Black-Tailed Prairie Dogs (otherwise known as the "Old Slim Jim"). (*Id.*) The cover letters to the direct mail packages that Respondent distributed in November 2007 were dated October 31, 2007, and directed recipients to contact Jim Knuth, High Plains District Sales Manager for Respondent (CO, KS, NE, and WY), and Mark Newman, Southwest District Sales Manager (NM, OK, and TX), for "any questions" and "suggestions on best baiting practices." (CX14a, EPA171, 190, 209, 228, 247, 266). The cover letters also provided the email addresses for Mr. Knuth and Mr.

Newman, as well as their mobile phone numbers. (*Id.*) The Research Bulletin and Old Slim Jim also included company contact information for Respondent. (CX14a, EPA180, 189, 199, 208, 218, 227, 246, 256, 265, 275, 284).

After receiving a referral from another EPA Region in January 2008, Complainant initiated an investigation to determine Respondent's compliance with FIFRA. (CX8, EPA59; CX14, EPA129-36). The focus of the January 2008 referral and Complainant's initial investigation was Respondent's compliance with FIFRA § 12(a)(2)(E). As a result of its initial investigation, Complainant issued a Stop Sale, Use, or Removal Order ("SSURO") pursuant to FIFRA § 13(a), 7 U.S.C. § 136k(a), on June 2, 2008. (CX13, EPA122-26; CX 15, EPA363-68). This SSURO was issued as a result of Respondent's failure to disclose Rozol's restricted use classification in the radio advertisements. (*Id.*)

To rectify the compliance issues with its advertisements, Respondent sent EPA various information with a letter dated August 5, 2008. (CX17, EPA370-409). With this letter, Respondent provided "a list of distributor companies that distribute[d] Rozol Prairie Dog Bait" when it was registered under FIFRA § 24(c) in Kansas, Nebraska, Wyoming, Colorado, Texas, and Oklahoma. (*Id.*, EPA370, 378). In addition, Respondent noted that it was "advising [its] distributor companies that all of the advertising and literature in their possession concerning Rozol Prairie Dog Bait must be destroy[ed], to be replaced with updated materials as soon as possible." (*Id.*, EPA371). In order to ensure that these distributor companies destroyed the material, Respondent sent a letter requesting that the companies destroy, among other documents that failed to disclose Rozol's restricted use classification, the Research Bulletin and a document entitled "Understanding the True Cost of Treatment" (otherwise known as the "White Paper"). (*Id.*, EPA371, 407). With the letter, Respondent included a confirmation form that each

distributor was instructed to complete to ensure that the Research Bulletin and White Paper were destroyed or discarded. (*Id.*, EPA371, 408).

On August 22, 2008, EPA issued an amended SSURO to Respondent, which amended the original SSURO, issued on June 2, 2008, "to allow for the distribution or sale of the inventory of 'Rozol,' EPA Registration Number 7173-244, held in storage, subject to certain conditions identified in the" amended SSURO. (CX21, EPA433). The amended SSURO allowed Respondent to distribute Rozol on the following condition:

> [Respondent] does not distribute the following marketing materials or labeling for "Rozol," EPA Registration Number 7173-244: (1) the handout titled "Black-tailed Prairie Dog Control Research Bulletin," (2) the handout titled "Understanding the True Cost of Treatment" by Ted Bruesch, National Technical Support Manager, Liphatech, (3) the booklet titled "Control Pocket Gophers & Black-Tailed Prairie Dogs," and (4) any other similar technical labeling for "Rozol," EPA Registration Number 7173-244, that has not been subjected to a compliance review by U.S. EPA, until further notice from U.S. EPA.

(CX21, EPA436). Therefore, the amended SSURO conditioned Respondent's ability to distribute Rozol on the fact that Respondent was prohibited from distributing the Research Bulletin, Old Slim Jim, and White Paper. (*Id.*)

Both before and after the issuance of the amended SSURO, Claudia Niess, Environmental Engineer and Credentialed Enforcement officer for the Pesticide and Toxics Compliance Section, Land and Chemicals Division of U.S. EPA Region 5 (Niess Tr. at 27:1-12), communicated by phone and email with Mr. Schmit. On June 11, 2008, Ms. Niess spoke with Mr. Schmit over the phone and Mr. Schmit confirmed that Respondent advertises for Rozol using brochures through dealers, print media, and radio advertisements. (CX16, EPA369). Ms. Niess received a telephone call from Mr. Schmit on November 12, 2008. (CX25, EPA495). During this call, Mr. Schmit asked whether EPA would be amending the amended SSURO to

allow Respondent to distribute the Research Bulletin, Old Slim Jim, and White Paper. (*Id.*) Mr. Schmit indicated that the materials "were expensive" and that Respondent wanted to distribute the materials together. (*Id.*) During this phone call, Ms. Niess informed Mr. Schmit that Respondent cannot distribute these materials because doing so would violate FIFRA. (*Id.*)

In addition to the June 11 and November 12, 2008 telephone calls with Mr. Schmit, Ms. Niess sent Mr. Schmit an email on November 18, 2008. (CX20, EPA428-32). In this email, Ms. Niess sent Mr. Schmit an attached file that identified "the specific claims in the Research Bulletin which EPA Headquarters identified as unacceptable." (*Id.*, EPA429). The file Ms. Niess attached to her November 18, 2008 email was of select pages of the Research Bulletin, highlighted certain statements, and explained why the highlighted statements violated FIFRA. (*Id.*, EPA430-32). In her November 18, 2008 email, Ms. Niess advised Mr. Schmit that the Research Bulletin "may not be distributed as informational literature or advertising for Rozol as the claims identified differ substantially from the claims made as part of Rozol's registration with EPA; distribution of this material would be a violation of Section 12(a)(1)(B)" of FIFRA. (*Id.*) In a subsequent email to Mr. Schmit on December 4, 2008, Ms. Niess informed him that two additional brochures, the Old Slim Jim and the White Paper, also "may not be distributed as informational literature or advertising for Rozol since the claims made in these documents differ from the claims made as part of Rozol's registration with EPA, and would be an unlawful act according to Section 12(a)(1)(B) of FIFRA." (*Id.*, EPA428; Niess Tr. at 55:20-57:12).

Following Ms. Niess' email and telephone conversations with Mr. Schmit in June and November 2008, EPA sent Respondent a letter, dated January 26, 2009, requesting "all records between October 1, 2007 to June 2, 2008 showing the delivery, movement, or holding of 'Rozol,' including the quantity, the date of shipment and receipt, and the name of the consignor

and consignee." (CX22, EPA445). Respondent provided the requested information in a letter, dated February 5, 2009. (CX23, EPA446-92). With its letter, Respondent provided 43 shipment records for Rozol that covered this time period, 41 of which were Uniform Straight Bills of Lading (*id.*, EPA450-90) and two of which were Customer Order Picklists (*id.*, EPA491-92).

Ms. Niess continued her investigation into Respondent's compliance with FIFRA by monitoring the content made available to the public on Respondent's website at www.liphatech.com from November 18, 2009 to February 23, 2010. (CX28-31; Niess Tr. at 68:18-21, 68:25-69:2). Ms. Niess searched Respondent's website on November 18, 2009, February 10, 19, and 23, 2010. (CX28-31). After each of these searches, Ms. Niess printed the materials that she discovered and documented how and where she found the materials on Respondent's website. (*Id.*) The documents Ms. Niess printed after each search of Respondent's website included: webpage printouts for Rozol Prairie Dog Bait and Rozol Pocket Gopher Bait ("Product Information Sheets"), (CX28, EPA512-14; CX29, EPA534-35; CX30, EPA554-55; CX31, EPA574-575, 596-97), a copy of a new version of the White Paper, (*id.*, CX28, EPA516-21; CX29, EPA536-41; CX30, EPA556-61; CX31, EPA576-81), and a copy of the new version of the slim jim ("New Slim Jim") (*id.*, CX28, EPA22-32; CX29, EPA542-52; CX30, EPA562-72; CX31, EPA582-92). (*Id.*)

Ms. Niess also searched Respondent's website on or about February 25, 2010. (Niess Tr. at 77:10-14). On this date, Ms. Niess "found a page on Respondent's website under the news section that appeared to be similar to the cover letter to the direct mail packages" that Respondent sent in November 2007. (*Id.* at 77:16-19). This letter was dated November 2009 and was from Mr. Knuth and Mr. Newman, Respondent's district sales managers. (*Id.* at 77:20-21; 98:13-17). "The letter provided updated information to ranchers, landowners, and

cattelemen with updated information since Rozol Prairie Dog Bait had been registered under Section 3 of FIFRA." (*Id.* at 77:24-78:2). The letter also referenced an "enclosed brochure," namely the New Slim Jim, which indicated to Ms. Niess "that additional brochures were being sent to customers, ranchers, cattlemen, and landowners." (*Id.* at 78:6-10, 98:1-7). The letter closed by inviting "cattlemen, farmers, and landowners to try Rozol Prairie Dog Bait for themselves." (*Id.* at 98:5-7).

As a result of compliance issues associated with the materials Ms. Niess discovered on Respondent's website in late 2009 and early 2010, Complainant issued a third SSURO to Respondent. Complainant issued the third SSURO on March 4, 2010. (CX32, EPA598-606). Pursuant to the third SSURO, Respondent was ordered to, among other things, immediately cease making claims for Rozol that substantially differ from any claims made for Rozol as part of the statements required for registration under FIFRA § 3. (*Id.*, EPA605 ¶ 29). The third SSURO specified that the violative claims must be removed from Respondent's website, as well as any "print advertisements" and "marketing materials (including brochures, pamphlets, posters, and any other such materials used in the advertisement, distribution or sale)" for Rozol. (*Id.*)

After the third SSURO was issued, Respondent contacted Complainant. To rectify the violations identified in the third SSURO, Respondent stated that it would again be sending a letter to its distributors, requesting that they destroy or discard all literature, flyers, and advertisements concerning Rozol. (CX 53, EPA994). Respondent sent Complainant a list of 48 distributors who "received the destroy/discard letter" that Respondent sent on March 9, 2010. (*Id.*, EPA3516). Respondent sent Complainant a sample "confirmation form" that it would be sending to its distributors, requesting that each of the 48 distributors complete and sign the form certifying that they have discarded the advertisements and "other literature, flyers, and

advertisements concerning" Rozol. (CX 53, EPA996-97). Respondent also agreed to send Complainant the "'confirmation forms' as they are executed and returned." (CX145, EPA3518). Complainant has never received any executed "confirmation forms."

On April 1, 2010, Complainant issued an "Updated Notice of Intent to File an Administrative Complaint" letter to Respondent. (CX33, EPA607). The April 1, 2010 letter informed Respondent that it superseded the Notice of Intent letter dated September 18, 2009. (*Id.*; CX24, EPA493-94). In addition, this letter informed Respondent that EPA planned to file an administrative complaint against Respondent, alleging violations of FIFRA related to Respondent's advertisements for Rozol. (*Id.*, EPA607-08). Finally, this letter also stated that EPA planned to propose a penalty of approximately $2.9 million dollars for Respondent's alleged violations of FIFRA. (*Id.*, EPA607).

## IV. STANDARD OF PROOF

In an administrative penalty action initiated under the Consolidated Rules, the standard of proof is the "preponderance of the evidence." 40 C.F.R. § 22.24(b). Under 40 C.F.R. § 22.24(a), EPA bears "the burdens of presentation and persuasion that the violation[s] occurred as set forth in the Complaint and that the relief sought is appropriate." The proponent must show that the evidence as a whole proves that the facts sought to be proven are more probable or likely than not to have occurred. As the Environmental Appeals Board ("EAB" or "the Board") has observed, the complainant has the burden of going forward with and providing evidence that the violation occurred. *In re Sandoz, Inc.*, 2 E.A.D. 324, 337 (CJO 1987).

## V. RESPONDENT SHOULD BE HELD LIABLE FOR THE VIOLATIONS ALLEGED IN COUNTS 2,141 THROUGH 2,231 OF THE COMPLAINT

In Counts 2,141 through 2,231 of the Complaint, Complainant alleges violations of FIFRA § 12(a)(1)(B). The FIFRA § 12(a)(1)(B) violations alleged in Counts 2,141 through

2,183 cover the time period of October 1, 2007 through May 30, 2008, and involve the claims Respondent made in the cover letters to the November 2007 direct mail packages and the Research Bulletin. (Compl. Counts 2,141-2,183). The FIFRA § 12(a)(1)(B) violations alleged in Counts 2,184 through 2,231 of the Complaint cover the time period November 18, 2009 through February 23, 2010, and involve the claims Respondent made on its website in the Product Information Sheets for Rozol Prairie Dog Bait and Rozol Pocket Gopher Bait and in the New Slim Jim. (*Id.*, Counts 2,184-2,231).

FIFRA § 12(a)(1)(B) makes it unlawful "for any person in any State . . . to distribute or sell to any person . . . any registered pesticide if any claims for it as part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under [7 U.S.C. § 136a]." 7 U.S.C. § 136j(a)(1)(B). Complainant must prove five elements to establish liability under FIFRA § 12(a)(1)(B)[5]:

1) Respondent is a "person" under FIFRA Section 2(s), 7 U.S.C. § 136(s);
2) Respondent is located in a state;
3) Respondent "distributed or sold" as defined by FIFRA Section 2(gg), 7 U.S.C. § 136(gg);
4) A registered pesticide;
5) Using claims made for the pesticide as part of its distribution or sale that substantially differ from the claims made for the pesticide as part of the statement required in connection with its registration.

*In re Microban Prods. Co.*, 11 E.A.D. 425, 440 (EAB 2004) ("*Microban II*") (quoting *In re Microban Prods. Co.*, 9 E.A.D. 674, 687 (EAB 2001) ("*Microban I*"). Elements 1), 2), and 4) have been established for all of the violations alleged in Counts 2,141 through 2,231 of the Complaint. (Joint Stipulated Facts ("Joint Stips.") at 2). Respondent is a corporation located in

[5] In previous briefs, Complainant has listed four and five elements required to establish liability under FIFRA § 12(a)(1)(B). To avoid conflating elements, Complainant lists five elements in this brief.

Wisconsin and is the registrant of Rozol. (*Id.*) For 41 of the 43 alleged violations in Counts 2,141 through 2,183 of the Complaint, Respondent has stipulated that it "distributed or sold" Rozol. (Joint Stips. at 9-12; Compl. ¶¶ 213-15, 217-49, 251-57). Consequently, for Counts 2,141 through 2,183 of the Complaint, element 5) remains at issue for all of the counts and element 3) remains at issue for Counts 2,144 and 2,178 of the Complaint only. Elements 3) and 5) remain at issue for Counts 2,184 through 2,231 of the Complaint.

### A. Respondent "Distributed or Sold" Rozol

#### 1. "Distribution or Sale" is Defined Broadly By FIFRA

"[T]o distribute or sell" is defined by FIFRA § 2(gg) as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver." 7 U.S.C. § 136(gg). The definition of "to distribute or sell" includes the grammatical variations of these words such as "distributed or sold" and "distribution or sale." 40 C.F.R. § 152.3. Under FIFRA, "distribution or sale" covers several acts that are precursors to an actual sale of a pesticide. *See* 7 U.S.C. § 136(gg); 40 C.F.R. § 152.3. By including acts that precede an actual distribution or sale in FIFRA's broad definition of "distribution or sale," Congress sought to further FIFRA's goal of protecting "purchasers from being induced into purchasing a pesticide based on unapproved claims that are potentially false or misleading . . . ." *Microban I*, 9 E.A.D. at 686.

#### 2. Respondent "Distributed or Sold" Rozol as Alleged in Counts 2,144 and 2,178 of the Complaint

The distributions or sales that are the subject of Counts 2,144 and 2,178 of the Complainant are demonstrated by two "Liphatech, Inc. Customer Order Picklist(s)." (CX23, EPA491-92). Located at the top left-hand corner of the picklists are the names of the individuals, Jim Knuth and Mark Newman, to whom the Rozol was allegedly "sold." (CX23,

EPA491-92). Selling a pesticide constitutes "distribution or sale" under FIFRA. 7 U.S.C. § 136(gg). In addition, at the bottom left-hand side of these picklists, there is information showing that Respondent shipped, and therefore distributed or sold, Rozol to the Snow King Resort in Jackson Hole, Wyoming on October 29, 2007, and to the attention of Todd Martin of Helena Chemical Co. in Hartley, Texas on April 28, 2008. (CX23, EPA491-92).

The Rozol "sold to" Mr. Knuth was shipped to the Snow King Resort on October 29, 2007. (CX23, EPA491). About one week after Rozol was shipped to the Snow King Resort, during the week of November 5, 2007[6], the resort "was hosting a Wyoming Weed and Pest Conference. (Niess Tr. at 60:21-61:13). Mr. Knuth, as a district sales manager for Respondent, undoubtedly was using this shipment of Rozol for demonstration purposes at this conference. Consequently, the "sale" of Rozol to Mr. Knuth clearly meets the definition of "distribution or sale" in FIFRA. *See In re Sultan Chemists, Inc.*, Docket No. FIFRA-95-H-05, 1999 EPA ALJ LEXIS 46, at *10 (ALJ Aug. 4, 1999) (holding that shipments to the respondent's salespeople for demonstration purposes constituted distributions or sales under FIFRA).

Similarly, the Rozol "sold to" Mr. Newman on April 18, 2008 was shipped to Todd Martin, the branch manager of one of Respondent's regular distributors, Helena Chemical Co. (CX132, EPA3186; CX23, EPA492). Mr. Martin and Helena Chemical Co. appear on a list of companies that were authorized to distribute Rozol Prairie Dog Bait when it was registered under FIFRA § 24(c). (CX17, EPA378; *see also* Schmit Tr. at 194:21-25 (stating that CX17, EPA378 is a list of the "universe of distributors" authorized by Respondent to distribute Rozol Prairie Dog Bait when it was registered under FIFRA § 24(c))). Mr. Martin and the Hartley, Texas location of Helena Chemical Co. received six shipments of Rozol as established by the uniform

[6] The picklist specifically stated, in the bottom, left-hand corner, "Please ship to arrive by 11/05/07." (CX23, EPA491).

straight bills of lading provided by Respondent with its February 5, 2009 letter. (CX23, EPA465-68, 470, 485). Furthermore, various locations of Helena Chemical Co. are listed in the other lists of Respondent's distributors that are in the record. (CX145, EPA3522; CX149, EPA3567; *see also* CX50, EPA932).

Respondent has admitted that the "sales" of Rozol to Mr. Knuth and Mr. Newman fall within the definition of "distribution or sale" under FIFRA. In its February 5, 2009 letter to EPA, Respondent stated that "[t]here is no 'movement' of the 'Rozol' products registered under EPA Reg. No. 7173-244, *other than for sale and shipping to customers*." (CX23, EPA448 (emphasis added)). Similarly, Respondent stated that it "has no records of 'holding' of the products registered under EPA Reg. No. 7173-244, *other than for sale and shipping to customers*." (*Id.* (emphasis added)). Respondent further conceded that Rozol "is manufactured at our Milwaukee, WI facility and stored there. None of this product was moved or transferred to any other storage facility *other than for the sale and shipping to customers*." (*Id.* (emphasis added)). The admissions in Respondent's February 5, 2009 letter demonstrate that the October 29, 2007 and April 18, 2008 "sales" to Mr. Knuth and Mr. Newman constitute "distributions or sales" under FIFRA.

In addition to memorializing "sales" to Mr. Knuth and Mr. Newman, the picklists show that Rozol was shipped to the "Snow King Resort" in Jackson Hole, Wyoming and "Helena Chemical Co. Attn: Todd Martin" in Hartley, Texas. There can be no dispute that Todd Martin, Helena Chemical Co., and the Snow King Resort are all persons as defined by FIFRA. 7 U.S.C. § 136(s) (defining "person" to mean, among other things, individuals, corporations, or "any organized group of persons whether incorporated or not").

For all of the foregoing reasons, Complainant has demonstrated by a preponderance of the evidence that Respondent distributed or sold Rozol as alleged in Counts 2,144 and 2,178 of the Complaint.

3. On 48 Separate Occasions, Respondent "Offered [Rozol] for Sale" as Alleged in Counts 2,184 through 2,231 of the Complaint

In Counts 2,184 through 2,231, Complainant alleges that Respondent "offered [Rozol] for sale" to 48 distributor partners between November 18, 2009 and February 23, 2010. (Compl. ¶644). "Offer for sale" is included in FIFRA's definition of "distribution or sale." 7 U.S.C. § 136(gg). It is not, however, independently defined by FIFRA. *See id.* EPA has promulgated a rule interpreting "offer for sale" in the context of FIFRA § 12(a)(1)(B) "as extending to advertisements in any advertising medium to which pesticide users or the general public have access." EPA's interpretation in 40 C.F.R § 168.22(a) is consistent with FIFRA's remedial nature and its goal of protecting "consumers from misrepresentations as to pesticides' efficacy, safety, or other qualities." *Antkiewicz*, 8 E.A.D. at 242.

a. 40 C.F.R. § 168.22(a) Governs in This Proceeding

"When construing an administrative regulation, the normal tenets of statutory construction are generally applied." *In re Bil-Dry Corp.*, 9 E.A.D. 575, 595 (EAB 2001) (citing *Black & Decker Corp. v. Comm'r*, 986 F.2d 60, 65 (4th Cir. 1993)). "A fundamental canon of statutory construction is that if language is plain and unambiguous it must be given effect." *In re Arecibo & Aguadila Reg'l Wastewater Treatment Plants*, 12 E.A.D. 97, 130 n.60 (EAB 2005). The EAB has stated that if a regulation's language is clear and unambiguous, it "generally follows the unambiguous intent expressed by the language." *In re Rochester Pub. Utilities*, 11 E.A.D. 593, 603 (EAB 2004).

The language of 40 C.F.R. § 168.22(a) is unambiguous. Section 168.22(a) states as

follows:

> FIFRA sections 12(a)(1) (A) and (B) make it unlawful for any person to "offer for sale" any pesticide if it is unregistered, or if claims made for it as part of its distribution or sale differ substantially from any claim made for it as part of the statement required in connection with its registration under FIFRA section 3. EPA interprets these provisions as extending to advertisements in any advertising medium to which pesticide users or the general public have access.

40 C.F.R. § 168.22(a). This provision unambiguously extends "offer for sale" in the context of FIFRA § 12(a)(1)(B) to mean "advertisements in any medium to which pesticide users or the general public have access." Therefore, 40 C.F.R. § 168.22(a) should be applied as written. *See also Microban II*, 11 E.A.D. at 444 n.26 (rejecting the respondent's argument on the scope of EPA's authority to regulate advertising and noting that EPA interpreted the claims referenced in FIFRA § "12(a)(1)(B) to 'extend[] to advertisements in any advertising medium to which pesticide users or the general public have access'") (citing 40 C.F.R. § 168.22(a)).

The regulatory history of 40 C.F.R. § 168.22(a) sheds additional light on its meaning. The proposed version of 40 C.F.R. § 168.22(a) was, in relevant part, as follows:

> (a) FIFRA section 12(a)(1)(A) and (b) [*sic*] make it unlawful for any person to "offer to sell" any pesticide if it is unregistered, or if claims made for it as part of its distribution or sale substantially differ from any claim made for it as part of the statement required in connection with its registration under FIFRA section 3. EPA interprets these provisions as making unlawful for any person who sells, holds for sale, or distributes any pesticide to place or sponsor ***certain kinds of advertisements*** in any advertising medium to which pesticide users or the general public have access.
>
> (b) The ***kinds*** of advertisements that EPA regards as unlawful under this interpretation are those which recommend or suggest the purchase or use of . . . .

(CX84, EPA1548 (emphasis added)). The final rule includes an important difference from the proposed rule. Unlike the proposed rule, the second full sentence of the final version of 40

C.F.R. § 168.22(a) is not limited to "certain kinds of advertisements." *Compare* 40 C.F.R. § 168.22(a) *with* (CX84, EPA1548). In addition, unlike the proposed version of subsection(b), which uses the common word "kinds" to refer back to subsection (a) of the proposed rule, the first full sentence in 40 C.F.R. § 168.22(b) does not refer back to 40 C.F.R. § 168.22(a). Section 168.22(a)'s transformation into its current form is compelling and demonstrates that the Agency intended it to apply in proceedings such as this.

In addition, the Ninth Circuit's recent decision in *United States v. Snapp*, 423 Fed. Appx. 706 (9th Cir. 2011) (unpublished) is instructive on whether 40 C.F.R. § 168.22(a) governs in this proceeding. In *Snapp*, the defendant appealed his conviction for offering to sell an endangered wildlife species in violation of the Endangered Species Act ("ESA"). *Id.* at 707 (citing 16 U.S.C. § 1538(a)(1)(F)). The sole basis for the appeal was that the trial judge erred in rejecting the defendant's proposed jury instruction on the meaning of the term "offer for sale" as used in 16 U.S.C. § 1538(a)(1)(F). The appellate court affirmed, finding that the ESA's implementing regulation "assuming that most advertisements are 'offers for sale' under the [ESA]" was consistent with the statute's goal of eliminating the extinction of endangered species. *Id.* at 707-08 (citing 50 C.F.R. § 17.21(f)(2) and *Babbit v. Sweet Home Chapter of Cmtys for a Great Oregon*, 515 U.S. 687, 698 (1995)). In so holding, the court rejected the defendant's argument that the jury should have been instructed to use the "narrower definition of 'offer for sale' in the Restatement (Second) of Contracts."[7] *Id.* at 708. Like the court in *Snapp*, this Tribunal should conclude that 40 C.F.R. § 168.22(a)'s language providing that most advertisements constitute

[7] Alternatively, the court in *Snapp* held that any error with respect to the proposed jury instructions was harmless, as the evidence showed that "[t]he government introduced evidence that [the defendant] listed the elephant skull for sale on Craigslist and communicated with potential buyers in a manner evidencing his intent to complete a transaction." *Id.* The primary holding of the Court in *Snapp*, however, was that the regulation interpreting offer for sale under 16 U.S.C. § 1538(a)(1)(F) as applying to most advertisements, was consistent with the ESA's goal of eliminating the extinction of endangered species. *Id.*

"offers for sale" for purposes of FIFRA § 12(a)(1)(B) is consistent with FIFRA's goal of protecting "consumers from misrepresentations as to pesticides' efficacy, safety, or other qualities." *Antkiewicz*, 8 E.A.D. at 242.

A narrower interpretation of 40 C.F.R. § 168.22(a) would create a large loophole in FIFRA's "comprehensive regulatory scheme." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984). Congress intended FIFRA § 12(a)(1)(B) and (a)(2)(E) to work in tandem. FIFRA § 12(a)(1)(B) makes it illegal to make claims for a registered pesticide that substantially differ from the claims that were made as part of the statement required under FIFRA § 3. 7 U.S.C. § 136j(a)(1)(B). FIFRA § 12(a)(2)(E) declares one particular claim – "restricted use" – as being so important that it must be disclosed in advertising. 7 U.S.C. § 136j(a)(2)(E). If Congress intended FIFRA § 12(a)(2)(E) to be the only provision in FIFRA § 12 to address advertising, it would send a conflicting message to the regulated community: FIFRA § 12 would make it illegal to advertise a restricted use pesticide without disclosing that it is a restricted use pesticide or its terms of restriction, but it would impose no sanction for advertising a pesticide using claims that substantially differed from "any claims made for it as part of the statement required in connection with its registration." 7 U.S.C. § 136j(a)(1)(B). Congress could not have intended such a result. EPA's interpretation of "offer for sale" in 40 C.F.R. § 168.22(a) reinforces FIFRA's comprehensive regulatory scheme and provides an additional layer of protection for consumers from misleading claims about registered pesticides.

