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

February 22, 2011

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 Judge Biro:

Please find enclosed a copy of *Complainant's Reply In Support of its Motion for Accelerated Decision on Liability for Counts 2,184 through 2,231 of the Complaint*, which was filed on February, 22 2011, in the above referenced-matter.

Sincerely,

Gary E. Steinbauer
Assistant Regional Counsel

Enclosures

cc: Mr. Michael H. Simpson
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1000 North Water Street, Suite 1700
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(*via UPS overnight delivery*)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

IN THE MATTER OF:	)	
Liphatech, Inc.	)	Docket No. FIFRA-05-2010-0016
Milwaukee, Wisconsin	)	
	)	Hon. Susan L. Biro
Respondent.	)	
	)	

Complainant's Reply in Support of its Motion for Accelerated Decision on Liability for Counts 2,184 through 2,231 of the Complaint

Pursuant to Rules 16(b) 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(b) and 22.20, Complainant files the instant Reply in support of its Motion for Accelerated Decision on Liability for Counts 2,184 through 2,231 of the Complaint and in response to the Memorandum of Respondent opposing the same.

I. Respondent's Collateral Challenge to 40 C.F.R. § 168.22 is Presumptively Improper and Should Be Rejected

Respondent admits that the Advertisements include "advertising' in a general sense.[1] Resp.'s Resp. at 19. Respondent also acknowledges that under the plain language of 40 C.F.R. § 168.22(a) an "advertisement" has been interpreted to be an "offer for sale" for purposes of FIFRA Sections 12(a)(1)(A) and 12(a)(1)(B). *Id.* at 15. Notwithstanding its admission and acknowledgment, Respondent attempts to challenge the plain language of 40 C.F.R. § 168.22(a),

[1] Respondent's admission that the Advertisements are "'advertising' in a general sense" is impossible to square with the December 3, 2010 Declaration of Carl Tanner, the CEO for Respondent, in which Mr. Tanner states that the literature Respondent provides to its distributors is intended to educate and inform individuals about Respondent's products, not to induce or create sales or distribution of the product. Respondent is a for-profit business engaged in the marketing and developing of pest management products. *See* www.liphatech.com (last visited Feb. 21, 2011). Asserting that Respondent disseminates its Advertisements to merely inform *distributors* about its products is disingenuous. Such conclusory statements in an affidavit, without any factual support, do not create a genuine issue of material fact. *See, e.g., Scaife v. Cook Co.*, 446 F.3d 735, 740 (7th Cir. 2006). Additionally, the authority Respondent cites in its brief (*Int'l Ins. Co. v. Florists' Mut. Ins. Co.*, 550 N.E.2d 7, 10 (Ill. App. Ct. 1990) cited at Resp.'s Resp at 19) is easily distinguishable because there is clear evidence in this case that the Advertisements Respondent sent to its distributors were also posted on its website and made available to the general public.

arguing that Complainant is somehow attempting to extend its authority beyond the statutory limits in FIFRA. Respondent's challenge to EPA's interpretation of FIFRA Sections 12(a)(1)(A) and 12(a)(1)(B), as codified in 40 C.F.R. § 168.22(a), is presumptively improper in this forum.

