



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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REPLY TO THE ATTENTION OF:
C-14J

May 19, 2011

Honorable Susan L. Biro
Office of Administrative Law Judges
U.S. EPA Office of Hearing Clerk
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:

Please find enclosed a copy of *Complainant's Response to Non-Party Brief in Opposition to Complainant's Motion for Accelerated Decision on Liability for Counts 2,141 Through 2,183 of the Complaint*, which was filed on May 19, 2011, in the above referenced-matter.

Sincerely,

Gary E. Steinbauer
Assistant Regional Counsel

Enclosure

cc: Mr. Timothy D. Backstrom (*via UPS overnight*)
Bergeson & Campbell, P.C.
1203 Nineteenth Street, NW, Suite 300
Washington, DC 20036-2401

Mr. Michael H. Simpson (*via UPS overnight*)
Reinhart Boerner Van Deuren s.c
1000 North Water Street, Suite 1700
Milwaukee, WI 53202

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

IN THE MATTER OF:)

Liphatech, Inc.)
Milwaukee, Wisconsin)

Respondent.)
)

Docket No. FIFRA-05-2010-0016

**COMPLAINANT’S RESPONSE TO NON-PARTY BRIEF IN OPPOSITION
TO COMPLAINANT’S MOTION FOR ACCELERATED DECISION ON
LIABILITY FOR COUNTS 2,141 THROUGH 2,183 OF THE COMPLAINT**

On January 6, 2011, CropLife America and Responsible Industry for a Sound Environment (collectively, the “Non-Parties”) filed a Motion for Leave to File a Non-Party Brief Opposing Complainant’s Construction of FIFRA Section 12(a)(1)(B) (the “Non-Parties’ Motion”). On May 4, 2011, this Honorable Court granted the Non-Parties’ Motion, deemed the Non-Party Brief in Opposition to Complainant’s Motion for Accelerated Decision on Liability for Counts 2,141 through 2,183 of the Complaint¹ (the “Non-Parties’ Brief”) filed as of that date, and gave Complainant until May 20, 2011 to file a response to the Non-Parties’ Brief. In accordance with this Court’s May 4 order, Complainant submits this Response to the Non-Parties’ Brief.

I. Summary of Complainant’s Argument

In their brief, the Non-Parties take exception to Complainant’s application of Section 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B), of the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”) as it applies to Counts 2,141 through 2,183 of the Complaint.² In so arguing, the

¹ “Complaint” in this document refers to Complainant’s First Amended Complaint.

² At the outset, the Non-Party Brief at times appears to be limited to the efficacy claims at issue in Counts 2,141 through 2,183 of the Complaint. At others, however, it appears to be directed at all of the claims at issue in these counts. For purposes of this response, Complainant assumes that it applies to all claims at issue in Counts 2,141

Non-Parties suggest that Complainant's application of FIFRA Section 12(a)(1)(B) is somehow inconsistent with the plain language of FIFRA, its legislative history, and the implementing regulations promulgated by the United States Environmental Protection Agency ("EPA" or "Agency").

All of the arguments advanced by the Non-Parties are without merit. Complainant's application of FIFRA Section 12(a)(1)(B) is consistent with FIFRA, the applicable case law, FIFRA's legislative history, FIFRA's purpose, and EPA's implementing regulations. Furthermore, the claims that Respondent made for Rozol³ that resulted in the violations alleged in Counts 2,141 through 2,183 of the Complaint are misleading. Therefore, the Non-Parties' concern that a ruling in Complainant's favor on liability for Counts 2,141 through 2,183 will somehow infringe upon their members' right to engage in commercial speech is misplaced.

In sum, Complaint respectfully requests that this Honorable Court adopt EPA's well-supported application of FIFRA Section 12(a)(1)(B) and give the Non-Parties' Brief little weight when deciding whether Complainant is entitled to accelerated decision on liability for Counts 2,141 through 2,183 of the Complaint.

II. The Non-Parties' Suggested Construction of FIFRA Section 12(a)(1)(B) is at Odds With the Plain Language of FIFRA, its Purpose, and its Implementing Regulations

a. The plain language of FIFRA supports Complainant's application of FIFRA Section 12(a)(1)(B)

The Non-Parties' argument that the entire registration statement under FIFRA Section 3(c)(1), 7 U.S.C. § 136a(c)(1), forms the baseline for determining whether an advertising claim "substantially differs" under FIFRA Section 12(a)(1)(B) is contrary to the plain language of the

through 2,183 of the Complaint.

