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January 5, 2011

Via Federal Express

Regional Hearing Clerk (E-19J)
U.S. EPA, Region 5
77 West Jackson Boulevard
Chicago, IL 60604

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

Dear Regional Hearing Clerk:

On behalf of Non-Parties CropLife America and Responsible Industry for a Sound Environment, I enclose an original and two copies of a motion pursuant to 40 C.F.R. § 22.11(b) for leave to file a non-party brief in the above referenced proceeding, along with the proposed non-party brief and the exhibits thereto.

Please file stamp one of the enclosed copies of the motion and brief and return it to me in the enclosed prepaid envelope. Thank you for your assistance.

Respectfully submitted,

Timothy D. Backstrom
Counsel for CropLife America and
Responsible Industry for a Sound Environment

Enclosures
cc: Honorable Barbara A. Gunning (w/enclosures) (via Federal Express)
Ms. Nidhi K. O'Meara (C-14J), Counsel for Complainant (w/enclosures) (via Federal Express)
Mr. Michael S. Simpson, Counsel for Respondent (w/enclosures) (via Federal Express)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

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

MOTION OF CROPLIFE AMERICA AND RESPONSIBLE INDUSTRY FOR A SOUND ENVIRONMENT FOR LEAVE TO FILE A NON-PARTY BRIEF OPPOSING COMPLAINANT'S CONSTRUCTION OF FIFRA SECTION 12(a)(1)(B)

Non-parties CropLife America (CLA) and Responsible Industry for a Sound Environment (RISE) hereby move pursuant to 40 C.F.R. § 22.11(b) for leave to file the appended non-party brief. CLA and RISE are both national nonprofit trade associations representing producers and suppliers of pesticide products. CLA primarily represents registrants of agricultural pesticide products, while RISE primarily represents producers of specialty pesticides and fertilizers.

CLA and RISE are submitting this brief for consideration by the Presiding Administrative Law Judge because the construction of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B), suggested by the Director of the Lands and Chemicals Division of Region 5 (Complainant) of the U.S. Environmental Protection Agency (EPA) in Complainant's Motion for Accelerated Decision on Liability For Counts 2,141 through 2,183 of the Complaint submitted on November 18, 2010, (Complainant's Motion) is contrary to the vital interests of pesticide registrants, distributors, retailers, and users.

In the attached brief, CLA and RISE demonstrate that Complainant's proposed construction of FIFRA Section 12(a)(1)(B) is incorrect as a matter of law because it is contrary to the text and legislative history of FIFRA and because it is intrinsically inconsistent with an interpretive rule concerning pesticide advertising claims EPA promulgated. CLA and RISE also believe that Complainant's construction of FIFRA Section 12(a)(1)(B) would unnecessarily and improperly constrain the rights of pesticide registrants, distributors, and retailers to commercial free speech. CLA and RISE will further demonstrate that, although Complainant's construction of this provision is not legally permissible, it should not be adopted in any case because it would impede pesticide registrants and other persons from furnishing critical information on product efficacy to pesticide users and divert critical EPA resources to review of efficacy data that is currently waived pursuant to FIFRA Section 3(c)(5), 7 U.S.C. § 136a(c)(5).

The appended brief will be useful in this proceeding because the issues raised by CLA and RISE are significant and of central relevance to the disposition of Complainant's Motion. In the appended brief, CLA and RISE also raise some legal issues and discuss pertinent precedent not addressed by either the Complainant or the Respondent, Liphatech, Inc. (Respondent), in their respective briefs concerning Complainant's Motion. Although the Respondent is a member of RISE, CLA and RISE offer their brief solely to address the Complainant's proposed construction of FIFRA Section 12(a)(1)(B). CLA and RISE take no position on any of the other matters that may be at issue in this proceeding.

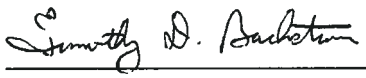
Granting leave to CLA and RISE to file the appended brief will not be disruptive because the Presiding Administrative Law Judge has not yet scheduled a hearing or taken any other action on Complainant's Motion. Neither the Complainant nor the Respondent will be prejudiced if CLA and RISE are granted leave to file the appended brief. If leave is granted, 40

C.F.R. § 22.11(b) provides that both Complainant and Respondent will have 15 days to respond to the brief.

WHEREFORE, non-parties CLA and RISE request that the Presiding Administrative Law Judge issue an order granting them leave to file the appended non-party brief, and setting an appropriate schedule for any responses to the brief by the Complainant or the Respondent.

DATED: January 5, 2011

Respectfully submitted,



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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

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

NON-PARTY BRIEF OF CROPLIFE AMERICA AND RISE IN OPPOSITION TO COMPLAINANT'S MOTION FOR ACCELERATED DECISION ON LIABILITY FOR COUNTS 2,141 THROUGH 2,183 OF THE COMPLAINT

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DATED: January 5, 2011

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Authorities upon which the non-parties filing this brief chiefly rely are marked with asterisks.

INTRODUCTION

Pursuant to 40 C.F.R. § 22.11(b), non-parties CropLife America (CLA) and Responsible Industry for a Sound Environment (RISE) hereby submit this non-party brief. CLA and RISE are both national nonprofit trade associations representing producers and suppliers of pesticide products.[1] CLA and RISE submit this non-party brief in opposition to the Motion for Accelerated Decision on Liability For Counts 2,141 through 2,183 of the Complaint (Complainant's Motion or Comp. Mot.) submitted on November 18, 2010, on behalf of the Director of the Lands and Chemicals Division of Region 5 (Complainant) of the U.S. Environmental Protection Agency (EPA).

The construction of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B), suggested by Complainant's Motion and Complainant's December 13, 2010, Reply to Respondent's Response to that Motion (Complainant's Reply or Comp. Reply) is incorrect as a matter of law because it is contrary to the text and to the legislative history of FIFRA and it is inconsistent with the interpretive rule concerning advertising claims promulgated by EPA. Complainant's construction of FIFRA Section 12(a)(1)(B) would also unnecessarily and improperly constrain the rights of pesticide registrants, distributors, and retailers to commercial free speech.