On several occasions, "the Board [EAB] has refused to review final Agency regulations that are attacked because of their substantive content or alleged invalidity, both in the exercise of the Board's permit review authority and in the enforcement context." *In re Woodkiln Inc.*, 7 E.A.D. 254, 259 (EAB 1997) (citing *In re Suckla Farms, Inc.*, 4 E.A.D. 686, 698 (EAB 1993) ("We will not allow this permit appeal to be used as a vehicle for collaterally challenging the distinction drawn by the UIC program regulations between 'hazardous' and 'nonhazardous' injection wells."); *In re Ford Motor Co.*, 3 E.A.D. 677, 682 n.2 (Adm'r 1991) (administrative permit appeal does not "provide a forum for entertaining challenges to the validity of the application regulations"); *In re B.J. Carney Indus.*, 7 E.A.D. 171, 172 (EAB 1997) (affirming that "there is a strong presumption against entertaining challenges to the validity of a regulation in an administrative enforcement proceeding *** 'and a review of a regulation will not be granted absent the most compelling circumstances'") (quoting *In re Echevarria*, 5 E.A.D. 626, 634 (EAB 1994)). "The decision to entertain such challenges is at best discretionary, and review of a regulation will not be granted absent the most compelling circumstances." *Echevarria*, 5 E.A.D. at 634 (citations omitted). The strong "presumption against challenges to the validity of a regulation in enforcement proceedings is a rule of practicality." *Id.*; *see also RSR Corp. v. Donovan*, 747 F.2d 294, 301 (5th Cir. 1984) ("An Agency has an interest in finality and conservation of its resources. It should not be compelled to defend the same regulation against identical attacks in successive enforcement actions, when those challenges could and should have been asserted in the period before pre-enforcement review.").

Respondent has failed to raise any compelling reason as to why this Tribunal should entertain its challenge to 40 C.F.R. § 168.22(a). After affording the regulated community notice and the opportunity to comment, the Agency promulgated 40 C.F.R. § 168.22(a). The proposed rule was published in the Federal Register and copies of it were "supplied to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition and Forestry of the Senate." 51 Fed. Reg. 24393, 24395 (July 3, 1986). "No comments were received from either of the Congressional Committees." *Id.* The Congressional Committees' silence after receiving the proposed rule undermines Respondent's argument that Congress did not intend to allow advertising, which is available to the pesticide user or the general public, to be a part of the distribution or sale of the pesticide because such advertisements constitute "offers for sale." Resp.'s Resp. at 11-12.

The Congressional Committees may have opted not to comment on the promulgation of 40 C.F.R. § 168.22 because it is consistent with FIFRA's statutory scheme. If FIFRA Section 12(a)(1)(B) were read as narrowly as Respondent suggests, it would be virtually indistinguishable from FIFRA Section 12(a)(1)(E). Section 12(a)(1)(E) makes it unlawful to distribute or sell any pesticide which is misbranded. 7 U.S.C. § 136j(a)(1)(E). A product is misbranded under FIFRA if "its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false and misleading in any particular." *Id.* § 136(q)(1)(A). Because most claims that "differ substantially" from registration claims would be either false or misleading, Section 12(a)(1)(B) would be rendered superfluous if it did not apply to advertising claims that are not on the product's labeling.

In addition, contrary to Respondent's argument, FIFRA Section 12(a)(2)(E) is best understood to work in tandem with Section 12(a)(1)(B). Section 12(a)(1)(B) makes it illegal to

advertise claims not approved in the registration process; Section 12(a)(2)(E) declares one particular claim – "restricted use" – as being so important that it must be affirmatively disclosed in advertising. 7 U.S.C. § 136j(a)(2)(E). If Congress intended Section 12(a)(2)(E) to be the only provision in FIFRA Section 12 to address advertising, it would send a conflicting message to the regulated community: FIFRA Section 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 the approved label. Congress could not have intended such a result.

Furthermore, Respondent's restrictive interpretation of 40 C.F.R. § 168.22 is not only contradicted by the FIFRA's statutory scheme and the plain language of the regulation, it is contrary to EPA's official position expressed in the preamble to the final version of 40 C.F.R. § 168.22. In the preamble, EPA stated that the "regulation is being promulgated because of numerous instances of pesticide advertising that EPA believes to be false or misleading." 54 Fed. Reg. 1122 (Jan. 11, 1989). More specifically, EPA justified the final rule by stating that "[f]or the purpose of FIFRA Section 12(a)(1)(B), EPA believes that claims made in kinds of advertising covered by this interpretive rule are 'part of [the] distribution or sale' of the pesticide to which the advertising relates.' . . . In this rule, EPA is not seeking to define the outer reaches of its FIFRA jurisdiction over advertising claims, but merely to state clearly its position with regard to claims in advertising that are made 'to induce the * * * sale and use' of a pesticide and that therefore are a part of the distribution or sale of the pesticide." *Id.* at 1124 (citation omitted). The language used by EPA in the preamble demonstrates that 40 C.F.R. § 168.22 is not limited to the five categories of advertisements that are always unlawful under 40 C.F.R. § 168.22(b). Simply because Respondent's Advertisements do not fit into one of these five categories does

not mean that they escape coverage under 40 C.F.R. § 168.22(a).