Respondent's contention that the EAB's decision in *In re Tifa Ltd.*, 9 E.A.D. 145, 160 (EAB 2000) governs in this case falls short. (Resp.'s Prehrg. Br. at 47-51). The primary issue before the Board in *Tifa* was whether the respondent had properly requested a hearing after receiving a suspension order, rendering the suspension order ineffective until a hearing was held.

*Id.* at 147. The EAB dealt with the "offer for sale" issue independently, because it reversed the ALJ's finding on the primary issue. *Id.* at 156 (citing 40 C.F.R. § 22.30(f) and *In re Comm. Cartage Co.*, 7 E.A.D. 784 (EAB 1998)).

For one of the counts at issue, the Board had to decide whether the record evidence established an "offer for sale." *Id.* at 157. The Board noted that "[t]he issue of what constitutes an 'offer for sale' under FIFRA is a matter of first impression." *Id.* Because "the parties [did not cite] any relevant cases on this point, and there is no legislative history to provide guidance in this area," the Board decided to consult general contract law principles to determine what constitutes an "offer for sale" under FIFRA. *Id.* at 158-59. Ultimately, the Board held that a facsimile sent by the respondent to a pesticide user, which included a price quote and notified the prospective user that the pesticide was "in stock and available for prompt shipment," was insufficient to show an "offer for sale." *Id.* at 160.

Despite the fact that 40 C.F.R. § 168.22 existed in its current form at the time of the Board's decision, the Board stated that "[n]either FIFRA *nor the underlying regulations define 'offer for sale.'*" *Id.* at 518 (emphasis added). Furthermore, the Board did not make any reference to 40 C.F.R. § 168.22 in its decision, presumably because the parties never brought the regulation to the Board's attention. In its final order, the Board was careful to note that the decision was based solely on the "authorities cited" by it and the parties. *Id.* The EAB's decision in *Tifa* should be narrowly construed as applying only to the specific facts in that case. *Compare Microban II*, 11 E.A.D. at 444 n.26 (citing 40 C.F.R. § 168.22(a) and describing it as "interpreting the claims referenced under 12(a)(1)(B) to 'extend to advertisements in any advertising medium to which pesticide users or the general public have access'"); *In re Sporicidin Int'l*, 3 E.A.D. 589, 605 (CJO 1991) (acknowledging the existence of 40 C.F.R. §

168.22 and holding that "distribution [which includes an offer for sale, 7 U.S.C. § 136(gg),] includes both marketing and merchandising a commodity" and that "merchandising means 'sales promotion as a comprehensive function'").

In conclusion, the plain language of 40 C.F.R. § 168.22 makes it clear that advertising constitutes an "offer for sale" under FIFRA § 12(a)(1)(B) and a contractual offer is not needed. As this Tribunal recognized in *In re 99 Cents Only Stores*, a violation of FIFRA § 12(a)(1) can occur if EPA discovers a violative product in the market place on a shelf waiting to be sold. *In re 99 Cents Only Stores*, Docket No. FIFRA-09-2008-0027, 2010 EPA ALJ LEXIS 10, at *41 (citing "*Johnson Pacific, Inc.*, 5 E.A.D. 696 (EAB 1995)(retailer charged with one violation for one unregistered product sold to inspector despite many units of the product available for sale); *Sav Mart, Inc.*, 5 E.A.D. 732, 1995 EPA App. LEXIS 13, at *1-5 (EAB 1995)(retailer charged with one violation for selling an unregistered pesticide although evidence indicated that it produced and offered for sale ten bottles of unregistered pesticide and made one sale of two bottles to the inspector)"). In this case, the Rozol sat on a "virtual shelf" for the taking – a simple phone call from a distributor or prospective customer to one of Respondent's sale managers, whose email addressed and mobile phone numbers were listed on several documents, could have been made to initiate the purchase of the product. (*See, e.g.,* CX14a, EPA171, 190, 209, 228, 247, 266; Niess Tr. at 97:21-23). As explained below, Respondent's internet advertisements, which were reinforced by the direct mail packages that enclosed the New Slim Jim, are sufficient to show that offers for the sale of Rozol were made in accordance with 40 C.F.R. § 168.22(a).

b. Respondent's advertisements fall within 40 C.F.R. § 168.22(a) and are therefore offers for the sale of Rozol

The materials containing the claims that are at issue in the Counts 2,184 through 2,231 of

the Complaint are "offers for sale," because they are advertisements that Respondent made available to pesticide users or the general public in print media and on its website. 40 C.F.R. § 168.22(a). There are two types of materials at issue in Counts 2,184 through 2,231 of the Complaint: (1) the Product Information Sheets for Rozol and (2) the New Slim Jim.[8] (*See generally* Compl. ¶¶275-336; CX 28, EPA512-14, 522-32; CX29, EPA534-35, 542-52; CX30, EPA554-55, 562-72; CX31, EPA574-75, 582-92, 596-97). Respondent has admitted that these materials were "advertisements." (Answer ¶¶349-51 (referring to the materials found on its website in November 2009 and February 2010, which include the subject materials, as "these advertisements").[9] Notwithstanding Respondent's admission, there can be no doubt that the Product Information Sheets and the New Slim Jim fall within the ordinary meaning of the word advertisement. *In re Bil-Dry Corp.*, 9 E.A.D. at 595.

The contents of the Product Information Sheets and the New Slim Jim demonstrate that these materials were intended "to call public intention to esp. by emphasizing desirable qualities so as to arouse a desire to buy or patronize." MERRIAM WEBSTER'S COLLEGE DICTIONARY 18 (10th Ed. 1994) (defining "advertise"); *see also* BLACK'S LAW DICTIONARY 55 (7th Ed. 1999) (defining "advertising" as "[t]he action of drawing the public's attention to something to promote its sale"). The Product Information Sheets for Rozol Prairie Dog Bait and Rozol Pocket Gopher Bait include bulleted lists of the "unique benefits" of the products. (CX31, EPA574, 596). The

[8] When Ms. Niess discovered the Product Information Sheets for Rozol and the New Slim Jim on Respondent's website on November 18, 2009, she also discovered the New White Paper. (CX28, EPA516-21; CX29, EPA536-41; CX30, EPA556-61; CX31, EPA576-81). The New White Paper, although not a subject of Counts 2,183 through 2,231, includes claims that are very similar to the Product Information Sheets and New Slim Jim. (*Compare id. with* CX 28, EPA512-14, 522-32; CX29, EPA534-35, 542-52; CX30, EPA554-55, 562-72; CX31, EPA574-75, 582-92, 596-97).

[9] In its pre-hearing brief, Respondent attempts to rewrite history and backpedal from this admission. (Resp.'s Prehrg. Br. at 53 n. 33). Respondent, however, failed to offer any evidence at the hearing substantiating the prior affidavit of Carl Tanner, Chief Executive Officer of Respondent, which was not admitted into the record. (*See* 6/24/11 Or. at 25 (noting Mr. Tanner's affidavit and statement that he will testify at hearing)). Consequently, Respondent must be bound by its admission in its answer.

New Slim Jim is filled with even more descriptions and depictions of the benefits one can expect from Rozol. It begins by warning prospective users of the "major damage" an "infestation" of prairie dogs or pocket gophers can have on land and livestock. (CX31, EPA583-84). These warnings are followed by noting that "Rozol offers unique advantages." (*Id.*, EPA585). Similar to the Product Information Sheets, the New Slim Jim includes a lengthy list of the "benefits of Rozol" and many graphs and charts comparing Rozol to other rodenticides. (*Id.*, EPA585-86, 589). Both the Product Information Sheets and the New Slim Jim describes the various "convenient" sizes of Rozol packages that are available and the coverage areas a user can expect from these package sizes; they also include directions for using Rozol and information on the different types of application equipment. (*Id.*, EPA574, 588, 591, 596).

Respondent made the Product Information Sheets and the New Slim Jim available to the general public and to pesticide users on its website between November 18, 2009 and February 23, 2010. (CX28, EPA511; CX29, EPA533; CX30, EPA553; CX31, EPA573 (stating that the materials were printed from Respondent's website); (Niess Tr.68:25-69:1) (testifying that Respondent's website was available to the public)). In addition, Ms. Niess discovered a November 2009 letter from Respondent's district sales managers to "cattlemen, landowners, and farmers" on Respondent's website on February 25, 2010. (Niess Tr. at 77:10-14). This letter was "similar to the cover letter to the direct mail packages" that Respondent sent in November 2007. (*Id.* at 77:15-19). In this letter, which stated that it enclosed the New Slim Jim, Respondent announced that it had obtained a FIFRA § 3 registration for Rozol Prairie Dog Bait and invited cattlemen, landowners, and farmers to try Rozol Prairie Dog Bait for themselves. (Niess Tr. at 97:9-98:17). Cattlemen, landowners, and farmers are all targeted in the New Slim Jim. (*See* CX31, EPA583-84 (describing potential "major damage" from prairie dogs and pocket

gophers to "alfalfa, grassland, lawns and golf courses" and their potential effects on "grazing capacity" and "livestock weight gain")). Therefore, in addition to making the Product Information Sheets and New Slim Jim available on its website, there is strong circumstantial evidence showing that Respondent disseminated the New Slim Jim to a target audience of cattlemen, landowners, and farmers.

Based on the foregoing, this Tribunal should conclude that the evidence shows that the requirements of 40 C.F.R. § 168.22(a) have been satisfied. The Product Information Sheets and New Slim Jim fall squarely within the definition of an "advertisement." Both seek to communicate the benefits one can expect from the use of Rozol to kill black-tailed prairie dogs and pocket gophers, generally and as compared with other rodenticides. These materials undoubtedly were used by Respondent to promote the sale and use of Rozol. Respondent made the Product Information Sheets and the New Slim Jim available to the general public on its website, and it also sent the New Slim Jim to prospective customers in its November 2009 letter. Applying 40 C.F.R. § 168.22(a), Complainant has established that Respondent offered Rozol for sale as alleged in Counts 2,184 through 2,231 of the Complaint.

**B. <u>Respondent's Advertisements Included Numerous "Claims" for Rozol</u>**

"Claim," as used in FIFRA § 12(a)(1)(B), "connotes an affirmative representation, whether express or implied, as to certain attributes, results, and so on." *Antkiewicz*, 8 E.A.D. at 242-43; *see also Lowe v. Sporicidin Int'l*, 47 F.3d 124, 130 (4th Cir. 1995) (referencing "claims" made "in connection with" a pesticide's registration as including label statements such as "avoid skin contact," "avoid eye contact," and "use in ventilated areas"); *In re Sporicidin Int'l*, Docket No. FIFRA-88-H-02, 1988 EPA ALJ LEXIS 14, at *46 (ALJ Nov. 1, 1988) (describing "claim" as "an 'assertion, statement or implication (as to value, effectiveness, qualification, eligibility)

often made or likely to be suspected of being made without adequate justification'"). As explained in detail below, Respondent made numerous "claims" for Rozol.

1. Counts 2,141 through 2,183

Counts 2,141 through 2,183 are based on claims that were made by Respondent in three different media: (1) print advertisements, including the Research Bulletin, that Respondent circulated through direct mail packages sent to customers in Colorado, Kansas, Nebraska, Oklahoma, Texas, and Wyoming (CX14a, EPA175-80, 194-99, 213-18, 232-37, 251-56, 270-75); (2) radio advertisements that were broadcast in Colorado, Kansas, Nebraska, and Texas (CX14a, EPA346-47, 352-53, 361-62; CX42-45); and (3) internet advertisements through Respondent's website, www.liphatech.com (CX 52, EPA973-93). (*See generally* Compl. ¶¶146-209). Respondent's direct mail packages included the following documents: (1) cover letters, dated October 31, 2007; (2) the Research Bulletin; (3) a copy of the state-appropriate FIFRA § 24(c) special local needs labeling; and (4) the Old Slim Jim. (CX14a, EPA150). Respondent admits that these direct mail packages were "distributed in a single mailing done in November of 2007" in the states of Colorado, Kansas, Nebraska, Oklahoma, Texas, and Wyoming. (*Id.*)

Respondent has admitted that several of the statements made in the advertisements that are the subject of Counts 2,141 through 2,183 are claims for Rozol. The direct mail package cover letters referred to the use of Rozol to kill black-tailed prairie dogs and pocket gophers. (*See, e.g.,* CX14a, EPA171, 190, 209, 228, 247, 266). With respect to the direct mail package cover letters, Respondent admits that three statements are claims. (Joint Stips. at 7; Compl. ¶¶ 146, 149, 152; CX14a, EPA 172, 191, 210, 229, 248, 267 (emphasis in original)). Respondent also admits that several statements in the Research Bulletin are claims.[10] (CX14a, EPA175-80,

[10] In the Old Slim Jim, dated August 27, 2007, that was also included in the direct mail packages, Respondent made identical or nearly identical claims to those that Respondent admitted making in the Research Bulletin. For

194-99, 213-18, 251-56, 270-75; Joint Stips. pp. 7-8; Compl. ¶¶ 155, 158, 161, 164, 167, 170, 182 (emphasis in original)). Finally, Respondent has admitted that several statements in its radio advertisements are claims. (CX14a, EPA352, 353, 361; Joint Stips. p. 9; Compl ¶¶ 199, 202 (emphasis in original)).

There are five statements in the Research Bulletin, however, that Respondent has admitting making, but it denies that the statements were claims for Rozol. The statements compare the efficacy or toxicity of Rozol (chlorophacinone) to the efficacy or toxicity of zinc phosphide or Kaput-D (diphacinone) are as follows:

- Traditional control products such as zinc phosphide or diphacinone-based anticoagulants have not proven to effectively prevent population recovery, leading to the need for costly re-treatment.
- Kaput-D Prairie Dog Bait (22 PPM) achieved only 53% to 56% control.
- Kaput-D Pocket Gopher Bait* (50 PPM) 2 times (2X) the rate of active ingredient, achieved only 56% to 57% control. *Not labeled for Black-Tailed Prairie Dog.
- Rozol's active ingredient (chlorophacinone) is ten times (10X) less toxic to dogs as Kaput-D's (diphacinone).
- Chlorophacinone is over 100X more effective on mice than diphacinone.

(Joint Stips. p. 8; Compl. ¶¶ 173, 176, 179, 185, 188). Respondent has suggested that these statements are not claims, because the statements are about its competitor's registered pesticides.

Respondent also denies that several statements in the chart entitled "Compare the products for yourself – there are many differences," which is on page five of the Research Bulletin, are claims under FIFRA § 12(a)(1)(B). (CX14a, EPA179, 198, 217, 236, 255, 274).

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example, the Old Slim Jim included claims such as "lower primary poisoning potential," "Rozol is easy-to-use," and "proven single application effectiveness." (CX14a, EPA184, 203, 222, 241, 260, 279).

The statements within the chart are very similar to the five statements referenced above, except they are provided in a graphic representation. (*Compare id. with* Compl. ¶¶ 173, 176, 179, 185, 188). By presenting the information in this manner, there is no question that Respondent sought to convey that Rozol is a safer and less costly alternative to Kaput-D (diphacinone) and zinc phosphide.

The five statements and the statements within the chart comparing Rozol (chlorophacinone) to zinc phosphide and Kaput-D (diphacinone) fall squarely within the description of "claim" in *Antkiwiecz* and the description of claim in *Sporicidin*. *Antkiewicz*, 8 E.A.D. at 242-43; *Sporicidin Int'l*, 1988 EPA ALJ LEXIS 14, at *46; *see also Lowe*, 47 F.3d at 130. All of these statements make affirmative representations about the effectiveness of: (1) a registered pesticide, whether it be Rozol or Kaput-D; or (2) an active ingredient in a pesticide, i.e., chlorophacinone (Rozol), diphacinone (Kaput-D), and zinc phosphide. Referring to a product as "easy-to-apply," providing its expected percentage of control (i.e., death rate), its effectiveness at killing mice, and stating whether "costly re-treatment" will be needed are statements about the alleged advantages of using Rozol compared with the lower death rates and added expense a prospective user can expect from use of the products of Respondent's competitors. Furthermore, representing that Rozol is "ten times less toxic to dogs than Kaput-D" is intended to convey that Rozol is a safer alternative to Kaput-D.

In addition, the context in which these statements were made cannot be ignored. All of these statements were made in the Research Bulletin. The first three comparative statements listed above were made on a page of the Research Bulletin entitled "Comparative Field Trials." (CX14a, EPA178, 198, 217, 236, 255, 274). The first sentence of this page warns prospective users that "[w]ithout proper control methods, black-tailed prairie dog (BTPD) populations can

quickly expand, or recover from greatly reduced numbers." (*Id.*) After making these three claims, Respondent closes by directing prospective users to "[c]hoose Rozol for proven single application effectiveness . . . Why waste time & money with other products? Why re-treat acreage sooner than necessary?" (*Id.*) When viewed in context, there is no question that Respondent made the three comparative claims from the results of the "field trials" in an attempt to demonstrate to prospective users that Rozol is superior. Respondent has admitted that at least one of the five comparative claims in the Research Bulletin inferred that Rozol was more efficacious. (*See* Schmit Tr. 154:23-24 (stating that with respect to the claim alleged in Compl. ¶173, "we are not only inferring about the efficacy of our product, but we are referring to the efficacy of the competing products")).

Similarly, the context of the two claims dealing with Rozol and Kaput-D's (diphacinone's) relative toxicity to dogs and ability to kill mice show that these statements are claims for purposes of FIFRA § 12(a)(1)(B). These statements are made on a page of the Research Bulletin entitled "Prairie Dog Bait Comparisons." (CX14a, EPA179, 198, 216, 235, 254). Although the first sentence of this page states that "Rozol's active ingredient and toxicity profile are different from other baits," the "conclusion" at the bottom of this page is "Rozol – the lowest risk profile among BTPD bait alternatives . . . Why risk potential harm to employees, livestock, birds, pets or other non-targets?" (*Id.*) To the extent that there is any doubt regarding the two statements in the Research Bulletin page entitled "Prairie Dog Bait Comparisons," the context of this page and the ultimate message shows that these two statements are claims under FIFRA § 12(a)(1)(B).

Finally, Respondent's argument that these comparative claims referencing its competitors products do not fall within the ambit of FIFRA § 12(a)(1)(B) would lead to absurd results. *City*

*of Columbus v. Ours Garage & Wrecker Serv.*, 536 U.S. 424, 449 n. 4 (2002) (referencing "the rule that a statute should not be interpreted to produce absurd results"). For Counts 2,141 through 2,183, Respondent has admitted that its direct statements about Rozol in the advertisements are claims under FIFRA § 12(a)(1)(B). Assuming for the purposes of this argument that these admitted claims run afoul of the prohibition in § 12(a)(1)(B) and Respondent were to escape liability on the five comparative claims in the Research Bulletin, the message for pesticide registrant's would be clear: one can avoid liability (and perhaps even mislead potential customers) by making comparative claims referencing a competitor's product. Clearly, this is not what Congress intended when it enacted FIFRA § 12(a)(1)(B).

With respect to all but five of the claims alleged in the Counts 2,141 through 2,183 of the Complaint, Respondent has admitted that the statements are claims for purposes of FIFRA § 12(a)(1)(B). Respondent's statements in the Research Bulletin comparing Rozol (chlorophacinone) to zinc phosphide and Kaput-D (diphacinone) fall within the ordinary meaning of "claim," particularly when they viewed in the context of the pages of the Research Bulletin on which they are found. The Chief Judge should hold that Complainant has established by a preponderance of evidence that the five comparative statements in the Research Bulletin are claims under FIFRA § 12(a)(1)(B).

2. Counts 2,184 through 2,231

The claims at issue in Counts 2,184 through 2,231 are found in the Product Information Sheets for Rozol and the New Slim Jim. (CX28-31; *see also* Niess Tr. at 68:25-69:2). Like the claims at issue in Counts 2,141 through 2,183, Respondent has admitted that the majority of the claims in the Product Information Sheets and the New Slim Jim that are alleged in Counts 2,184 through 2,231 of the Complaint are "claims" under FIFRA § 12(a)(1)(B). (CX28, EPA512, 526; CX29, EPA534, 546; CX30, EPA554, 566; CX31, EPA574, 586; Joint Stips. at 13-14; Compl.

¶¶ 275, 278, 281, 284, 287, 290, 293, 296, 299, 302, 305, 308). Similar to Counts 2,141 through 2,183, however, Respondent denies that the statements for Rozol Pocket Gopher Bait alleged in Counts 2,184 through 2,231 of the Complaint are claims under FIFRA § 12(a)(1)(B).

Respondent has denied that the following statements about Rozol Pocket Gopher Bait in the New Slim Jim, and statements in a separate Product Information Sheet for Rozol Pocket Gopher Bait, are claims under FIFRA § 12(a)(1)(B):[11]

Product Information Sheet

- **Proven Single Application Effectiveness** – When properly applied in all active burrows of a colony, control typically exceeds 85%, and can be as high as 100%.
- **Low cost per acre** – Savings in time, labor and fuel exceed comparative total costs of other methods such as zinc phosphide, diphacinone, phos-toxin, and foam or propane-based systems.
- **Superior Weatherability** – Rozol does not lose its effectiveness when wet. It outlasts Zinc Phosphide.
- **Best Bait Acceptance & Favorable Toxicity Profile** – According to the EPA's overall risk assessment, Rozol offers lower overall risk than Zinc Phosphide or Diphacinone. And Prairie dogs will eat it in the burrow, so there is less risk to non-target wildlife.
- **Lower Primary Poisoning Potential** – Rozol's toxicity to birds is 20X (times) less than ZP. Rozol less toxic to dogs than ZP or Diphacinone.

New Slim Jim

[11] Complainant has alleged that the same statements in the New Slim Jim are claims for both Rozol Prairie Dog Bait and Rozol Pocket Gopher Bait. (*Compare* Compl. ¶¶ 311, 314, 317, 320, 323, 326 *with id.* ¶¶ 293, 296, 299, 302, 305, 308). Unlike the comparative statements at issue in Counts 2,141 through 2,183 of the Complaint, where Respondent admitted making the statements but denied that the statements were claims, Respondent did not stipulate to making the statements or that the statements were claims. Respondent, however, did stipulate to CX28 through CX31, the exhibits in which these statements were made by Respondent. (Joint Stips. at 19). Consequently, Respondent has admitted making these statements, and Complainant will treat Respondent's unqualified stipulation to the admissibility of CX28 through CX31 as a stipulation to making the statements within the exhibits.

- **Outstanding Single Application Effectiveness**

- **Proven Reliability** – In university trials on over 11,400 burrows to provide over 94% control in one treatment (when properly and thoroughly applied to all active burrows in a colony).

- **Highly Palatable** – Food-grade winter wheat grain (10% protein) is a preferred feed source for field rodents and provides excellent acceptance and control.

- **Superior Weatherability** – Rozol does not lose its effectiveness when wet – it outlasts zinc phosphide and can be used under diverse weather conditions.

- **Easy-to-Use/Less Work** – No need to pre-treat and less repeat applications.

- **Lower Primary Poisoning Potential to Non-Target Birds and Livestock** – Rozol's primary toxicity to birds is much less than that of acute toxicants.

(Compl. ¶¶ 311, 314, 317, 320, 323, 326; CX28, EPA526; CX29, EPA546; CX30, EPA566; CX31, EPA586). Respondent also denies that that the following statement in its Product Information Sheet for Rozol Pocket Gopher Bait is a claim: "More readily available and less toxic than strychnine-treated millo products labeled for burrow-builder use." (Compl. ¶335; CX31, EPA596).

Respondent has admitted that these same statements in the New Slim Jim are claims for Rozol Prairie Dog Bait. The New Slim Jim is an advertisement for both Rozol Prairie Dog Bait and Rozol Pocket Gopher Bait. The title of the brochure and the information listed on the first page demonstrate that it covers both of Respondent's products. (*See* CX31, EPA582 (including the title "Control Range Rodents" and listing both Rozol products at issue in this matter)). While certain pages of the New Slim Jim differentiate between black-tailed prairie dogs and pocket gophers, the page on which the alleged claims are listed does not differentiate between the two Rozol products or the two pests. (CX28, EPA 526; CX29, EPA546; CX30, EPA566; CX31,

EPA586). By referring to "rodents" in a footnote at the bottom of the page, Respondent uses these statements to convey the "features and benefits" of both Rozol Pocket Gopher Bait and Rozol Prairie Dog Bait. (*Id.*) The page immediately prior to the page of the New Slim Jim containing the violative claims also refers to both products and pests. (CX28, EPA525; CX29, EPA545; EX30, EPA565; CX31, EPA585) (stating "Rozol formulations have been proven very effective in burrow applications on pocket gophers and black-tailed prairie dogs")). Respondent cannot selectively admit that these statements are claims for Rozol Prairie Dog Bait and not Rozol Pocket Gopher Bait without differentiating between the two products. Because the statements in the New Slim Jim are not product-specific, and because the New Slim Jim covers both Rozol products at issue in this case, the Chief Judge should hold that these statements are claims for both Rozol Pocket Gopher Bait and Rozol Prairie Dog Bait.

Furthermore, as for the statement "[m]ore readily available and less toxic than strychnine-treated millo products labeled for burrow-builder use" in the Product Information Sheet for Rozol Pocket Gopher Bait, (CX31, EPA596), this Tribunal should hold this statement is an affirmative representation of Rozol Pocket Gopher Bait's attributes and is thus a claim for Rozol Pocket Gopher Bait. It is one of several "unique benefits" of Rozol Pocket Gopher Bait listed by Respondent. (CX31, EPA596). Furthermore, contextual clues from the Product Information Sheet confirm that this statement is a claim under FIFRA § 12(a)(1)(B). In the Product Information Sheet, Respondent states that Rozol Pocket Gopher Bait offers "some additional advantages" to "the original Pocket Gopher Bait" and "is priced more favorably." Therefore, the Chief Judge should conclude that the statement alleged in paragraph 335 of the Complaint and contained in the Product Information Sheet for Rozol Pocket Gopher Bait is a claim for purposes of FIFRA § 12(a)(1)(B).

Respondent has admitted that the majority of statements alleged in Counts 2,184 through 2,231 are "claims" under FIFRA § 12(a)(1)(B). As to the remaining statements, Complainant has demonstrated by a preponderance of the evidence that the statements that form the basis of the violations in Counts 2,184 through 2,231 are claims for purposes of FIFRA § 12(a)(1)(B).

### C. Respondent's Claims for Rozol Substantially Differed from Claims Made for Rozol as Part of Statements Required for Registration

FIFRA § 12(a)(1)(B) prohibits the distribution or sale of "any registered pesticide if any claims made for it . . . substantially differ from any claims made for it as part of the statement required in connection with its registration under [section 3 of FIFRA]." 7 U.S.C. § 136j(a)(1)(B). "Substantially differ" is not defined in FIFRA. An undefined term in a statute is to be given its ordinary meaning. *See, e.g., Asgrow Seed Co. v. Winterboerer*, 513 U.S. 179, 187 (1985). "Substantial" is defined as, among other things, "consisting of or relating to substance" or "being largely but not wholly that which is specified." MERRIAM WEBSTER'S COLLEGIATE DICTIONARY 1174 (10th Ed. 1994). Congress could have easily used the term "materially" in the place of "substantially" in FIFRA § 12(a)(1)(B). "Differ" means "to be unlike or distinct in nature, form, or characteristics." *Id.* at 323. Putting these two terms together, "substantially differ" as used in FIFRA § 12(a)(1)(B) must mean substantively or materially unlike.

