



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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REPLY TO THE ATTENTION OF:
C-14J

January 27, 2011

Honorable Barbara A. Gunning
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 Judge Gunning:

Enclosed please find a copy of *Complainant's Motion for Accelerated Decision on Liability for Counts 2,184 through, 2,231 of the Complaint and Memorandum in Support*, which was filed on January 27, 2011, in the above-referenced matter.

Sincerely,

Gary E. Steinbauer
Assistant Regional Counsel

Enclosure

cc: Mr. Michael H. Simpson (w/ enclosure)
Reinhart Boerner Van Deuren s.c.
1000 North Water Street, Suite 1700
Milwaukee, WI 53202
(*via UPS Overnight Delivery*)

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

IN THE MATTER OF:)
)
Liphatech, Inc.) Docket No. FIFRA-05-2010-0016
Milwaukee, Wisconsin)
) Hon. Barbara A. Gunning
Respondent.)
)
)

**COMPLAINANT'S MOTION FOR ACCELERATED DECISION
ON LIABILITY FOR COUNTS 2,184 THROUGH 2,231 OF
THE COMPLAINT AND MEMORANDUM IN SUPPORT**

Complainant, the Director, Land and Chemicals Division for Region 5 of the United States Environmental Protection Agency ("Complainant") files this Motion for Accelerated Decision on Liability for Counts 2,184 through 2,231 of the First Amended Complaint ("Complaint"), pursuant to Sections 22.16(a) and 22.20 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. §§ 22.16(a) and 22.20. Complainant respectfully requests that the Presiding Officer grant accelerated decision on liability in its favor for Counts 2,184 through 2,231 of the Complaint. In support of this Motion, Complainant relies on the Memorandum in Support that immediately follows, the Consolidated Rules, and the pleadings and documents on file with this Tribunal.

MEMORANDUM IN SUPPORT

I. Introduction

This is Complainant's third motion for accelerated decision on liability in this matter. Through the instant Motion, Complainant respectfully requests that this Tribunal enter accelerated decision on liability against Liphatech, Inc. ("Respondent") for Counts 2,184 through 2,231 of the Complaint. In Counts 2,184 through 2,231 of the Complaint, Complainant alleges

that Respondent violated Section 12(a)(1)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136j(a)(1)(B). Complainant alleges that Respondent unlawfully offered for sale “Rozol Pocket Gopher Bait II” (Alternative name: “Rozol Pocket Gopher Burrow Builder Formula”), EPA Reg. No. 7173-244 (“Rozol Pocket Gopher Bait”), and Rozol Prairie Dog Bait, EPA Reg. No. 7173-286 (“Rozol Prairie Dog Bait”), to 48 of Respondent’s distributors between November 18, 2009 and February 23, 2010.¹ (Complaint (“Compl.”), ¶¶ 644, 646). Complainant further alleges that Respondent made claims in connection with the offers for sale of Rozol that substantially differed from the claims approved for Rozol. (*Id.*). The violative claims were made by Respondent in “literature, flyers, or advertisements” available on its website. (*Id.* ¶¶ 351-52; *see also* CX 28-31). Respondent admits that it sent letters to 48 of its distributors requesting that they “destroy/destroy” all “literature, flyers, or advertisements” regarding Rozol that were dated September 24, 2009 or older. (Answer ¶352; *see also* CX 53).²

As explained in detail below, there is no genuine issue as to any material fact required to demonstrate Respondent’s liability for the violations alleged in Counts 2,184 through 2,231. Many of the facts needed to establish Respondent’s liability for the violations alleged in Counts 2,184 through 2,231 of the Complaint are admitted by Respondent. The pivotal issues presented in this Motion are (1) whether the subject advertisements constitute “offers for sale” as this phrase is used in Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), and (2) whether the claims made by Respondent in the subject advertisements substantially differ from those claims approved by the United States Environmental Protection Agency (“EPA”) in connection with the registration

¹ For ease of reference, Complainant will refer to Rozol Pocket Gopher Bait, EPA Reg. No. 7173-244, and Rozol Prairie Dog Bait, EPA Reg. No. 7173-286, collectively as “Rozol” in this document.

² When referring to Respondent’s Answer in this document, Complainant refers to Respondent’s Answer to the original Complaint.

of the products. These issues can be decided as a matter of law based on the record facts. Consequently, accelerated decision in Complainant's favor on Respondent's liability for the violations alleged in Counts 2,184 through 2,231 is both supported and appropriate.