In sum, Respondent's collateral challenge to 40 C.F.R. § 168.22 is presumptively improper and should be denied. Even if Respondent could cite "compelling reasons" to allow a collateral challenge, such a challenge must fail. EPA's interpretation of "offer for sale" in 40 C.F.R. § 168.22 is consistent with FIFRA's statutory scheme and was explained in detail in the Federal Register notices that led to the promulgation of this rule. Had Respondent actually submitted the claims made in the Advertisements when it applied to register Rozol, it would have learned of EPA's interpretation of FIFRA Section 12(a)(1)(B) and the scope of 40 C.F.R. § 168.22(a). *See* CX 92, EPA1689-90 and CX 93, EPA1697 (examples of two Notices of Pesticide Registration in which "optional marketing claims" were approved by EPA; in both Notices, EPA informed the applicant that "**regardless of whether a website is referenced on your product's label**, claims made on a website may not substantially differ from those claims approved through the registration process") (emphasis in original). Respondent must not be permitted to collaterally attack 40 C.F.R. § 168.22, a regulation codified in the Code of Federal Regulations for almost two decades, in this action.

II. The *Tifa* Decision Should Be Narrowly Construed Based on Its Facts and the Limited Authorities Presented By the Parties

The EAB in *In re Tifa Limited* took great pains to craft a narrow decision that was based on the arguments and authorities cited by the parties before it. The Board was careful in explaining that its decision was based solely on the "authorities cited" by it and the parties. *In re Tifa Ltd.*, 9 E.A.D. 145, 160 (EAB 2000). Notably, despite the fact that 40 C.F.R. § 168.22(a) 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 158 (emphasis added). Clearly, the EAB in *Tifa* did not have the benefit of 40 C.F.R. 168.22(a) and the underlying

Federal Register notices that led to its promulgation. This is evident because the decision fails to acknowledge the existence of a regulation that would have provided guidance on the issue before it. Furthermore, the Board also appears not to have had the benefit of the decision of the Chief Judicial Officer (CJO) in *In re Sporicidin International*, a case dealing with FIFRA Section 12(a)(1)(B) violations arising from the respondent's dissemination of promotional literature. In *Sporicidin*, the CJO held 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.'" 3 E.A.D. 589, 605 (CJO 1991) (also acknowledging the existence of 40 C.F.R. § 168.22); *see also In re Bug Bam Product, LLC*, Docket No. FIFRA-09-2009-0013, 2010 EPA ALJ LEXIS 8, at *11 (ALJ April 23, 2010). According to *Sporicidin*, something less than a contractual offer to sell a product gives rise to an "offer for sale." *Id.* at 603.

The Board's decision in *Tifa* to resort to general contract law to determine what constitutes an "offer for sale" in a remedial federal statute was made without the benefit of the parties bringing 40 C.F.R. § 168.22(a), its underlying Federal Register notices, and *Sporicidin* to the Board's attention. Therefore, the Board's fact specific decision in *Tifa* should be viewed narrowly.

III. Respondent's Interpretation of 12(a)(1)(B) is Fundamentally Flawed, Contrary to Its Own Past Applications to Register Other Pesticide Products, and Illogical

Respondent again urges this Tribunal to accept its fundamentally flawed interpretation of Sections 3(c) and 12(a)(1)(B) of FIFRA. More specifically, Respondent asserts that "the entire registration statement [including a full description of the tests made and the results upon which the claims are based as described in Section 3(c)(1)(F) of FIFRA] be reviewed to determine if claims made for a pesticide product as part of its sale or distribution are substantially different."