³ 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.

statute. “All statutory interpretation begins with the language of the statute itself, and where the statute’s language is plain, the sole function of the court is to enforce it according to its terms.” *Pittway Corp. v. United States*, 102 F.3d 932, 934 (7th Cir. 1996).

The Non-Parties’ attempt to rewrite FIFRA is identical to the argument raised by Respondent in response to Complainant’s motions for accelerated decision on liability for Counts 2,141 through 2,231 of the Complaint. Complainant has addressed this argument in prior filings and incorporates those filings by reference.⁴ Simply put, Complainant’s application of FIFRA Section 12(a)(1)(B) is wholly consistent with the plain language of this provision and FIFRA Section 3(c)(1). The Non-Parties’ and Respondent’s construction of FIFRA Section 12(a)(1)(B) is not. *See Lowe v. Sporicidin*, 47 F.3d 124, 130 (4th Cir. 1995) (explaining that FIFRA Section 12(a)(1)(B)’s use of “claims made for [the pesticide] as part of the statement required in connection with its registration under section 136a” refers to the “statement of all claims to be made for [the pesticide]” in FIFRA Section 3(c)(1)(C), not the entire registration statement required under FIFRA Section 3(c)(1)). For this reason alone, the Non-Parties’ suggested interpretation of FIFRA should be rejected. *Pittway Corp.*, 102 F.3d at 934.

b. Complainant’s application of FIFRA Section 12(a)(1)(B) furthers FIFRA’s goal of consumer protection

The Non-Parties’ suggested interpretation of FIFRA Section 12(a)(1)(B) is not only contrary to the plain language of FIFRA – it undermines FIFRA’s goal of protecting “purchasers from being induced into purchasing a pesticide based on unapproved claims that are potentially false or misleading,” *In re Microban Prods. Co.*, 9 E.A.D. 674,686 (EAB 2001), because it

⁴ *See* Complainant’s Reply to Respondent’s Response to Complainant’s Motion for Accelerated Decision on Liability for Counts 2,141 through 2,183 of the Complaint (“Compl.’s Reply 2nd Mot. Acc. Dec.”) (pages 3-8), Complainant’s Motion for Accelerated Decision on Liability for Counts 2,184 through 2,231 of the Complaint (“Compl.’s 3rd Mot. Acc. Dec.”) (pages 16-17), and Complainant’s Reply in Support of its Motion for Accelerated Decision on Liability for Counts 2,184 through 2,231 of the Complaint (“Compl.’s Reply 3rd Mot. Acc. Dec.”) (pages 6-11).

severely undermines EPA's ability to enforce FIFRA Section 12(a)(1)(B). "[E]xamining the statutory purpose and plain language of a statute go hand in hand." *Microban Prods. Co.*, 9 E.A.D. at 686 (citations omitted); *see also In re Harpoon P'ship*, 12 E.A.D. 182, 194 (EAB 2005) ("The Supreme Court has stated that '[i]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.'") (quoting *Nat'l Bank of Oregon v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 455 (1993)).

Under the Non-Parties' proposed construction, at the time the Agency is contemplating enforcement, EPA would have to go through all the data and references submitted by the registrant to determine if the claims in question were violative. In this case, such a review would have included thousands of pages associated with multiple applications for registration of Rozol sent to EPA and several state agencies. As is evident by this case, such an approach would result in protracted arguments as to what claims can or cannot be made. *See Compl.'s Reply 3rd Mot. Acc. Dec.* at 8-9. A finite list of approved claims provides registrants and EPA with the clarity that is needed while preserving EPA's approval authority and a registrant's right to advertise.

c. Complainant's application of FIFRA Section 12(a)(1)(B) is consistent FIFRA Section 3(c)(5) and with the legislative history of FIFRA

The Non-Parties urge the Court to consider FIFRA Section 3(c)(5), 7 U.S.C. § 136a(c)(5), (and its associated legislative history) when determining how FIFRA Section 12(a)(1)(B) should be interpreted. This approach is nonsensical because it incorrectly assumes that the waiver for the submission of efficacy data in FIFRA Section 3(c)(5) creates an exemption from the submission of all efficacy claims to be made for the pesticide under FIFRA Section 3(c)(1)(C). It does not. Nor does it absolve registrants from having to comply with FIFRA Section 12(a)(1)(B).