II. Relevant Statutory and Regulatory Background

"FIFRA is a federal statute regulating the manufacture, sale, distribution, and use of pesticides by means of a national registration system." *In re Microban Prods. Co.*, 9 E.A.D. 674, 675 (EAB 2001) ("*Microban I*") (citing 7 U.S.C. §§ 136-136y). FIFRA's "comprehensive regulatory scheme," *Indian Brand Farms, Inc. v. Novartis Crop Protection, Inc.*, 617 F.3d 207, 209 (3d Cir. 2010), was enacted to, among other things, protect consumers. *Microban I*, 9 E.A.D. at 686. More specifically, FIFRA was enacted "to protect purchasers from being induced into purchasing a pesticide product based on unapproved claims that are potentially false or misleading." *Id.*

FIFRA Section 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 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 section 136a of this title." 7 U.S.C. § 136j(a)(1)(B). To "distribute or sell" is defined broadly in 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) (emphasis added). EPA's regulatory definition ensures that the grammatical equivalents of verbs in FIFRA's definition, such as "distributing," "selling," or "offering for sale," are included within the definition of "distribute or sell." 40 C.F.R. § 152.3.

Although "offer for sale" has not been explicitly defined in FIFRA or EPA's regulations, EPA has promulgated a regulation, which provides, in pertinent part, that FIFRA Section

12(a)(1)(B) makes it unlawful for any person to “offer for sale” any pesticide “if claims made for it as part of its distribution or sale differ substantially from any claims made for it as part of the statement required in connection with its registration under FIFRA Section 3.” 40 C.F.R. § 168.22(a). This regulation also specifically provides that “EPA interprets these provisions as extending to advertisements in any advertising medium to which pesticide users or the general public have access.” *Id.*³

The coverage of 40 C.F.R. § 168.22 is explained further in the proposed rule, which states in relevant part:

Advertising or promotional material in media to which pesticide users or the general public have access, such as television, radio, newspapers, trade journals, industry magazines, or billboards, would be covered by this interpretive rule. News items or announcements would not be covered if the information they contain regarding the pesticide did not extend beyond that contained in EPA’s approval, and if the limitations on use were clearly specified.

51 Fed. Reg. 24,393, 24,393-4 (July 3, 1986). Further, the preamble to 40 C.F.R. § 168.22 states in pertinent part as follows: “[t]his rule only applies to advertisements. In another regulation issued under FIFRA, EPA has defined advertising as : (1) Brochures, pamphlets, circulars, and similar material offered to purchasers at the point of sale or by direct mail; ... 53 FR 15987 (May 4, 1988).” (CX 85, EPA1552 (54 Fed. Reg. 1122, 1124 (Jan. 11, 1989))).

Also relevant to this Motion is FIFRA Section 3(c)(1), which provides in relevant part:

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(A) the name and address of the applicant and of any other person

³ See also *In re Sporidicin Int’l*, 3 E.A.D. 589, 605 (CJO 1991) (acknowledging the broad reach of FIFRA Section 12(a)(1)(B), acknowledging the promulgation of 40 C.F.R. § 168.22, and also noting that “distribution includes both marketing and merchandising a commodity” and that “merchandising means ‘sales promotion as a comprehensive function’”) (citations omitted).

whose name will appear on the labeling;

(B) the name of the pesticide;

(C) 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;

(D) the complete formula of the pesticide;

(E) a request that the pesticide be classified for general use or for restricted use, or for both; and

(F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, 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 have been submitted to the Administrator

7 U.S.C. § 136a(c)(1)(C)(emphasis added).

III. Relevant Factual Background

Respondent is a Wisconsin corporation who is in the business of developing and marketing pest management products. Among other pesticide registrations, Respondent holds registrations for two pesticides that are at issue in this Motion: (1) Rozol Pocket Gopher Bait, and (2) Rozol Prairie Dog Bait. Although originally registered to control pocket gophers, Rozol Pocket Gopher Bait was also registered under the authority of FIFRA Section 24(c) to control black-tailed prairie dogs under “Special Local Needs” (“SLN”) supplemental labels for certain States⁴. (CX 2-7; *see also* RX 4-9). After obtaining approval for SLN labels for Rozol Pocket Gopher Bait, Respondent obtained registration for Rozol Prairie Dog Bait. (CX 27; *see also* RX1). On February 2, 2010, EPA announced its receipt of applications by Respondent to cancel the SLN registrations for Rozol Pocket Gopher Bait. (CX 108).