Resp.'s Resp. at 17. As explained in detail in Complainant's initial memorandum, Respondent's urged interpretation of Sections 3(c)(1) and 12(a)(1)(B) of FIFRA would render the requirement that an applicant submit "a statement of all claims to be made for" the pesticide in Section 3(c)(1)(C) of FIFRA void or insignificant. Compl.'s Memo. at 16-20; *see also supra* pages 2-3. Complainant will not repeat such arguments here.

Complainant, however, notes that Respondent's suggested interpretation of these provisions of FIFRA is not only contrary to the statute's plain language, it is contrary to the Board's interpretations. The Board, in *In re Roger Antkiewicz & Pest Elimination Products of America, Inc.*, dealt with, among other things, the dismissal of a claim for a violation of FIFRA Section 12(a)(1)(B). 8 E.A.D. 218, 234-35 (EAB 1999). Importantly, immediately prior to quoting FIFRA Section 12(a)(1)(B), the Board quoted FIFRA Section 3(c)(1)(C). *Id.* The Board's quote of FIFRA Section 3(c)(1)(C) when dealing with an alleged violation of FIFRA Section 12(a)(1)(B) was no accident. The Board understood that FIFRA Section 3(c)(1)(C), particularly the requirement that an applicant for registration submit "a statement of all claims to be made for" the pesticide, is exactly what Congress was referring to when it enacted FIFRA Section 12(a)(1)(B). *See also Lowe v. Sporicidin*, 47 F.3d 124, 130 (4th Cir. 1995) (emphasizing that FIFRA Section 3(c)(1)(C) requires an applicant for registration submit "a statement of all claims to be made for" the pesticide before emphasizing that this identical language is in FIFRA Section 12(a)(1)(B)).

In addition, Respondent's suggested interpretation of FIFRA Section 12(a)(1)(B) is also contrary to its own past applications for pesticide registration. As explained in the February 17, 2011 Declaration of Ms. Claudia Niess, she was assigned to review a Notice of Arrival of Pesticides and Devices submitted by Respondent for a shipment of the registered pesticide

"Metarex 4% Slug and Snail Bait," EPA Registration Number 7173-257 ("Metarex") on February 7, 2011. (**Attachment 1**, Declaration of Ms. Claudia Niess ("Niess Decl."), ¶ 4). As part of her review, Ms. Niess obtained and printed a copy of the accepted amended label for Metarex, which is attached to Ms. Niess' declaration. (*Id.* ¶¶6-8). The accepted amended label for Metarex reveals that Respondent submitted an entire page, including two columns of single-spaced text, of "optional marketing statements." (Niess Decl., **Exhibit 1** at 4). Therefore, even if Respondent's suggested interpretation of FIFRA Section 12(a)(1)(B) found support in the statutory language or in prior EAB decisions (it does not), it is contradicted by Respondent's own applications to register its other pesticide products.

If Respondent's flawed interpretation of FIFRA Section 12(a)(1)(B) were accepted by this Tribunal, it would impose insurmountable burdens on EPA and require EPA to be clairvoyant. Furthermore, if Respondent were correct that approved claims include any information submitted by the registrant pursuant to Section 3(c)(1)(F) of FIFRA, EPA would be forced to review voluminous application packages (and anything referenced therein) to determine which claims it has "approved." It would also usurp EPA's ability to reject studies or data it deems invalid, as it did here. See CX 81, EPA1359. In effect, this would render FIFRA Section 12(a)(1)(B) unenforceable (which certainly is contrary to Congress' intent).