All registrants must develop efficacy data and have it available for EPA review upon request.⁵ 7 U.S.C. § 136a(c)(1)(F); 40 C.F.R. § 158.400. Once the pesticide is registered, EPA will send the registrant a Notice of Pesticide Registration, which includes an accepted label⁶ that must be used for the pesticide. The label will identify what the pesticide does and how it must be used. Without further approval, the registrant will not be allowed to make claims about the level or degree at which it can mitigate such pests.⁷ Additionally, the registrant will be prohibited from making claims that contradict, undermine, or exaggerate the claims in the approved label. *See Compl.’s Reply 3rd Mot. Acc. Dec. at 9-10.* Contrary to what the Non-Parties suggest, their members can continue to communicate efficacy information to consumers as long as such information does not contradict, undermine, or exaggerate the efficacy claims contained in their accepted labels and any approved marketing claims – as Respondent did for Rozol.

d. Complainant’s application of Section 12(a)(1)(B) is consistent with its implementing regulations

The Non-Parties argue that Complainant’s application of FIFRA Section 12(a)(1)(B) cannot be reconciled with 40 C.F.R. § 168.22(b)(5). Complainant is perplexed by this argument. 40 C.F.R. § 168.22(b)(5) allows registrants to advertise their pesticides for unregistered uses as long as the claims made are in compliance with FIFRA Section 2(ee), 7 U.S.C. § 136(ee).

Section 168.22(b)(5) specifically states: “**as a matter of policy, the Agency will not regard as**

⁵ In the case of Rozol, because Respondent sought to register the pesticide to control a public health pest, i.e., black-tailed prairie dogs (CX 101), Respondent was required to submit efficacy data with its application for registration. *See* 40 C.F.R. § 158.400.

⁶ The Notice of Pesticide Registration may also include marketing claims approved by EPA.

⁷ As an example, EPA would not allow a registrant to claim that a pesticide is “95% effective” without reviewing underlying data to support such a claim. Under the Non-Parties’ theory, their members would be allowed to make such claims without EPA approval because FIFRA Section 3(c)(5) waives the requirement to submit such data when applying for registration for certain types of pesticides. Under Complainant’s application, the registrant would submit such claims to EPA for approval. EPA may then request supporting data to verify that such a level of efficacy is achievable. Once verified and approved by EPA, the registrant could make such claims. This approach is consistent with FIFRA’s consumer protection goals.

unlawful the advertisement of uses permitted by FIFRA section 2(ee) provided the product is not an antimicrobial pesticide targeted against human pathogens.” 40 C.F.R. § 168.22(b)(5) (citation omitted, emphasis added). For example, if a registrant states in its advertising that its pesticide kills aphids but the accepted label states that the product is intended to kill Japanese beetles (without specially limiting the use of the pesticide to ONLY Japanese beetles and without specifying other pests such as aphids), EPA would not consider this to be a violation of FIFRA Section 12(a)(1)(B) under 40 C.F.R. § 168.22(b)(5). 40 C.F.R. §168.22(b)(5), however, does not apply to the fact pattern of the case before this Court. *See* Compl.’s Reply 2nd Mot. Acc. Dec. at 7. Therefore, the Non-Parties’ attempts to use this regulatory policy to invalidate or rewrite the plain language of FIFRA Section 12(a)(1)(B) should be rejected.

III. Complainant’s Application of Section 12(a)(1)(B) in Counts 2,141 through 2,183 of the Complaint Avoids the First Amendment Concerns Raised by the Non-Parties

The Non-Parties argue that Complainant should adopt an alternate construction of Section 12(a)(1)(B) of FIFRA that would not infringe on their right to engage in constitutionally protected commercial speech. Again, the Non-Parties miss the mark. The Non-Parties’ First Amendment argument is identical to that raised by Respondent in response to Complainant’s dispositive motions related to Counts 2,141 through 2,231 of the Complaint, which Complainant has addressed previously. *See* Compl.’s Reply 3rd Mot. Acc. Dec. at 15-16. Nonetheless, a brief discussion of the Non-Parties’ First Amendment argument is necessary.

Where commercial speech is misleading, as it was in this case, there is no constitutional protection. *United States v. Benson*, 561 F.3d 718, 725 (7th Cir. 2009) (stating that “false or misleading commercial speech receives no protection at all”) (citing *Cent. Hudson Gas & Elec. Corp. v. Pub. Service Comm’n of N.Y.*, 447 U.S. 557, 563 (1980)). In this matter, Respondent has made many claims that contradict, undermine, or exaggerate the claims in the accepted

label.⁸ Such claims are misleading and therefore they are not protected commercial speech. *Benson*, 561 F.3d at 725.