Pursuant to a referral sent by another EPA Region in January 2008, Complainant initiated an investigation to determine Respondent’s compliance with FIFRA. As a result of its

⁴ These States included Kansas, Nebraska, Wyoming, Colorado, Texas and Oklahoma.

investigation, Complainant issued original and amended Stop, Sale, Use, or Removal Orders (“SSUROs”) pursuant to Section 13(a) of FIFRA, 7 U.S.C. § 136k(a), on June 2, 2008 and August 22, 2008, respectively. (CX 15, 21). These SSUROs were issued as a result of violations stemming from Respondent’s radio and print advertisements for Rozol. (See CX 15, 21; see also Compl. (Counts 1-2,140)).

After it issued the original and amended SSUROs, Complainant continued its investigation of Respondent’s compliance with FIFRA by monitoring the content made available to the public on Respondent’s website at www.liphatech.com. On November 18, 2009, an EPA Inspector, Ms. Claudia Niess, searched Respondent’s website and observed a “Product Information Sheet” for Rozol Prairie Dog Bait, which included the following claims⁵:

- “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%.
- “Lower 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 wet. It outlasts Zinc Phosphide.”
- “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.”
- “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 for ZP [Zinc Phosphide]. Rozol less toxic to dogs than ZP or Diphacinone.”

(CX 28, EPA512-13). Respondent admits to making all of these statements on its website but denies that they are “claims” under FIFRA. (Answer ¶¶ 275, 278, 281, 284, 287 and 290).

⁵ For the purpose of brevity, this list of claims is not an exhaustive list of violative claims made by Respondent.

Also, on November 18, 2009, Ms. Niess observed a brochure entitled “Control Range Rodents” on Respondent’s website. The brochure was dated September 24, 2009. (CX 28, EPA532). This brochure included the following claims for Rozol Pocket Gopher Bait and Prairie Dog Bait⁶:

- “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.”

(CX 28, EPA522-32). With respect to Rozol Prairie Dog Bait, Respondent admits to making all of these statements in this brochure, which, among other places, could be found on its website, but Respondent denies that they are “claims” under FIFRA. (Answer ¶¶ 293, 296, 299, 302, 305, and 308).

Finally, on the same day, November 18, 2009, Ms. Niess observed another brochure on Respondent’s website entitled “Understanding the true cost of treatment: Proper Prairie Dog Management Saves Time and Money,” which contained claims similar to those in the above-referenced materials. (*Compare* CX 28, EPA512-13, 522-32 *with* CX 28, EPA516-21). This brochure was also dated September 24, 2009.

On February 10, 19, and 23, 2010, Ms. Niess returned to Respondent’s website and

⁶ See *supra* footnote 4.

observed claims identical to those observed in the above-referenced materials during the November 18, 2009 inspection of Respondent's website. (CX 29-31). On February 23, 2010, Ms. Niess noted the following additional claim on Respondent's website in its "Product Information Sheet" for Rozol Pocket Gopher Bait⁷: "More readily available and less toxic than strychnine-treated millo products labeled for burrow-builder use." (CX 31, EPA596).⁸

The continued presence of the violative claims on Respondent's website in late 2009 and early 2010 resulted in Complainant issuing a third SSURO to Respondent. Complainant issued the third SSURO on March 4, 2010. (CX 32). 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 Section 3. (*Id.* ¶ 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)" of 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 again⁹ be sending a letter to its distributors, requesting that they destroy or discard all literature, flyers, and advertisements concerning Rozol. (CX 53). 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

⁷ See *supra* footnote 4.

⁸ For ease of reference, all of the materials obtained by Ms. Niess from Respondent's website on November 18, 2009 and February 10, 19, and 23, 2010, collectively will be referred to as the Advertisements" in this document.

⁹ Respondent had previously taken the same measures to correct the identified violations after the first SSURO was issued. (CX 17).

and “other literature, flyers, and advertisements concerning” Rozol. (CX 53, EPA996-997). Respondent also agreed to send Complainant the “‘confirmation forms’ as they are executed and returned.” (CX 54, EPA999). To date, Respondent has not sent Complainant any returned and executed “confirmation forms” despite repeated requests by Complainant to do so.

In addition to providing Complainant with a sample “confirmation form,” Respondent also provided a list of its distributors to whom it planned to send the “confirmation forms” in an e-mail message dated March 10, 2010. (CX 54). According to this e-mail message, Respondent sent the “confirmation forms” to 48 distributors. (*Id.*, EPA1004-05). The receipt of Respondent’s Advertisements by these 48 distributors, which this Tribunal can infer from Respondent’s request to these distributors to destroy the Advertisements, is the basis for the final 48 counts of the Complaint (Counts 2,184-2,231).