Under Respondent's interpretation, EPA would have been forced to review thousands of pages of information from eight registration applications for Rozol (six Section 24(c) SLN applications and two Section 3 applications) to determine whether Respondent made claims that substantially differed than those approved by EPA. Thus, it is Respondent's suggested interpretation of FIFRA Section 12(a)(1)(B) that would lead to absurd results.[2] *Comptom*

[2] Exhibit F to Respondent's Response, which is flawed and discussed below in section IV of this reply, is a perfect illustration of why Respondent's interpretation should be rejected. In this chart, Respondent cherry picks

Unified Sch. Dist. v. Addison, 598 F.3d 1181, 1184 (9th Cir. 2010) ("We read statutes as a whole, and avoid statutory interpretations which would produce absurd results.")

Finally, Respondent relies upon the declaration of Mr. James V. Aidala, which was submitted with the proposed non-party brief of CropLife and RISE on January 5, 2011[3], and the declaration of Mr. Henry M. Jacoby, which was submitted by Respondent with a previous brief, in arguing that Complainant's interpretation of FIFRA Section 12(a)(1)(B) would negate the 1978 amendments to FIFRA authorizing the waiver of filing efficacy data. Resp.'s Resp. at 19; *see also* 7 U.S.C. § 136a(c)(5). This argument is flawed for at least two reasons.

First, the waiver for the submission of efficacy data in FIFRA Section 3(c)(5)[4] did not apply to Respondent's applications to register Rozol because black-tailed prairie dogs are considered public health pests (CX 101). Therefore, efficacy data was required to be submitted (RX 10) and reviewed by both the EPA Registration Division (CX 80) and the EPA Environmental Fates and Effects Division (CX81). Consequently, the limited waiver for the submission of efficacy data has no bearing on this matter.

Second, contrary to what CropLife, RISE and Respondent argue, the waiver for the submission of efficacy data in FIFRA Section 3(c)(5) actually supports Complainant's position

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information and takes statements out of context to justify its violative claims, which undermine, exaggerate, or contradict the language used in the accepted label. For many violative claims, EPA can locate other information in the registration record that is contradictory. In other instances, EPA has reviewed the submitted information and rejects conclusions drawn by Respondent. The need for clarity by the submission of a statement of claims for the pesticide that must be approved (which often is simply the accepted label) by EPA allows EPA to avoid protracted arguments with a registrant as to what claims were approved. It also minimizes any attempts by the registrant to manipulate the data it submits or bury unacceptable claims in voluminous data submittals. Finally, it gives EPA the opportunity to carry out its role as the approving authority in the registration process as it has been authorized to do by Congress.

[3] The fact that Respondent is using arguments and the affidavit of Mr Aidala for purposes of this Motion is another reason for this Tribunal to conclude that Crop Life and RISE are merely surrogates of Respondent.

[4] It is also important to note that there is no equivalent data waiver to demonstrate the safety of a pesticide. In this matter, Respondent makes numerous safety claims that substantially differ from the claims approved by the EPA.

with respect to FIFRA Section 12(a)(1)(B). The waiver for the submission of efficacy data in Section 3(c)(5) of FIFRA in no way creates a waiver from having to submit the information set forth in Section 3(c)(1)(C) of FIFRA. Nor does it create an exemption from Section 12(a)(1)(B) for efficacy claims. Therefore, registrants must still ensure that the efficacy claims that they make are not substantially different from the claims they are approved to make by EPA in the registration process. Further, the waiver for the submission of efficacy data for some applications does not absolve registrants from developing and retaining efficacy data for their pesticides and submitting it to EPA upon request. Thus, each registrant must have the efficacy data on hand to support any efficacy claims it makes.

The fact that efficacy data is not required to be submitted for some registration applications is all the more reason that specific claims must be approved through the accepted label and through the submittal of additional marketing claims if the registrant so wishes. This allows EPA to review the claims to ensure that the claims do not undermine, exaggerate, or contradict the claims or other required language in the accepted label. Respondent's concern that EPA will be inundated with supporting data is a red herring, because under Complainant's interpretation, a registrant would not be required to submit efficacy data if the waiver applies. Rather, under Complainant's interpretation, the registrant would be required to submit a "statement of claims" as contemplated in Section 3(c)(1)(C). If the waiver applies, the only time efficacy data would be required to be submitted is if the registrant felt it could support a claim that EPA decided to disallow. Even in such an instant, the registrant would need only to submit the data that supports the specific claim in contention.