To establish liability under FIFRA § 12(a)(1)(B), one must show that a claim is substantively or materially unlike "any claims made for it as part of the statement required in connection with its registration under [section 3 of FIFRA]." 7 U.S.C. § 136j(a)(1)(B). In this case, Respondent is liable under FIFRA § 12(a)(1)(B) because the claims at issue in this matter contradict or undermine the approved labels for Rozol. *In re Microban Prods. Co.*, Docket No. FIFRA 98-H-01, 1998 EPA ALJ LEXIS 135, at *21 (ALJ Sept. 18, 1998) (stating that the "notice of pesticide registration, [which includes an accepted label or EPA's comments on a

proposed label,] represents the base line from which allegations of a Section 12(a)(1)(B) violation must be measured").[12] Comparing Respondent's claims to accepted labels for Rozol Prairie Dog Bait and Rozol Pocket Gopher Bait to determine whether Respondent's claims substantially differed from the accepted labels is supported by (1) the text of FIFRA and the EAB and federal appellate court decisions interpreting the same, (2) the manner in which EPA's Office of Pesticide Programs ("OPP") has historically implemented FIFRA's registration provisions and FIFRA § 12(a)(1)(B), and (3) the interpretation of FIFRA § 12(a)(1)(B) in several publicly-available EPA documents.

When considered with the provisions of FIFRA dealing with the registration process, it is clear that Congress' use of "any claims made for it as part of the statement required in connection with its registration under [FIFRA § 3]" in FIFRA § 12(a)(1)(B), means affirmative statements (i.e., claims) that accompany an application to register a pesticide, not all test data submitted with a registration application or citations to data or studies in the public domain. FIFRA § 3(c)(1) lists the information that constitutes the "statement required" in an application for the registration of a pesticide. 7 U.S.C. § 136a(c)(1). "Under FIFRA, an applicant wishing to register a pesticide must file a statement that includes 'a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use.'" *Antkiewicz*, 1999 EPA App. LEXIS 8, at *37-38 (quoting 7 U.S.C. § 136a(c)(1)(C)). FIFRA Section 3(c)(1)(F) also requires an applicant for a pesticide registration to submit "a full description of the tests made and the results thereof ***upon which the claims are based***, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator," if such data are requested by the Administrator. *Id.* § 136a(c)(1)(F) (emphasis

[12] For Rozol Pocket Gopher Bait, the notice of pesticide registration included an accepted label (CX 1, EPA2-3). For Rozol Prairie Dog Bait, the notice of pesticide registration included an accepted label with comments (CX27, EPA504-510)

added). The criteria for "[a]pproval of [a pesticide] registration" are listed in 7 U.S.C. § 136a(c)(5). Under this subsection, EPA is required to register a pesticide if, among other requirements, the pesticide's "composition is such as to warrant the proposed claims for it." 7 U.S.C. § 136a(c)(5)(A). Finally, if the criteria for registration have been met, EPA will "notify the applicant of the approval of his application by a Notice of Registration for new registration, or by a letter in the case of an amended registration." 40 C.F.R. § 152.117.

Congress' use of the words "claims made for it" in FIFRA § 12(a)(1)(B) is a clear reference to its mandate in FIFRA § 3(c)(1)(C) that an applicant must submit "a statement of all claims to be made for [the pesticide]" at the time of registration and the mandate in FIFRA § 3(c)(5)(A) that the Administrator shall register a pesticide if "its composition is such as to warrant the proposed claims for it." *Id.* §§ 136a(c)(1)(C), (c)(5)(A), and 136j(a)(1)(B). Indeed, apart from the use of "to be" in FIFRA § 3(c)(1)(C) to convey the proposed future act of using the claims, and the word "proposed" in FIFRA § 3(c)(5)(A) to convey the same, the words "claims made for it [i.e., the pesticide]" are identical in FIFRA §§ 12(a)(1)(B), 3(c)(1)(C), and 3(c)(5)(A). *See Envtl. Def. v. Duke Energy Corp.*, 549 U.S. 561, 574 (2007) (noting the "natural presumption that identical words used in different parts of the same act are intended to have the same meaning"). Therefore, the cross-reference in FIFRA § 12(a)(1)(B) to FIFRA § 3 and Congress' use of nearly identical language in FIFRA § 12(a)(1)(B) and § 3(c)(1)(C) and (c)(5)(A) show that the onus is on the applicant to submit a statement of claims to be made for the pesticide at the time of registration should it wish to obtain EPA's approval of any submitted claims. It follows from Congress' careful use of language that, to determine whether a claim substantially differs under FIFRA § 12(a)(1)(B), it must be compared to the statements that were approved by EPA in the notice of pesticide registration. *Sporicidin Int'l*, 1991 EPA App. LEXIS

3, at *29-30 (holding that FIFRA § 12(a)(1)(B) "prohibits sellers or distributors from making pesticidal claims until the Agency has made a determination that they have been adequately substantiated by test data"); *see also Microban I*, 9 E.A.D. at 686-88 (referring to the claims at issue as "unapproved claims").

EPA's implementation of FIFRA's registration provisions further supports Complainant's position that the accepted labels are the proper baseline for comparison for purposes of FIFRA § 12(a)(1)(B). Mr. John Hebert, a twenty-year veteran and product manager in OPP's Registration Division whose team has "regulatory responsibilities over all rodenticides," and who is the person that makes many "final regulatory decision[s]" related to rodenticides (Hebert Tr. at 7:16-10:23), explained the registration process when he testified at the hearing in this matter. Mr. Hebert and his team review rodenticide registrations from the application stage to any label amendments and are ultimately called upon to provide opinions to the EPA Regions on whether advertising claims are substantially different from the claims approved in the rodenticide's registration. (*Id.* at 39:9-40:3). Mr. Hebert's testimony lends further support for Complainant's position with respect to FIFRA § 12(a)(1)(B).

Mr. Hebert and his team's review starts with determining whether the registration application is complete. (*Id.* at 16:14-23). A registration application is complete when it includes, among other things, a draft label and any data that needs to be submitted or citations to data already reviewed. (*Id.*). Mr. Hebert explained that his team does not "typically see a separate document in the registration package labeled statement of claims." (*Id.* at 17:3-5). If such a document is submitted with the registration package, Mr. Hebert explained that his team would review it for acceptability. (*Id.* at 18:3-7). To do so, Mr. Hebert and his team would ask that any applicant include the statement of claims on the proposed label, because the label "sets

the basic parameters of what could be said about the product." (*Id.* at 18:14-18).

Mr. Hebert also explained the opportunity for applicants to submit and have his team review "optional marketing claims." (*Id.* at 19:1-24). He testified that he and his team receive "optional marketing claims" quite often "for professional use consumer products." (*Id.* at 19:18-19). "Optional marketing claims," if submitted, are handled in the same manner that Mr. Hebert and his team handle the submission of a separate statement of claims. Upon receipt, Mr. Hebert and his team would ask the applicant to submit the "optional marketing claims" with the draft label. (*Id.* at 20:3-7). If any "optional marketing claims" are approved during the registration process, the "registrant has the option of actually including them on their final printed label" and "in advertising." (*Id.* at 19:3-12).

Mr. Hebert testified about one example of an applicant that submitted "optional marketing claims" with its registration. Using the Notice of Pesticide Registration for Hawk Rodenticide AG to explain his point (CX92, EPA1695), Mr. Hebert testified that the applicant for this particular registration included "optional marketing statements" with its registration application. (*Id.*, EPA1695; Hebert Tr. at 26:14-16). The majority of these "optional marketing claims" were accepted by EPA in the registration process, which means that the registrant could use these accepted claims in advertising. (CX92, EPA1695; Hebert Tr. at 27:7-10). With respect to the "optional marketing statement" "easy to use," however, EPA notified the registrant that the claim was not allowed. (*Id.*, EPA1689; Hebert Tr. at 27:5-6). The Notice of Pesticide Registration also advised the registrant that "regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process." (CX92, EPA1689-90). Thus, the submission of "optional marketing claims," as in the case of Hawk Rodenticide AG, gives EPA the ability to

review and, if necessary, reject unsupported claims before they are used in advertising.

Mr. Hebert also described two occasions where Respondent submitted "optional marketing statements" with its application to register a pesticide. The first was with the application to amend the label for Metarex Slug and Snail Bait ("Metarex"), which Respondent submitted on November 15, 2007. (Hebert Tr. at 81:12-84:10; CX138, EPA3322). Respondent submitted an entire page with two separate columns of "optional marketing statements" with the application to amend Metarex's label. (CX138, EPA3321). Notably, EPA first requested data to determine whether that data was adequate to support one of the proposed claims Respondent submitted ["Protects for up to 4 weeks"]. (CX138, EPA3322-23). After EPA reviewed the data submitted in support of this claim, EPA ultimately concluded that the claim was adequately supported by the data. (*Id.*) As it did for Hawk Rodenticide AG, OPP first reviewed the "optional marketing statements" and then notified Respondent that two of the proposed "optional marketing statements" were not accepted or approved by EPA. (*Id.*, EPA3318).

The second occasion where Respondent submitted "optional marketing statements" was for the original, general use version of Rozol Pocket Gopher Bait, EPA Reg. No. 7173-184. On June 18, 2007, Respondent submitted two proposed "optional marketing statements" when it notified EPA of changes on the label for the general use Rozol Pocket Gopher Bait, EPA Reg. No. 7173-184. (CX107, EPA2506). Therefore, Respondent clearly is aware of and has availed itself of the ability to seek approval for "optional marketing statements" by EPA.

At hearing, Mr. Hebert explained that there are many reasons that proposed claims may not be approved by EPA. (*Id.* at 34:18-21). He noted that "[a]nything that contradicts or undermines the label" would not be accepted. (*Id.* at 34:22-35:1). Mr. Hebert testified about the importance of EPA's review of claims prior to registration at hearing:

Q. Tell us why it's important for the purposes of registration of the product to make sure that there's no . . . claims being made that undermine or contradict the accepted label?

A. In many cases, probably most cases, the label really serves as the only reference that the user has - - the consumer or the user has on how to safely and properly apply that [product]. So if there's anything that undermines or contradicts that, we would consider that to be a problem.

Q. So what's the purpose of reviewing the proposed claims associated with a product at the time of registration?

A. To ensure that they don't contradict or undermine the required language on the label.

Q. All right. And you talked about the parameters of the label. What's the intention of the parameters of the label?

A. Well, it's to - - Several things. It's to instruct the user on how to properly apply a product, to use the product; it's to tell the registrant what types of claims they could make on the product; it also allows us to impose any mitigation measures that we think are necessary to address the risk associated with the product.

Q. What do you mean by that last - -

A. Mitigation measures?

Q. Yes.

A. Language that we think [is] necessary to address potential risk associated with the use of the product.

(Hebert Tr. 35:12-36:18).

Mr. Hebert further explained that the mere submission of data or citation to data as part of the registration application does not mean that the data are accepted by EPA. He offered two reasons for this:

> One, the data are sometimes not acceptable. We could have problems with the data. There could be conflicting information, there could be problems with the way a study was conducted.
>
> And, secondly, studies do not typically list claims. They are scientific works, but they do not include lists of optional marketing claims or marketing claims.

(*Id.* at 30:19-31:2). Mr. Hebert's testimony highlights the importance of allowing EPA to

review claims prior to registration to ensure that the proposed claims do not contradict or undermine other language on the label. (*See id.* at 36:19-37:21 (explaining how the Registration Division considers the potential impact the product may have on the environment)).

When the Registration Division generally, and Mr. Hebert's team specifically, decides it is appropriate to register a pesticide, they issue "a notice of pesticide registration along with a stamped accepted label." (Hebert Tr. at 22:5-13). A "stamped accepted label" is "either accepted with no comment or with comments." (*Id.* at 21:22-24). The significance of the Notice of Pesticide Registration was described by Mr. Hebert as follows:

> The notice of registration will outline any conditions of registration that are associated with the registration, if there are any. And more importantly it will outline any kind of labeling changes or comments that we have that need to be implemented on the label before it is marketed.

(*Id.* at 22:8-13). Mr. Hebert's testimony is consistent with the Fourth Circuit's interpretation of FIFRA § 12(a)(1)(B). In *Lowe v. Sporicidin*, the Fourth Circuit described FIFRA's "involved process" for pesticide registrations as "culminating in approval of the label under which the product may be marketed." 47 F.3d 124, 127 (4th Cir. 1995) (quoting *Worm v. Am. Cyanamid Co.*, 5 F.3d 744, 747 (4th Cir. 1993)).

Once a pesticide is registered, the registrant can propose changes to the pesticide's label. (*Id.* at 22:14-21). Indeed, for the FIFRA § 3 registrations of Rozol, EPA informed the Respondent as follows: "Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce." (CX1, EPA2; CX7, EPA504). As Mr. Hebert explained, the purpose of this notification "is to inform registrants that if they want to change their label in any significant way, that they must submit it to the agency first and get our acceptance." (Hebert Tr. at 24:7-12). He further explained that a registrant has the ability to submit a request to amend

a label at any time and that there may be a variety of reasons for doing so. (*Id.* at 40:4-12).

Mr. Hebert and his team also receive inquiries from EPA's regional offices regarding FIFRA compliance. Among other inquiries, Mr. Hebert and his team are asked to determine "whether a specific claim in advertising is substantially different from what [was] in the registration." (*Id.* at 39:9-14). When asked what he uses to determine whether a claim is substantially different from any claim that was accepted for the specific product in question, Mr. Hebert answered that he "would look at the accepted label, along with either the notice . . . of pesticide registration, or the accompanying letter that goes along with the accepted label." (*Id.* at 39:19-22). Mr. Hebert explained that "everyone [he] work[s] with" uses the Notice of Pesticide Registration and the accepted label as the base line for comparison when asked by an EPA regional office for an opinion or determination about a potential FIFRA § 12(a)(1)(B) violation. (*Id.* at 41:11-13). Mr. Hebert's testimony regarding the involved process of registering a pesticide, and the ability of an applicant to seek approval of claims in this process, is consistent with Complainant's position, namely that the Notice of Pesticide Registration, which includes the accepted label, is the proper baseline for comparison under FIFRA § 12(a)(1)(B).

Finally, several publicly-available EPA documents provide additional support for Complainant's position with respect to FIFRA § 12(a)(1)(B). In Chapter 12 of EPA's Label Review Manual, a "guidance document" that has been available to the public on EPA's website for "quite some time" (Hebert Tr. at 42:7-8), EPA includes a separate section entitled "Claims made in advertising." (CX88, EPA1572). This section succinctly explains FIFRA § 12(a)(1)(B)'s application to claims in advertising as follows:

> Advertising and collateral literature or verbal claims for the product must not substantially differ from any claims made on the label or labeling. See *FIFRA § 12(a)(1)(B)*. In other words, if a claim is not on the label or substantially differs from what appears

> on the label (or any part of its distribution or sale which for example appears on a brochure), it cannot be made in advertising. Although OPP does not routinely review advertising in connection with the registration, the Agency may require advertising used in the marketing of the product to be submitted upon request and then reviewed [] to see that it is in compliance with *FIFRA § 12(a)(1)(B)*.

(*Id.*) Another publicly-available document on EPA's website provides further guidance on this issue. In a section of EPA's website entitled "Pesticide Labeling Questions & Answers," EPA provides the following illustration:

> **A lawn care operator (LCO) has advertising in a local newspaper advertising its service, claiming mosquito and other pest elimination from customer yards. At the bottom of the ad, it states "Safe." Is stating a service using a registered product is "safe" in an advertisement a violation of FIFRA or its associated regulations? (LC08-0177)**
>
> Section 12(a)(1)(B) of FIFRA makes unlawful any sale or distribution of "any registered pesticide if any claims made for it as part of its distribution or sale substantially differ from any claims made for it as part of the statement required in connection with its registration." The statement required for registration must include "a statement of all claims to be made for [the pesticide]." FIFRA 3(c)(1)(C). . . . If the use of the term "safe" has not been allowed in labeling and the use of the term hasn't been otherwise approved, use of "safe" in advertising the sale or distribution of a pesticide product would generally be considered to substantially differ from what was approved in the registration and sale or distribution of the pesticide would be unlawful under section 12(a)(1)(B) of FIFRA.

(CX135, EPA3266 (emphasis in original)). Both of these publicly-available explanations by EPA on the application of FIFRA § 12(a)(1)(B) inform registrants, such as Respondent, that EPA interprets FIFRA § 12(a)(1)(B) as applying to advertisements and that any claims in such advertisements cannot substantially differ from any claims on the accepted label.

In addition to making aforementioned documents available to the public, EPA also notified a certain trade group, known as Responsible Industry for a Sound Environment ("RISE"), directly about advertising claims that are in violation of FIFRA § 12(a)(1)(B). RISE

"represents sellers and manufactures of what [Respondent calls] specialty pesticides rather than agricultural pesticides." (Schmit Tr. at 8:20-9:2). In a letter dated May 15, 2009, Lois Rossi, the Director of the Registration Division, sent a letter to the President of RISE. (CX135, EPA3261-62). In this letter, Ms. Rossi informed RISE that EPA is aware of certain pesticides "being sold, distributed, and promoted with the inappropriate words 'Professional' and 'Professional Grade' in product names and advertising." (*Id.*) Ms. Rossi explained that the Registration Division was "soliciting the aid of RISE in getting key messages regarding permissible claims on distributor products out to your membership" and requested that RISE circulate the letter to its membership. (*Id.*, EPA3261-62) With respect to the application of FIFRA § 12(a)(1)(B) to the subject advertising, Ms. Rossi explained:

> The product advertising includes phrases that use the term "professional", include the following: "Professional Grade Ingredients!", "Professional Grade Results! Now Available to Consumers," and "Put the Power of the Professionals in your Hands." Section 12(a)(1)(B) of FIFRA states that it is unlawful to distribute or sell "any registered pesticide if any claims made for it as part of its distribution or sale substantially differ from any claims made for it as part of the statement required in connection with its registration." OPP has not approved the use of 'professional' in claims for these products either at the distributor or basic registrant level.

(*Id.*, EPA3262).

Respondent's involvement with RISE spans at least a decade. Mr. Schmit testified that he has been a member of the regulatory affairs committee of RISE since 1995 or 1996. (Schmit Tr. at 414:15-22). Also, Respondent's current Chief Executive Officer, Carl Tanner, was elected to the board of directors for RISE sometime before October 6, 2008, and served as a voting member for RISE for several years prior to his election to its board. (*See* CX143, EPA3443). Through its involvement with RISE, Respondent was aware of and privy to the May 15, 2009 letter from Ms. Rossi. (Schmit Tr. at 415:5-6). The May 15, 2009 letter from Ms. Rossi to

RISE, and the fact that Respondent knew of and was privy to this letter, demonstrates that Respondent was aware of EPA's position with respect to FIFRA § 12(a)(1)(B), and should have been aware of EPA's position during the time it was disseminating the advertisements at issue in Counts 2,184 through 2,231.

For all of the foregoing reasons, the Chief Judge should use the accepted labels for Rozol as the baseline for comparison to determine whether Respondent's claim substantially differ under FIFRA § 12(a)(1)(B). As indicated above, this interpretation of FIFRA § 12(a)(1)(B) is warranted based on the Act's plain language and goal of consumer protection, is supported in the EAB's and the Fourth Circuit's description of the prohibition in FIFRA § 12(a)(1)(B), is consistent with EPA's implementation of FIFRA's registration provisions and application of FIFRA § 12(a)(1)(B), and is consistent with information EPA has made available to the public regarding advertising and FIFRA § 12(a)(1)(B). Even Mr. Schmit testified that the first step of his own test for determining whether Respondent's advertising claims are acceptable involves comparing the claim to the product label to make sure they do not contradict one another. (Schmit Tr. at 72:17-21). Mr. Schmit also admitted that undermining a pesticide label is also impermissible. (*Id.* at 446:12-14).

1. The claims made in Respondent's advertisements for Rozol substantially differ from the accepted labels for Rozol[13]

Respondent made several claims in its advertisements that substantially differ from those that were approved in connection with the registrations for Rozol. Although there is some overlap, Respondent's claims can be grouped into two basic categories: (1) toxicity claims; and

[13] It should be noted that Complainant need only show that one claim in each of the sets of Counts alleging violations of FIFRA § 12(a)(1)(B) (Counts 2,141 through 2,183 and Counts 2,184 through 2,231) is substantially different to establish liability.

(2) efficacy claims. As explained below, the claims in each of these categories contradict and undermine the approved labels for Rozol.

a. Toxicity Claims

The most egregious and problematic claims made in Respondent's advertisements are those regarding the toxicity of Rozol. All of these claims state or imply that Rozol, a restricted use pesticide due to its hazard to non-target organisms, is safe and non-toxic. The toxicity claims are as follows:

- Poses low primary poisoning potential to birds and other non-targets. (Compl. ¶149; CX14a, EPA172, 191, 209, 229, 248, 267).
- Secondary Hazard / Nearly all Prairie Dogs expired underground. (Compl. ¶161; CX14a, EPA176, 195, 214, 233, 252, 271).
- Conclusion: above-ground exposure risk to non-targets from Rozol is insignificant. (Compl. ¶164; CX14a, EPA176, 195, 214, 233, 252, 271).
- Comparative toxicity profile overall risk to birds and mammals/Rozol is ranked over 50% lower than zinc phosphide in the EPA's overall risk index and 1/3 lower than Diphacinone (Kaput-D). (Compl. ¶182; CX14a, EPA179, 198, 217, 236, 255, 274).
- Rozol's active ingredient (chlorophacinone) is ten times (10X) less toxic to dogs as Kaput-D's (diphacinone). (Compl. ¶185; CX14a, EPA179, 198, 217, 236, 255, 274).
- Conclusion: Rozol – the lowest risk profile among Black-Tailed Prairie Dog bait alternatives . . . Why risk potential harm to employees, livestock, birds, pets or other non-targets? (Compl. ¶191; CX14a, EPA179, 198, 217, 236, 255, 274).
- Best bait acceptance and favorable toxicity profile – according to the EPA's overall risk assessment, Rozol offers lower overall risk than zinc phosphide or diphacinone, and prairie dogs will eat it in the burrow, so there is less risk to non-target wildlife. (Compl. ¶287; CX28, EPA512; CX29, EPA534; CX30, EPA554; CX31, EPA574).
- Lower primary poisoning potential – Rozol's toxicity to birds is 20X (times) less than for ZP. Rozol less toxic to dogs than ZP or diphacinone. (Compl. ¶290; CX28, EPA512; CX29, EPA534; CX30, EPA554; CX31, EPA574).
- Lower primary poisoning potential to non-target birds and livestock – Rozol's primary toxicity to birds is much less than that of acute toxicants. (Compl. ¶¶308, 326; CX28, EPA526; CX29, EPA546; CX30, EPA566; CX31, EPA586).

These toxicity claims all contradict or undermine the approved labels for Rozol. All of labels for Rozol Prairie Dog Bait and Rozol Pocket Gopher Bait state that the product was and is a restricted use pesticide either "due to hazard to nontarget organisms" or "due to potential secondary toxicity to nontarget organisms." (CX1, EPA5; CX2, EPA24; CX3, EPA32; CX4, EPA42; CX5, EPA50; CX6, EPA52; CX7, EPA57; CX27, EPA509). Respondent's claims that the "above-ground exposure risk to non-targets is insignificant" and that there "is less risk to nontarget wildlife" or "lower overall risk" from using Rozol are at odds with the very reason that Rozol has been classified as a restricted use pesticide. As Mr. Hebert aptly noted at the hearing, Rozol's classification as a restricted use pesticide is "because of its hazards to non-targets, which would include birds." (Hebert Tr. at 94:6-8). Moreover, the fact that the FIFRA § 3 accepted labels for Rozol state that "[d]ogs and other predatory scavenging mammals and birds might be poisoned if they feed upon animals that have eaten the bait" means that, contrary to Respondent's claims, some black-tailed prairie dogs do die aboveground. (*Compare* CX1, EPA5; CX27, EPA509 *with* Compl. ¶161; CX14a, EPA176, 195, 214, 233, 252, 271). Despite Mr. Schmit's testimony to the contrary, claiming that Rozol is not hazardous or less hazardous to birds contradicts and undermines the very reasons, all of which are listed prominently on the labels, that Rozol is classified as a restricted use pesticide. (Schmit Tr. at 75:7-8 ("We don't make advertising claims that contradict the label."); CX2, EPA24; CX3, EPA32; CX4, EPA42; CX5, EPA50; CX6, EPA52; CX7, EPA57).

In addition, these claims also undermine several restrictions and precautions on the various accepted labels for Rozol. The accepted labels include several important restrictions and precautions. Notably, the "Environmental Hazards" section of the FIFRA § 3 labels for Rozol provides in relevant part as follows:

> This product is toxic to fish and wildlife. Dogs and other predatory scavenging mammals and birds might be poisoned if they feed upon animals that have eaten the bait.

(CX1, EPA5; CX27, EPA509).[14] In no uncertain terms, the accepted labels notified potential users that the products are "toxic to fish and wildlife." (*Id.*) Furthermore, because of Rozol's hazard to non-target organisms, particularly those organisms that eat any bait on the surface or prey upon dead or dying black tailed prairie dogs or pocket gophers on the surface, the labels for Rozol Prairie Dog Bait instruct users to "**not apply bait on or above ground level. Treat only active burrows.**" (CX2, EPA24; CX3, EPA32; CX4, EPA42; CX5, EPA50; CX6, EPA52; CX7, EPA57; CX27, EPA509) (emphasis in originals); *see also* CX1, EPA2 ("Do not apply bait on surface of soil.")). Claiming that Rozol has "[l]ower primary poisoning potential to non-target birds," that its "primary toxicity to birds is much less than that of acute toxicants," and that it poses a low or lower toxicity to birds and dogs runs counter to the clear language referenced in the "Environmental Hazards" section of in the labels for Rozol. (*Compare id. with e.g.,* Compl. ¶149; CX14a, EPA172, 191, 209, 229, 248, 267; Compl. ¶182; CX14a, EPA179, 198, 217, 236, 255, 274; Compl. ¶191; CX14a179, 198, 217, 236, 255, 274; Compl. ¶¶308, 326; CX28, EPA512, 526; CX29, EPA534, 546; CX30, EPA554, 566; CX31, EPA574, 586).