IV. Standard of Review

Under the Consolidated Rules, an accelerated decision is appropriate “if no genuine issue of material fact exists and a party is entitled to judgment as a matter of law.” 40 C.F.R. § 22.20(a). As the Environmental Appeals Board (“EAB” or “the Board”) has explained, the standard for deciding motions for accelerated decision is similar to the standard for granting summary judgment set forth in Rule 56 of the Federal Rules of Civil Procedure. *See, e.g., In re BWX Techs., Inc.*, 9 E.A.D. 61, 74-75 (EAB 2000).

Summary judgment is appropriate for the moving party when “it demonstrates that the record shows no genuine issue as to any material fact and that it is entitled to judgment as a matter of law.” *Ass’n Benefit Servs. v. Caremark RX*, 493 F.3d 841, 849 (7th Cir. 2007) (citations omitted). Although courts must resolve all evidentiary ambiguities and “must take the facts and all reasonable inferences from those facts in the light most favorable to the non-moving party,” *id.*, “the mere existence of some alleged factual dispute between the parties will not defeat an

otherwise properly supported motion for summary judgment.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-248 (1986). The non-moving party “may not avoid summary judgment by resting on the allegations of its pleadings; it must come forward with specific facts showing that there is a genuine issue for trial.” *Ass’n Benefit Servs.*, 493 F.3d at 849.

V. Applicable Law and Argument

A. Complainant Must Prove Four Elements for Each of the Violations Alleged in Counts 2,184 through 2,231 of the Complaint

The violations alleged in Counts 2,184 through 2,231 of the Complaint arise under FIFRA Section 12(a)(1)(B), which prohibits the distribution or sale of a registered pesticide by any person in any State when “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 Section 3. 7 U.S.C. § 136j(a)(1)(B). As the EAB has stated, “the elements of a FIFRA Section 12(a)(1)(B) violation are four-fold.” *In re Microban Prods. Co.*, 11 E.A.D. 425, 440 (EAB 2004) (“*Microban IP*”).

First, there must be a person charged with the violation. Second, that person must be located in a state. Third, that person must have distributed or sold a registered pesticide to another person. Fourth, there must be “claims made [for the registered pesticide] *as a part of its distribution or sale* [that] substantially differ from any claims made for it as a part of the statement required in connection with its registration.”

Id. (quoting *Microban I*, 9 E.A.D. at 687 (citing 7 U.S.C. § 136j(a)(1)(B)) (alteration and emphasis in original). For the reasons explained below, there is no genuine issue of material fact as to any of these four elements. Therefore, Complainant is entitled to accelerated decision in its favor against Respondent on liability for Counts 2,184 through 2,231 of the Complaint.

B. There is No Genuine Issue of Material Fact as to the First Two Elements of the Violations Alleged In Counts 2,184 through 2,231

The first two elements required to prove a FIFRA Section 12(a)(1)(B) violation are easily

satisfied. Respondent admits that it is a “person” as that term is defined in FIFRA Section 2(s), 7 U.S.C. § 136(s). (Answer ¶ 22). Respondent further admits that it owned a place of business in Wisconsin. (*Id.* ¶¶ 3, 23). Thus, there can be no dispute that Complainant has satisfied the first two elements required to prove the violations alleged in Counts 2,184 through 2,231.

C. There is No Genuine Issue of Material Fact as to the Third Element of the Violations Alleged In Counts 2,184 through 2,231

One of the pivotal issues in this Motion is whether the Advertisements Complainant found on Respondent’s website from November 18, 2009 through February 23, 2010, and that Respondent admits it provided to 48 of its distributors (CX 54), constitute “offer[s] for sale” of Rozol as that term is used in FIFRA’s definition of “distribute or sell.” 7 U.S.C. § 136(gg). Neither FIFRA nor EPA’s implementing regulations define “offer for sale” as used in the definition of “to distribute or sell.” 7 U.S.C. § 136(gg). Nevertheless, the definition of “to distribute or sell,” which includes “offer for sale,” should be broadly construed to effectuate the purpose of FIFRA. *In re Sporicidin Int’l*, 3 E.A.D. at 604 (holding that because it is a remedial statute, FIFRA “should be construed liberally so as to effectuate its purposes”). In reference to “offer for sale,” EPA’s implementing regulation, codified at 40 C.F.R. § 168.22(a), explicitly states that “EPA interprets this provision as extending to advertisements in any advertising medium to which pesticide users or the general public have access.”¹⁰