Moreover, although Complainant's construction of this provision is not legally permissible, it should not be adopted in any case because it would have a highly disruptive

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[1] As explained in the accompanying motion to file a non-party brief, CLA and RISE are submitting this brief for consideration by the Presiding Administrative Law Judge only because the construction of FIFRA Section 12(a)(1)(B) suggested by the Complainant is both incorrect as a matter of law and contrary to the vital interests of all pesticide registrants, distributors, retailers, and users. Although Respondent Liphatech, Inc. (Liphatech) is a member of RISE, CLA and RISE take no position on any of the other matters that may be at issue in this proceeding.

impact. Complainant's suggested construction would impede pesticide registrants and other persons from furnishing critical information on product efficacy to pesticide users. Complainant's construction would also needlessly divert EPA personnel and resources from other critical tasks to review of data and information on product efficacy that Congress has expressly afforded EPA the discretion not to review.

BACKGROUND

A. FIFRA Section 12(a)(1)(B)

The principal provision of FIFRA at issue in Complainant's Motion is FIFRA Section 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B), which states:

> (1) Except as provided by subsection (b) of this section, it shall be unlawful for any person in any State to distribute or sell to any person--
> ...
> (B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 136a of this title;

In Complainant's Motion, Complainant contends that this provision prohibits certain claims made in written and radio advertisements by Liphatech, including claims regarding the efficacy of the pesticide product Rozol when used in accordance with the terms and conditions of its registration, because these claims were not previously reviewed and approved by EPA.

B. Registration Statement under FIFRA Section 3(c)(1)

FIFRA Section 12(a)(1)(B) refers to the "statement required in connection with its registration under section 136a of this title," which is the registration statement that an applicant must submit under FIFRA Section 3(c)(1), 7 U.S.C. § 136a(c)(1). That section provides:

> 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 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 had been submitted to the Administrator....

Complainant appears to take the position that compliance with FIFRA Section 12(a)(1)(B) is determined only by reference to the subset of these application materials described in subsection (C), but there is no clear legal authority that supports this strained construction. More importantly, Complainant ignores the effect of the provision in FIFRA Section 3(c)(5) that allows EPA to waive review of efficacy data that would otherwise be required to make the necessary findings for registration.

C. Waiver of Efficacy Data under FIFRA Section 3(c)(5)

To grant a pesticide registration, FIFRA Section 3(c)(5), 7 U.S.C. § 136a(c)(5), requires EPA to make several findings, including a finding that the pesticide "will perform its intended function without unreasonable adverse effects on the environment." This finding appears to contemplate that registrants will submit and EPA will review data demonstrating that a pesticide product is efficacious. In 1978, FIFRA Section 3(c)(5) was amended to allow EPA to waive data requirements that would support efficacy claims:

> In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy.

7 U.S.C. § 136a(c)(5). Moreover, this amendment established a "presumption" that, when a State finds a product to be efficacious as part of a decision to grant registration for an additional

"use" of a currently registered pesticide to serve a "special local need" under FIFRA Section 24(c), 7 U.S.C. § 136v(c),[2] EPA will waive any data requirements for efficacy:

> If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

7 U.S.C. § 136a(c)(5).

The legislative history of these 1978 amendments is critical in understanding why EPA does not generally review the data supporting efficacy claims for pesticide products. The Report of the Senate Committee on Agriculture, Nutrition, and Forestry on these amendments (Exhibit A to this brief) states:

> The requirements in present law for the submission of such [efficacy] data for agricultural pesticides are of questionable value. The expenditure of resources by the Environmental Protection Agency in reviewing efficacy data is not the best use of resources since a pesticide manufacturer is not likely to expend the substantial investment in time and money needed to obtain registration of a pesticide on a non-efficacious product.

S. Rep. No. 95-334, 95th Congress, 1st Session (Exhibit A), at 9.

The amendment to FIFRA Section 3(c)(5) permitting waiver of efficacy data was adopted at the specific request of EPA. A report entitled "FIFRA: Impact on the Industry" prepared by the EPA Office of Pesticide Programs and submitted to Congress states:

> Because of the large amounts of efficacy data which are on file, considerable resources would have to be dedicated to complete validation of those tests. EPA believes that except for public health and disinfectant type products, the user community can best judge a product's efficacy, based on local conditions and pest resistance. Because of this and because a manufacturer would not find it in his best interests to go to the expense of registering a product which did not work,

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[2] This provision is important in this proceeding because the efficacy claims in Liphatech's advertisements concerned a "special local use" of Rozol to control black-tailed prairie dogs. These claims are based on a study that was originally submitted to support of a registration under FIFRA Section 24(c) for this additional use.

> public resources can be most effectively put to use in hazard rather than efficacy evaluation of products other than public health/disinfectant uses.

S. Rep. No. 95-334 (Exhibit A), at 47.

EPA still requires that each registrant conduct testing to ensure that a pesticide product is efficacious when used in accordance with the label and commonly accepted practices. Nevertheless, EPA has also utilized the discretion afforded by FIFRA Section 3(c)(5) to waive any requirement to submit efficacy data for most pesticide products. 40 C.F.R. § 158.400(e)(1) states:

> The Agency has waived the requirement to submit product performance data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user .... However each registrant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration.

As CLA and RISE will show below, both EPA and the Congress explicitly contemplated that registrants will use methods including advertising to communicate information on pesticide efficacy to users, even if EPA has expressly declined to require or review efficacy data. Accordingly, Complainant's construction that would prohibit such activity unless EPA has expressly reviewed and approved efficacy claims is contradictory to the purpose and legislative history of the 1978 amendments to FIFRA.

D. EPA's Interpretive Rule Concerning Advertising

In 1989, EPA adopted an interpretive rule that addresses the relationship between advertising claims and FIFRA Section 12(a)(1)(B). 54 Fed. Reg. 1122 (Jan. 11, 1989). This interpretive rule states:

> FIFRA sections 12(a)(1) (A) and (B) make it unlawful for any person to "offer for sale" any pesticide if it is unregistered, or if claims made for it as part of its

> distribution or sale differ substantially from any claim made for it as part of the statement required in connection with its registration under FIFRA section 3. EPA interprets these provisions as extending to advertisements in any advertising medium to which pesticide users or the general public have access.

40 C.F.R. § 168.22(a). While this rule establishes that EPA regards advertising claims to be claims made as part of "distribution and sale" under FIFRA Section 12(a)(1)(B), the rule does not expressly address how EPA is to determine whether such claims "substantially differ" from the claims made by an applicant in the registration statement required by FIFRA Section 3(c)(1).