Finally, many of the toxicity claims in Respondent's advertisements conflict with and significantly undermine the specific mitigation measures required by the accepted labels regarding follow-up, bait collection, and storage of the bait. (Niess Tr. at 42:12-23). The accepted labels for Rozol include specific directions regarding follow-up directions. For

[14] When the SLN labels were in effect, the supplemental SLN labels referred potential users to the accepted label for Rozol Pocket Gopher Bait and relied upon that label to inform users of additional restrictions and precautions that were not otherwise listed on the supplemental SLN labels. (CX2, EPA24 CX3, EPA32; CX4, EPA42; CX5, EPA50; CX6, EPA52; CX7, EPA57).

example, the FIFRA § 3 accepted label for Rozol Prairie Dog Bait requires applicators to "return to the site within 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" and require a "second carcass search and collection" within "14 to 21 days after bait application." (CX27, EPA509; *see also* CX2, EPA24; CX3, EPA32; CX4, EPA42; CX5, EPA50; CX6, EPA52; CX7, EPA57 (requiring similar, and sometimes more stringent, follow-up)). Any carcasses collected and buried on site "must be in holes dug at least 18 inches deep, or in inactive burrows, to avoid scavenging by non-target animals." (*Id.*). Therefore, the labels for Rozol Prairie Dog Bait expressly state that the purpose of the follow-up directions is to mitigate the risk to non-target organisms. The labels also instruct users to "[k]eep [Rozol] away from humans, domestic animals and pets" or "[s]tore this product away from humans, domestic animals, pets and nontarget wildlife." (*Id.*) In fact, the accepted FIFRA § 3 labels for Rozol include notices to both physicians and veterinarians, providing instructions on what to do in the event that a human or animal ingests (or is suspected of ingesting) the bait or exhibits poisoning symptoms. (CX1, EPA2; CX27, EPA509). Claiming that the risk to "employees, livestock, birds, pets or other non-targets" is low or lower than the alternative minimizes the importance of the follow-up, bait collection, and storage requirements included on the labels for Rozol.

For all of the foregoing reasons, toxicity claims in Respondent's advertisements contradict or undermine the accepted labels for Rozol. Therefore, this Tribunal should conclude that the toxicity claims in Respondent's advertisements substantially differ from the approved labels for Rozol under FIFRA § 12(a)(1)(B).

b. Efficacy Claims

In addition, Respondent's advertisements also included several unapproved efficacy claims that contradicted or undermined the accepted labels for Rozol. The efficacy claims were, in one form or another, included in all of Respondent's advertisements. Respondent made the following efficacy or single application effectiveness claims in its advertisements:

- Provides the most control available in single application. (Compl. ¶146; CX14a, EPA172, 191, 209, 229, 248, 267).
- Both restricted use and general use Rozol products are formulated using proven anticoagulant chlorophacinone at 50 PPM (parts per million) – unlike other half-strength, diphacinone-based baits containing as low as 25PPM. (Compl. ¶152; CX14a, EPA172, 191, 209, 229, 248, 267).
- Rozol consistently controlled Prairie Dog populations using single application. (Compl. ¶155; CX14a, EPA176, 195, 214, 233, 252, 271).
- Conclusion: Rozol delivers proven single application effectiveness. (Compl. ¶158; CX14a, EPA176, 195, 214, 233, 252, 271).
- Over all sites, 95% average population reduction was achieved as measured by the 'plugged burrow' census method. (Compl. ¶167; CX14a, EPA176, 195, 214, 233, 252, 271).
- Over all sites, 94% average population reduction was achieved when measured by the 'visual count' census method. (Compl. ¶170; CX14a, EPA176, 195, 214, 233, 252, 271).
- Traditional control products such as zinc phosphide or diphacinone-based anticoagulants have not proven to effectively prevent population recovery, leading to the need for costly re-treatment. (Compl. ¶173; CX14a, EPA178, 197, 216, 235, 254, 273)
- Kaput-D Prairie Dog Bait (25 PPM) achieved only 54% to 56% control. (Compl. ¶176; CX14a, EPA178, 197, 216, 235, 254, 273).
- Kaput-D Pocket Gopher Bait* (50 PPM) 2X the rate of active ingredient, achieved only 56% to 57% control. *Not labeled for Black-Tailed Prairie Dog. (Compl. ¶179; CX14a, EPA178, 197, 216, 235, 254, 273).
- Chlorophacinone is over 100X more effective on mice than diphacinone. (Compl. ¶188; CX14a, EPA179, 198, 217, 236, 255, 274).
- Rozol – proven single application effectiveness for the control of black-tailed prairie dogs. (Compl. ¶199; CX14a, EPA346-47, EPA352-53, EPA361-62).

- Proven in university studies on over 10,000 burrows to get 94% control with a single treatment. (Compl. ¶202; CX14a, EPA346-47, EPA352-53, EPA361-62).

- Proven single application effectiveness – when properly applied in all active burrows of a colony, control typically exceeds 85%, and can be as high as 100%. (Compl. ¶275; CX28, EPA512; CX29, EPA534; CX30, EPA554; CX31, EPA574).

- Low cost per acre – Savings in time, labor and fuel exceed comparative total costs of other methods such as zinc phosphide, diphacinone, phos-toxin, and foam or propane-based systems. (Compl. ¶278; CX28, EPA512; CX29, EPA534; CX30, EPA554; CX31, EPA574).

- Superior weatherability – Rozol does not lose its effectiveness when wet. It outlasts zinc phosphide. (Compl. ¶¶281, 320; CX28, EPA512; CX29, EPA534; CX30, EPA554; CX31, EPA574, 593).

- Provides control, regardless – with many alternative methods, if the target rodent is not in the burrow during application – success is reduced or control is lost altogether. (Compl. ¶284; CX28, EPA512; CX29, EPA534; CX30, EPA554; CX31, EPA574).

- Outstanding single application effectiveness. (Compl. ¶¶293, 311; CX28, EPA526; CX29, EPA546; CX30, EPA566; CX31, EPA586).

- Proven reliability – In university trials on over 11,400 burrows to provide over 94% control in one treatment (when properly and thoroughly applied to all active burrows in a colony). (Compl. ¶296, 314; CX28, EPA526; CX29, EPA546; CX30, EPA566; CX31, EPA586).

- Highly palatable – food-grade winter wheat grain (10% protein) is a preferred feed source for field rodents and provides excellent acceptance and control. (Compl. ¶¶299, 317; CX28, EPA526; CX29, EPA546; CX30, EPA566; CX31, EPA586).

- Superior weatherability – Rozol does not lose its effectiveness when wet – it outlasts zinc phosphide and can be used under diverse weather conditions. (Compl. ¶¶302, 320; CX28, EPA526; CX29, EPA546; CX30, EPA566; CX31, EPA586).

- Easy-to-use/Less work – no need to pre-treat and less repeat applications. (Compl. ¶305, 323; CX28, EPA526; CX29, EPA546; CX30, EPA566; CX31, EPA586).

- "More readily available and less toxic than strychnine-treated millo products labeled for burrow-builder use." (Compl ¶335; CX31, EPA596).

Respondent's efficacy claims, and specifically Respondent's "single application effectiveness claim" and its many permutations, contradict the reapplication directions on the

labels for Rozol. All of the accepted labels at issue in this case include directions for reapplication. The labels for Rozol Prairie Dog Bait include the follow instructions regarding "Reapplication":

> If prairie dog activity persists several weeks or months after the bait was applied, a second application prior to March 15 is allowed, by treating burrows in the same manner and procedure as the first application. Follow all baiting and animal disposal directions as above.

(CX2, EPA24; CX3, EPA32; CX4, EPA42; CX5, EPA50; CX6, EPA52; CX7, EPA57; CX27, EPA509 (emphasis in original)). The Rozol Pocket Gopher Bait label made reapplication mandatory, instructing users to "[m]ake 2-3 treatments per burrow system." (CX1, EPA2). Claiming that Rozol "consistently controlled Prairie Dog populations using a single application" or exhibits "proven [or outstanding] single application effectiveness" when used to kill black-tailed prairie dogs or pocket gophers exaggerates the effectiveness of Rozol. The label directions provide for a second application in the event that the first application does not achieve adequate control in the case of Rozol Prairie Dog Bait and require 2-3 applications in the case of Rozol Pocket Gopher Bait. (Hebert Tr. at 92:24-93:21). Even Mr. Schmit admits that a second application of Rozol may be warranted. (Schmit Tr. at 24:9-12).

Similarly, Respondent's efficacy claims that include the percentages of control that Rozol can achieve are also problematic. As Mr. Hebert testified, achieving a certain level or percentage of control in one study does not necessarily translate into the same or a similar level or percentage of control in all situations; it is a mere snap shot of efficacy achieved during a given study. (Hebert Tr. at 96:3-8 ("Out in the field, it will not be replicated every single time.") Respondent's claim that a single application of Rozol can achieve 100% control claim is an exaggeration given the variations of efficacy in the different studies upon which Respondent allegedly relied. (*See* RX63, RX_3364: "Most Ranchers want 100% mortality although it is

difficult to obtain 100% mortality in a single treatment regardless of the product used." *See also* RX26, RX_1832).

In addition, many of the efficacy claims state or imply that using Rozol is less costly than using zinc phosphide because pre-baiting is required for zinc phosphide. These claims ignore the time and effort that is required to conduct a proper bait and carcass search (and subsequent retrieval and disposal) following application of Rozol Prairie Dog Bait. As Dr. Thomas Steeger testified, "chlorophacinone is a chronically toxic compound, and zinc phosphide is an acutely toxic compound, so trying to compare one with another is very misleading." (Steeger Tr. at 21-24). "[A]cute toxicity is expressed within hours." (*Id.* at 18:12-13). Chronic toxicity, on the other hand, "is taking place over much longer periods of time." (*Id.* at 18:17-18).
The accepted labels for Rozol Prairie Dog Bait are designed based on chlorophacinone's chronic mode of action. (CX2, EPA24; CX3, EPA32; CX4, EPA42; CX5, EPA50; CX6, EPA52; CX7, EPA57; CX27, EPA509 (noting that "[p]rairie dogs that have eaten this bait will begin to die off in 4 to 5 days after they eat a lethal amount")).

The carcass search, retrieval and disposal requirement on Rozol Prairie Dog Bait's accepted labels is a two-step process. First, the applicator must return to the site after application within a specified amount of time, depending on the label. As noted above, the accepted SLN labels for Nebraska, Texas, and Oklahoma, for example, required applicators to return to the site as early as 1-2 days after application.[15] (CX3, EPA32; CX6, EPA 52, CX7, EPA57). The Kansas SLN label and the FIFRA § 3 label for Rozol Prairie Dog Bait required applicators to return to the site within 4 to 5 days after application to begin a carcass search. (CX2, EPA24;

[15] The original version of Rozol Prairie Dog Bait's SLN label for Wyoming included the requirement that the applicator "return to the site within 1 to 2 days after bait application." (CX4, EPA38; *see also* RX6, RX_361). Subsequent SLN labels for Wyoming, however, were amended to delete the specific follow-up requirements. (CX4, EPA42; RX6, RX_370, 376).

CX27, EPA509). Second, after the initial carcass search, the applicator is required to return to the site at specified intervals, and in some cases, "until dead animals are no longer found." (CX3, EPA32; CX6, EPA 52, CX7, EPA57). Thus, although pre-baiting is not required for Rozol Prairie Dog Bait, it takes a significant amount of time and effort to complete a proper bait and carcass search in accordance with the accepted labels. (*See* RX5, RX_321 (stating with respect to "labor costs" that "Rozol requires the pickup of carcasses that are above ground, which could be substantial"). Claiming that using Rozol saves time and labor costs compared with using the zinc phosphide significantly undermines the specific carcass search and disposal instructions on the labels for Rozol Prairie Dog Bait.

In sum, the efficacy claims in Respondent's advertisements contradict or undermine the accepted labels for Rozol. Therefore, this Tribunal should conclude that the efficacy or single application effectiveness claims in Respondent's advertisements substantially differ under FIFRA § 12(a)(1)(B).

2. In the alternative, many of the claims made in Respondent's advertisements are not supported or are false or misleading

In addition to testifying that he determines whether an advertising claim is acceptable by ensuring that it does not contradict or undermine the accepted label, Mr. Schmit testified that he next reviews the claim to determine whether it is "a fact that is supportable." (Schmit Tr. at 72:17-24). Mr. Schmit testified that he will accept three things "as a demonstration of truthfulness" for a particular statement:

> One is either a study or data that Liphatech itself has developed so that we know that it's true. Secondly, that it's available in public literature, not just something that's in the newspaper or on the Internet, but something that I can demonstrate, I know where it came from, I can look it up, I could find it in usually a scientific publication is what we are referring to.

> And then there's a third source. A lot of the information that we use is EPA itself. EPA publishes many, many, many documents that contain a tremendous amount of information. And I consider that if EPA publishes information in a document, that it's true at least as far as compliance goes.[16]

(Schmit Tr. at 73:5-20). Mr. Schmit also testified that he "relied" upon one or more of the following documents to determine whether many of the claims in Respondent's advertisements were true or supportable:

> (1) Field Efficacy and Hazards of Rozol Bait for Controlling Black-Tailed Prairie Dogs (*Cynoyms ludovicianus*) by Charles E. Lee and Scott D. Hyngstrom (July 26, 2007) ("Lee and Hyngtrom Study") (RX10);
>
> (2) Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: A Comparative Approach by William Erickson and Douglas Urban (July 2004) ("Comparative Risk Assessment") (RX12 (also at CX38));
>
> (3) Efficacy of Several Rodenticide Baits for Controlling Black-Tailed Prairie Dogs (*Cynoyms ludovicianus*) by Shay Boatman (March-April 2007) ("Boatman Study") (RX26);
>
> (4) Efficacy of Three In-Burrow Treatments to Control Black-Tailed Prairie Dogs by Charles D. Lee and Jeff LeFlore (2007) ("Lee and LeFlore Study") (RX63); and
>
> (5) IRB Branch Review – TSS for Rozol Prairie Dog Bait® by William Jacobs (July 2, 2004) ("IRB Review") (RX72).

(*See generally* Schmit Tr. at 97:12-189:17).

As explained in more detail below, there are at least three fundamental problems with Mr. Schmit's testimony regarding the alleged truthfulness of the claims in Respondent's advertisements. First, Mr. Schmit's personal test for avoiding FIFRA § 12(a)(1)(B) liability is contrary to the statute and not recognized by the case law. Second, the evidence demonstrates

[16] Complainant notes that FIFRA § 3(c)(1) does not provide any support for Respondent's reliance generally on "EPA documents" as a basis for pesticidal claims, nor does it allow respondent to rely on documents that it prepared, like the White Paper. (Schmit Tr. at 305:-306:2).

that several of the claims for Rozol in Respondent's advertisements are not supported by the documents upon which Mr. Schmit allegedly relied and are false or misleading. Third, Mr. Schmit's testimony should be given no weight because it is contradicted by the documentary evidence in the record.

a. Respondent's defense is contrary to FIFRA and the case law interpreting FIFRA

Complainant will not restate its argument as to the proper application of FIFRA § 12(a)(1)(B). *See supra* Section V.C. Nevertheless, to the extent that Respondent is relying on Mr. Schmit's testimony as a defense to liability, Mr. Schmit's test as to whether a claim is supportable or true is contrary to the plain language of FIFRA § 12(a)(1)(B). The EAB has stated that "truthfulness is not a defense" to liability under FIFRA § 12(a)(1)(B). *Sporicidin*, 3 E.A.D. at 601. Under FIFRA, the tests or data that an applicant submits or cites during the registration process are the "basis" for the proposed claims in the registration application, 7 U.S.C. §§ 136a(c)(1)(C), (F), (5)(A), and EPA reviews the proposed claims to determine whether they are supported by the tests or data. Indeed, this is exactly what happened when Respondent submitted an amendment to the registration for Metarex. (CX138, EPA3322-23). Respondent did not submit any of the claims at issue in this case to EPA. (Schmit Tr. at 419:19-420:1). Respondent's determinations about whether certain claims are "supportable" or "true" without having submitted such claims in connection with the registrations of Rozol circumvented the procedure for submission or citation to data or tests and the review of proposed claims by EPA. For this reason alone, Respondent's defense fails.

b. Most of Respondent's claims are either not supported or are false or misleading

Assuming *arguendo* that Respondent's defense is consistent with FIFRA, this Tribunal should hold that the Comparative Risk Assessment, the Lee and Hyngstrom Study, the Boatman

Study, the Lee and LeFlore Study, and the IRB Review do not support many of the claims in Respondent's advertisements. In addition, several of these documents show that several claims made in Respondent's advertisements are false or misleading.

i. The EPA's Comparative Risk Assessment

For many of the toxicity claims in Respondent's advertisements dealing with Rozol's primary and second poisoning potential, Mr. Schmit testified that he relied upon the EPA's Comparative Risk Assessment to support such claims. First and foremost, Respondent's reliance and citation to the Comparative Risk Assessment to support claims in its advertisements about Rozol's toxicity directly or indirectly implies that EPA recommends or endorses the use of Rozol for the control of black-tailed prairie dogs and pocket gophers. EPA, albeit with respect to "labeling," has made a regulatory determination that such statements are false or misleading. 40 C.F.R. § 156.10(a)(5)(v); *see also In re Starlink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d 828, 837 (N.D. Ill. 2002) ("The EPA's approval of a product's FIFRA label does not constitute a finding or an endorsement that its design is safe.") (citations omitted). The same logic should apply to Respondent's advertising claims citing the Comparative Risk Assessment. In addition, Mr. Schmit admitted that the Comparative Risk Assessment was conducted before Rozol was registered for the control of black-tailed prairie dogs. (Schmit Tr. at 465:17-19; *see also* RX12, RX_978 (describing the various registered uses for the nine rodenticides)). Nevertheless, Respondent allegedly relied on the Comparative Risk Assessment to support several claims regarding Rozol's toxicity when used to control black-tailed prairie dogs. This fact alone makes Respondent's reliance on this document to support claims about primary and second poisoning potential to non-targets from the use of Rozol to control black-tailed prairie dogs questionable.

Although Mr. Schmit testified that he relied on the Lee and Hyngstrom Study and the Lee and LeFlore Study to support the claim "Conclusion: above-ground exposure risk to non-targets

from Rozol is insignificant," (Schmit Tr. at 150:14-23), this claim is false, or at the very least misleading, when considered with reference to the Comparative Risk Assessment. Rozol's active ingredient is chlorophacinone, and the Comparative Risk Assessment stated that "the comparative analysis model results indicate that diphacinone, chlorophacinone, and brodifacuom pose the greatest potential secondary risk to mammals." (RX12, RX_1054). The Comparative Risk Assessment also stated that "[l]aboratory studies indicate that chlorophacinone and diphacinone present a hazard to mammalian predators and scavengers." (*Id.*, RX_1016). Claiming that Rozol poses an "insignificant" risk to non-target organisms simply is not true and certainly is not supported by the Comparative Risk Assessment.

Furthermore, Respondent's claims that Rozol poses a low "secondary hazard" and that Rozol poses "less risk to non-target wildlife," including birds, are likewise at odds with the Comparative Risk Assessment. (Compl. ¶¶161, 287; Schmit Tr. at 147:21-148:8; 181:2-19). The Comparative Risk Assessment noted that "because raptors may be wide-ranging and anticoagulants are slow-acting, radio-tracking individual birds is essential to evaluate interactions with target species and to determine their fate." (RX12, RX_1053). Thus, the authors of the Comparative Risk Assessment expressly acknowledged that there is a data gap related to secondary toxicity for slow-acting anticoagulants like Rozol. Respondent ignored this significant data gap and made claims about Rozol's low "secondary hazard" to nontargets and birds.

Finally, in his rush to approve Respondent's claims about Rozol's low risk to non-target organisms, Mr. Schmit overlooked other key information in the Comparative Risk Assessment. For example, when discussing the rodenticides that were registered for field uses at the time of the assessment, the Comparative Risk Assessment warned that even with the increased

protection provided by the classification of these rodenticides as restricted use pesticides, "there remains a potential risk to nontarget organisms from these uses since the rodenticides are lethal to birds and mammals and not selective, and their grain-based bait formulations may be highly attractive to nontarget organisms." (RX12, RX_975). Respondent's claim that Rozol "poses low [or lower] primary poisoning potential to birds and other non-targets" directly contradicts this warning. (Compl. ¶¶149, 290; Schmit Tr. at 134:21-135:9).

For all of the foregoing reasons, the Comparative Risk Assessment does not support the claims in Respondent's advertisements.

ii. Lee and Hyngstrom Study

Mr. Schmit testified that he relied upon the Lee and Hyngstrom Study for several of the claims in Respondent's advertisements, including toxicity claims and efficacy claims. Respondent sponsored this Study and Mr. Schmit served as the quality assurance manager. (Schmit Tr. at 29:3-10, 283:11-17). Prior to sponsoring this Study, Respondent sponsored or hired the researchers, Mr. Charles Lee and Dr. Scott Hyngstrom, for other studies and a review. (*See* RX5, RX_309-12; RX11, RX_ 947-62). As explained in detail below, Mr. Schmit and Respondent's reliance on the Lee and Hyngstrom Study was misplaced because the results of the study were exaggerated. Mr. Schmit, as the quality assurance reviewer, should have known that as a result of certain critical data recording errors, the results of the Lee and Hyngstrom study were exaggerated.

As the quality assurance manager for the Lee and Hyngstrom Study, Mr. Schmit was "responsible for monitoring [the] study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls" conformed to the Good Laboratory Practice ("GLP") Standards codified at 40 C.F.R. part 160. 40 C.F.R. § 160.35(a). More specifically, Mr. Schmit was required to "[d]etermine that no deviations from approved protocols or standard

operating procedures were made without proper authorization and documentation" and "[r]eview the final study report to assure that such report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study." *Id.* §§ 160.35(b)(5)-(6). At the hearing, Mr. Schmit acknowledged that according to the protocol or study plan he developed, deviations from the protocol must be recorded. (Schmit Tr. at 336:23-25). Mr. Schmit also acknowledged that all deviations from the protocol must be recorded in order for a study to satisfy the GLP standards. (*Id.* at 377:7-9).

The record evidence, however, shows that Mr. Schmit ignored or overlooked several critical, unrecorded deviations from the protocol he developed for the Lee and Hyngstrom Study.[17] Complainant will limit its discussion of the unrecorded deviations to a few salient examples that are representative of the depth and breadth of the unrecorded deviations. For the Chief Judge's convenience, Complainant attaches a chart that includes all 78 unrecorded deviations from the study protocol for the Lee and Hyngstrom Study as Attachment A. In this document, Complainant summarizes the unrecorded deviation, lists the corresponding standard operating procedure from which Mr. Lee and Dr. Hyngstrom deviated, and includes citations to the relevant portions of the Lee and Hyngstrom Study. Complainant also lists several other data quality issues with the Lee and Hyngstrom Study in Attachment A and includes references to corresponding raw data forms. The unrecorded deviations from the study protocol for the Lee and Hyngstrom Study cast considerable doubt on the reported results from the Study and Respondent's ability to rely on the Study to support the claims in its advertisements. (Schmit Tr. at 374: 14-16 (admitting that "there were some other deviations . . . noted during the quality assurance review")).

One particularly egregious deviation that was not recorded occurred on December 1,

[17] The five recorded deviations can be found at RX10, RX_702.

2006. According to the raw data form, Mr. Lee was simultaneously conducting a post-treatment visual count census and a plugged burrow census at two different study plots. (*Compare* RX10, RX_809 *with* RX10, RX_828). The "plugged burrow index record" for the Lashley site shows that Mr. Lee began plugging at 11:18 a.m. and completed the plugging at 12:49 p.m. (RX10, RX_809). A "visual count index record" for the Faiman site, however, shows that Mr. Lee arrived at that site at 11:22 a.m. and left at 11:40 a.m. (RX10, RX_828). It would have been impossible for Mr. Lee to simultaneously perform a visual scan of the 8.0-acre Faiman site, two times using 7X binoculars (*id.*, RX_665, 695), while simultaneously performing a plugged burrow index at the 3.8-acre Lashley site (*id.*, RX_665), which would have required Mr. Lee to walk two transect lines, plug 50 burrows along these transect lines, and mark each burrow with turf paint (*id.*, RX_696, RX_809). This unrecorded deviation, which is one of many, demonstrates that the results of the Lee and Hyngstrom Study cannot be trusted.

Four of the 78 unrecorded deviations listed in Attachment A were from the study protocol for the post-treatment visual count index census. (*See* Attachment A, deviations 16-18, 20, 73; RX10, RX_720, 743, 859, 904; *see also* RX10, RX_656-57 (describing trial period and locations) and RX_664 (schedule of activities)). The visual count census index was used by Lee and Hyngstrom to determine both the percent change in black-tailed prairie dog populations and percent efficacy. (RX10, RX_694). According to the raw data, Mr. Lee failed to record four deviations from the requirement that the observer wait for 15 minutes after arriving at the site before beginning the visual count. (RX10, RX_720, 743, 859, 904). The protocol notes that this requirement was intended "to minimize effects of human disturbance" on black-tailed prairie dog activity. (RX10, RX_695). Not surprisingly, for all four of these deviations, the numbers of black tailed prairie dogs counted using the visual census method was two or less. (RX10,

RX_720, 743, 859, 904). In addition, the study sites where these deviations were not recorded had some of the highest reported percentages of change in black-tailed prairie dog populations. (*See id.*, RX_667 (Sal, Hog, Sow, WeW)). Consequently, the percent change in black-tailed prairie dog populations and percent efficacy resulting from the use of Rozol reported by the Lee and Hyngstrom Study are likely inaccurate.

There is another reason that Respondent's reliance on the Lee and Hyngstrom Study is problematic: the protocol developed by Mr. Schmit, with input from Lee and Hyngstrom over a period of "five to six months" (Schmit Tr. at 31:10-14), lacks specificity and this lack of specificity likely skewed the results. Mr. Schmit admitted at the hearing that the protocol did not include a specified time frame for the researcher to conduct the visual count census before and after treatment. (Schmit Tr. at 364:12-15; RX10, RX_695). The study protocol also did not require more time for the visual count census at the larger treatment sites, did not require the use of a specific timing device (e.g., stop watch), and did not require the use of anything stronger than 7X binoculars for the visual count index census. (RX10, RX_695; *see also* Schmit Tr. at 345:25-347:9). As a result, several of the post-treatment visual count censuses were performed in much less time than the pre-treatment censuses. (*See, e.g.,* Schmit Tr. at 364:9-367:20; RX10, RX_717, 720). Moreover, with respect to the carcass search component of the Lee and Hyngstrom Study, the protocol did not require the researcher to record whether the site was scanned by foot or in a vehicle, such as an ATV, whether binoculars were even used, how long the carcass search lasted, or the time of day that any searches occurred. (Schmit Tr. at 368:12-21; RX10, RX_729). The protocol prepared by Mr. Schmit for the Lee and Hyngstrom Study gave the researcher unfettered discretion (and arguably an incentive) to perform shorter and less thorough visual count censuses post-treatment.