It is undisputed that Respondent sent 48 distributors the Advertisements that are the

¹⁰ It is worth noting that the EAB has opined on the meaning of “offer for sale” as that phrase is used in the definition of “to distribute or sell.” *In re Tifa Ltd.*, 9 E.A.D. 145, 158 (EAB 2000). After concluding that the “parties have not cited any relevant cases on this point, and [that] there is no legislative history to provide guidance in this area,” the Board consulted general common law contract principles to determine whether the evidence supported a finding of an “offer for sale.” *Id.* at 158-59. Notably, the Board relied on two treatises and cases applying common law contract principles in delineating what constituted an “offer for sale.” *Id.* at 159. Ultimately, the Board held that the record facts did not establish an “offer for sale.” *Id.* at 160.

Tifa is distinguishable from this case. Unlike the parties in *Tifa*, Complainant relies on 40 C.F.R. 168.22(a), which was not mentioned by the Board in *Tifa*. On this basis alone, *Tifa* is of limited, if any, precedential value to this matter.

subject of this Motion. (Answer ¶¶352; CX 53 and 54). The subject Advertisements were also located on Respondent's website, which is available to the general public, and the same brochures found on the website were sent to the 48 distributors. (CX 28-31; CX 54). Consequently, the Advertisements Respondent sent to the 48 distributors are covered by 40 C.F.R. § 168.22(a). *See also* 54 Fed. Reg. at 1124 (describing examples of advertising or promotional materials).

The only remaining issue as to this element is whether the subject Advertisements are in fact "advertisements" as that term is used in 40 C.F.R. § 168.22(a).¹¹ "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)). "The plain meaning of words is ordinarily the guide to the definition of a regulatory term." *Id.* (citing *T.S. v. Bd. of Educ.*, 10 F.3d 87, 89 (2d Cir. 1993)). Because "advertisement" is not defined in FIFRA or its implementing regulations, this Tribunal should give "advertisement" its ordinary meaning. "Advertisement" is defined as "the act or process of advertising." MERRIAM WEBSTER'S COLLEGE DICTIONARY 18 (10th Ed. 1994). To "advertise" is defined as, among other things, "to call public attention to especially by emphasizing desirable qualities so as to arouse a desire to buy or patronize." *Id.*; *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"). With these definitions as guideposts, this Tribunal should hold that there is no genuine issue of material fact that the subject

¹¹ Respondent admits that the materials in question are "advertisements." (Answer ¶¶ 349-51). In response to a prior motion for accelerated decision by Complainant, however, Respondent argued, in a declaration by its Chief Executive Officer, that certain materials were not sent to "induce sales or distribution of the product, but rather were sent "to inform and educate the distributors and/or dealers about Liphatech's products." (12/3/10 Declaration of Carl Tanner, ¶4). Therefore, Complainant will assume for the purposes of this Motion that, despite Respondent's admission, it will contend that the Advertisements do not fall within the ambit of 40 C.F.R. § 168.22(a).

Advertisements fall within the ambit of 40 C.F.R. § 168.22(a).

A close look at the subject Advertisements reveals that they were intended to promote Rozol's sale. (*See* CX 28-31). Each of the subject Advertisements compares the benefits of using Rozol with the potential pitfalls of using the products of Respondent's competitors. (*Id.*) For example, the basic structure of the brochure entitled "Understanding the true cost of treatment" is to (1) describe "non-chemical alternatives" to controlling black-tailed prairie dogs, (2) discuss the use of "zinc phosphide rodenticides" and "burrow fumigants," and then (3) to discuss the use of "anticoagulant rodenticides." (CX 31, EPA576-78). Rozol features prominently in the discussion of "anticoagulant rodenticides" in this brochure. (*Id.*, EPA578). The efficacy of Rozol treatments, Rozol's advantages versus zinc phosphide, and Rozol's advantages versus diphacinone-based products are all touted in this brochure. (*Id.*, EPA578-80). The brochure closes by providing the reader with contact information, including telephone and fax numbers, for Respondent, self-described as "the world's leading developer of rodent control products." (*Id.*, EPA581).