For example, with respect to counts 2,141 through 2,183 of the Complaint, Respondent made the following safety claim in its advertisements for Rozol: “*above-ground* risk to non-targets from Rozol is insignificant.” (CX 14A, EPA000176) (emphasis in original). As explained in Complainant’s Motion for Accelerated Decision on Liability for Counts 2,141 through 2,183 of the Complaint (page 12), this safety claim is a direct contradiction to Respondent’s accepted label, which alerts consumers to the dangers of Rozol by stating prominently in all capital letters that Rozol is a “Restricted Use Pesticide Due to Hazard to Nontarget Organisms.” (CX 1b; *see also* CX 2g, 3e, 4g, 5c, 5e, 6b, 7b). As Respondent’s accepted label states, Rozol is classified as a restricted use pesticide due to the danger it poses to non-target organisms. Claiming that this danger is insignificant is misleading.

Because several claims at issue in Counts 2,141 through 2,183 of the Complaint are misleading, the Court can decide that FIFRA Section 12(a)(1)(B) prohibits Respondent from making these misleading claims in its advertising without curtailing the constitutional right of the Non-Parties’ members to engage in commercial speech. *See United States v. Cote*, 504 F.3d 682, 686 (7th Cir. 2007) (“[W]hen it is fairly possible, courts construe statutes to avoid substantial constitutional questions.”) (citing *United States v. X-Citement Video*, 513 U.S. 64, 69 (1994)); *see also* Compl.’s Reply 3rd Mot. Acc. Dec. at 15-16.

IV. Conclusion

For all of the above reasons, the Non-Parties have failed to present any compelling arguments or demonstrate how the vital interests of their members will be adversely affected if

⁸ It is worth noting that Complainant need only prove that one of the claims forming the basis of Counts 2,141 through 2,183 of the complaint are violative under FIFRA Section 12(a)(1)(B).

Complainant's application of FIFRA Section 12(a)(1)(B) is accepted and accelerated decision is granted in Complainant's favor on liability for Counts 2,141 through 2,183 of the Complaint. Therefore, Complainant respectfully requests that the Non-Parties' Brief be given little, if any, weight in this Court's consideration of Complainant's Motion for Accelerated Decision on Liability for Counts 2,141 through 2,183 of the Complaint.

Respectfully submitted,

DATED: 5/19/2011



Nidhi K. O'Meara
Erik H. Olson
Associate Regional Counsels
Gary E. Steinbauer
Assistant Regional Counsel
United States EPA – ORC Region 5
77 W. Jackson Blvd. (C14-J)
Chicago, IL 60604
(312) 886-0568
Attorneys for Complainant

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

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CERTIFICATE OF SERVICE

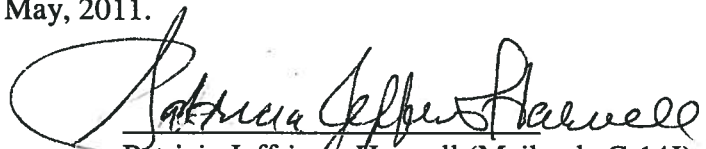
I hereby certify that the original and one true, accurate and complete copy of
*Complainant's Response to Non-Party Brief in Opposition to Complainant's Motion for
Accelerated Decision on Liability for Counts 2,141 Through 2,183 of the Complaint*, was filed
with the Regional Hearing Clerk, U.S. EPA, Region 5, on the date indicated below. True,
accurate and complete copies were sent, via UPS overnight delivery, on the date indicated below,
to the following addressees:

Honorable Susan L. Biro
Office of Administrative Law Judges
U.S. EPA Office of Hearing Clerk
1099 14th Street NW
Suite 350, Franklin Court
Washington, D.C. 20005

Mr. Timothy D. Backstrom
Bergeson & Campbell, P.C.
1203 Nineteenth Street, NW, Suite 300
Washington, DC 20036-2401

Mr. Michael H. Simpson
Reinhart Boerner Van Deuren s.c
1000 North Water Street, Suite 1700
Milwaukee, WI 53202

Dated in Chicago, Illinois, this 19th day of May, 2011.



Patricia Jeffries-Harwell (Mailcode C-14J)
Legal Technician
U.S. EPA, Region 5
77 West Jackson Blvd.
Chicago, IL 60604
(312) 353-7464