The Lee and Hyngstrom Study cannot and does not support claims like "provides most control available in single application," (Schmit Tr. at 123:17-21), "control typically exceeds 85%," (*id.* at 175:25-176:3), and "outstanding single application effectiveness," (*id.* at 182:22-183:2). The "[e]fficacy results by visual observation (direct method)" for the Lee and Hyngstrom Study were a 71.6% reduction. (RX10, RX_653). While the efficacy percentage is different from the percentage for population reduction in the Lee and Hyngstrom Study, (RX10, RX_659), the efficacy percentage, unlike the percentage for population reduction, took into account the control plots. (*Id.*) Because the efficacy percentage from the Lee and Hyngstrom Study was barely over "EPA's lenient criteria of 70% control" required for EPA to register a pesticide (RX72, RX_3591), it does not support claims like "over all sites, 94% average population reduction was achieved when measured by the 'visual count' census method outstanding single application effectiveness," (Compl. ¶170; CX14a, EPA176, 195, 214, 233, 252, 271); "Rozol – proven single application effectiveness for the control of black-tailed prairie dogs," (Compl. ¶199; CX14a, EPA346-47, EPA352-53, EPA361-62); "[p]roven in university studies on over 10,000 burrows to get 94% control with a single treatment," (Compl. ¶202; CX14a, EPA346-47, EPA352-53, EPA361-62); "[p]roven single application effectiveness – when properly applied in all active burrows of a colony, control typically exceeds 85%, and can be as high as 100%," (Compl. ¶275; CX28, EPA512; CX29, EPA534; CX30, EPA554; CX31, EPA574); "[o]utstanding single application effectiveness," (Compl. ¶¶293, 311; CX28, EPA526; CX29, EPA546; CX30, EPA566; CX31, EPA586); and"[p]roven reliability – In university trials on over 11,400 burrows to provide over 94% control in one treatment (when properly and thoroughly applied to all active burrows in a colony), (Compl. ¶296, 314; CX28, EPA526; CX29, EPA546; CX30, EPA566; CX31, EPA586).[18]

[18] It is also worth noting that Mr. Lee's prior "Final Report" on "In Burrow Application of Rozol to Manage Black-

Finally, Mr. Schmit's misplaced reliance on the Lee and Hyngstrom Study is further illustrated by the fact that EPA's Environmental Fate and Effects Division (EFED) deemed the study invalid for the purposes of assessing non-target exposure. (CX 81, EPA1359)("EFED concludes that the hazard component of the attached field study provides limited information regarding non-target primary exposure and is totally insufficient for evaluating non-target secondary exposure"). Dr. Steeger explained what it means for a study to be deemed invalid by EFED at the hearing: "An invalid classification means that the study is not considered scientifically sound and it may not be used at all in ecological risk assessment." (Steeger Tr. at 62:15-17). In its review of the Lee and Hyngstrom Study, EFED noted:

> [T]he hazard component of the attached field study provides for limited information regarding non-target primary exposure and is totally insufficient for evaluating non-target secondary exposure. Non-target exposure assessment could be improved if: (1) populations of potential non-target exposed animals were assessed prior to initiation of the study; (2) target animal carcasses were monitored and left for scavenging/predation for longer periods of time; (3) a carcass recovery efficiency test was performed; and (4) carcass search areas were expanded to include the ranges of al potentially exposed non-target animals to ensure that study mortalities are not lost due to a small search area.

(CX 81, EPA1360). EFED also concluded that Lee and Hyngstrom Study significantly underestimated non-target primary and non-target secondary exposure. (*Id.*, EPA1364). Furthermore, as explained by Dr. Steeger, the EFED review "indicated that animals are found on the surface and they don't simply die underground, and that because they're available on the surface, that they would be vulnerable to providing a source of secondary toxicity to animals that may predate on incapacitated prairie dogs and that there are other predators and scavengers that

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Tailed Prairie Dogs" (April 22, 2005) reported the following results: "Rozol applied as treatment in burrows to reduce burrow activity was effective in all counties with means ranging from 75 to 100%." (RX11, RX_954). Although this study was not performed in accordance with the GLP requirements (Schmit Tr. 27:22-24), its results are much different from the 94% and 85 to 100% efficacy claims in Respondent's advertisements.

would be taking advantage of animals that had actually died." (Steeger Tr. at 62:25-63:17).

In conclusion, the results of the Lee and Hyngstrom Study cannot be used to substantiate claims for Rozol in Respondent's advertisements. As the quality assurance manager for this study, Mr. Schmit knew or should have known that the results of the Lee and Hyngstrom Study cannot be trusted. Instead, he rushed to judgment and used the study to approve claims that lacked adequate support. (Schmit Tr. at 397:6-7 (admitting that the Lee and Hyngstrom Study was "the only study that we had available that we had any real knowledge of")).

iii. The Boatman Study

Mr. Schmit's reliance on the Boatman Study is also questionable. As Mr. Boatman candidly noted, in his study:

> There may have been some variables that might have affected this study. It is necessary to mention that all plots treated received more than average rainfall, possibly causing an early green-up. Also, two days after the treatment of the Rozol plot a rodeo took place approximately 200 yards from the plot. This may have affected normal prairie dog behavior, possibly affecting the findings.

(RX26, RX_1833). Mr. Schmit did not heed Mr. Boatman's warning. Instead, he allegedly relied upon the Boatman Study to support claims about Rozol's percent efficacy and the percent control for Kaput-D Prairie Dog Bait and Kaput-D Pocket Gopher Bait. (Schmit Tr. at 155:15-20, 156:8-11, 156:15-23). Given the fact that Mr. Boatman, the researcher, included an explicit warning that the results of his study may have been affected by a rodeo that took place 200 yards from the plot treated with Rozol and higher than average rainfall, the Chief Judge should hold that the Boatman Study cannot support the claims in Respondent's advertisements.

iv. The Lee and LeFlore Study

The Lee and LeFlore Study, like the Boatman Study, included similar warnings that its results may have been affected by study conditions. For example, the Lee and LeFlore Study

noted:

> Annual precipitation in the region averages 39 cm with about 57 cm of snow. However, this year an unusual weather event blanketed the area with more than 100 cm of snow for more than 90 days while the study was underway.

(RX63, RX_3360). This "unusual weather event" affected the Lee and LeFlore's ability to conduct the post-treatment census. The researchers stated as follows:

> The post-treatment census was to be taken 21 days after application of the bait, but deep snow delayed the post-treatment census for 105 days. The weather conditions were described as normal for the first two weeks of the trial followed by an extended period of ice and snow that covered the colony to a depth of more than 91 cm for more than 90 days. This depth of snow kept the prairie dogs below ground for an extended period of time.

(*Id.*, RX_3361). Despite acknowledging that he was aware of the fact that study conditions may have affected the results of the Lee and LeFlore Study, Mr. Schmit testified that he still relied on it to support several claims. (*See, e.g.,* Schmit Tr. at 423:8-13). Because the results of the Lee and LeFlore Study were compromised as a result of the "unusual weather event" that blanketed the study area with almost twice the average annual snow fall, the Lee and LeFlore Study cannot support the various claims in Respondent's advertisements.

v. IRB Review

Mr. Schmit also testified that he relied upon the efficacy review performed by Dr. William Jacobs of OPP for the first Kansas SLN registration for Rozol Prairie Dog Bait to support several efficacy claims, toxicity claims, and claims comparing Rozol to zinc phosphide. (Schmit Tr. at 456:2-5, 8-17, 457:11-458:6). Mr. Schmit, however, admitted that the following statement in Dr. Jacobs' review does not support Respondent's single application effectiveness claims:

> Although Lee [i.e., Charles Lee] has been on the scene in Kansas for a while and reportedly was around for 16 applications of 7173-

> 184 to control black-tailed prairie dogs, I feel that his conclusion that the bait that he used was effective was overdrawn. From most treatments, efficacy estimates were mediocre and not even up to EPA's lenient criteria of 70 percent control despite the absence of adjustment for seasonal and other effects that might have suppressed prairie dog activity in fall and winter months during the two treatment seasons. The best results that he reports were obtained after what appears to have been a second round of baiting at a rate four times that of the initial application.[19]

(RX72, RX_3591; Schmit Tr. at 457:8-10). In addition, Mr. Schmit admitted that Dr. Jacobs' review also included the following conclusion about how zinc phosphide outperforms Rozol:

> Below, I discuss these points in order of their presentation.
>
> When used following prebaiting and under otherwise favorable conditions, zinc phosphide has been shown to work better than the results that Charles Lee has reported for the product that has become [the first Kansas SLN].
>
> . . .
>
> This much is clear, Zinc Phosphide's risk are almost purely of a primary nature whereas Chlorophacinone's risks would be both primary and secondary.

(RX72, RX_3593). Although Mr. Schmit testified that he believes this quote from Dr. Jacobs' review somehow supports the claims about Rozol's superiority over zinc phosphide and that Rozol "poses low primary poisoning potential to birds and other non-targets" (Schmit Tr. at 459:1-10), it is clear that Mr. Schmit's selective reliance on certain portions of Dr. Jacobs' review was misplaced given Dr. Jacobs' statements about the risk and benefits of using zinc phosphide versus those of using Rozol, and the low efficacy results from Mr. Lee's study.

c. Mr. Schmit's testimony should be given no weight

Even if Mr. Schmit's personal test was consistent with the law, and even if the documents upon which he allegedly relied supported Respondent's claims, the Chief Judge should give Mr.

[19] Dr. Jacobs is referring to Mr. Lee's initial study at RX11.

Schmit's testimony little weight, as it conflicts with the documentary evidence in the record. Contrary to his testimony, Mr. Schmit could not have relied upon "raw data" from the Lee and Hyngstrom Study, the Boatman Study, the Lee and LeFlore Study, or other "drafts or information" from these studies to support any of the claims in the Research Bulletin. (Schmit Tr. at 152:7-153:10, 218:18-219:4, 442:5-13). These studies commenced after Respondent made the same or similar claims in the February 17, 2006 version of the slim jim. Therefore, "raw data" would not have been available, nor was "raw data" submitted to EPA with the registration application as required by FIFRA § 3(c)(1)(F).

Mr. Schmit testified that he relied "essentially exclusively" on the Lee and Hyngstrom Study for the claim "[s]econdary hazard, nearly all prairie dogs expired under ground." (Schmit Tr. at 147:21-23, 148:3-8). This claim was made in the Research Bulletin that was included in Respondent's first set of direct mail packages. (CX14a, EPA176, 195, 214, 252, 271). The date listed on the Research Bulletin was October 17, 2007. (*Id.*, EPA180, 199, 218, 256, 275 (bottom right-hand corner)). A remarkably similar claim was made in a version of the slim jim with a date of February 17, 2006. (CX74, EPA1188 (see bottom left-hand corner for print date), EPA1191[20]). This was over eight months before the Lee and Hyngstrom Study began. (RX10, RX_653 (listing October 19, 2006 as the "experimental start")).

In addition, the February 17, 2006 version of the slim jim included the following claim: "[w]hen properly and thoroughly applied in all active burrows in a colony, control typically exceeds 85%." (CX74, EPA1191). This claim is nearly identical to the following claim in the Product Information Sheet for Rozol Prairie Dog Bait on Respondent's website: "[p]roven single

[20] This claim is as follows: "Since pocket gophers and prairie dogs are fossorial rodents, they prefer to die underground, particular when the onset is slow with anti-coagulants. This reduces the chances of a secondary toxicity hazard, as to a scavenger or raptor." (CX74, EPA1191).

application effectiveness – when properly applied in all active burrows of a colony, control typically exceeds 85%, and can be as high as 100%." (Compl. ¶ 275; CX28, EPA512; CX29, EPA534; CX30, EPA554; CX31, EPA574; Schmit Tr. at 175:25-176:10). All of these studies began eight months or more after the February 17, 2006 version of the slim jim. (RX10, RX_653; RX26, RX_1832 (stating that the study started on March 14, 2007); RX63, RX_3360 (stating that the study started in December 2006)). Again, no "raw data" could have been available from these studies when Respondent made similar claims in the February 17, 2006 version of the slim jim. (*Compare* Schmit Tr. at 152:7-153:10).

Mr. Schmit also testified that with respect to the various claims in the chart entitled "Compare the products for yourself – there are many difference," he allegedly relied upon, among other documents, the Lee and Hyngstrom Study, the Boatman Study, and the Lee and LeFlore Study. (Schmit Tr. at 158:20-159:159:21). Nevertheless, the February 17, 2006 version of the slim jim includes a chart that is remarkably similar to the chart in the Research Bulletin. (*Compare* CX74, EPA1190 *with* CX14a, EPA179, 198, 217, 255, 274). Mr. Schmit acknowledges that these charts are similar. (Schmit Tr. at 440:12-14).

Mr. Schmit's reliance on the Comparative Risk Assessment for many of the claims related to Rozol's toxicity to non-targets is also questionable. As Mr. Schmit acknowledged at the hearing, he submitted "extensive comments" prior to the publication of the EPA's 2004 Comparative Risk Assessment. (*Id.* at 135:17-20, 449:19). He also personally wrote a letter, dated March 26, 2003, in which he expressed his severe criticism of the Comparative Risk Assessment. (Schmit Tr. at 450:25-451:8). In his March 28, 2003 letter to EPA, Mr. Schmit stated he endorsed the conclusion of the Rodenticide Registrants' Task Force ("RRTF") "that the [Comparative Risk Assessment] contains significant errors that result in improper and

misleading 'risk conclusions' and a scientifically-indefensible risk-ranking of rodenticide products." (CX153, p. 1).[21] Mr. Schmit's March 28, 2003 letter continued and stated under the heading "The CRA Document Does Not Assess 'Risk'":

> The CRA states (page 1) that "Risk is a function of exposure and hazard (toxicity)." The document discusses the difficulty in quantifying the "exposure" and then states that "exposure estimates are largely based on the amount of active ingredient available per kilogram of bait." This is a highly misleading way of estimating exposure . . . .
>
> . . .
>
> Without a valid assessment of "exposure," it is not possible to assess risk. This is a fundamental flaw of this CRA document – and a FATAL flaw. This flaw prevents this document from reaching any meaningful "risk conclusions" and makes it inappropriate for creating "risk management strategies."
>
> In addition, we emphasize that this document makes no assessment of the "absolute risk" of rodenticide use in the real world. It compares the purported risk among the 9 different active ingredient chemicals, but it is silent about the magnitude of this "risk" in relation to the risks that confront all wildlife in the natural setting.

(*Id.* at p. 2 (emphasis in original)). Finally, in another section of his letter under the heading "Use of Inappropriate Data and Speculation", Mr. Schmit criticized the use of "raw data (ie the % mortality) without any consideration of these wide variations" in the "many different studies" that EPA used to address "secondary risk to mammals." (*Id.* at 5). Yet, Mr. Schmit testified that he allegedly relied upon "raw data" from the Lee and Hyngstrom Study, the Boatman Study, and the Lee and LeFlore Study to support Respondent's claims. (Schmit Tr. at 152:21-25).

Mr. Schmit testified that the Comparative Risk Assessment is a "very important document" and admitted that "the information that we talk about in terms of toxicity and risk are

[21] CX153 was admitted into the record at the hearing. (Schmit Tr. at 455:13-14). It is not bates stamped. When referring to it in this brief, Complainant will use the hand-written page numbers located at the bottom of each page.

largely based on that document." (Schmit Tr. at 135:15-137:11). Nevertheless, Mr. Schmit attempted to explain his criticisms in his March 28, 2003 letter as being limited to "how the EPA assessed the hazards and risk that are associated with the second-generation active ingredients . . . that Liphatech registers . . . ."[22] (Schmit Tr. at 463:5-14). Mr. Schmit, however, never differentiated between first- and second-generation anti-coagulants in his March 28, 2003 letter. Moreover, in another letter to EPA, dated August 30, 2006, Mr. Schmit criticized the July 27, 2006 "SLN Review" for the Nebraska and Wyoming FIFRA § 24(c) registrations for Rozol Prairie Dog Bait by EPA's Environmental Fate and Effects Division ("EFED") by stating that it "contains many of the same errors" as the Comparative Risk Assessment. (RX28, RX_1859; CX75, EPA1196). Thus, it is clear from Mr. Schmit's August 30, 2006 letter that his criticisms of the Comparative Risk Assessment were not limited to the second-generation active ingredients.

### D. The Requisite Nexus Exists Between Respondent's Distributions or Sales and the Substantially Different Claims Made by Respondent in its Advertisements

#### 1. Nexus Has Been Interpreted Broadly by the EAB

The phrase "as part of" in FIFRA § 12(a)(1)(B) "requires that a nexus exist between the unapproved claims and the distribution or sale of the pesticide." *Microban I*, 9 E.A.D. at 688. This statutory phrase has been interpreted broadly "so as not to require a contemporaneous sale or distribution." *Microban I*, 9 E.A.D. at 688 (citing *Sporicidn*, 3 E.A.D. at 604). "[B]roadly construing the phrase 'part of its distribution or sale' so as not to require a contemporaneous sale or distribution furthers the overall purposes of FIFRA." *Sporicidin*, 3 E.A.D. at 604.

"[A] rigid test, applicable to all situations, for determining whether claims have been

[22] Chlorophacinone, the active ingredient in Rozol, is a first-generation anti-coagulant.

made as part of the distribution or sale of a pesticide is not contemplated as part of [FIFRA's] statutory scheme." *Microban I*, 9 E.A.D. at 688. Contrary to Respondent's contentions, one need not show a direct cause and effect relationship to demonstrate nexus. Furthermore, an unapproved claim need not be attached to any subsequent shipment to show nexus under FIFRA § 12(a)(1)(B). *Microban II*, 11 E.A.D. at 444 (rejecting the respondent's argument that there can be no violation of FIFRA § 12(a)(1)(B) "unless the unapproved claims are *attached* to the subsequent shipments") (emphasis in original). Instead, the specific facts and circumstances of each case must be analyzed to determine whether a "sufficiently close link" exists between the distribution or sale of a pesticide and the substantially different claims. *Id.* As a general matter, however, "common sense suggests that a claim followed by a sale evinces nothing more than a cause-and-effect relationship, and a time interval spanning the two events is common." *Sporicidin*, 3 E.A.D. at 603.

2. The Requisite Nexus Exists for Counts 2,141 through 2,183 of the Complaint

A "sufficiently close link" exists between the violative claims that form the basis of Counts 2,141 through 2,183 of the Complaint and the 43 shipments of Rozol by Respondent from October 1, 2007 to May 30, 2008. (CX14a, EPA450-92). The claims that are the subject of these violations were included in direct mail packages that were sent by Respondent in a single mailing in November 2007 in the six different states in which Rozol was registered for use on black-tailed prairie dogs under FIFRA § 24(c). (CX14a, EPA150). In addition, two of the violative claims at issue in Counts 2,141 through 2,183 were in Respondent's radio advertisements that were broadcast in the six SLN states from September 26, 2007 to April 26, 2008. (CX14a, EPA331-61)

a. Requisite nexus exists for shipments before November 1, 2007

In Counts 2,141 through 2,144 of the Complaint, Complainant alleges that Respondent distributed or sold Rozol on four separate occasions on October 1, 8, 19, and 29, 2007. (Compl. ¶¶471-86). Respondent contends that Complainant cannot establish a nexus between these sales and the substantially different claims because the sales occurred prior to November 2007, when it first distributed the direct mail packages. (Resp.'s Prehrg. Br. at 39-40). Contrary to Respondent's contention, the record evidence shows that a "sufficiently close link" exists between the distributions or sales that occurred before November 2007 and the substantially different claims Respondent made for Rozol.

The record evidence shows that a "sufficiently close link" exists for the shipments of Rozol before November 1, 2007 and the substantially different claims made in Respondent's advertisements. The two shipments at issue in Counts 2,142 and 2,143 of the Complaint were sent on October 8 and 19, 2007, to Respondent's distributors in Nebraska during the time that Respondent was broadcasting its illegal radio advertisements in that State.[23] (Compl. ¶¶ 476, 480; CX14a, EPA348-49; CX23, EPA486-87). In addition, Respondent's October 1, 2007 shipment of Rozol to Eldora, Iowa was to a different location of one of Respondent's "authorized" distributors for Rozol, and occurred after the February 17, 2006 version of the slim jim was in the marketplace.[24] (Compl. ¶472; CX17, EPA378; CX23, EPA488; CX74, EPA1188[25]). Because the October 1, 8 and 19, 2007 shipments occurred after the February 17, 2006 version of the slim jim was circulating through the marketplace, during Respondent's radio

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[23] Contrary to Respondent's assumption, the violations alleged in Counts 2,141 through 2,183 of the Complaint involve Respondent's substantially different claims in its radio advertisements, as well as those made in its direct mail packages. (Compl. ¶¶ 199, 202, CX14a, EPA346-47, 352-53, 361-62).

[24] As indicated above, the February 17, 2006 version of the slim jim includes claims that are very similar to the claims Respondent made in its other advertisements. (*Compare* CX14a, EPA176, 195, 214, 252, 271 *with* CX74, EPA1191).

[25] Mr. Creger is the Pesticide Program Manager for the Bureau of Plant Industry in Nebraska. (CX3, EPA31).

advertising campaign, and to another location of one of Respondent's "authorized" distributors, it is reasonable to conclude that these shipments were induced by one or more of the different types of Respondent's advertisements. Finally, the October 29, 2007 shipment to the Snow King Resort in Wyoming was used at a Weed and Pest Conference for purposes of demonstration or to induce further sales of Rozol. (Compl. ¶484; CX23, EPA491; Niess Tr. at 60:21-61:13). Based on the totality of the circumstances, Complainant submits that the requisite nexus has been demonstrated for the FIFRA § 12(a)(1)(B) violations alleged in Counts 2,141 through 2,144 of the Complaint.

b. Requisite nexus exists for shipments after November 1, 2007

A "sufficiently close link" exists between the substantially different claims in Respondent's radio advertisements, direct mail package cover letters, and Research Bulletins and the remaining 39 shipments at issue in Counts 2,145 through 2,183. The remaining 39 shipments began on December 3, 2007 and continued every couple of days until May 30, 2008. (CX23, EPA450-85, 489-90, 492; Compl. ¶¶217-55). All but four of these shipments were to various distributors in one of the six states in which Respondent disseminated its direct mail packages in November 2007. (CX23, EPA, 450-61, 463-80, 484-85, 489-90, 492). Four of these shipments were sent to Van Diest Supply's location in Webster City, Iowa on December 4, 2007 (two shipments), December 6, 2007, and March 7, 2008. (*Id.*, EPA462, 481-83). According to other bills of lading produced by Respondent, Van Diest Supply has another location in McCook, Nebraska, the location of four radio stations that broadcasted Respondent's radio advertisements, and a state in which Respondent disseminated its direct mail packages. (CX14a, EPA209-27; *id.*, EPA348-49).

In addition, 32 of the 39 shipments of Rozol from December 3, 2007 to May 30, 2008 were to 13 companies and individuals or affiliates of the companies that were authorized by

Respondent to distribute Rozol Prairie Dog Bait when it was registered under FIFRA § 24(c). (Schmit Tr. at 194:21-25). Of these 32 shipments, 21 were sent to five of the authorized distributors that Respondent admits had access the Research Bulletin: (1) Arrow Seed Company in Broken Bow, Nebraska; (2) Van Diest Supply Co. in McCook, Nebraska; (3) Helena Chemical in Hartley, Texas; (4) Estes Incorporated in Lubbock, Texas; and (5) Pro Chem Sales in Amarillo, Texas. (CX23, EPA450-51, 454, 458, 460-61, 463-68, 470, 473, 475, 477-80, 485, 491; CX17, EPA371 (noting that Respondent will be sending the list of distributors at CX17, EPA378 requests to destroy "all of the advertising and literature in their possession"); CX17, EPA378; CX17, EPA407 (listing the Research Bulletin as a piece of literature "to which you or your sales representatives have access" that is "non-compliant" and must be discarded)). All of the 21 shipments to the distributors that Respondent authorized to distribute Rozol were received after the direct mail packages were sent and after Respondent's radio advertisements for Rozol Prairie Dog Bait were broadcast in Nebraska and Texas. (CX23, EPA450-51, 454, 458, 460-61, 463-68, 470, 473, 475, 477-80, 485; CX14a, EPA346-62).

Furthermore, 11 of the shipments were sent to different locations of the companies authorized by Respondent to distribute Rozol Prairie Dog Bait. (*Compare* CX17, EPA378 *with* CX23, EPA462, 481-83 (Van Diest Supply in Webster City, Iowa), EPA469, 484 (Helena Chemical Co. in Holdredge, Nebraska and Bridgeport, Nebraska), EPA472, 489 (Wilbur-Ellis Company in Hereford, Texas and Frionia, Texas), EPA474, 476, 490 (Estes Incorporated in Clinton, Oklahoma)). All 11 shipments to the affiliates of the distributors that Respondent authorized to distribute Rozol were received after the direct mail packages were sent in the six SLN states and after Respondent's radio advertisements for Rozol were broadcast in Kansas, Nebraska, and Texas. (*Id.*; CX14a, EPA331-61). Furthermore, it should come as no surprise

that affiliates of the authorized distributors received the shipments after the direct mail packages were sent to the authorized distributors. At least three of the five individuals listed for the authorized distributors that received 21 of the shipments were in either managerial or sales positions for their respective companies: (1) Dan Watson of Van Diest Supply Co. in McCook, Nebraska was the Vice President Specialty Division; (2) Todd Martin of Helena Chemical Co. in Hartley, Texas was the Branch Manager; and (3) Arnold Frost of Estes Incorporated in Lubbock, Texas was the Manager. (CX17, EPA378; *see also* CX132, EPA3185 ¶7.C., EPA3186 ¶¶9.B., 10.D.) Because these three individuals were in positions that could influence sales at their respective locations and perhaps other locations of their companies, it is reasonable to conclude that they contacted their respective company's other branches after receiving the direct mail packages from Respondent.

Based on the totality of the circumstances, this Tribunal should hold that a "sufficiently close link" exists between the violative claims and the shipments at issue in Counts 2,145 through 2,183 of the Complaint. The record evidence shows that 35 of the 39 shipments at issue in these counts were sent to distributors in Colorado, Nebraska, Oklahoma, and Texas after Respondent disseminated the direct mail packages in those states. (CX14a, EPA151; CX23, EPA450-61, 463-80, 484-85, 489-90, 492). Furthermore, 32 of the 39 shipments were to 13 companies and individuals or affiliates of the companies that were authorized by Respondent to distribute Rozol when it was registered under FIFRA § 24(c). (Schmit Tr. at 194:21-25; CX23, EPA450-51, 454, 458,460-70, 472-85, 489, 490-91). Finally, the four shipments to Van Diest Supply in Webster City, Iowa, an affiliate of Van Diest Supply in McCook, Nebraska, an authorized distributor of Rozol (CX17, EPA378), were sent after the radio advertisements for

Rozol were broadcast on four different radio stations out of McCook, Nebraska. These facts demonstrate the requisite nexus for Counts 2,145 through 2,183 of the Complaint.

3. The Requisite Nexus Exists for Counts 2,184 through 2,231 of the Complaint

The record evidence demonstrates that there is a "sufficiently close link" between the offers for sale Respondent made for Rozol on its website and in the brochure it distributed in the second direct mail package and the various illegal claims Respondent made for Rozol. Unlike *Microban* and *Sporicidin*, cases in which the alleged FIFRA § 12(a)(1)(B) violations involved shipments of pesticides, the violations alleged in Counts 2,184 through 2,231 involve "offers for sale" of pesticides. In this case, the violative claims were made in the "offers for sale" themselves. As explained above, the violative claims were made for Rozol in the New Slim Jim and in the Product Information Sheets for Rozol on Respondent's website. Because all the violative claims were made in "advertisements made available to pesticide users or the general public," and thus constitute "offers for sale," Complainant has demonstrated the requisite nexus for purposes of FIFRA § 12(a)(1)(B). Indeed, no closer link is possible than here, where the offers for sale include the violative claims.