The brochure entitled "Control of Range Rodents" goes even further in describing the "benefits" of using Rozol. (CX 31, EPA582-90). It states that "Rozol offers unique advantages" over zinc phosphide and strychnine. (*Id.*, EPA585). It includes bulleted lists of the "benefits of Rozol," as well as several graphs and charts comparing Rozol to other rodenticides. (*See generally id.*) It urges readers to "protect your livestock and your land" and "put an end to prairie dog damage with Rozol®." (*Id.*, EPA571). This brochure also describes the various "convenient" sizes of Rozol that are available, giving the Rozol retailer or user options for sale and use of the product. (*Id.*, EPA571). Like the "Understanding the true cost of treatment" brochure, the "Control of Range Rodents" brochure includes telephone and fax numbers to

contact Respondent and Respondent's website url. (*Id.*, EPA572).

After examining the subject Advertisements, in light of EPA's interpretation of what constitutes an "offer for sale" as set forth in § 168.22(a), and based on Respondent's admission that the materials in question are advertising (Answer ¶¶ 349-51), this Tribunal should conclude that, as a matter of law, Complainant has established that Respondent offered Rozol, registered pesticides¹², for sale (i.e., distributed or sold Rozol) when it posted the Advertisements on its website and sent the Advertisements to 48 of its distributors, each of which are persons as that term is defined by FIFRA section 2(s), 7 U.S.C. § 136(s). Therefore, Complainant has demonstrated, as a matter of law, the third element required to prove the violations alleged in Counts 2,184 through 2,231 of the Complaint.

D. There is No Genuine Issue of Material Fact as to the Fourth Element of the Violations Alleged In Counts 2,184 through 2,231

1. The Statements Made in Respondent's Advertisements for Rozol are "Claims" Within the Meaning of FIFRA Section 12(a)(1)(B)

FIFRA Section 12(a)(1)(B) makes it unlawful to distribute or sell "any registered pesticides 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 Section 3" of FIFRA. 7 U.S.C. § 136j(a)(1)(B)(emphasis added). Therefore, as part of the fourth element, Complainant must demonstrate that the statements in Respondent's Advertisements were "claims" as that word is used in FIFRA.

Respondent admits that it made all of the statements listed in Section III of this Motion in its Advertisements.¹³ Respondent, however, denies that these statements were "claims" under

¹² Respondent admits that for calendar years 2009 and 2010, both Rozol Pocket Gopher Bait and Rozol Prairie Dog Bait were registered pesticides. (*Id.* ¶¶ 266-67).

¹³ (Answer ¶¶ 275, 278, 281, 284, 287, 290, 293, 296, 299, 302, 305, and 308).

FIFRA Section 12(a)(1)(B).¹⁴ Judge McCallum of Environmental Appeals Board (“EAB”), in his concurring opinion in *In re Roger Antikiewicz*, 8 E.A.D. 218 (EAB 1999), defined what constitutes a “claim” for purposes of FIFRA Section 12(a)(1)(B). He defined “claim” as follows:

In plain English, the term “claim” connotes an affirmative representation, whether express or implied, as to certain attributes, results, and so on. For example, the phrases “repel insects,” “safe for use on tomatoes,” “does not irritate skin,” “effective only if user allows 8 months to elapse after application before planting follow crops,” “kills mold and mildew on contact,” “for best results, use before first frost,” and “nontoxic to humans and pets” all constitute “claims” because they provide the reader with definitive, EPA-validated information about the product’s efficacy, safety, or other qualities.

8 E.A.D. at 242-43. Based on this definition, there can be no dispute that the statements made by Respondent in its Advertisements for Rozol constitute “claims” under FIFRA.

2. The Requisite Nexus Exists Between Respondent’s Illegal Claims and Respondent’s “Offers for Sale” of Rozol

For purposes of the fourth element necessary to prove the violations alleged in Counts 2,184 through 2,231, Complainant also must demonstrate that the claims made by Respondent in the Advertisements were made “as part of” an offer for sale. 7 U.S.C. § 136j(a)(1)(B). In *Microban I*, the EAB described this requirement as follows:

[t]he statutory term “as part of” requires that a nexus exist between the unapproved claims and the distribution or sale of the pesticide. The Chief Judicial Officer in *In re Sporidicin International, Inc.*, 3 E.A.D. 589, 602-03 (CJO 1991) ruled that a “sufficiently close link” existed between the claims and sales and distributions of pesticides in that case. He construed the statutory phrase broadly, and ruled that claims and corresponding distributions or sales need not be contemporaneous. *Sporidicin* at 603. It follows, therefore, that a rigid test, applicable to all situations, for determining whether claims have been made as part of the distribution or sale of a pesticide is not contemplated as part of the statutory scheme. Rather, it is necessary to examine all of the surrounding facts and circumstances to make such a determination.

