## Exhibit E: Declaration of James V. Aidala

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY BEFORE THE ADMINISTRATOR

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