In addition, the evidence in the record demonstrates that the 48 distributors to whom Respondent sent the New Slim Jim are Respondent's regular customers. *See Microban II*, 11 E.A.D. at 449 (finding an ongoing buyer-seller relationship significant for purposes of nexus). Respondent has admitted that the 48 distributors listed in CX145, EPA3522 had the New Slim Jim in their possession. As it did when it received the SSURO in June 2008 regarding certain advertisements that did not contain the classification for Rozol (CX17, EPA407-08), Respondent sent a letter, on or about March 9, 2010, to each of the 48 distributors requesting that they all destroy, among other advertisements, the New Slim Jim. (CX53, EPA994, 996). These letters

required each of the 48 distributors "to immediately discard the Rozol® Pocket Gopher Bait – Burrow Builder Formula / Prairie Dog Bait literature . . . to which you or your sales representatives have access." (*Id.*, EPA996). The letters go on to list the New Slim Jim as one of the pieces of literature to which these 48 distributors had access. (*Id.*) Of the 48 distributors that had access to the New Slim Jim, more than half were different locations of the seven companies that Respondent originally authorized to distribute Rozol Prairie Dog Bait when it was registered under FIFRA § 24(c). (*Compare* CX145, EPA3522 (listing various locations of Helena Chemical, individually and in connection with Panhandle Coop, United Suppliers, Estes, Wilbur-Ellis, Arrow Seed Company, Van Diest Supply Co., and Pro-Chem 29 times) *with* CX17, EPA378 (listing various locations of Estes Incorporated, Helena Chemical Company, Pro Chem Sales, United Suppliers, Wilbur-Ellis Company, Arrow Seed, and Van Diest Supply Co.)). Furthermore, a list of 80 distributors that Respondent filed pursuant to a court order, showed that the majority of the 48 distributors that had the Research Bulletin from November 18, 2009 to February 23, 2010 were still distributing Rozol Prairie Dog Bait from August 29, 2010 to August 29, 2011. (CX145, EPA3522; CX149, EPA3565-66).

Respondent's ongoing and continuous commercial relationship with many of the 48 distributors that had access to the New Slim Jim, beginning in 2007 when Rozol Prairie Dog Bait was registered under FIFRA § 24(c) and continuing until at least August 29, 2011, demonstrates that 48 distributors that Respondent sent the New Slim Jim were selected as part of an existing network of Respondent's expanding pool of distributors. *Microban II*, 11 E.A.D. at 449. In addition, after it received a registration under FIFRA § 3 for Rozol Prairie Dog Bait, Respondent, either in connection with sending the New Slim Jim to these 48 distributors or separately, sent a direct mail package enclosing advertising and urging prospective customers to give Rozol a try.

(Niess Tr. at 98:1-12). The cover letter for this direct mail package was signed by Mr. Knuth and Mr. Newman, Respondent's district sales managers and members of cattleman's organizations. (Niess Tr. 97:21-23 (explaining that a cover letter to the November 2009 direct mail package was from Mr. Knuth and Mr. Newman); *see also* Schmit Tr. at 67:17-20 (explaining that Respondent's salespeople are members of cattleman's associations)). Sending direct mail packages in November 2009, after it received a FIFRA § 3 registration for Rozol Prairie Dog Bait, is consistent with Mr. Schmit's acknowledgment that "once a product is federally registered, they [Respondent's marketing professionals] want to sell it." (Schmit Tr. at 11:54-5; *see also id.* at 207:17-20 (admitting that Respondent advertises to let potential customers know that its products are in the marketplace)).

For all of the foregoing reasons, Complainant has demonstrated, by a preponderance of the evidence, that the claims at issue in Counts 2,184 through 2,231 of the Complaint were made "as part of the distribution or sale" under FIFRA § 12(a)(1)(B).

## VI. THE PROPOSED PENALTY OF $2,891,200 SHOULD BE IMPOSED

FIFRA § 14(a)(4) of sets forth the factors which must be considered in determining the amount of the penalty to be assessed for such violations. FIFRA § 14(a)(4), states in pertinent part as follows:

> In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation.

7 U.S.C. § 136*l*(a)(4). EPA developed the FIFRA Enforcement Response Policy (December, 2009) ("ERP"), which sets forth a methodology for the calculation of an appropriate civil penalty in accordance with FIFRA § 14(a). (CX 51). The goal of the FIFRA ERP is "to provide fair and equitable treatment of the regulated community, predictable enforcement responses, and

comparable penalty assessments for comparable violations" and is also intended "to allow swift resolution of environmental problems and to deter future violations of FIFRA by respondents, as well as other members of the regulated community." (CX51, EPA937); *see also In re Tremont Supply Inc.*, Docket No. FIFRA-09-99-0011, 2000 EPA ALJ LEXIS 46, at *12 (ALJ June 30, 2000).

For Respondent's violations of FIFRA § 12(a)(2)(E) and (a)(1)(B), EPA proposed a civil penalty of $2,891,200 in the Complaint. EPA's penalty calculation is set forth in CX 55(a) and (b). As explained in those documents, EPA calculated the proposed penalty based on the facts and circumstances of this case, after applying the statutory penalty factors in FIFRA §14(a)(4), 7 U.S.C. §136*l*(a)(4), and the requirements of the FIFRA ERP.

**A. Application of the Statutory Penalty Factors**

Complainant has considered each of the statutory penalty factors set forth in FIFRA § 14(a)(4), and has met its burdens of production and persuasion with respect to the appropriateness of the penalty proposed in the Complaint. Respondent has waived any argument regarding "size of business" or "ability to pay." (Joint Stips., p. 16). The gravity of the violation is the only remaining statutory penalty factor where Complainant and Respondent disagree. EPA's application of this statutory penalty factor to the evidence presented in this case is discussed below.

1. The Appropriateness of the Penalty to the Size of the Business of the Person Charged

Complainant considered the appropriateness of the penalty to Respondent's size of business by examining publicly-available information in the form of a Dun & Bradstreet report for Respondent, which indicated that Respondent had gross annual sales in the amount of $39,500,000. (CX 55, EPA1008). Respondent stipulated that "it has already waived any

challenge, argument or objection to the penalty based on or otherwise relating to the factors 'the size of the business of the person charged' and 'the effect on the person's ability to continue in business.'" (Joint Stips. at 16).

2. The Effect on the Person's Ability to Continue in Business

Complainant has also met its burden to consider the effect of the proposed penalty on Respondent's ability to continue in business. The same financial information EPA referenced to determine the size of Respondent's business supports a determination that Respondent can pay the proposed penalty and continue in business. As noted above, Respondent stipulated that "it has already waived any challenge, argument or objection to the penalty based on or otherwise relating to the factors 'the size of the business of the person charged' and 'the effect on the person's ability to continue in business.'" (Joint Stips. at 16).

3. The Gravity of the Violation

Complainant also has met its burdens of production and persuasion with respect to the appropriateness of the proposed penalty based on the statutory penalty factor "the gravity of the violation." Respondent's violations of FIFRA § 12(a)(2)(E) and (a)(1)(B) both present a potential for serious or widespread harm to non-target species, including endangered species. As Complainant demonstrated at the hearing, and as will be discussed in detail below, the use of Rozol to control black-tailed prairie dogs can result in the injury and death of animals other than prairie dogs, including seed-eating birds, raptors, and mammals. Because of this danger, EPA invoked all the mechanisms that FIFRA's statutory scheme provides to mitigate environmental hazards during the registration of Rozol. These mechanisms included restricting the sale and application of Rozol to certified applicators or persons under their direct supervision. EPA also included stringent label language instructions on how to handle and apply Rozol as well as post

application requirements such as bait and carcass search, retrieval, and disposal.

Respondent's violations undermine the statutory scheme at several levels, nullifying the intended protections afforded to non-target species by FIFRA. The claims made by Respondent in its advertising contradict or undermine critical label language, including hazard language and bait and carcass search, retrieval, and disposal requirements. Additionally, Respondent mischaracterized Rozol's effectiveness and minimized Rozol's potential to cause harm to the environment, all to increase sales of Rozol. To that end, Respondent inappropriately and without regard to scientific norms twisted the results of studies by selectively choosing data to cite in support of advertising claims for the product, and ignoring study results that contradicted those claims. These actions clearly could mislead the consumer about both the effectiveness and the dangers of Rozol. Finally, several years after being notified by EPA that its website failed to include the Rozol products' restricted use classifications or terms of restriction, Respondent was in violation of FIFRA § 12(a)(2)(E) at the time of the hearing. Respondent's cavalier attitude towards compliance warrants the penalty proposed in this case.

a. Field use of Rozol endangers non-target wildlife, including endangered species

It is undisputed that the field use of rodenticides often carries risk to wildlife that share the target species' habitat. The EPA's Comparative Risk Assessment states:

> A major concern in using rodenticides is that they are not selective to the target species; birds and nontarget mammals that feed on grain-based baits (pellets, meal, treated grains, wax blocks) or meat-based, vegetable, or fruit baits are potentially at risk. The available information from laboratory and pen studies, field studies, control programs, reported incidents, and toxicokinetics also indicates that a variety of avian and mammalian predators and scavengers are potentially at risk from consuming animals poisoned with some of these rodenticides.

(CX38, EPA625). The use of Rozol in the field to poison black-tailed prairie dogs is no

exception, and this use carries risks to wildlife that share the prairie dogs' habitat. Field use of Rozol to control prairie dogs presents risks both to animals that consume the bait itself, and to predators that consume animals that consume the bait. At the hearing, Dr. Nimish Vyas, an expert witness and U.S. Geological Survey research biologist, explained that the former is known as primary poisoning, and the latter is called secondary poisoning. (Vyas Tr. at 26:8-16).

EFED has conducted a number of environmental risk assessments for the use of Rozol to poison prairie dogs. These include five separate reviews of state SLN registrations for Rozol Prairie Dog Bait in 2006 and 2007, a review of expanded use of Rozol in 2008, and a review specifically addressing threatened and endangered species in 2010. (CX75-79, 118). In its review of state SLN applications for Nebraska and Wyoming for use of Rozol to control prairie dogs, EFED scientists concluded "that use of chlorophacinone bait to control prairie dogs has a considerable potential for both primary and secondary risks to birds and nontarget mammals and possibly reptiles." (CX75, EPA1196). EFED came to the same conclusion in its reviews of other state SLN applications and in its review of the expansion of the SLN label to include four other states. (CX76, EPA1216; CX77, EPA1232; CX78, EPA1249-1250; CX79, EPA1272).

There is evidence in the record showing that when applied to kill prairie dogs, Rozol can kill non-target wildlife through primary poisoning. In Dr. Vyas' study of field use of Rozol in Colorado in 2010, he noted the death of several thirteen-lined ground squirrels and a horned lark, members of species that consume seeds as part of their diets, but do not prey on or scavenge other animals. (CX127, EPA3143-44; Vyas Tr. at 45:1-13, 43:11, 24). In its risk characterization for primary non-target toxicity, EFED described those risks as follows:

> Nontarget primary consumers are likely to be exposed to Rozol bait applied for prairie dog control. Bait applied only six inches into entrances of open-burrow systems may be visible from the surface and may result in substantial exposure of nontarget

> animals, including migratory birds and threatened and endangered species. Digging by predators such as badgers, skunks, and coyotes also may bring bait to the surface.

(CX75, EPA1201).

It is clear that Rozol, when used to control black-tailed prairie dogs, is also a threat to non-target wildlife through secondary poisoning. In 2006 and 2007, the U.S. Fish and Wildlife Service Office of Law Enforcement investigated the death of a bald eagle in Red Willow County, Nebraska. (CX90, EPA1577–1612). On December 6, 2006, Nebraska Conservation Officer Virgil Gosch found the dead eagle, and due to the lack of other observed hazards, believed the eagle may have been poisoned. (*Id.*, EPA1577-78). Officer Gosch collected the carcass as evidence, froze the carcass to preserve it, and contacted the U.S. Fish and Wildlife Service. (*Id.*) Special Agent Mike Damico of the U.S. Fish and Wildlife Service took custody of the bird on January 10, 2007, and forwarded it, still frozen, to the U.S. Fish and Wildlife National Forensics Lab by Federal Express on the same day. (*Id.*, EPA1578). At the National Forensic Lab, Dr. Rhoda Rhalston conducted a necropsy of the eagle and found extensive internal hemorrhaging, consistent with anti-coagulant poisoning. (*Id.*, EPA1610). During the necropsy, Dr. Rhalston collected samples of the eagle's liver and had them analyzed by one of the National Forensic Lab's forensic chemists, Dr. Mark Kirms, who used high performance liquid chromatography/ mass spectrometry to determine that the liver tissue contained chlorophacinone. (*Id.*, EPA1612). Based on the necropsy she performed and Dr. Kirms' chemistry report, Dr. Rhalston determined the cause of death of the eagle to be ingestion of chlorophacinone. (*Id.*, EPA1611).

Special Agent Damico continued the investigation by tracking down a certified pesticide applicator that had applied Rozol to a nearby field on November 8, 2006, four weeks before the eagle was discovered. (*Id.*, EPA1588, 1578). The applicator, who had made previous Rozol

applications in addition to the one investigated by the U.S. Fish and Wildlife Service, noted that he had seen intoxicated prairie dogs on the surface after applying Rozol. (*Id.*) As documented by Special Agent Damico's report, the applicator described the intoxicated prairie dogs "to be in a stupor, and not wary at all," and that the applicator "could often walk right up to these poisoned prairie dogs and they would not run away." (*Id.*) Based on results of Special Agent Damico's investigation, the U.S. Fish and Wildlife Service determined the cause of death of the eagle to be poisoning by Rozol. (*Id.*, EPA1592).

As bald eagles are raptors, and do not eat seeds or grain, it is almost certain that the eagle died from consuming dead or dying animal(s) that had eaten Rozol, and the chlorophacinone that killed the eagle was in the tissue of the preyed upon or scavenged animal(s). This conclusion is supported by the scientific studies that have found that chlorophacinone remains in the tissues of the animals that consume the poisoned bait, and that chlorophacinone in prey tissue is a hazard to predators. The study entitled "Secondary Hazard Study Using Chlorophacinone-Killed Laboratory Rats Fed to Domestic Ferrets," which was performed by Genesis Laboratories at the request of Respondent, demonstrated that, among other things, chlorophacinone was available in rat tissues, where the rats were fed chlorophacinone-laced bait. (RX14, RX_1311). In the same study, 55% of domestic ferrets that ate the poisoned rats in turn died from chlorophacinone poisoning. (*Id.*, RX_1284). Finally, EFED, in its Risk Characterization for secondary toxicity, described the risk to predators in this way:

> Dead and dying prairie dogs and non-target animals that have eaten bait pose a risk to predators and scavengers because chlorophacinone is stored in body tissues of bait consumers. Tests with captive mustelids, domestic ferrets, mongooses, weasels and wild canids, coyotes and red foxes, indicate that poisoned prey pose a significant risk to mammalian predators and scavengers.

(CX75, EPA1202).

Dr. Thomas Steeger, an expert in animal toxicology, summarized EFED's conclusions about the risk Rozol posed to non-target species during the hearing:

> [M]ammals and birds can be affected by the proposed use of the compound, and that these data, these incident data are consistent with EFED's estimation that effects will not just occur to the target organisms in direct consumption of the bait but that other non-target organisms will consume the bait and potentially die and that organisms such as predators and scavengers who would in turn predate or scavenge these animals that were succumbing to primary consumption of the bait would also show effects that would include mortality.

(Steeger Tr. at 33:24-34:9). Dr. Vyas has conducted research on the effects of Rozol on non-target animals, specifically on raptors. His recent experience in the field supports the risks described by EFED. At the hearing, Dr. Vyas described the relationship between black-tailed prairie dogs and raptors in the following manner:

> Especially in the wintertime, the black-tailed prairie dog colonies are an important food source for raptors. Because there isn't a lot of food available, and this is a nice concentrated food source for them. A lot of the birds like the ferruginous hawks are very strongly correlated to the prairie dog colonies.

(Vyas Tr. at 25:8-13).

To fully understand the potential risk to non-target species, it is important to understand the nature of the toxicity of Rozol, or how it kills both target and non-target animals. Chlorophacinone is a first generation anticoagulant rodenticide. (CX38, EPA630). As described in the Comparative Risk Assessment, "the anticoagulant rodenticides are vitamin-K antagonists that disrupt normal blood-clotting mechanisms and induce capillary damage. Death results from hemorrhage, and exposed animals may exhibit increasing weakness prior to death. Behavior also may be affected." (*Id.*) As noted by Dr. Steeger at the hearing, "[c]hlorophacinone is a chronic toxicity pesticide. While it can be acutely toxic, particularly in mammals, other non-targets are more likely to be affected through prolonged and chronic exposure to the compound." (Steeger

Tr. at 66:20-23). Dr. Vyas similarly explained the toxicity time frames he had witnessed in his field study of Rozol at the hearing:

> Q: Can you tell us, is Rozol a chronic or acute toxicant?
>
> A: It is chronic.
>
> Q: Can you explain the difference?
>
> A: Acute toxicity chemical is usually—exhibits its toxicity soon afterwards as opposed to chronic, you see the effects later.
>
> Q: And when you say later, are you talking hours? Days?
>
> A: With acute it would be hours, days. With Rozol it could be up to two, three weeks after getting sufficient exposure.
>
> Q: What do you mean by sufficient exposure?
>
> A: Sufficient exposure in terms of enough vitamin K that synthesis has been affected.
>
> Q: How would that take place?
>
> A: From repeated feeding, primarily of the chemical. That's the other thing, if it's an acute toxicant, it usually doesn't require—onetime feeding would be sufficient to cause an adverse effect. In the case of the chronic toxicant, they need multiple days of feeding in general. So it's a chronic toxicant, and it has chronic effects because it requires multiple feedings to get enough for the mode of action to completely affect the animal. Then it could take two weeks, three weeks for an animal to die, or it could die sooner.

(Vyas Tr. at 26:17-27:16).

The fact that Rozol's mode of action is chronic rather than acute affects the potential for harm to non-target organisms through secondary toxicity. As Dr. Vyas goes on to point out:

> Q: The fact that it's a chronic toxicant, does that impact how Rozol might contribute to non-targets' exposure?
>
> A: Yes, from two perspectives. One is from the chronic toxicant perspective, just a prairie dog doesn't have to eat a lot of Rozol as long as it eats it on a regular basis for several days. That's sufficient. So the same way the raptor that's feeding on the prairie dog doesn't have to eat very high levels of the Rozol in the

prairie dogs as long as it's getting relatively reasonable exposure over time.

Q: In your experience, is that happening? Is it getting repeated exposure?

A: Yes, they are.

Q: Why is that?

A: Because its wintertime, food is scarce. There's a lot of competition and parasitism going on, stealing food from another bird. What happens is usually when there's a prairie dog kill, the ferruginous hawks will show up. Then the red-tailed hawks will come and try and displace them, and the bald eagles will come, and they're stronger, and will displace them. So a bigger hawk might come and displace that one, so no one hawk is getting to eat the whole prairie dog.

Q: How is it that they're getting repeated exposure though?

A: Oh, because the prairie dogs are dying over the course of three weeks or whatever, so there are some prairie dogs available over time.

(Vyas Tr. at 27:17–28:19).

The testimony of Dr. Steeger regarding his review of the studies of the toxicity of Rozol corroborated the observations of Dr. Vyas. During his direct examination, Dr. Steeger noted:

> [H]aving incident information and having residue information has given us a very clear understanding that residues do persist in the carcass of animals that have died, and these residues are sufficient, based on laboratory studies and based on incident information, to result in secondary toxicity, and that these effects, these residues are sufficient in not just affecting predators and scavengers but affecting a broad range of taxa that go beyond what you might expect in a mode of action.

(Steeger Tr. at 72:23-73:7).

The hazard to non-target organisms as a result of the use of Rozol to poison black-tailed prairie dogs is especially concerning where those non-target species are threatened or endangered. In a nationwide risk assessment conducted by EFED in 2010, EPA identified 21

threatened and endangered species that are expected to be adversely affected by the use of Rozol to control prairie dogs. (CX118, EPA2678). For example, a species most commonly associated with black-tailed prairie dogs is the black-footed ferret, which is listed on the federal endangered species list. (*Id.*, EPA2681). Because the black-footed ferret primarily feeds on prairie dogs, the use of Rozol to control prairie dogs can expose the ferrets to death by secondary poisoning. (*Id.*) A less well-known endangered species, the American Burying Beetle, is another of the species that EFED determined to be at risk from this use of Rozol. (*Id.*) The American Burying Beetle lays its eggs in mammalian and avian carcasses, and tests on similar beetles have demonstrated that the presence of chlorophacinone in carcass tissue may decrease the reproductive ability of the insects. (*Id.*; *see also* RX19, RX_001586; CX 126, EPA3121).

b. EPA used restricted use status to mitigate the danger to non-target wildlife

Inherent in the statutory scheme of FIFRA is a risk benefit analysis. 7 U.S.C. § 136a(c)(5)(C), *see also* 7 U.S.C. § 136(bb). As long as all other regulatory requirements are met, if the benefits derived from the use of a pesticide outweigh the risks of that use, EPA registers the pesticide. *Id.* EPA has a number of tools it can use in the registration process to help reduce risks, including classifying a pesticide as restricted use, and including mitigation measures as application requirements or conditions on the label. *See* 7 U.S.C. § 136a(d)(1)(C). Mr. Hebert of OPP testified generally about EPA's mechanisms for reducing risk to the environment at the hearing:

> Q: When you're determining if a product should be registered, does the Registration Division consider how the product will impact the environment when used by the consumer?
>
> A: Yes.
>
> Q: And how do you make that assessment? Does someone help you make that assessment?

A: We can consult with our Environmental Fate and Effects Division. They help us make those calls.

Q: And do they give you a written risk assessment?

A: Typically, yes.

Q: And how might the … EFED risk assessment impact your decision to register a product?

A: Their conclusions on the risks associated with the product; we take their recommendations. They're the risk assessors. We mitigate the risks. And we determine what we need to put on the label to mitigate those risks.

* * * *

Q: Let's talk quickly about a classification. Does EPA classify a product when it's registered?

A: Yes.

Q: And tell us a little bit about that?

A: Products need to be classified as general use or restricted use. Most products are general use, and they aren't labeled general use on the product. If they're not labeled restricted use, it's assumed that they are general use.

Q: And what is the classification of restricted use classification based on?

A: It can be based on several things, acute toxicity to humans, risks to non-targets, to the environment, those types of things.

Q: And what's the importance of this classification?

A: The classification restricts the use and sale of the product to certified applicators or persons under their direct supervision.

(Hebert Tr. at 36:19-38:16).

EPA classified Rozol Prairie Dog Bait as a restricted use pesticide, as it does with most field use rodenticides where there is significant risk of exposure of non-target animals to primary

or secondary poisoning. As Mr. Hebert described at the hearing:

> Q: From 2007 onward – which is the relevant time frame here – were the SLNs[26] all classified as restricted use pesticides?
>
> A: Yes, they were.
>
> Q: And for the same reasons? Why were they classified as restricted use pesticides?
>
> A: Due to potential hazards to non-target organisms.
>
> * * * *
>
> Q: ....What was going on with the SLNs that was targeting the black-tailed prairie dogs that it was also considered [a] restricted use pesticide?
>
> A: We consider treatment of prairie dogs to be a field use. And because of that, the potential for exposure to non-targets is greater, because the prairie dogs can live in – we call them prairie dog towns – that could cover hundreds of acres. So the potential for exposure to non-targets is magnified because of that.

(Hebert Tr. at 57: 1-25). Restricting the sale and use of pesticides to certified applicators is a mechanism EPA uses to "significantly reduce the potential for adverse effects, whether from normal use or misuse." (RX 60, RX_3300).

c. <u>EPA required strict application directions and bait and carcass search requirements to mitigate the danger to non-target wildlife</u>

In addition to classifying Rozol as a restricted use pesticide, EPA included in the pesticide labels strict application directions and bait and carcass search, retrieval, and disposal requirements to mitigate the danger to non-target wildlife. These mitigation measures were included to ensure that bait was not available on the surface, and that chlorophacinone-laced carcasses were not available to predators and scavengers.

EPA first included these requirements as a result of its review of the first state SLN

[26] The discussion of SLNs refers to the Rozol registrations found at CX2-7.

registration of Rozol Pocket Gopher Bait, EPA Registration Number 7173-184, for use against prairie dogs, in 2004. In a July 30, 2004 letter to the Kansas Department of Agriculture, EPA concluded that the SLN registration of Rozol for use against prairie dogs was acceptable as long as, among other changes, the following language was included on the label:

> Use Restrictions: This product may only be used in underground applications to control black-tailed prairie dogs (Cynomys ludovicianus) on rangeland and noncrop areas in Kansas.
>
> - Bait must be applied at least 6 inches down prairie dog burrows, measuring from the portion of the burrow opening that is farthest back into the tunnel. Usually this will be the top part of the burrow opening. Do not apply bait on or above ground level.
>
> Baiting: Before applying this product, identify active prairie dog burrows by visual observation. The openings of active burrows generally will be free of leaves, seeds, other debris, or spider webs, and will show freshly turned earth and have prairie dog feces nearby.
>
> Apply ¼ cup (52 grams or nearly 2 ounces) of bait at least 6 inches down active prairie dog burrows. Make sure that no bait is left on the soil surface. Treat all of the active burrows within the prairie dog colony (or "town"). Victims of this bait will begin to die off 4 to 5 days after they eat a lethal amount. If prairie dog activity persists several weeks after the bait was applied, make a second application 1 to 2 months after the first, treating all active burrows using the same baiting procedures and at the same rate as the first application.
>
> Retrieve and properly apply or dispose of bait that is spilled above ground or inside the burrow within 6 inches of the entrance. Following treatment, collect and properly dispose of any bait that may have come to the surface. Collect and properly dispose of all dead animals found above ground. Carcasses buried on site must be in holes dug at least 18 inches deep.[27]

(CX 2, EPA19).

[27] The very first SLN registration for Rozol use on prairie dogs was based on the general use product, Rozol Pocket Gopher Bait, EPA Reg. No. 7173-184. At EPA's insistence, subsequent SLN's were based on the restricted use product, Rozol Pocket Gopher Bait Burrow Builder Formula. (CX 2, EPA22).

The same or similar language was required on subsequent SLN labels for Rozol used to control black tailed prairie dogs. (CX2, EPA24; CX3, EPA28, 32, 34; CX4, EPA36, 42; CX5, EPA48, 50; CX6, EPA52; CX7, EPA57). Each time EPA reviewed the state SLN registrations, EFED evaluated the associated risks, and provided recommendations as to the mitigation measures. For example, on July 27, 2006, EFED completed a review of the Nebraska and Wyoming SLN registration packets. (CX 75). EFED's review noted as follows:

> The Nebraska SLN label provides some additional information and post-application requirements not on the Wyoming SLN label. It notes that poisoned prairie dogs will begin to die 4-5 days after eating a lethal amount. The applicator must return to the site within 1-2 days after bait application and at 1- to 2- day intervals to collect and properly dispose of any dead or dying prairie dogs found above ground. Collections should be done near sundown. Carcasses must be buried on site, at least 18" deep, or placed in inactive burrows and covered and packed with soil. Any non-target animals found must be reported to the NDA (telephone number is provided on the label).

(CX75, EPA1198). EFED went on to recommend that the Wyoming SLN label include, among other things, label language like that of the Nebraska label to include explicit carcass search requirements and requiring the applicator to notify the Wyoming Department of Agriculture if any non-target animals are killed as a result of the application of Rozol. (*Id.*, EPA1204). EFED also stated that "EFED believes it is essential that applicators adhere to instructions to conduct carcass searches periodically after baiting and to properly dispose of carcasses collected." (*Id.*) At the hearing, Dr. Steeger noted in his direct examination that EFED had made these recommendations. (Steeger Tr. at 34:25-35:2).