The interpretive rule describes particular types of advertising claims that EPA will regard as unlawful. In the same part of this rule, EPA makes a distinction that is critical in evaluating the construction of FIFRA Section 12(a)(1)(B) upon which the interpretive rule is based. EPA states that it regards it to be "unlawful" to advertise:

> A registered pesticide product for an unregistered use, unless the advertisement is one permitted by paragraph (b) (2) or (3) of this section. However, as a matter of policy, the Agency will not regard as 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). FIFRA Section 2(ee), 7 U.S.C. § 136(ee), allows use of a registered pesticide "against any target pest not specified on the labeling," unless EPA requires label language precluding such use which is based on a determination that use of the pesticide against other pests would cause unreasonable adverse effects on the environment. As discussed below, this provision is critically important, because it cannot be reconciled with Complainant's proposed construction of FIFRA Section 12(a)(1)(B).

E. EPA Policy on Advertising Claims That Violate FIFRA Section 12(a)(1)(B)

The established policy of EPA concerning those claims in advertising that would be deemed to violate FIFRA Section 12(a)(1)(B) is not as restrictive as Complainant's Motion and Reply suggest. In a number of instances, EPA has acted to bring enforcement actions or issue

warnings when a registrant makes claims that conflict with the approved labeling of a product. EPA has also brought enforcement actions against registrants of antimicrobial products who make claims in advertising concerning control of human pathogens when the product in question has not been registered by EPA for such use. See, e.g., In the Matter of Microban Products Company, Docket No. FIFRA 98-H-01 (Sept. 18, 1998), 1998 WL 743912, at 6.

In addition, EPA has taken the position that FIFRA Section 12(a)(1)(B) generally prohibits claims in advertising that would be deemed "false or misleading" under 40 C.F.R. § 156.10(a)(5) if they were included by an applicant in proposed product labeling. See EPA, "Pesticide Labeling Questions and Answers," at Section 1 ("Advertising Claims"), *available at* http://www.epa.gov/pesticides/regulating/labels/label_review_faq.htm. This component of EPA's construction of FIFRA has not been clearly tested. Arguably, there is an important difference between claims that EPA may define as false and misleading for purposes of proposed labeling, and claims that actually are inherently misleading. See Bioganic Safety Brands, Inc. v. Ament, 174 F. Supp.2d 1168, 1180-81 (D. Col. 2001) (State may not prohibit particular types of pesticide advertising claims as "inherently misleading" unless they actually are).

In any event, the EPA policy that purports to apply prohibitions on claims in pesticide labeling regulations to pesticide advertising is not at issue in this case. Complainant takes the position that the actual truthfulness of Liphatech's advertising claims, including efficacy claims, is not relevant because EPA has never expressly "approved" them.[3]

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[3] Complainant does assert in passing that some of the Liphatech claims would not have been permissible in product labeling. Comp. Mot. at 13, n. 9.

F. Complainant's Suggested Construction of FIFRA Section 12(a)(1)(B)

CLA and RISE have prepared this non-party brief because Complainant advocates a construction of FIFRA Section 12(a)(1)(B) which is overbroad and more severe than even the untested EPA policy that purports to apply the prohibitions in EPA labeling regulations to advertising. Complainant argues that any claim in advertising "differs" from the statement required for registration if the claim has not been expressly "approved" by EPA. Comp. Mot. at 11-12; Comp. Reply at 2. According to Complainant, no advertising claim is permissible unless it is literally included in the approved product labeling, Comp. Mot. At 11; Comp. Reply at 4, or has been approved by EPA in response to a separate statement of claims submitted by the applicant. Comp. Reply at 4-5.

According to Complainant, this construction applies with equal force to efficacy claims. Comp. Mot. At 12-13; Comp. Reply at 5. In Complainant's view, it does not matter whether EPA has waived any requirement for submission or review of efficacy data in determining what advertising claims are permissible.

ARGUMENT

A. EPA May Not Lawfully Prohibit Claims in Pesticide Advertising Unless They Differ from Claims Made as Part of the Statement Supporting Registration of the Pesticide

In the preamble to its interpretive rule, EPA acknowledged that "FIFRA does not grant EPA plenary authority to regulate advertising as such." 54 Fed. Reg. at 1124. Because FIFRA does not provide EPA with general authority to regulate the content of pesticide advertising, allegations that advertising claims violate FIFRA must typically be based solely on the applicability of the prohibition in FIFRA Section 12(a)(1)(B).[4]

[4] CLA and RISE recognize that Complainant has also alleged that Liphatech violated FIFRA Section 12(a)(2)(E), 7 U.S.C. § 136j(a)(2)(E), which applies to advertising of

There are several distinct problems with the construction of this provision offered by Complainant. First, Complainant interprets the phrase "substantially differ" to require that EPA must have expressly "approved" any advertising claims, rather than to prohibit claims that conflict with the approved labeling language and other terms of the registration. Second, Complainant contends that the claims against which advertising is compared must be included in the approved product labeling or in a separate "statement of claims," rather than in any other part of the materials submitted by the applicant as part of the registration statement required by FIFRA Section 3(c)(1). Finally, Complainant contends that claims regarding product efficacy are among those that must be specifically approved by EPA, even though EPA requires registrants to develop efficacy data but typically declines to require that such data be submitted or reviewed.

CLA and RISE believe that the most reasonable construction of the phrase "substantially differ" in FIFRA Section 12(a)(1)(B) is that advertising claims may not be made as part of the sale and distribution of a pesticide if they materially conflict with the approved product labeling, or with other terms and conditions of the product registration. Complainant proposes an alternate construction under which no advertising claim is permissible, regardless of its subject matter and accuracy, unless it has been expressly approved in advance by EPA. Under Complainant's construction, even those claims that are demonstrably true based on materials submitted or cited by the applicant as part of the registration process, or based on EPA's own analyses prepared as part of the reregistration process, would be prohibited if not expressly "approved" by EPA.

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pesticides classified for Restricted Use. CLA and RISE take no position with respect to those allegations.

In Lowe v. Sporicidin International, 47 F.3d 124, 130 (4th Cir. 1995), the Court evaluated advertising claims that were not included in approved labeling for compliance with FIFRA Section 12(a)(1)(B). In that case, the Court's analysis focused on whether the claims were "at odds with the labeling claims." The Court noted that the label stated that a concentrated solution of the product might cause skin irritation, but found that a claim concerning the lack of skin irritation from a more dilute solution "[a]t least arguably ... would not 'substantially differ" from the label." This is the sensible construction of this provision that should be adopted here.