¹⁴ (*See id.*).

Microban I, 9 E.A.D. at 688. After examining all of the facts relevant to Counts 2,184 through 2,231, this Court should conclude that Complainant has demonstrated that a nexus exists between the unapproved claims in the Advertisements and Respondent's offers to sell Rozol.

Unlike *Microban* and *Sporicidin*, cases in which the alleged FIFRA Section 12(a)(1)(B) violations involved the shipment of a pesticide, the violations alleged in Counts 2,184 through 2,231 involve "offers for sale" of a pesticide. The violative claims in this case were made in the "offers for sale" themselves, i.e., the Advertisements. Because all the violative claims were made in the Advertisements, which constitute "offers for sale," *see supra*, Complainant has demonstrated a "sufficiently close link" between the unapproved claims and the offers for sale. *See Microban I*, 9 E.A.D. at 688; *Sporicidin*, 3 E.A.D. at 602-05. Indeed, no closer link is possible than here, where the offer for sale includes the violative claims. Further, the preamble to 40 C.F.R. § 168.22 states that for the purpose of Section 12(a)(1)(B) of FIFRA, "EPA believes that claims made in the kinds of advertising covered by this interpretive rule are 'part of [the] distribution or sale' of the pesticide to which the advertising relates."¹⁵ (CX 85, EPA1552 (54 Fed. Reg., 1122, 1124 (Jan. 11, 1989))). Therefore, this Tribunal should conclude that there is no genuine issue of material fact as to whether the violative claims were made "as part of the distribution or sale" under FIFIRA Section 12(a)(1)(B).

3. The Claims Made in Respondent's Advertisements for Rozol Substantially Differ From the Claims Submitted by Respondent and Approved by EPA in Conjunction with the Registrations of Rozol

FIFRA Section 12(a)(1)(B) makes it unlawful to distribute or sell "any registered pesticides if any claims made for it as part of its distribution or sale substantially differ from **any**

¹⁵ The preamble actually references FIFRA Section 12(a)(2)(B). (CX 85, EPA1552). The reference to FIFRA Section 12(a)(2)(B) appears to be a typographical error, because a violation of FIFRA Section 12(a)(2)(B) does not require a distribution or sale of a pesticide. *See* 7 U.S.C. § 136j(a)(2)(B).

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)(emphasis added). FIFRA Section 3(c)(1) includes a list of documents and information that must be submitted by each applicant for registration and that are included in the “statement required” as that phrase is used in FIFRA Section 12(a)(1)(B). *Id.* § 136a(c)(1). One crucial subset of information in the “statement required” is found in FIFRA Section 3(c)(1)(C), which requires each applicant for a pesticide registration to provide “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.” *Id.* § 136a(c)(1)(C)(emphasis added). Another piece of information that must be included in the “statement required,” if it is requested by the Administrator, is “a full description of the tests made and the results thereof **upon which the claims are based.**” *Id.* § 136a(c)(1)(F)(emphasis added).

It is clear that the phrase “**any claims made for it** as part of the statement required,” as used in FIFRA Section 12(a)(1)(B), and the phrase “**upon which the claims are based,**” as used in FIFRA Section 3(c)(1)(F), are direct references to the requirement that an applicant submit “a **statement of all claims to be made for**” the pesticide pursuant to Section 3(c)(1)(C) of FIFRA. Any other reading of Sections 3(c)(1)(C) and (F) and 12(a)(1)(B) would render the phrase “a **statement of all claims to be made for it**” void or insignificant. This would be in direct contradiction to “one of the most basic interpretative canons,” which is “that ‘a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant’” *Corley v. United States*, 129 S. Ct. 1558, 1566 (2009).

The Administrative Law Judge (ALJ) in *In re Microban Products Company* described the “notice of pesticide registration” as the “baseline from which allegations of Section 12(a)(1)(B) must be measured.” 1998 EPA ALJ LEXIS 9, at *17 (ALJ April 3, 1998). The ALJ further

stated that establishing a FIFRA Section 12(a)(1)(B) “violation ‘involves holding up, on the one hand, the terms of EPA’s registration approval and then, per [Section 12(a)(1)(B)], determining whether [the respondent] made any claims as part of its distribution or sale which substantially differ from those made in connection with its registration approval.’” *Id.* (citing cases). The ALJ’s interpretation of FIFRA Section 12(a)(1)(B) in *Microban* undoubtedly was the product of her application of the well-recognized canons of statutory interpretation.