By way of comparison, the Nebraska, Colorado, Texas, and Wyoming SLN labels all included the most stringent carcass search requirements, requiring that carcass searches be conducted within one to two days of application and repeated thereafter on one to two day

intervals until dead animals are no longer found. (CX3, EPA28, 32 and 34; CX5, EPA48 and 50; CX6, EPA52; and CX7, EPA57). The Kansas SLN label had less stringent carcass search requirements, requiring the first search four to five days after application and another search seven to fourteen days after application, but it included the requirement that the applicator contact the State if non-target animal carcasses were found, as did the Colorado and Nebraska labels. (CX2, EPA24; CX5, EPA48, 50; CX3, EPA28, 32, 34).

In order to perform an application of Rozol to a site following the Nebraska SLN label requirements, for example, the applicator would have had to:

- Identify the active burrows;
- Place the bait, by hand, at least six inches down each burrow, cleaning up any bait that was not six inches down the burrow;
- Clean up any bait spilled on the ground during the placement of the bait in the burrow;
- Return to the application site one to two days after application, in late afternoon before sundown, to search for any bait and prairie dog or other animal carcasses;
- If any carcasses were found, dig an 18 inch deep hole, and bury the carcasses in the hole, making sure to pack the hole with soil;
- If any non-target animals were found, contact the state department noted on the label;
- If any bait was found on the surface, collect the individual grains of Rozol and properly dispose of any bait that may have come to the surface;
- Return to the application site one to two days later and conduct the bait and carcass search, disposal, and notification requirements again;
- Repeat the bait and carcass search, disposal, and notification requirements again until no dead animals are found.

Given that it may take three to four weeks for the prairie dogs to die from the application of Rozol, a certified applicator following the label, coming to the site every other day, may conduct the carcass search, disposal, and notification step fourteen times. A certified applicator intent on

minimizing non-target exposure, conducting the carcass search, disposal, and notification requirements on a one day interval, would complete those steps every day for several weeks.

d. Respondent's failure to include restricted use language in advertisements undermined protection afforded non-target wildlife by FIFRA § 12(a)(2)(E)

As the Chief Judge held in the May 6, 2011 order granting accelerated decision on Counts 1 through 2,140, "the statute and regulation governing advertising [FIFRA § 12(a)(2)(E) and 40 C.F.R. § 152.168, respectively] are clearly intended as prophylactic health and safety measures designed to communicate the risks inherent in the product's use and *discourage even preliminary interest in the product by those who are not legally permitted to use it.*" (5/6/11 Or. at 12 (emphasis added)). For the violations of FIFRA § 12(a)(2)(E), in which Respondent failed to include the terms of restriction in advertisements of a restricted use pesticide, we can posit that the protections intended by Congress could be short-circuited several ways. In either of the following scenarios, and as the Chief Judge pointed out, the regulatory scheme begins to fail when potential customers of Respondent, e.g. people who want to control black tailed prairie dogs on rangeland, hear the radio advertising, or read the magazine advertisements, but are not informed that Rozol is a restricted use pesticide when used for prairie dogs.

The first scenario occurs when the potential customer who is not a certified applicator, unaware of the restricted use status of the pesticides due to Respondent's violative advertisements, attempts to purchase the restricted use pesticide, and the store clerk sells the restricted use pesticide to the customer without requiring proof that she/he is a certified applicator. Circumstantial evidence that this scenario has occurred is found in Complainant's Exhibit 102, the Final Order in which the Kansas Department of Agriculture determined that, on or about March 12, 2008 an uncertified applicator purchased the restricted use pesticide Rozol in Colby, Kansas, and on or about March 15, 2008, applied the restricted use pesticide ("Withers

case").[28,29] (CX102, EPA 2472-73). It is worth noting that in the months before the purchase, KXXX radio in Colby, Kansas, ran the radio advertisements for Rozol 120 times from October 8, 2007 to December 21, 2007.[30] Additionally, in the two months immediately prior to the illegal purchase, between January 15, 2008 and March 7, 2008, the radio advertisements for Rozol were aired on KBUF in Holcomb, approximately 100 miles south of Colby, 229 times.[31] (CX 47, EPA873-878). The advertisements also aired 322 times on KICX radio in McCook, Nebraska, approximately 70 miles from Colby, and 139 times on KFNF radio in Oberlin, Kansas, approximately 50 miles from Colby, from September 26 to November 30, 2007.[32] Beginning on September 26, 2007 to April 26, 2008, Respondent blanketed the airwaves of western Kansas with illegal radio advertisements of Rozol. In addition, Respondent placed illegal magazine advertisements in the Kansas Stockman magazine throughout the same period, providing another series of advertisements that could have influenced the purchase in the Withers case and potentially in other situations like the Withers case. (CX14, EPA289-93).

The second scenario occurs when a potential customer, having heard the illegal Rozol advertisement, is sold general use Rozol Pocket Gopher Bait (EPA Reg. No. 7173-184), available without a certified pesticide applicator's license, and uses it to control black-tailed

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[28] EPA Region VII brought an enforcement action against the seller of the product. (*See* RX73, RX_3600-04; *In re Thomas Co. Noxious Weed Dept.*, 2010 WL 2787715 (E.P.A. July1, 2010)).

[29] The sale of restricted use pesticides to an unlicensed applicator is not an isolated occurrence. *In re Frontier Ag, Inc.*, Dkt. No. FIFRA-07-2010-0036, 2010 WL 3879675 (E.P.A. August 27, 2010); *In re Agri-Producers, Inc.*, 2010 WL 1255515, (E.P.A. March 17, 2010); *In re Helena Chem. Co.*, 2009 WL 3401069 (E.P.A. Sept. 28, 2009); *In re Farmers Coop Elevator Co.*, Dkt. No. FIFRA-07-2009-0007, 2009 WL 1220219 (E.P.A. March 31, 2009).

[30] The violations represented by these broadcast advertisements are found in Counts 1-120 of the Complaint.

[31] The violations represented by these broadcast advertisements are found in Counts 121-349 of the Complaint.

[32] The violations represented by these broadcast advertisements are found in Counts 350-671 and Counts 1,350 - 1,488, respectively, of the Complaint.

prairie dogs.[33] In this scenario, the customer could apply the product without ever being aware of prairie dog specific labeling, including applying the poison at least six inches into active burrows, the significant bait and carcass search and disposal requirements, and the notification requirements in the event the user discovers non-target animals that have been poisoned. In this scenario, the buyer may out of ignorance make no attempt to pick up spilled bait or collect carcasses, leaving the poison available to the full range of non-target wildlife. The potential for misuse increases the potential harm to the environment through primary and secondary poisoning of non-target organisms.

In either of these situations, the protective mechanism provided for in the statute - the requirement that the poison be applied by a person who has undergone special training to become a certified applicator - is circumvented. Because Respondent violated FIFRA by failing to disclose that Rozol is a "restricted use pesticide" or providing the terms of restriction for Rozol, Respondent caused potential serious or widespread harm to the environment in the form of increased risk of primary and secondary poisoning of non-target wildlife.

Respondent continues to argue that the part of the FIFRA regulatory scheme that prohibits the sale of restricted use products to uncertified applicators somehow excuses their violations. (Resp.'s Prehrg. Br. at 27). Respondent ignores the fact that different pieces of the statute are designed to work in conjunction with one another to create a complete regulatory scheme that, in its entirety, is protective. Where one piece of that scheme is bypassed, the scheme is weakened and is therefore less protective. In the case of restricted use pesticides, FIFRA § 12(a)(2)(E) is a critical component of the overall regulatory scheme.

The potential for harm to the environment from Respondent's violations clearly exists.

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[33] Respondent noted in its October 14, 2011 Pre-Hearing Brief, on page 4, that "Rozol Pocket Gopher Bait is a general use pesticide that is still being sold and used today."

Any applications of Rozol made by uncertified applicators as a result of Respondent's violative advertisements would likely be on private land, many times in remote locations. No authority or other person or groups of persons are routinely or actively looking for animal carcasses on millions of acres of rangeland. Predators and scavengers that die from secondary poisoning from these applications are often highly mobile, and unlikely to die at the application site. Smaller mammals that might die from primary poisoning are difficult to find in a landscape as vast as the western prairie. The nature of Rozol, which often takes days or weeks to kill animals, also allows animals to move away from the poison site. During the hearing, Dr. Vyas explained that the lack of the discovery of dead wildlife after application, or "incident data," does not mean that no non-target poisoning has occurred:

> With regards to the mode of action, because it's a chronic contaminant, the effects are chronic, meaning the animal does not necessarily die where it feeds. If it's a hawk that can fly a considerable amount of time, if it feeds on the prairie dog and dies a week later, it could die ten miles down the road or five miles down the road, and it's not necessarily related to the cause of death because people usually just search within that study area and—within that area that's monitored where the Rozol is applied and don't expand their monitoring.
>
> ****
>
> In general, the vastness of the habitat where Rozol is used [precludes] any monitoring, so nobody is out there looking. The other thing is most of it is on private land, so again, no one is necessarily looking for dead animals. Even if someone were to look, because a lot of dead non-target animals are cryptically colored, camouflage well with the soil and dirt, vegetation, they're hard to find, especially the smaller animals. So most of the mortality that occurs is never even observed.

(Vyas Tr. at 30:10-31:7). Often, the true extent of environmental harm that occurs due to violations is difficult to discover or quantify. Contrary to what Respondent suggests, the ERP does not require EPA to demonstrate certain environmental harm, however, to demonstrate that

the penalty it is seeking is appropriate. (CX 51, EPA967); *see also In re FRM Chemicals*, 12 EAD 739, 760 (EAB 2006).[34]

e. Respondent's claims contradicted and undermined critical label requirements aimed at protecting non-target wildlife

i. Easy to Use/Less Work/Single Application/Low Cost per Acre

As described in Section V.C.A., above, the claims Respondent made in its advertisements differed from the registration statement. One of the themes in Respondent's claims is that Rozol is "easy to use," requires "less work," and is "effective in a single application." The parties have stipulated to the fact that Respondent made these claims, in direct mail packages, radio advertisements, and on its website. (*See* Joint Stips., ¶¶146, 155, 158, 199, 202, 275, 278, 293, 305).

These differing claims contradict or undermine important label requirements, in effect encouraging applicators to disregard the label requirements, and understating the risks associated with the use of the product. As Dr. Steeger explained at the hearing in this matter:

> I think when you advertise a product .... You're going to send it to people who you think are going to use the product. You put verbiage there, this is easy to use, knock out this pest, and really nothing else, you create an expectation for the user group that it's almost a panacea, that I can accomplish what I need. You get the label and you read it, you go, this isn't easy to use.

(Steeger Tr. at 96: 2-12).

Advertising claims that the product is easy to use are problematic in two ways. First,

[34] The EAB has found a value of 3 for "environmental harm" on the basis of harm to the FIFRA regulatory program alone: "The ERP's two gravity adjustment criteria that deal specifically with harm, i.e., the "harm to human health" and the "environmental harm" criteria, do not explicitly mention "harm to the regulatory program," nor do they equate a value for such harm. We have, however, previously affirmed a presiding officer's assignment of a value of "3" to *both* the "environmental harm" and "harm to human health" criteria where the risks to the environment and to human health were unknown and respondent's actions were harmful to the FIFRA regulatory program. *In re Microban*, 11 E.A.D. 425, 454 (EAB 2004), (citing *In re Sultan Chemists, Inc.*, 9 E.A.D. 323, 351 (EAB 2000), *aff'd*, 281 F.3d 73 (3d Cir. 2002).

such claims encourage customers to buy Rozol instead of choosing another product. Customers may choose differently if they are aware of the extensive application and bait and carcass search requirements associated with Rozol.[35] Second, claims that Rozol is "easy to use," and has "low cost per acre" undermine the importance of following the label language that directs the user to conduct the bait and carcass search, collection and disposal requirements. If the user does not follow these label requirements, the potential for harm to non-target organisms is greatly increased.

ii. Low Poisoning Potential/Expire Underground/Above Ground Exposure Risk Insignificant

Similarly, Respondent's various claims that Rozol has "low poisoning potential" because of the low toxicity of the product or because the prairie dogs expire underground are untrue, unsupported by the available data, and undermine the labeling requirements imposed by EPA to mitigate harm to non-target animals. These claims create an expectation that there will not be harm to non-target organisms. Thus these claims minimize the importance of conducting bait and carcass search, retrieval, and disposal activities required by the label.

As noted above, Respondent testified that its low toxicity claims were supported by EPA's Comparative Risk Assessment (CX 38). (Schmit Tr. at 134:22-135:9). Dr. Steeger described the genesis of this document at the hearing:

> The purpose of this document is to provide the risk management divisions with an understanding of various components of the risk assessment relative to several compounds, first-generation anticoagulant, second-generation anticoagulant and non-anticoagulant rodenticides.
>
> ****

[35] The other product most frequently available for prairie dog elimination, zinc phosphide, does not include carcass search requirements. (RX65, RX_3375).

> They looked at the different toxicities of the chemicals. They looked at the environmental fate of the chemicals, and they examined the risk quotients of the chemicals.

(Steeger Tr. at 41: 12-25). It is important to note that EPA did not create the document for the general public, or for pesticide producers to use in their advertising. The audience for which the document was produced included EPA staff like expert witness John Hebert, who will use the document as the basis for sound decisions regarding pesticide registrations. (See Hebert Tr. at 37:7-21)

In its advertising materials, Respondent cited to the Comparative Risk Assessment and compared the toxicity of Rozol to zinc phosphide. It did this graphically in two separate advertising charts, one titled "Primary Toxicity to Birds" and the other titled "LD Data," printed together on the same page. (*See* CX 14, EPA184; CX 28, EPA526). Respondent printed the charts, or substantially similar charts, on at least two separate occasions, once in a pamphlet titled "Control Pocket Gophers and Black-tailed Prairie Dogs" dated August 27, 2007, and again in a pamphlet titled "Control Range Rodents" dated September 24, 2009. (*Id.*) These charts purport to demonstrate that zinc phosphide is far more toxic to non-target animals than Rozol. This graphic demonstration is incorrect and certain to mislead the customer. At the hearing, Dr. Steeger discussed these charts:

> This chart, which is titled Primary Toxicity to Birds, the subtitle is "the higher the number, the lower the toxicity," is, with its vertical axis, describing the number of pellets required for a lethal dose to a bird, and it's comparing Rozol, strychnine and zinc phosphide, and above the bar graph for Rozol it depicts a value of 2,580 pellets that would be needed to result in the lethal dose of the compound. And for the other compound, strychnine, it's depicting single digit values, 3, roughly, and -- .3—for strychnine and zinc phosphide respectively.
>
> Again, the toxicity of chlorophacinone either to mammals or to birds is affected by the frequency at which the animals consume the product. So while on a single dose it may take a very large

> number of pellets to elicit an effect in a chronically toxic compound compared to a small number of an acute toxic compound, chlorophacinone is intended to be consumed over a period of several days, and we know from available data that the prolonged exposure to chlorophacinone feeding over several days has a considerably different toxicity profile than consuming a single dose of the compound.

(Steeger Tr. at 88:1-22).

In another advertisement, the Research Bulletin (CX 14, EPA175 -180), Respondent inappropriately cites to another section of the Comparative Risk Assessment document to suggest that Rozol is less toxic than other pesticides to control black tailed prairie dogs. (CX 14, EPA179). Here, Respondent compares the "risk quotients" assigned by EPA scientists to several of the compounds. At another point in his testimony, Dr. Steeger critiqued the chart, and Respondent's comparative use of the risk quotients:

> First of all, the chart is entitled Comparative Toxicity Profile Overall Risks to Birds and Mammals. The toxicity profile just is the effects threshold of the compound. It does not speak to risk. That's a separate issue because risk is a function above toxicity and exposure.
>
> My other difficulty is this: Apparently the units that are making up an axis, horizontal axis of this graph is expressing risk quotients. The EPA went through its formal peer review process with the scientific advisory panel to lay out, this proves potentially using and comparing risk quotients across chemicals, a scientific advisory panel, and I sat with Doug Urban [co-author of EPA's Comparative Risk Assessment] on that panel, and we were chided for making any effort to compare risk quotients. As I indicated in the beginning of my testimony, risk quotients are dimensionless numbers. So there's no stated ratio between how one risk quotient differs to another. For one to say that risk quotients for chlorophacinone of 1.95 is roughly a third less that a risk quotient of 3 for diphacinone or essentially half of the risk that's associated with zinc phosphide is an inappropriate and misleading use of risk quotients because they are not linearly related.

(Steeger Tr. at 83:18-84:16).

If the applicator has been led to believe that non-target poisoning is not a problem, she or

he is less likely to diligently follow the bait and carcass search, retrieval, and disposal requirements. As explained by Dr. Steeger:

> When you tell people that things are easy to use and this product is going to be consumed mostly by animals underground, they're not going to come to the surface, the incentive to go around and collect carcasses, which is very time consuming, it is time consuming enough to put the products in each little hole, and it's winter.
>
> ****
>
> ... the expectation is that maybe you can cut corners and that they're not going to come to the surface. So why go around and look for animals if they're not going to be there, and if the toxicity is as low as implied in the ads, does it matter because birds aren't going to be affected. They're probably the biggest predator and I don't know, like coyotes, I don't care if they die. I think it really does broaden the potential for abuse because you create an atmosphere that there is some latitude there in how cautious you need to be regardless of how much training you've had.

(Steeger Tr. at 96:2-97:16).

f. The studies upon which Respondent purported to rely do not support the claims it made in advertising, and its selective reliance on study data was self-serving

As noted above, Respondent relied on a number of studies in making the differing claims alleged Counts 2,141 – 2,231 of the Amended Complaint. Section V.C.2., *infra*, details how Respondent's reliance upon the EPA's Comparative Risk Assessment, the Lee and Hyngstrom Study, the Boatman Study, the Lee and LeFlore Study, and the IRB Review to support Respondent's violative claims was unsupported at best. At worst, the claims are contradicted by the very documents upon which Respondent purported to rely. Rather than discussing Respondent's reliance on these studies again, Complainant incorporates the earlier discussion by reference and notes that Respondent's self-serving and inappropriate reliance on these studies is relevant to the issue of Respondent's culpability, and therefore to the statutory penalty factor of the gravity of the violations.

g. Respondent continued to violate FIFRA § 12(a)(1)(B) and (2)(E) after repeated stop sale orders, and even at the time of the hearing

Throughout the course of events leading to the filing of the complaint in this matter, and even at the time of the hearing, Respondent failed to come into compliance with the requirements of FIFRA § 12(a)(1)(B) and (a)(2)(E). As noted above, EPA issued the first SSURO to Respondent on June 2, 2008 and amended that SSURO on August 22, 2008. (CX 15 and 21). These orders, and the communication that occurred between EPA and Respondent during and after the negotiation of the amended order, should have made it abundantly clear to Respondent that it could neither: 1) advertise a restricted use product without including the words "restricted use pesticide" or a statement of the terms of restriction; nor 2) make claims in its advertising that differed from the registration statement. (*Id.*, *see also* CX 16, 17, and 20). Beyond that, these communications identified in detail the claims that Respondent could not make without violating the law. (CX 20, EPA428-432). Subsequently, on September 18, 2009, EPA notified Respondent that EPA intended to commence an enforcement action based on these violations. (CX 24).

Despite these enforcement efforts on the part of Complainant, and even after being notified by EPA in November of 2009 that several claims in its Research Bulletin violated FIFRA § 12(a)(1)(B) (CX20, EPA429-32), Respondent continued to violate the law, and on March 4, 2010, Complainant had to issue another SSURO to attempt to bring Respondent into compliance. (CX 32). Specifically, Respondent was again making violative claims on its website, including the claims "Lower Primary Poisoning Potential" and "Outstanding Single Application Effectiveness." (*Id.* at EPA602).

On May 6, 2011, the Chief Judge issued an order finding that Respondent was liable for 2,140 counts of failing to identify Rozol as a restricted use pesticide in its advertising. Even the

Chief Judge's decision on liability for the alleged violations of FIFRA § 12(a)(2)(E) did not cause Respondent to comply with the law. On the day Ms. Niess testified at the hearing, February 7, 2012, Ms. Niess found, before breakfast that very morning, that Respondent was still advertising Rozol on its website with ads that: 1) did not include the required "restricted use product" language or a statement of the terms of restriction, and 2) claimed low primary poisoning potential compared with zinc phosphide. (Niess Tr. at 130:6-131:5). Respondent knew that these advertisements were violations, and yet it continued to use them on its website, a fact very relevant to Respondent's culpability.[36]

### B. The FIFRA ERP's Application of FIFRA Statutory Penalty Criteria

Complainant used the FIFRA ERP to calculate the penalty proposed in the Complaint. *See, e.g. Microban II*, 11 E.A.D. at 451 (noting that "the Board takes not only the statutory penalty criteria but generally any relevant penalty policies into account when assessing the penalty"). Under the ERP, computation of the penalty amount is determined in a six stage process in consideration of the FIFRA § 14(a)(4) criteria. These steps are:

> (1) Determination of the gravity or "level" of violation using Appendix A of the ERP;
>
> (2) Determination of the size of the business category for the violator, found in Table 2 of the ERP;
>
> (3) Use of the FIFRA civil penalty matrix found in Table 1 of the ERP to determine the base penalty associated with the gravity level of the violation and the size of business category of the violator;
>
> (4) Further Gravity Adjustments of the base penalty in consideration of the specific characteristics of the pesticide involved, the actual or potential harm to human health and/or the environment, the compliance history of the violator, and the

[36] Ms. Niess continued her on-line investigation after the hearing ended. Sometime between March 7, 2012, and March 12, 2012, a month after the hearing, Respondent appears to finally have removed the violative advertisements from its website. (Attachment B, Declaration of Claudia Niess dated June 12, 2012).

culpability of the violator, using the "Gravity Adjustment Criteria" found in Appendix B of the ERP;

(5) Consideration of the effect that payment of the total civil penalty will have on the violator's ability to continue in business, in accordance with the criteria established in the ERP; and

(6) If appropriate, use of the graduated penalty calculation where inspectors or case developers collect evidence of multiple violations.

In the May 6, 2011 order on motions for accelerated decision regarding alleged violations of FIFRA § 12(a)(2)(E), the Chief Judge found Respondent liable for Counts 1 through 2,140 of the Complaint. In the Order, however, the Chief Judge did not rule on the appropriate unit of violation to assess, deferring that determination until after the hearing. (5/6/11 Or. at 13). Because of the importance of the determination of the unit of violation, Complainant will address this issue separately from its discussion of the application of the ERP.

1. Unit of Violation for Counts 1-2,140

This is the first time a Court (administrative or judicial) will decide on a case where the respondent has been charged with violating FIFRA § 12(a)(2)(E), 7 U.S.C. § 136j(a)(2)(E). Therefore, the issue of what a "unit of violation" is in the context of FIFRA § 12(a)(2)(E) has not previously been addressed.[37] However, both the FIFRA ERP (CX 51) and administrative case law shed light on what constitutes a "unit of violation" in the context of FIFRA generally. When the ERP and the administrative case law are applied to the specific facts of this matter, one can only conclude that a "unit of violation" for purposes of FIFRA § 12(a)(2)(E) is each separate act of illegally advertising a restricted use product.

In a section entitled "Independently Assessable Violations," the ERP states "[a] separate

[37] In its prehearing brief, Respondent makes much of having comparable penalties for comparable violations, but ignores the fact that no violations of FIFRA § 12(a)(2)(E) have been adjudicated. Resp.'s Prehrg Br. at 16-17.

civil penalty, up to the statutory maximum, will be assessed for each independent violation of the Act. A violation is considered independent if it results from an act (or failure to act) which is not the result of any other violation for which a civil penalty is to be assessed or if at least one of the elements of proof is different from any other violation." (CX 51, EPA949).

Further, the EAB in *In re Chempace Corporation*, 9 E.A.D. 119 (EAB 2000), when addressing what constitutes "unit of violation" for purposes of FIFRA §§ 12(a)(1)(A) and (E), 7 U.S.C. §§ 136j(a)(1)(A) and (E), stated that "[t]he prohibited act is the sale or distribution of an unregistered, adulterated, or misbranded pesticide. Thus, under section 12(a)(1)(A) and (E), the 'unit of violation' is the sale or distribution. Each such sale or distribution of a pesticide to any person constitutes a distinct unit of violation, and thus is grounds for the assessment of a separate penalty. While Chempace argues that the FIFRA provisions in question 'merely state a general prohibition against the sale and distribution of unregistered or misbranded pesticides,' Chempace Br. at 22, the prohibitions are expressed in plain language making it unlawful to sell or distribute *any* unregistered or *any* misbranded pesticides to *any* person." 9 E.A.D. at 129-30 (emphasis in original, footnote deleted). As Chief Judge Biro stated in *99 Cents*, the Board in *Chempace Corp.* "set for the Agency the *upper limit* of the number of violations the Agency could charge under FIFIRA." *In re 99 Cents Only Stores*, Docket No. FIFRA-09-2008-0027, 2010 EPA ALJ LEXIS 10, at *108 (ALJ June 24, 2010) (emphasis in original).

This same logic applies here and leads to the unassailable conclusion that each broadcast or circulation of a violative advertisement constitutes a distinct "unit of violation" for purposes of FIFRA § 12(a)(2)(E), 7 U.S.C. § 136j(a)(2)(E). The plain language of Section 12(a)(2)(E) provides that it is unlawful for any person to **advertise** a restricted use product without giving the classification of the product. 7 U.S.C. § 136j(a)(2)(E) (emphasis added). Clearly,

demonstrating that the respondent "advertised" is one element of proof that is different in each of the 2,140 counts. Respondent has admitted that it advertised Rozol on 2,140 separate occasions. The record clearly demonstrates that each of these separate acts of advertising took place, and the Chief Judge has found Respondent liable for each of these 2,140 acts.

Further, Respondent has failed to provide any support for its assertion that the "unit of violation" should be less than the number of times it advertised the product. It simply suggests that the "unit of violation" should be based on one advertisement or four versions of its radio advertisements or the six states in which it advertised Rozol over the radio or the eleven radio stations through which it advertised its product. In rejecting the respondent's argument that a unit of violation was something less than each act of sale or distribution, the Board in *Chempace* made note of the respondent's failure to point "to anything in the language, legislative history, or context of section 12(a)(1)(A) and (E) that supports its position that the unit of violation in this case should be less than the number of individual sales or distributions." *Chempace Corp.*, 9 E.A.D. at 130. Respondent's arguments here likewise lack such support.

In addition to the lack of legal support for Respondent's suggested interpretation, if adopted, Respondent's interpretation would also frustrate the purpose of the statute. Congress could not have intended to create a law that allows for only a nominal penalty for repeat violators. In *Chempace Corp.*, the EAB provided the following additional rationale in its decision to reject the respondent's unsupported limited interpretation of a "unit of violation:"

> [The respondent's] suggested reading of these FIFRA sections as treating a course of conduct involving multiple sales or distributions as a single violation not only fails to follow the plain language of the statute, but also undermines the deterrent purpose that civil penalties are intended to effectuate. For example, [the respondent's] interpretation results in charging a seller or distributor of unregistered pesticides with only one count of violating FIFRA section 12(a)(1)(A) with a resultant current

> maximum penalty of $ 5,500 regardless of whether that person sold or distributed all or part of his stock, and whether those sales or distributions were made to one or hundreds of customers. Thus, the potential liability for civil penalties would no longer provide an incentive to a seller or distributor of unregistered pesticides to refrain from continuing that unlawful activity after the first illegal sale or distribution.