In any case, as CLA and RISE will show below, Complainant's proposed construction conflicts with both the legislative history of the 1978 amendments to FIFRA and EPA's own interpretive rule concerning pesticide advertising. This proposed construction would also present significant issues of constitutionality. In these circumstances, the Presiding Administrative Law Judge should not adopt the severe construction suggested by Complainant, when there is another plausible construction that would avoid these problems.

B. Complainant's Position That Advertising Claims Are Prohibited Unless Specifically Included in Product Labeling or an Additional Statement of Claims Is Inconsistent with the Text and Legislative History of FIFRA and Conflicts with EPA's Policy

1. The Statement Supporting Registration of a Pesticide Consists of More Than the Approved Labeling

In addition to contending that all claims must be previously "approved" by EPA, Complainant argues that advertising claims should be compared only against approved product labeling, and an additional "statement of claims" if the applicant has submitted one. The contents of the registration statement required by FIFRA Section 3(c)(1), however, are much broader than the materials cited by Complainant. See Lescs v. William R. Hughes, Inc. et al., 1999 U.S. App. LEXIS 475, at 28 (4th Cir. 1999) (In determining whether advertising claims

substantially differ from those made in "the registration statement," the materials to be considered "included the EPA-approved labeling.").

In particular, the registration statement required by FIFRA Section 3(c)(1) must include "a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator...." FIFRA Section 3(c)(1)(F), 7 U.S.C. § 136a(c)(1)(F). Complainant presents no persuasive reason to conclude that these materials included in the "registration statement" should be disregarded in evaluating advertising claims. Rather, Complainant argues only that claims based on these materials should be disallowed because any other construction would give "the registrant *carte blanche* to pick and choose among the various data it submitted to use in its advertising materials." Comp. Reply at 2. Complainant is concerned that construing the registration statement to include everything specified by FIFRA Section 3(c)(1) will cause applicants to submit "any study, documents or data it desires, despite the relevancy or reliability" of such material. Comp. Reply at 2. This concern is ironic, when the natural consequence if Complainant's construction were to be adopted would be to cause registrants to submit many additional materials, including the content of pesticide advertising itself, for prior review and approval by EPA. The considerable practical problems with Complainant's construction are addressed separately below.

Although claims concerning pesticide efficacy will typically be based on testing that has neither been submitted to nor reviewed by EPA, in this case the principal study upon which Liphatech bases its efficacy claims was actually submitted to EPA. Complainant incorrectly argues that this study was submitted only in connection with the subsequent grant of a FIFRA Section 3 registration for Rozol Prairie Dog Bait. Comp. Reply at 5.. This study was first

submitted to EPA in connection with a Special Local Needs registration issued by the State of Kansas in 2007 under FIFRA Section 24(c). See Registration Jacket for Rozol Prairie Dog Bait, EPA SLN No. KS-070003, at 54-57, *available at* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2007-1024-0946.

This registration history is important in evaluating efficacy claims based on the Liphatech study. As explained above, FIFRA Section 3(c)(5) was amended in 1978 to establish a "presumption" that EPA "shall waive data requirements pertaining to efficacy" if "a pesticide is found to be efficacious by any State" under FIFRA Section 24(c)." Thus, it would make no sense to disallow Liphatech from making efficacy claims based on a study that supports such a State finding, because Congress has directed EPA to forego any review of efficacy data in this exact circumstance.

2. Complainant's Construction Conflicts with the Legislative History of FIFRA Section 3(c)(5)

As explained above, the 1978 amendments to FIFRA included a provision explicitly authorizing EPA to "waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy." FIFRA Section 3(c)(5), 7 U.S.C. § 136a(c)(5). In addition, the legislative history of that provision demonstrates that both Congress and EPA anticipated that registrants would continue to provide efficacy information to users.

The Senate Report and House Report accompanying this amendment both state:

> This authority would be used most commonly with respect to agricultural pesticides, due to the high level of knowledge concerning pesticidal efficacy which prevails in the agricultural community, **the existence of means for communicating efficacy information to users**, the organizational expertise of the Department of Agriculture, the Extension Services, and the universities in this area, and the stake the industry has in marketing products that are efficacious.

S. Rep. No. 95-334 (Exhibit A), at 20 (emphasis added); see also H. Rep. No. 95-663, 95 Congress, 1st Session, at 27.

This language demonstrates that, at the same time that Congress authorized EPA to waive requirements for submission and review of efficacy data, Congress also expressed its expectation that pesticidal efficacy information would continue to be communicated to pesticide users. Since such information would typically be communicated to users as part of promotion of the product by the registrant or other parties working with the registrant, EPA would likely construe such communications to be part of the distribution and sale of the product, and therefore subject to scrutiny under FIFRA Section 12(a)(1)(B). This underscores the irrationality of Complainant's proposed construction. The very activities that Congress identified as part of its rationale for the 1978 amendment authorizing waiver of efficacy data would then be deemed to be prohibited whenever EPA elects to utilize this authority. This cannot be what Congress intended.

Perhaps Complainant would suggest that a more permissive standard can be utilized for communications to users other than advertising. Even if Complainant were to take this position, this would ignore the central role of advertising in communicating efficacy information to pesticide users. Indeed, the report that the EPA Office of Pesticide Programs submitted to Congress in support of the 1978 amendments indicates an expectation by EPA that efficacy information will be used in advertising and marketing pesticides. That report states:

> There should be little reduction in field testing for efficacy. This development cost is a standard part in the commercial marketing of a pesticide. **Demonstration plots which serve to prove efficacy are a common form of advertising in pesticide marketing.** In general, pesticides which are commercially successful have gained acceptance based on their efficacy.

S. Rep. No. 95-334 (Exhibit A), at 65 (emphasis added).

Complainant's proposed construction is illogical because it would prohibit claims concerning data that EPA does not even require or review. Moreover, the proposed construction is also clearly contrary to statements made both by Congress and by EPA when the 1978 amendment to FIFRA Section 3(c)(5) authorizing EPA to waive efficacy data was adopted. Because Complainant's position that efficacy claims are impermissible in advertising unless expressly "approved" by EPA is contrary to this legislative history, it should be rejected.