For all of these reasons, the Presiding Officer should reject Respondent's suggested interpretation of FIFRA Section 12(a)(1)(B). Respondent's attempts to create a genuine issue of

material fact regarding an issue of law, namely statutory interpretation, by submitting the declarations of Messrs. Aidala and Jacoby must be rejected.

IV. The Claims in Respondent's Advertisements Substantially Differ from the Claims Respondent Submitted Under Section 3(c)(1)(C) of FIFRA

Based on its incorrect reading of FIFRA, Respondent asserts that the claims giving rise to the violations alleged in Counts 2,184 through 2,231 of the Complaint do not substantially differ from its "registration materials." Resp.'s Resp. 24. In so arguing, Respondent relies on a chart, attached as Exhibit F to its response. This chart is irrelevant if this Tribunal rules that the baseline for determining if claims are substantially different is the information submitted in Section 3(c)(1)(C) of FIFRA, rather than any information Respondent decides to submit with its registration application. Assuming *arguendo* that Respondent's flawed interpretation of FIFRA Section 12(a)(1)(B) was somehow correct, Respondent's reliance on this chart does not create a genuine issue of material fact.

There are at least ***five*** reasons why Exhibit F would be unhelpful to Respondent, even if Respondent's interpretation were accepted. ***First***, as explained in Complainant's principal memorandum in support of this motion, many of the violative claims at issue in Counts 2,184 through 2,231 contradict the approved labels. Compl.'s Memo. at 19. Respondent cannot possibly believe that it can make claims in advertising that contradict the approved labels for Rozol.

Second, at least one study Respondent now relies on to "substantiate" one or more of the violative claims in its Advertisements was deemed invalid by the Environmental Fates and Effects Division of EPA (EFED). See CX 81, EPA1359. Pesticide registrants should not be permitted to rely on studies that are deemed scientifically invalid to substantiate claims made in advertising.

Third, in some instances, the quotes Respondent provides to substantiate its claims do not even substantiate the claims made. As an example, in an attempt to substantiate its claim "lower cost per acre" it points to the following quote "EPA understands that when an applicator chooses bait from an economic standpoint, they may prefer Rozol even though it costs more than zinc phosphide products." Ex. F to Resp.'s Resp. at 1. Clearly, these two claims are substantially different.

Fourth, many of the quotes Respondent selected to substantiate the claims contradict other quotes in the record. As an example, Respondent attempts to substantiate its claim that "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%" by citing to the results of a study (RX 10). In RX225, however, the mean efficacy identified in another study is 63.49%. In RX310, the efficacy range identified is 57% to 90% and results are noted as variable. In RX954-55, the efficacy is estimated at 75% to 100% and is noted to be 90% effective only if applied under certain conditions. In fact, in EPA's review of the efficacy data (RX 29), it was noted that the pesticide will kill some but not all black tailed prairie dogs. RX1870. This is in direct contradiction to Respondent's claim. As another example, Respondent attempts to substantiate the safety claim "Best Bait Acceptance & Favorable Toxicity Profile – According to the EPA's overall risk assessment, Rozol offers lower risk than Zinc Phosphide or Diphacinone. And Prairie dogs will eat it in burrow, so there is less risk to non-target wildlife."[5] This claim, in addition to undermining the label which states that the product is a hazard to nontarget organisms, contradicts the conclusion of EFED. EFED concluded that the use of

[5] This claim both implies an EPA endorsement and improperly compares its products to others. Claims such as these run afoul of 40 C.F.R. 156.10(a)(5), as well as being substantially different from claims that were approved for this product.

chlorophacinone bait to control prairie dogs has considerable potential for both primary and secondary risk to birds and non target mammals. CX 75, EPA1196-97.