*Chempace Corp.*, 9 E.A.D. at 129-30. As the Board warned in *Chempace Corp.*, Respondent's interpretation of what constitutes a "unit of violation" for purposes of FIFRA § 12(a)(2)(E) would mean that a registrant could broadcast countless illegal radio advertisement on every radio station in the United States, or could distribute countless illegal print advertisements in every periodical or other publication in the United States, and the limit of its liability would be a maximum of $7,500.[38] Surely, Congress could not have intended such a result under Section 12(a)(2)(E) of FIFRA. *Microban II*, 11 E.A.D. at 447 (noting "the consumer protection goals of FIFRA").

Finally, Respondent argues that the Court could also count each day an advertisement was broadcast as a "unit of violation." It points out that this was the method used by Complainant prior to issuance of an updated prefiling letter (CX 33). In making this argument and interpreting *99 Cents,* Respondent muddles the difference between a "unit of violation" and Complainant's "prosecutorial discretion."

Clearly, Complainant "is vested with the discretion to determine the appropriate number of violations to pursue in an enforcement action." *99 Cents*, 2010 EPA ALJ LEXIS 10, at *104-105 (citing *B&R Oil Co.*, 8 E.A.D. 39, (EAB 1998), *Microban II*, 11 E.A.D. at n.20 (EAB 2004), *Chempace Corp.*, 9 E.A.D. at 127-31). Essentially, Respondent complains that Complainant did

[38] At the time of the *Chempace* decision, the maximum penalty for each violation under Section 14(a)(1) of FIFRA, 7 U.S.C. § 136l, adjusted for inflation, was $5,500. For violations after January 12, 2009, the statutory maximum penalty for each offense is $7,500. See 40 C.F.R. § 19.4.

not exercise its "prosecutorial discretion" in this case because the Complaint alleges more counts than Respondent feels it should. The undisputed facts, however, show that Respondent violated FIFRA § 12(a)(2)(E), 7 U.S.C. § 136j(a)(2)(E), on at least 2,140 occasions and Complainant calculated the penalty in accordance with the ERP for each of these counts.

As Respondent noted in its prehearing brief, the use of the graduated penalty calculation method in this case resulted in an average per count penalty of $1,060 per count for counts 1 through 2,140. (Resp.'s Prehrg. Br. at 11). The ERP allows that "[i]n cases involving violations that present potential serious or widespread harm to human health or the environment, the Region should decide whether application of the graduated penalty method is appropriate based on the circumstances of the individual case." (CX51, EPA958). The Region's penalty calculation is appropriate. As the Chief Judge noted in her Initial Decision in *In re Rhee Bros, Inc.*:

> [T]he maximum penalty allowed by law… should normally be reserved for the most horrific violator, who has committed the most horrific violations such as a respondent with a long history of committing serious FIFRA violations, who then commits other egregious violations which were knowing and willful, involving a pesticide of the highest toxicity, and/or which caused actual serious or widespread harm to human health and the environment.

*In re Rhee Bros., Inc.*, FIFRA-03-2005-0028, 2006 EPA ALJ LEXIS 32, at *101-02 (ALJ Sept. 19, 2006). The average penalty proposed by the Region for counts 1 through 2,140 is significantly less (more than six times less) than the statutory maximum penalty assessable for these violations, which was $6,500 per violation. See Niess Tr. at 103:8-12 (noting that for 1,740 violations at issue in Counts 1 through 2,140, Respondent was given a 90% reduction from the base penalty of $6,500.

2. Base Gravity Level of the Violations

The gravity "level" established for each violation of FIFRA is listed in Appendix A of the

FIFRA ERP. The "level" assigned to these violations represents an assessment of the relative gravity of each violation, considering the actual or potential harm to human health and/or the environment resulting from the violation. (CX51, EPA951).

Under Appendix A, the FIFRA ERP categorizes both violations of 12(a)(2)(E) (advertising a restricted use pesticide without indicating the product was restricted use) and 12(a)(1)(B) (claims made for a registered pesticide as part of its sale or distribution differed substantially from those accepted in connection with registration) as "Level 2" violations. (CX51, EPA962, 964). Complainant has assigned Level 2 as the gravity of each of the 2,231 counts violation alleged in the Amended Complaint. (CX55, EPA1101-03; Niess Tr. at101:13–105:10).

3. Size of the Business of the Violator

Under the FIFRA ERP, a respondent's size of business is determined by considering a respondent's gross revenue from all revenue sources during the prior calendar year. (CX51, EPA950-951). A respondent who is alleged to have violated FIFRA and whose gross revenues/sales exceed $10 million will be placed into "Business Category I." (CX51, EPA951). To determine Respondent's size of business, Complainant searched the Dun and Bradstreet Corporate Leads Portal and determined that Respondent had sales volume of over $39,500,000. (CX55, EPA1008, 1063). Additionally, Respondent's parent company, DeSangosse, reported on its website annual sales in 2009 of €272 million.[39] (CX55, EPA1008, 1066). As a "14(a)(1) violator" with sales exceeding $10,000,000, Complainant categorized Respondent's size of business as a "Category I." (CX55, EPA1008; Niess Tr. at 101:14-16). Prior to hearing, Respondent stipulated that "it has already waived any challenge, argument or objection to the

[39] Under the ERP, EPA considers gross sales for the entire corporate family. CX 51, EPA000950.

penalty based on or otherwise relating to the factors 'the size of the business of the person charged' and 'the effect on the person's ability to continue in business.'" (Joint Stips., at 16).

4. Civil Penalty Matrix

The FIFRA ERP's assignment of a base penalty relative to the gravity of the violation and size of the business occurs through a Civil Penalty Matrix, found in Table 2 of the ERP. (CX51, EPA952). Under the FIFRA ERP, the base penalty assigned to a violation which occurred after January 12, 2009, and that has been assigned a gravity of "Level 2," involving a respondent whose size of business places them in Category I is $7,150. (CX51, EPA 000943). The adjusted base penalty for an identical violation that occurred prior to January 12, 2009 is $6,500. (CX55, EPA1048). Counts 1 through 2,183 of the Complaint occurred prior to January 12, 2009 and counts 2,184 through 2,231 of the Complaint occurred thereafter, so the base penalty is $6,500 for the former counts, and $7,150 for the latter. (*Id.; see also* Niess Tr. at 101:18 – 105:22).

5. Gravity Adjustment Criteria

The ERP directs Complainant to apply the gravity adjustment criteria in the FIFRA ERP to the base penalty for each violation to correspond with the particular circumstances of each case. (CX51, EPA952-53). The gravity adjustment criteria are listed in Appendix B of the ERP, which provides a range of values to be applied to each violation relative to the specific characteristics of the pesticide involved, the actual or potential harm to human health, the actual or potential harm to the environment, the compliance history of the violator, and the culpability of the violator. (CX51, EPA967-68). The gravity adjustment values from each gravity category listed in Appendix B are then totaled. The base penalty is then raised or lowered, based on the total gravity values in Table 3 of the FIFRA ERP. (CX51, EPA953).

Complainant applied the same gravity adjustment criteria values across all the violations alleged in the Complaint, as described below.

a. Pesticide Toxicity

Appendix B of the FIFRA ERP provides three alternative values for pesticide toxicity, from one to three, depending on the toxicity of the pesticide. According to the ERP, a pesticide toxicity value of one is appropriate for violations involving a pesticide that is "Category III or IV, signal word "Caution" or pesticide unregistered and ingredients lower or minimum risk category." (CX51, EPA967). A pesticide toxicity value of two is to be assigned to violations involving a pesticide that is "Category II, signal word "Warning" or pesticide unregistered and unknown, but not expected to meet Category I toxicity criteria. (*Id.*) Finally, a pesticide toxicity value of three is appropriate for Category I pesticides, signal work "Danger", restricted use pesticides (RUPs), pesticides with flammable or explosive characteristics (i.e., signal words "Extremely Flammable" or "Flammable", **or** pesticides that are associated with chronic health effects (mutagenicity, oncogenicity, teratogenicity, etc.) **or** pesticide is unregistered and the ingredients or labeling indicate Category I toxicity." (*Id.* (emphasis added)).

For the violations in this matter, EPA assigned a pesticide toxicity value of three because the products are restricted use pesticides. (CX51, EPA967; CX55, EPA1009; Niess Tr. at 107:1-6). Respondent argues that the penalty policy is somehow ambiguous because an alternative basis of assigning a value for the toxicity criteria, the use of the signal word assigned to a pesticide as part of its registration, would result in a different assigned value. (Resp.'s Prehrg. Br. at 22). Ms. Niess, however, explained at hearing why classifying Rozol's pesticide toxicity based on its restricted use classification, rather than its signal word, was appropriate given the specific circumstances in this matter:

> Q: So why did you assign a pesticide toxicity value of three when the signal word on the various accepted labels is "caution?"
>
> A: A pesticide signal word is assigned based on its acute hazard to human health. And Rozol Prairie Dog Bait and Rozol Pocket Gopher Bait II have been classified as restricted use pesticides due to their hazard to non-target organisms. So had I assigned a pesticide toxicity based on their human health, that would not accurately reflect the pesticide toxicity of these pesticides.

(Niess Tr. at 107:20-108:5).

Additionally, the use of the disjunctive "or" in Appendix B of the policy describing the circumstances where the toxicity value of three is warranted is unambiguous. By Respondent's argument, which ignores the "or," in order to assign a pesticide value of three, the pesticide in question would have to be assigned the signal word of "Danger," be a restricted use pesticide, be extremely flammable or flammable, be associated with chronic health effects, and be unregistered and be labeled in a manner that indicates the product is a Category 1 toxicity. Clearly this is not how the policy is meant to be interpreted.

At the hearing, the Chief Judge questioned Ms. Niess about the connection between the "toxicity" value and the "harm to human health" value and the "harm to the environment" value in the penalty policy, inquiring whether or not assessing a value for both criteria might somehow be "double counting." (Niess Tr. at 241: 3-14). As Ms. Niess indicated, the toxicity value goes to the inherent toxicity of the pesticide. (Niess Tr. at 241: 15-24). In contrast, the "harm to human health" and the "harm to the environment" values address a specific violation's potential or actual harm to human health and the environment. While the toxicity of the pesticide is certainly relevant to the violation's potential harm to human health and to the environment, the use of a separate value for pesticide toxicity and the harm to human health and to the environment values is appropriate, as this rubric reinforces the notion that the gravity of a

violation should always be higher for a high toxicity chemical than for a low toxicity chemical. If the violation were one related to a record keeping requirement, for example, Complainant believes that the gravity of such a violation should be higher for a chemical that is inherently more toxic than for a chemical with lower toxicity.

Further, the Agency designed Appendix B and Table 3 together, so eliminating the gravity value for toxicity in applying the policy to the facts of this case would result in an artificially low Total Gravity value as assessed in Table 3. If the Agency had not drafted the policy with a separate criteria for pesticide toxicity, and instead incorporated the toxicity value into the harm to human health and to the environment criteria, the scoring system for gravity values utilized in Appendix B would likely be different. For example, the scoring system for the other four adjustment factors would likely have been different, e.g. the highest score for harm to the environment might have been a seven, instead of a five. In this scenario the "Enforcement Remedy" in Table 3 of the ERP could also have been different, e.g. a total "Gravity Value" score of six could have been the point where no penalty mitigation is given, rather than a score of nine. Importantly, the EAB has repeatedly calculated penalties that assessed separate values for pesticide toxicity, harm to human health, and harm to the environment. *See, e.g. In re FRM Chem, Inc.,* 12 E.A.D. 739, 760 (EAB 2006); *Microban II*, 11 E.A.D. at 455.

b. Harm to Human Health

Appendix B to the ERP lists four possible values to be assessed for "Harm to Human Health:" a value of five for actual or serious or widespread harm to human health; a value of three for unknown or potential serious or widespread harm to human health; a value of one for minor potential or actual harm to human health; and a value of zero for negligible harm to human health anticipated. (CX51, EPA967). A footnote states that, for the purposes of this ERP, minor

harm refers to actual or potential harm which is, or would be of short duration, not lasting effects or permanent damage, effects are easily reversible, and harm does not, or would not result in significant monetary loss. (*Id.* at 968).

At the time of the initial penalty calculation, Complainant assigned a value of one to "Harm to Human Health" due to the minor potential or actual harm to human health. (CX55, EPA1010; Niess Tr. at 108:17-109:19). The information Ms. Niess had available to her at the time of the Complaint about the potential health effects of the use of Rozol supports a finding that the violations could cause minor potential or actual harm to human health:

> Q: What information or documents did you rely on when you initially assigned a value of one for harm to human health?
>
> A: The product labels.
>
> Q: And what specific information on those labels did you rely on?
>
> A: The instructions to wear chemical resistant gloves when handling the bait; as well as the instructions to store the bait away from children and to keep people out of the application area; as well as the directions to perform carcass and bait searches.

(Niess Tr. at 109:8-19).

In addition to the information supporting the assessment of a value of one available to Ms. Niess at the time of the filing of the Complaint, Ms. Niess later became aware of additional information that supports this assessment:

> Q: Have you discovered any information since you calculated the proposed penalty that further supports your assignment of a value of one for harm to human health?
>
> A: Yes.
>
> ****
>
> A: I have learned of an instance in which an uncertified applicator was able to purchase and apply Rozol Prairie Dog Bait.

I've also learned of an additional application for special local needs registration of Rozol Prairie Dog Bait to allow for mechanical baiting.

Q: Let's talk about the instance where an uncertified applicator was able to purchase and use – which product was that?

A: It was the special local needs registration for Rozol Prairie Dog Bait based on Rozol Pocket Gopher Bait II.

Q: And you discovered an instance where an uncertified applicator was able to purchase and use that product?

A: Yes.

Q: If I could direct your attention to what has been previously admitted as Complainant's Exhibit 102.

****

Q: What is this document, Ms. Niess?

A: This is a final order that was filed by the Kansas Department of Agriculture in the matter of Gary Withers.

Q: How does it further support your assignment of value of one for harm to human health?

A: This documents one instance in which an uncertified applicator was not only able to purchase the product, but to apply the product. And Mr. Withers, in this case, did not have the proper training needed to apply these products. And his application of the product represents a potential harm to human health.

Q: Now, you also mentioned that there was another piece of information that you relied on that you believe further supports your assignment of a value of one for harm to human health. What other information did you rely on?

A: An application for a Section 24(c) registration in the state of Kansas for Rozol Prairie Dog Bait.

Q: And who submitted that application?

A: Respondent.

Q: Why do you believe that additional application further supports your assignment of a value of one for harm to human

health?

A: The application included letters of support. And one of the letters of support was written by Charles Lee, who I understand has experience with this product. His reasons for supporting the addition of mechanical application of Rozol Prairie Dog Bait was that hand baiting – which is required on the labels – is a risk to human health.

(Niess Tr. at 109:20-112:23).

Ms. Niess went on to identify in the record an application under FIFRA § 24(c) to apply Rozol Prairie Dog Bait using mechanical application, including Mr. Lee's letter of support. (CX140, EPA3345; Niess Tr. at 113:2-14). Ms. Niess then reviewed the statements in that letter that she believed supported her assignment of a value of one for harm to human health:

Q: And what statements in this letter from Charles Lee do you believe further support your assignment of a value of one for harm to human health?

A: The statement in the first paragraph on 3345 that says, "It seems incomprehensible that an agency with the stated purpose to protect human health and the environment from unreasonable adverse effects associated with pesticides would now require application of a toxicant by hand." It goes on to say, "The mechanical dispensing devices commonly used to help manage prairie dogs allow more accurate placement of the bait, more accurate amount of the bait applied to each burrow and improved human safety.

And then on Page EPA 003346 under the heading, "Potential Problems," and I understand that this is potential problems with requiring application by hand. The first bullet point or first numbered point says, "Applicator's safety will be jeopardized as they will be forced into closer contact with the bait with hand application." And Number 4 says, "Applicators will ignore the label and apply bait without regard to label language."

(Niess Tr. at 113:15-114:14 (referencing CX 140, EPA3345-46)).

There is abundant evidence that Rozol should be treated with care to avoid potential harm to human health. That evidence includes the label requirements that applicators wear protective

clothing, and the statements of Mr. Lee, Respondent's listed "expert" witness, in support of mechanized application.

Earlier in her testimony, Ms. Niess explained how the violations alleged in the Complaint might exacerbate an applicators exposure to Rozol, and therefore cause potential harm to human health:

> All three sets of violations minimize the toxicity of Rozol Pocket Gopher Bait II or Rozol Prairie Dog Bait, either through the failure to provide the restricted use classification, or making the claims that we have discussed previously.

(Niess Tr. at 108:24-109:3).

Both the failure to include the restricted use language in the radio and print advertisements and the violative claims that contradict the toxicity language on the label undermine the label language designed to protect the applicator's health. The less harmful the applicator believes the product to be, the less likely the applicator is to give such protective label language its full import, and to follow the label directions.

c. Harm to the Environment

As with "Harm to Human Health," Appendix B to the ERP lists four possible values to be assessed for "Environmental Harm," depending upon the circumstances of the violation: a value of five for actual serious or widespread harm to the environment (e.g., crops, water, livestock, wildlife, wilderness, or other sensitive natural areas); a value of three for unknown or potential serious or widespread harm to the environment; a value of one for minor potential or actual harm to the environment; and a value of zero for negligible harm to the environment anticipated. (CX51, EPA967). Footnote 1 states, "for the purposes of this ERP, serious or widespread harm refers to actual or potential harm which does not meet the parameters of minor harm or negligible harm, as described below." (*Id.*) As noted above, footnote 2 defines minor harm as

"actual or potential harm which is, or would be of short duration, not lasting effects or permanent damage, effects are easily reversible, and harm does not, or would not result in significant monetary loss." (*Id.* at EPA968). Finally, footnote 3 states "[f]or the purposes of this ERP, negligible harm refers to no actual or potential harm or actual or potential harm which is insignificant or unnoticeable and has no lasting effects or permanent damage or monetary loss." (*Id.*)

At the time of the Complaint, Complainant assigned a value of three for environmental harm for all the violations alleged in the Complaint. (CX55, EPA1010). In Ms. Niess' written explanation of her penalty calculation, she stated:

> EPA has discovered evidence of the fatal secondary poisoning of non-target species from applications of Rozol. The extent of such incidents is not known to EPA at this time, nor is it known if this poisoning occurred due to improper sale or use of the product. However, EPA considers this to be an indication of the potential serious threat of harm to the environment of the product. Actions minimizing the toxicity or danger of the product (i.e. not disclosing the product's restricted use classification or making false and misleading[40] claims about the safety of the product) would reasonably create a false impression in consumers' minds, resulting in increased use/misuse of the product.

(*Id.*)

At the hearing, Ms. Niess explained her assignment of the value of three for the environmental harm factor:

> Similar to my reasoning for the assessment of a one for harm to human health, I determined that the violations alleged in all three sets of violations minimizes [sic] the toxicity of the product to the applicator or the consumer or the user. Minimizing the requirements, minimizing the toxicity of the product in terms of [environmental harm] would result in a greater risk. So, again, based on the information I had at the time, I determined that the

[40] In the Complaint, Complainant removed allegations of false and misleading claims pleaded alternatively in the original complaint, but the same argument can be made for advertising claims that contradict the label language.

risk was either unknown or was potentially serious or widespread.

(Niess Tr. at 118:18-119:4).

In Section VI.A.3. of this brief describing its evaluation of the statutory penalty factor the gravity of the violations, above, Complainant explained at length how both the failure to include Rozol's restricted use classification in the radio and print advertisements and the use of claims that contradict and undermine the protective measures included in the label language could result in serious and widespread harm to non-target wildlife. For the sake of brevity, Complainant will not repeat those arguments in this discussion of the application of the penalty policy, but rather incorporates them by reference. Similarly, Complainant has previously discussed at length how the actual environmental harm from Respondent's violations is unknown, and incorporates that discussion by reference in the application of the penalty policy. Both of those discussions detail the ample evidence demonstrating that the assignment of a value of three for unknown or potential serious or widespread harm to the environment is appropriate and justified for the violations alleged in the Complaint.

d. Compliance History

In Complainant's calculation of the penalty, "Compliance History" was assigned a value of zero at the time of the Complaint, based on the absence of any record of a known prior violation of FIFRA memorialized in an enforcement action taken against the Respondent within the five years prior to the violations alleged in this matter.

e. Culpability

Appendix B of the ERP provides for a range of values based on the culpability of the violator in the circumstances of the violations. Appendix B assigns a value of four for "[k]nowing or willful violation of the statute. Knowledge of the general hazardousness of the activity." (CX51, EPA967). A value of two should be assigned for violations where the

violator's culpability is unknown or the violation resulted from negligence. (*Id.*) Where the "[v]iolation resulted from negligence" and the "[v]iolator instituted steps to correct the violation immediately after discovery of the violation" Appendix B assigns a value of one. (*Id.*) Finally, in circumstances where the "[v]iolation was neither knowing nor willful and did not result from negligence," and where the "[v]iolator instituted steps to correct the violation immediately after discovery of the violation," Appendix B allows for the assignment of a value of zero for culpability. (*Id.*)

At the time of the issuance of the Complaint, Complainant assigned a value of two for all the violations alleged therein, representing Complainant's evaluation that Respondent's culpability for the violations was unknown or the violations resulted from Respondent's negligence. (CX55, EPA1011). In evaluating the Respondent's culpability, Ms. Niess explained:

> In June of 2008, EPA issued a Stop Sale, Use or Removal Order to Liphatech for violations of 12(a)(2)(E) of FIFRA. At that time, the company worked with EPA to come into compliance and reported to EPA that it had implemented several internal steps to both remedy the violation and to prevent any such violation occurring in the future. In November of 2009, EPA became aware of Liphatech's continued violation of FIFRA.

(*Id.*)

At the hearing, Ms. Niess explained further her evaluation of Respondent's culpability:

> Q: Why did you assign a value of two for culpability?
>
> A: For the first set of violations, I noted that Respondent had provided the restricted use classification for other restricted use pesticides. The copy – for example, the copy of their website provided to us after the Wisconsin Department of Agriculture inspection included a printout of its Rozol products. And that page contained information on Rozol Prairie Dog Bait, on which the restricted use classification was not provided. Further down on the page, it provided information about Rozol Vole Bait. And the restricted use classification for Rozol Vole Bait was provided.

I have also noticed that in the Slim Jim, Rozol Prairie Dog Bait restricted use classification was provided. But in other brochures and in print advertisements that were being aired at the same time, Rozol's restricted use classification was not provided.

So I determined that the culpability for that first set of violations was either unknown or the violation had resulted from negligence.

Q: Thank you, Ms. Niess. Now, with respect to the second set of violations, why did you assign a value of two for culpability?

A: At the time of calculation, I assessed their culpability to be unknown.

Q: Have you discovered any information since you initially assigned a value of two for culpability that you believe further supports your assignment?

A: Yes.

Q: What is this information?

A: I discovered a stamped accepted label for one of Respondent's other registrations that included optional marketing statements.

****

So that indicated to me that Respondent was aware that EPA will review and accept and approve and make comments on optional marketing claims and optional marketing statements. And they could have submitted any of the claims in its advertising or on its website to EPA to review.

(Niess Tr. at 122:13-124:8).

In addition to the reasons cited by Ms. Niess at the hearing and in her written penalty discussion, in Section VI.A.3.g. of this brief, above, Complainant explained how Respondent's continued violation of FIFRA even after two SSUROs, the filing of a complaint, and an order from the Chief Judge finding Respondent liable for violations of FIFRA § 12(a)(2)(E) demonstrate Respondent's significant culpability.

Given the above analysis, a Total Gravity Adjustment Value of nine was assigned for

each violation. Under Table 3 of the FIFRA ERP, a Total Gravity Adjustment Value of nine calls for the assessment of the matrix value with no reduction or increase. (CX51, EPA953).

6. Graduation of the Penalty

The ERP provides for the graduation of the penalty where "inspectors or case developers obtain records which evidence multiple sales or distributions for the same violations." (CX 51, EPA958). Table 4 of the ERP describes how to graduate penalties. (*Id.*) For Category I size of business respondents, Table 4 states that for the first 100 violations, 100% of the gravity adjusted penalty be assessed; for the next 300 violations, 25% of the gravity adjusted penalty be assessed; and for any remaining violations, that 10% of the gravity adjusted penalty be assessed. (*Id.*) The ERP notes that "in no case is the graduated penalty method mandated, and the Agency maintains its statutory right to assess penalties of up to the statutory maximum for each violation." (*Id.*)

While the ERP suggests the use of graduated penalties for violations involving the "sale and distribution" of pesticides or devices, Complainant used its prosecutorial discretion to apply the graduated penalty scheme to the advertising violations in this matter, due to the large number of violations Respondent committed. CX 55, EPA1012. Because the number of violations of FIFRA § 12(a)(1)(B) in Counts 2,141 through 2,231 do not add up to more than 100, Complainant did not graduate those penalties. (*Id.*)

Complainant's graduation of the penalty in Counts 1-2,140 resulted in a significant reduction in the penalty proposed. Complainant proposed a penalty of $1,650 for each violation alleged in counts 101 through 400, which is a seventy-five percent reduction for each count, and a penalty of only $650 per count for the violations alleged in counts 401 through 2,140, which is a ninety percent reduction of the gravity adjusted penalty. If Complainant had not graduated these penalties, the penalty for the violations of § 12(a)(2)(E) alone would have been

$13,910,000.

7. Effect of Penalty on the Person's Ability to Continue in Business

FIFRA § 14(a)(4) requires the Agency to consider the effect of the penalty on the person's ability to continue in business. The ERP directs EPA enforcement professionals to consider the effect of penalty on the violator's ability to continue in business through the evaluation of the violator's financial information. (CX51, EPA957). Complainant considered the effect the proposed penalty would have on Respondent's ability to continue in business (CX55, EPA1008). Complainant also incorporates by reference Section VI.A.1.-2 of this brief.

## VII. CONCLUSION

For the reasons set forth above, Complainant respectfully requests that the Chief Judge issue an Initial Decision finding Respondent liable for the violations alleged in Counts 2,141 through 2,231 of the Complaint, and imposing a penalty of $2,891,200 for Respondent's violations of FIFRA.

Respectfully Submitted,

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



CERTIFICATE OF SERVICE

I hereby certify that the original and one true, accurate, and complete copy of *Complainant's Post-Hearing Brief* were filed with the Regional Hearing Clerk, U.S. EPA, Region 5, on the date indicated below. True, accurate, and complete copies also were sent to the persons designated below on this date via UPS overnight delivery:

Honorable Susan L. Biro
Administrative Law Judge
Office of Administrative Law Judges
U.S. Environmental Protection Agency
Mail Code 1900L
1099 14th Street, NW, Suite 350
Franklin Court
Washington, D.C. 20005

Mr. Mark A. Cameli
Reinhart Boerner Van Deuren s.c.
1000 North Water Street, Suite 1700
Milwaukee, WI 53202

Dated in Chicago, Illinois, this 15th day of June, 2012.

Patricia Jeffries-Harwell
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