3. Complainant's Construction Cannot Be Reconciled with EPA's Own Interpretive Rule Concerning Permissible Advertising Claims

Complainant's proposed construction of FIFRA Section 12(a)(1)(B) should also be rejected because it is inconsistent with EPA's interpretive rule addressing the legality of pesticide advertising. As explained above, that rule contains a provision stating that "as a matter of policy, the Agency will not regard as 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). FIFRA Section 2(ee), 7 U.S.C. § 136(ee), allows use of a registered pesticide "against any target pest not specified on the labeling" unless EPA requires label language to prohibit such use following a determination by EPA that use of the pesticide against other pests would cause unreasonable adverse effects on the environment.

This provision in the EPA interpretive rule is completely irreconcilable with Complainant's proposed construction of FIFRA Section 12(a)(1)(B). Under the interpretive rule, it is permissible for pesticide advertising to include claims addressing uses of a registered pesticide against pests that are not even mentioned on the label and that were never considered

in registering the product.[5] In contrast, Complainant's construction would prohibit any claims in advertising that have not been expressly reviewed and "approved" by EPA.

Complainant attempts to explain the inherent contradiction between 40 C.F.R. § 168.22(b)(5) and Complainant's suggested construction of FIFRA Section 12(a)(1)(B) by arguing that FIFRA Section 2(ee) relates to "use of a product." Comp. Reply at 7. This argument is invalid on its face. The provision in the EPA interpretive rule that addresses FIFRA Section 2(ee) expressly addresses the lawfulness of claims in advertising. Because EPA's own interpretive rule is intrinsically inconsistent with Complainant's proposed construction, that construction is clearly incorrect and should be disallowed.

4. FIFRA Should Not Be Construed in a Manner That Unnecessarily Limits the Right of Registrants to Truthful Commercial Speech

Finally, even if Complainant's suggested construction of FIFRA Section 12(a)(1)(B) could be somehow reconciled with the text and legislative history of FIFRA and with EPA's interpretive rule concerning pesticide advertising, it would be advisable for EPA to adopt an alternative construction that would not infringe so substantially on the right of pesticide registrants, distributors, and retailers to constitutionally-protected commercial speech. In proposing the interpretive rule concerning pesticide advertising, EPA expressly acknowledged that restrictions on pesticide advertising must be scrutinized to determine whether they conform to the First Amendment. EPA stated:

> Advertising is a form of "speech" for purposes of the First Amendment to the Constitution. Regulation of advertising thus must conform to the U.S. Supreme Court's decisions under that Amendment concerning freedom of speech.

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[5] The sole exception to this policy is for claims concerning use of antimicrobial products against human pathogens. This is a use pattern not subject to EPA's waiver of efficacy data under FIFRA Section 3(c)(5) and 40 C.F.R. § 158.400(e)(1), and also a type of efficacy claim that was found to be unlawful in the Microban decision.

51 Fed. Reg 24393, 24395 (July 3, 1986).

In Central Hudson Gas and Electric Corp. v. Public Service Comm. of New York, 447 U.S. 557, 566 (1980), the Supreme Court articulated a four-part test for restrictions on proposed commercial speech:

> In commercial speech cases, then, a four-part analysis has developed. At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more expansive than is necessary to serve that interest.

In the proposed interpretive rule, EPA also acknowledged that these tests would apply to any restrictions on pesticide advertising. 51 Fed. Reg. at 24395.

Complainant's proposed construction of FIFRA Section 12(a)(1)(B) thus raises serious and fundamental constitutional questions. Complainant takes the position that there is a governmental interest in prohibiting advertising claims that concern lawful activity regardless of whether or not the claims are misleading.[6] Complainant thus seeks to restrain and sanction commercial speech regardless of its truthfulness. In 44 Liquormart v. Rhode Island, 517 U.S. 484, 503 (1996), the Supreme Court stated:

> Precisely because bans against truthful, nonmisleading commercial speech rarely seek to protect consumers from either deception or overreaching, they usually rest on the offensive assumption that the public will respond "irrationally" to the truth. ... The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own

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[6] Subsequent cases have made it clear that the word "misleading" in the Central Hudson test means "inherently misleading." Even commercial speech that is potentially misleading can be entitled to protection under the First Amendment. See In Re R.M.J., 455 U.S. 191 (1982).

good. That teaching applies equally to state attempts to deprive consumers of accurate information about their chosen products.

Pesticide users rely on the availability of accurate and detailed information concerning the efficacy of a product against particular pests and in particular use conditions. EPA generally declines to review the test data upon which such information is based. In these circumstances, any construction of FIFRA that would operate to restrain pesticide registrants, distributors, and retailers from providing truthful information on pesticide efficacy would clearly raise very serious First Amendment issues.

Complainant states that any claim that FIFRA is unconstitutional is beyond the jurisdiction of this forum to consider. Comp. Reply at 8. This argument is immaterial because CLA and RISE are not contending that FIFRA is unconstitutional. Rather, they are opposing the construction of one provision in FIFRA that has been advanced by Complainant. Under the final prong of the Central Hudson test, regulation of commercial speech must not be more expansive than is necessary to serve the identified governmental interest. When evaluating potential restrictions on pesticide advertising, EPA has acknowledged that this test requires that "the regulation must be the least stringent needed to accomplish the governmental interest." 51 Fed. Reg. at 24395.

There is no reason to adopt a severe construction of FIFRA Section 12(a)(1)(B) that would raise significant concerns regarding constitutionality, particularly when there is a plausible alternative construction that is more consistent with the legislative history of FIFRA and EPA's own interpretive rule. The Supreme Court has instructed that "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." Thompson v. Western States Medical Center, 535 U.S. 357, 371 (2002). The Presiding Administrative Law Judge may reasonably decide to adopt a construction

of FIFRA that is plausible and supported by other legal authority in lieu of a broader construction that will inevitably invite a First Amendment challenge.

C. Complainant's Construction of FIFRA Section 12(a)(1)(B) Would Also Be Extremely Damaging and Disruptive for Both Registrants and EPA

1. Effective Pesticide Advertising Must Necessarily Include Information Addressing Product Efficacy

Although EPA has waived the submission and review of efficacy data for most products, Complainant seeks to construe FIFRA Section 12(a)(1)(B) in a manner that would preclude any claim concerning product efficacy in pesticide advertising unless it has been approved by EPA. Comp. Mot. At 12-13; Comp. Reply at 5. Complainant also seeks to sanction Liphatech for claims based on an efficacy study that was conducted to support a Special Local Needs registration under FIFRA Section 24(c), although FIFRA Section 3(c)(5) establishes a "presumption" that EPA will waive review of efficacy data in these circumstances. Thus, the inevitable effect of Complainant's construction will be to prohibit registrants like Liphatech from providing any information concerning product efficacy in their advertisements.