Fifth, at least two of the documents Respondent relies on in Exhibit F to "substantiate" several of its violative claims were not in existence at the time Respondent submitted any of its applications for Rozol. The first document, which is attached as Exhibit G to Respondent's Response and was submitted as RX 89 in its First Supplemental Prehearing Exchange, is EPA's November 16, 2010, response to the World Wildlife Fund's petition for the suspension of Rozol Prairie Dog Bait, one of the registrations of Rozol that is at issue in this matter. The second document is an EPA memorandum dated August 3, 2010, entitled "Benefits Assessment for Chlorophacinone (Rozol©) Use to Control Black-Tailed Prairie Dogs, DP 374422," which was attached as Exhibit H to Respondent's Response and was submitted as RX 90 in its First Supplemental Prehearing Exchange. Both of these documents were prepared well after Respondent submitted any of the applications that led to the registrations for Rozol that are at issue in this matter.[6]

In sum, even if Respondent's flawed interpretation of FIFRA Section 12(a)(1)(B) were accepted by the Tribunal, Respondent has failed to point to record evidence creating a genuine issue of material fact that the claims in its Advertisements do not substantially differ from the claims submitted in its "registration statement." For purposes of demonstrating Respondent's liability for Counts 2,184 through 2,231, Complainant need only show that one of the violative claims alleged in these Counts is substantially different. The claims in Respondent's Advertisements that contradict the accepted label are alone sufficient to impose liability.

[6] Even if these documents could have been used by Respondent when it applied to register Rozol, Respondent's various quotes from these documents are taken out of context and in some instances contradict statements made by EPA.

Therefore, assuming *arguendo* that Respondent correctly interprets FIFRA Section 12(a)(1)(B) (it does not), Complainant is still entitled to judgment as a matter of law on liability for Counts 2,184 through 2,231.

V. There is No *Genuine* Issue as to Whether the 48 Distributors Received the Advertisements

In its response brief, Respondent contends that Complainant "has not established a link between the website and any of Respondent's 48 distributors." Resp.'s Br. at 27. Respondent's argument misses the mark. As explained in Complainant's principal brief, the nexus requirement for Counts 2,184 through 2,231 is easily satisfied. The violative claims are in the "offers for sale." Complainant need not show a link between Respondent's 48 distributors and *its website* to satisfy the nexus requirement (although there can be no dispute that the Advertisements were made available to the general public on Respondent's website).

Furthermore, Respondent's conclusory argument that there is "no evidence" that the 48 distributors possessed the Advertisements is contradicted by the "confirmation form" and its cover letter. Resp.'s Resp. at 2. This argument falls well short of raising a "genuine" issue. "Whether an issue is 'genuine' hinges on whether, in the estimation of a court, a jury or other factfinder could reasonably find for the nonmoving party. If the evidence viewed in the light most favorable to the nonmoving party is such that no reasonable decisionmaker could find for the nonmoving party, summary judgment is appropriate." *In re BWX Techs., Inc.*, 9 E.A.D. 61, 75 (EAB 2000) (citing *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 158-59 (1970)).

No fact finder could find for Respondent on the issue of whether the 48 distributors received the Advertisements. Respondent admits that it sent the confirmation forms to the 48 distributors. (CX 54). The cover letter and confirmation form gave each of these distributors only one option: to "immediately discard" the Advertisements, "to which you or your sales

representatives have access," and to certify, in writing, that the Advertisements were in fact discarded. (CX 53, EPA996-97). The 48 distributors were not given the option to certify that they did not possess the Advertisements.

The only reasonable conclusion that can be drawn from the cover letter and confirmation form is that each of the 48 distributors had the Advertisements in their possession on or before March 8, 2010. Respondent has submitted no evidence to refute this fact. Therefore, the record evidence establishes, by a preponderance of the evidence, that the 48 distributors possessed the Advertisements. *BWX Techs., Inc.*, 9 E.A.D. at 75 (noting that the moving party's burden on summary judgment is tied directly to its substantive evidentiary standard of proof, which under Consolidated Rule 22.24 is proof by a preponderance of the evidence).