As required by FIFRA Section 3(c)(1)(C), Respondent did not submit any of the claims made in its Advertisements when it applied to register Rozol Pocket Gopher Bait and Rozol Prairie Dog Bait. (*See generally* RX 1-2). In addition, Respondent did not submit any of the claims made in its Advertisements when it sought “special local needs” registration of Rozol Pocket Gopher Bait to control black-tailed prairie dogs from various States pursuant to FIFRA Section 3(c)(1)(C). (*See generally* RX 3-9). While Respondent may contend that EPA does not “routinely” review advertising claims, other applications to register pesticides, examples of which are included at CX 92 and 93, have included such advertising claims in the “statement required” under FIFRA Section 3(c)(1)(C). When EPA received applications for pesticide registration that included proposed advertising claims, EPA reviewed such claims and informed the registrant that some of the advertising claims were prohibited or needed to be revised. (CX 92, EPA1695; CX 93, EPA1697). Therefore, the evidence in the record demonstrates that when EPA receives advertising claims in an application to register a pesticide, it reviews the claims and informs the registrant as to whether the claims comply with FIFRA.

Respondent made numerous unapproved efficacy, safety, and public health claims in its Advertisements in an effort to induce sales of Rozol without first obtaining EPA approval to make such claims. (*See* CX 28-31). Having failed to submit such claims for Rozol in its

applications for registration, Respondent assumed the risk that any claims that it made in its Advertisements and any other promotional material would be unlawful under FIFRA Section 12(a)(1)(B). Because Respondent failed to submit any statement of claims when it applied to register Rozol, the Presiding Officer need only look to the accepted labels contained in the notices of pesticide registration for Rozol to determine whether the claims in Respondent's Advertisements substantially differed from those submitted. *See In re Microban*, 1998 EPA ALJ LEXIS 9, at *17. Because the claims made in Respondent's Advertisement do not come even remotely close to the claims approved in the accepted label, and because some claims are even contrary to the approved label itself, this Tribunal should conclude that, as a matter of law, the claims made in the Advertisements are substantially different than those approved by EPA.

The efficacy claims made in Respondent's Advertisements, such as "proven single application effectiveness," are contrary to the approved language in the SLN labels for Rozol Pocket Gopher Bait and the labels for Rozol Prairie Dog Bait, all of which include "reapplication" directions. (*See* CX 2g, 3e, 4g, 5c, 6b, and 7b; CX 27, EPA509). The safety claims made in Respondent's Advertisements are similarly problematic when compared to the approved label. Nowhere in the accepted labels for Rozol or the notices of pesticide registration does EPA authorize Respondent to make claims such as "there is less risk to non-target wildlife" or "Rozol is less toxic to dogs than ZP [Zinc Phosphide] or Diphacinone." On the contrary, each of Rozol's accepted labels alert the user and consumer that Rozol is a "Restricted Use Pesticide Due To Hazard To Nontarget Organisms." (CX 1, EPA3; CX 27, EPA509). If claims such as these were submitted with its applications to register Rozol, Respondent would have been prohibited from making such claims by EPA. *See* 40 C.F.R. § 156.10(a)(5) (providing examples false or misleading statements in pesticide labeling).

Another example of claims that substantially differ from any claim submitted in conjunction with Respondent's applications to register Rozol and approved by EPA were found in the "Product Information Sheet" for Rozol Prairie Dog Bait on Respondent's website. In this Advertisement, Respondent stated as follows:

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.

(CX 28, EPA513). Had Respondent submitted these claims for approval, it would have learned, among other things, that it is prohibited from making any claims implying that Rozol has been endorsed by the Federal Government; it is prohibited from making any claims that make a false or misleading comparison with other pesticides; and it is prohibited from making claims as to safety without proper qualification. See 40 C.F.R. § 156.10(a)(5)(iv),(v) and (ix).

VI. Conclusion

For all of the foregoing reasons, Complainant respectfully requests that this Court issue an Order granting accelerated decision in its favor finding Respondent liable for the violations alleged in Counts 2,184 through 2,231 of the Complaint.

Respectfully submitted,

DATED: 1.27.2011



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Docket No. FIFRA-05-2010-0016

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CERTIFICATE OF SERVICE

I hereby certify that the original and one true, accurate and complete copy of
*Complainant's Motion for Accelerated Decision on Liability for Counts 2,184 through 2,231 of
the Complaint and Memorandum in Support* 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:

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Dated in Chicago, Illinois, this 27th day of January, 2011.



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