This result is both nonsensical and impractical. No prospective customer will want to buy a product unless he knows it will be efficacious for its intended use. Agricultural pesticide users in particular require detailed information concerning the efficacy of particular products against particular pests and in particular use conditions. Even after an agricultural user selects a particular product, determining how and when to apply a product can make a critical difference in how efficacious the product is in controlling a pest of interest. Failure to control pests effectively can result in crop damage and can reduce yields significantly. Even one bad season can threaten the livelihood of a farmer who must use pesticides to protect his crops. See Declaration of Dr. Ray S. McAllister (McAllister Declaration) (Exhibit B to this brief), at ¶ 5.

Professional pest control operators and consumers also need accurate information about product efficacy to make informed decisions regarding the correct product to address a particular pest problem.

All registrants of pesticide products, as well as the distributors and retailers of those products, need to provide accurate and comprehensive information on product efficacy to potential users. If a particular product does not perform as anticipated, the user can suffer substantial economic loss and is more likely to select an alternative product in the future. Accordingly, pesticide producers and users have a strong mutual interest in maintaining a robust and open dialogue concerning product efficacy. McAllister Declaration, at ¶ 6.

As explained above, the legislative history of the 1978 FIFRA amendment that authorized EPA to waive submission and review of efficacy data expressly recognized the importance of communicating information on pesticide efficacy to users. Pesticide producers use a variety of methods to communicate information on product efficacy to potential and actual customers. Advertising plays a critical role in disseminating information to the user community. Pesticide registrants may also use seminars, conferences, Internet sites, and other forms of direct outreach to communicate efficacy information to users, and to assure that their products are used in a manner that will yield the most satisfactory results. McAllister Declaration, at ¶ 7. Complainant wants to construe FIFRA in a manner that would create severe impediments to these essential activities.

2. Complainant's Construction Would Also Constrain the Ability of Parties Such as Retailers, Researchers, and Agricultural Extension Agents to Share Critical Product Information with Pesticide Users

The pernicious effects of Complainant's proposed construction of FIFRA Section 12(a)(1)(B) are not confined to advertising, or even to the activities of registrants. For example,

EPA acknowledged in the preamble of the final interpretive rule on pesticide advertising that "oral statements made at a growers' meeting" could be viewed as a claim under FIFRA Section 12(a)(1)(B) and that this section can apply to "[a]ny person making such statements." 54 Fed. Reg. at 1124.

The effects of Complainant's suggested construction of Section 12(a)(1)(B) would not be confined to registrants. Pesticide registrants may use their relationships with parties such as university researchers and agricultural extension agents as additional means of disseminating accurate information on product performance to the user community. McAllister Declaration, at ¶ 7. There is a significant prospect that EPA would regard statements made by other parties such as distributors, retailers, researchers, and agricultural extension agents as claims covered by Section 12(a)(1)(B), particularly if such statements are based on information developed by the registrant to support the product. All of these parties must be free to discuss product efficacy in a frank and open manner. They should not have to contact EPA to determine what efficacy claims (if any) EPA has approved before engaging in such discussions.

3. EPA Does Not Normally Review Product Advertising, and Complainant's Construction Would Require That Registrants Routinely Submit Efficacy Claims in Advertising for Prior Review and Approval by EPA

Ultimately, if the construction of FIFRA Section 12(a)(1)(B) advocated by Complainant is adopted, this will cause registrants to submit efficacy data that are not currently submitted and to demand that EPA review these data, regardless of the waiver adopted by EPA in 40 C.F.R. § 158.400(e)(1). Moreover, since almost any substantive statement in advertising might be viewed by EPA as a "claim," many registrants will decide as a prudential matter to request that EPA review their product advertising. Even though EPA does not typically review claims in pesticide advertising, Complainant blithely asserts that Liphatech "easily could have sought approval of

the claims for its advertising materials." Comp. Mot. at 13. CLA and RISE believe that, if EPA must routinely review and approve all advertising claims, this will be far more disruptive than Complainant infers.

Complainant's views are contrary to the report submitted by the EPA Office of Pesticide Programs in support of the 1978 amendments to FIFRA, which concluded that "public resources can most effectively be put to use in hazard rather than efficacy evaluation of products other than public health/disinfectant uses." S. Rep. 95-334 (Exhibit A), at 47. At the time that Congress adopted the 1978 amendments to FIFRA, Congress was very concerned about the slow pace of the "reregistration" of pesticides mandated by FIFRA. In subsequent years, the decision of EPA to waive efficacy data requirements for most pesticide products allowed EPA to devote more of its limited resources to this reregistration process. See Declaration of James V. Aidala (Aidala Declaration) (Exhibit C to this brief), at ¶ 5.

If EPA were to adopt the severe construction of FIFRA Section 12(a)(1)(B) advocated by the Complainant in this proceeding, this would be likely to have significant adverse consequences for EPA's future administration of the pesticide program. If registrants and other persons may no longer make any statement concerning product efficacy that might be construed as a "claim" unless that statement has been specifically reviewed and approved by EPA, the natural consequence of this construction will be to nullify the central purpose of the 1978 amendment to FIFRA Section 3(c)(5). Registrants will submit their efficacy studies to EPA and demand that EPA review them. Moreover, as a precaution, registrants may conclude that every statement that will be made in pesticide advertising or as part of other promotional activities must be submitted to EPA for prior review and approval. These additional review activities are likely to be highly disruptive. In particular, adoption of the construction advocated by

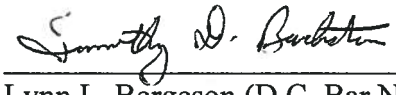
Complainant may require that significant resources be transferred from other parts of the EPA Office of Pesticide Programs to the Benefits and Economic Analysis Division. Aidala Declaration, at ¶ 7.

Complainant clearly has not considered the practical consequences for the daily administration of the pesticide program that would follow if EPA adopts Complainant's suggested construction of FIFRA Section 12(a)(1)(B). Even if Complainant's construction could be successfully reconciled with the text and legislative history of FIFRA and EPA's own interpretive rule, and even if this construction could withstand Constitutional scrutiny, these practical consequences would be so severe that the proposed construction should be rejected as a prudential matter.