VI. Respondent's As Applied First Amendment Challenge, Even if Proper, Does Not Affect this Tribunal's Ability to Impose Liability Under FIFRA Section 12(a)(1)(B)

Respondent has repeatedly argued, with minimal support or discussion, that Complainant's application of 40 C.F.R. § 168.22 in this action infringes on its right to engage in commercial speech under the First Amendment to the Constitution. Respondent admits that its advertisements are commercial speech. Resp.'s Resp. at 3, 25. Commercial speech is entitled to some protection, but government actions proscribing such speech are allowed if they advance substantial interests of the government and do so in a "direct and material" manner and the extent of the restriction is "in reasonable proportion to the interests served." *Edenfield v. Fane,* 507 U.S. 761, 767 (1993).

Where commercial speech is misleading, however, there is no constitutional protection. "There can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity." *Central Hudson Gas & Electric Corp. v. Public Service Commn. of New York,* 447 U.S. 557, 563 (1980); *see also Croplife America, Inc.*

v. City of Madison, 373 F. Supp 2d. 905, 918 (W.D. Wis. 2005) (holding that banning the advertisement of a pesticide including phosphorus was not unconstitutional where the use of such pesticides was illegal).

The violative claims in Respondent's Advertisements deserve no constitutional protection because they are misleading, and in contradiction to labeling language required under FIFRA. For example, "Proven Single Application Effectiveness" and "Lower cost per acre – Savings in time, labor, and fuel..." are misleading when the label language, which requires reapplication directions and requires the applicator to return to the application site and perform carcass searches, is considered. CX 28, EPA512-53; CX 1, EPA3; CX 27, EPA509. "[L]ower Primary Poisoning Potential – Rozol's toxicity to birds is 20X (times) less than for ZP [Zinc Phosphide]" is misleading when considered in light of the label language stating that the pesticide is restricted use due to hazard to nontarget organisms. *Id.*

Even if the advertisements were entitled to some constitutional protection, however, EPA's actions to halt the use of those advertisements advance a substantial interest of the government and do so in a direct and material manner, and the extent of the restriction is reasonable. The restrictions in 40 C.F.R. § 168.22 "have been tailored to further the governmental interest in preventing pesticide misuse while allowing necessary information to be furnished to persons who may legitimately benefit from the content of advertisements." 51 Fed. Reg. 24,393, 24,395 (July 3, 1986). Complainant is not seeking to prohibit Respondent from advertising its products. Instead, it is only seeking to prohibit Respondent from making statements in its advertising that are misleading or otherwise violate FIFRA. Therefore, even if properly developed, Respondent's First Amendment challenge to Complainant's application of 40 C.F.R. § 168.22 is without merit.

VII. Conclusion

For all of the foregoing reasons and the reasons set forth in Complainant's principal brief in support of this Motion, there is no genuine issue as to any material fact regarding Respondent's liability for the alleged violations in Counts 2,184 through 2,231. Complainant is therefore entitled to judgment as a matter of law as to liability for Counts 2,184 through 2,231 alleged in the Complaint. Complainant respectfully requests that this Tribunal grant its Motion for Accelerated Decision on Liability for Counts 2,184 through 2,231.

Respectfully submitted,

DATED: 2/22/2011

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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 Reply to Respondent's Response to Complainant's Motion for Accelerated Decision on Liability for Counts 2,184 through 2,231 of the Complaint* were filed with the Regional Hearing Clerk, U.S. EPA, Region 5, on the date indicated below. True, accurate and complete copies were also sent to the persons designated below on this date via UPS overnight delivery:

Honorable Susan L. Biro
Chief Administrative Law Judge
Office of Administrative Law Judges
U.S. Environmental Protection Agency
Mail Code 1900L
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Washington, D.C. 20005

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

Dated in Chicago, Illinois, this 22 day of February, 2011.

Gary E. Steinbauer