CONCLUSION

For all of the above reasons, CLA and RISE request that the Presiding Administrative Law Judge adopt a construction of FIFRA Section 12(a)(1)(B) under which advertising claims made as a part of the sale or distribution of a pesticide product would "substantially differ" only when they materially conflict with the approved labeling or other terms and conditions of the product registration. For the same reasons, the Presiding Administrative Law Judge should reject the broader construction of this provision that has been advocated by Complainant.

Respectfully submitted,



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Attorneys for CropLife America and Responsible Industry for a Sound Environment

DATED: January 5, 2011

CERTIFICATE OF SERVICE

I hereby certify that copies of the enclosed Motion of CropLife America and Responsible Industry for a Sound Environment For Leave To File a Non-Party Brief, the proposed Non-Party Brief of CropLife America and RISE in Opposition to Complainant's Motion For Accelerated Decision on Liability for Counts 2,141 Through 2,183 of the Complaint, and the Exhibits thereto, were today transmitted by depositing the documents with a commercial courier in Washington, DC, with all fees prepaid, in envelopes addressed to:

Honorable Barbara A. Gunning
Office of the Administrative Law Judges
Franklin Court Building
1099 14th Street, NW, Suite 350
Washington, DC 20005

Ms. Nidhi K. O'Meara (C-14J)
Office of Regional Counsel
U.S. EPA, Region 5
77 West Jackson Boulevard
Chicago, IL 60604

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

I further certify that the original and one copy of each of the enclosed documents, along with the original version and one copy of this Certificate of Service, were today transmitted for filing by depositing the documents with a commercial courier in Washington, DC, with all fees prepaid, in an envelope addressed to:

Regional Hearing Clerk (E-19J)
U.S. EPA, Region 5
77 West Jackson Boulevard
Chicago, IL 60604

Dated: January 5, 2011

Timothy D. Backstrom
Counsel for CropLife America and
Responsible Industry for a Sound Environment

(A)

Extension of the FIFRA

too Volumious to Copy/Scan


B

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

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

DECLARATION OF DR. RAY S. MCALLISTER

I, Dr. Ray S. McAllister, under penalty of perjury, do hereby depose and declare as follows:

1. I am the Senior Director of Regulatory Policy for CropLife America, a non-party that has moved for leave to file a brief in this proceeding. CropLife America is a national nonprofit trade association representing manufacturers, formulators, and distributors of agricultural pesticide products. I have substantial scientific training and expertise in the control of agricultural pests. I received B.S. and M.S. degrees in Plant Science from Utah State University, and a Ph.D. in Weed Science from the University of Nebraska-Lincoln. I joined CropLife America (then the National Agricultural Chemicals Association) in 1989 as Director of Regulatory Affairs. Since that time, I have worked with EPA on many matters related to regulation of agricultural pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

2 I am personally familiar with all of the subjects addressed by this Declaration, which I am submitting as part of CropLife America's opposition to the construction of FIFRA Section 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B), proposed by the Complainant in this proceeding in a

Motion for Accelerated Decision submitted on November 18, 2010. I believe that adoption by the U.S. Environmental Protection Agency (EPA) of this proposed construction would prevent or impede registrants, distributors, retailers, and researchers from communicating critical information on product efficacy to pesticide users. Consequently, this construction is contrary to the vital interests of both pesticide producers in particular and the agricultural community in general.

3. To support registration of a pesticide product, FIFRA Section 3(c)(5), 7 U.S.C. § 136a(c)(5), requires EPA to make several findings, including a finding that the pesticide "will perform its intended function without unreasonable adverse effects on the environment." Although this finding would normally require that registrants submit and that EPA review data concerning the efficacy of a pesticide product in controlling target pests, FIFRA Section 3(c)(5) was amended in 1978 to allow EPA to waive data requirements that would support efficacy claims. EPA still requires that producers conduct testing to ensure that a pesticide product is efficacious, but EPA has also utilized the discretion afforded by FIFRA Section 3(c)(5) to waive requirements that an applicant submit efficacy data for any pesticide product that is not used to control pests that pose a risk to human health. Thus, for the vast majority of agricultural pesticide products, there is no requirement that a registration applicant submit data on product performance or efficacy against particular pests, and there is also no requirement that EPA review such data if they are submitted.

4. EPA has retained discretion to require submission and review of pesticide efficacy data when it deems it useful or appropriate. EPA is most likely to consider information on the efficacy of pesticide products not registered for public health use when EPA has identified a potential risk it believes is sufficiently significant to require that EPA balance benefits against

risks. In general, this has been most likely to occur when products with a particular active ingredient are being evaluated as part of the reregistration process established by FIFRA Section 4, 7 U.S.C. § 136a-1, or as part of the periodic review of reregistered pesticides required by FIFRA Section 3(g), 7 U.S.C. § 136a(g).

5. Although EPA does not normally review efficacy data as part of the pesticide registration process, pesticide users have an obvious and critical interest in selecting those products that will be most efficacious in controlling the pests of interest. Agricultural pesticide users in particular require detailed information concerning the efficacy of particular products against particular pests and in particular use conditions. Even after an agricultural user selects a particular product, determining how and when to apply a product can make a critical difference in how efficacious the product is in controlling a pest of interest. Failure to control pests effectively can result in crop damage and can reduce yields significantly. It is not an exaggeration to say that even one bad cropping season can threaten the livelihood of a farmer who must use pesticides to protect his crops.

6. Registrants of pesticide products, as well as the distributors and retailers of those products, also have an essential need to provide accurate and comprehensive information on product efficacy to potential users. If a particular product does not perform as anticipated, the user can suffer substantial economic loss and is more likely to select an alternative product in the future. Accordingly, pesticide producers and users have a strong mutual interest in maintaining a robust and open dialogue concerning product efficacy.

7. Pesticide producers use a variety of methods to communicate information on product efficacy to potential and actual customers. Advertising plays a critical role in disseminating information to the user community. Pesticide registrants may also use seminars, conferences,

internet sites, and other forms of direct outreach to communicate efficacy information to users, and to assure that their products are used in a manner that will yield the most satisfactory results. Pesticide registrants may also use their relationships with other parties such as university researchers and agricultural extension agents as additional means of disseminating accurate information on product performance to the user community.

8. It is my understanding that the construction of FIFRA Section 12(a)(1)(B) proposed by Complainant would prevent registrants and others from making any "claim" concerning product efficacy that might be construed to be part of the sale and distribution of a particular pesticide product unless that claim is part of the approved product labeling or has been otherwise reviewed and approved by EPA. Since EPA generally declines to require submission of and to review data on product efficacy, I believe that the practical effect of such a construction would be to preclude the sort of open and detailed dialogue on product performance needed to assure that users select the best pest control strategies for a particular situation and then apply the products in a manner that will be most efficacious. If EPA creates unnecessary impediments to this essential dialogue, this could jeopardize successful production of a variety of valuable agricultural commodities.

I declare under penalty of perjury that the foregoing statements are true and correct to the best of my knowledge, information, and belief.

Ray S. McAllister

Dr. Ray S. McAllister

Date: January 5, 2011
Washington, D.C.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

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

DECLARATION OF JAMES V. AIDALA

I, James V. Aidala, under penalty of perjury, do hereby depose and declare as follows:

1. I have worked for over 30 years on matters related to the registration and regulation of pesticides by the U. S. Environmental Protection Agency (EPA). From 1991 to 1993, I worked for the Subcommittee on Environment, Energy, and Natural Resources in the U.S. House of Representatives, where I was involved in Congressional oversight of EPA's implementation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). In 1993, I was appointed by President Clinton as an Associate Assistant Administrator in the EPA Office of Prevention, Pesticides, and Toxic Substances (OPPTS), and I served in this position until 2000. In 2000, I was nominated by President Clinton to be the Assistant Administrator for OPPTS, and later that year I received a recess appointment to that position. I was the most senior political appointee in OPPTS for two years, from January 1999 until January 2001. Since leaving EPA, I have been a consultant representing clients concerning a variety of agricultural, industrial, and biological product approval matters involving pesticides and toxic substances.

2. I am personally familiar with all the subjects addressed by this Declaration. I am submitting this Declaration in support of a brief by non-parties CropLife America and Responsible Industry for a Sound Environment opposing the construction of FIFRA Section 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B), proposed by the Complainant in this proceeding in a Motion for Accelerated Decision submitted on November 18, 2010. Under this proposed construction, no person could make any statement as part of the sale and distribution of a pesticide product that has not been either included in the approved labeling for the product or otherwise specifically reviewed and approved by EPA during registration of the product. I do not believe that this proposed construction is required by the language of FIFRA Section 12(a)(1)(B), and I consider this construction to be inconsistent with the legislative history of the 1978 amendments to FIFRA and with EPA's own interpretive rule concerning pesticide advertising. In any case, I am convinced that adoption by EPA of this proposed construction would unnecessarily impede the dissemination to users of important information on pesticide efficacy. Moreover, I believe that the inevitable result if such a construction were to be adopted would be to reduce the EPA resources available for more critical tasks which result in greater protection of health and the environment because additional resources would be needed to review efficacy data and evaluate proposed advertising claims.

3. To grant a pesticide registration, FIFRA Section 3(c)(5), 7 U.S.C. § 136a(c)(5), requires EPA to determine that the pesticide "will perform its intended function without unreasonable adverse effects on the environment." On its face, the finding required by this provision would require that registrants submit and EPA review data demonstrating that a pesticide product is efficacious. In 1978, EPA requested that FIFRA Section 3(c)(5) be amended to allow EPA to waive data requirements concerning product efficacy. EPA told Congress that

allowing such a waiver would permit EPA to devote its limited resources to evaluating potential risks rather than product efficacy. The 1978 amendment also established a "presumption" that, when a State finds a product to be efficacious as part of a decision to grant registration for an additional "use" of a currently registered pesticide to serve a "special local need" under FIFRA Section 24(c), 7 U.S.C. § 136v(c), EPA will waive any data requirements for efficacy.

4. Although EPA requires that registrants conduct testing to ensure that a pesticide product is efficacious, EPA has also utilized the discretion afforded by the 1978 amendment to FIFRA Section 3(c)(5) to waive the requirement to submit efficacy data for pesticides other than products used to protect public health. EPA retains the discretion to require submission of efficacy data and may review such data when the circumstances warrant it. This most often occurs when EPA decides that registered pesticides including a particular active ingredient involve potential risks that may be significant enough to require that EPA balance such risks against benefits.

5. At the time that Congress adopted the 1978 amendments to FIFRA, Congress was very concerned about the slow pace of the "reregistration" of pesticides mandated by FIFRA. In subsequent years, including the time I served as Assistant Administrator and Associate Assistant Administrator in OPPTS, the decision of EPA to waive efficacy data requirements for most pesticide products allowed EPA to devote more of its limited resources to this reregistration process. Now that the comprehensive reregistration process mandated by FIFRA Section 4, 7 U.S.C. § 136a-1, is nearly complete, EPA is required to extend this process by conducting periodic reviews of registered pesticides under FIFRA Section 3(g), 7 U.S.C. § 136a(g).

6. Distribution of efficacy information to pesticide users can be of great commercial importance to pesticide registrants and their affiliated distributors and retailers. Pesticide users

also depend on the availability of detailed information to assist in selection of the most useful products for control of particular pests, as well as detailed guidance concerning the most efficacious methods for applying these products.

7. If EPA were to adopt the severe construction of FIFRA Section 12(a)(1)(B) advocated by the Complainant in this proceeding, I believe that it would have some significant adverse consequences for EPA's future administration of the pesticide program. If registrants and other persons may no longer make any statement concerning product efficacy that might be construed as a "claim" unless that statement has been specifically reviewed and approved by EPA, the natural consequence of this construction will be to nullify the central purpose of the 1978 amendment to FIFRA Section 3(c)(5). Registrants will submit their efficacy studies to EPA and demand that EPA review them. Moreover, as a precaution, registrants may conclude that every statement that will be made in pesticide advertising or as part of other promotional activities must be submitted to EPA for prior review and approval. Although the Complainant in this proceeding appears to presume that EPA can readily accommodate these additional review activities, I believe that they will be highly disruptive. In particular, I expect that adoption of the construction advocated by Complainant would require that significant resources be transferred from other parts of the EPA Office of Pesticide Programs to the Benefits and Economic Analysis Division.

I declare under penalty of perjury that the foregoing statements are true and correct to the best of my knowledge, information, and belief.

James V. Aidala

Date: January 5, 2011
Grand Rapids, Michigan