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August 13, 2012

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DELIVERED BY COURIER

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

Dear Regional Hearing Clerk:

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

On behalf of Respondent, Liphatech, Inc., I enclose for filing an original and two copies of Respondent's Post-hearing Brief.

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

Respectfully submitted,

Michael H. Simpson

Michael H. Simpson

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Encs.

cc Honorable Susan L. Biro (w/encs., by courier)
Ms. Nidhi K. O'Meara (C-14J) (w/encs., by First Class Mail)

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**REGION 5**

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| **In the Matter of:** | ) | **Docket No. FIFRA-05-2010-0016** |
| | ) | |
| **Liphatech, Inc.** | ) | **Hon. Susan Biro** |
| **Milwaukee, Wisconsin,** | ) | |
| | ) | |
| **Respondent.** | ) | |
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# RESPONDENT'S POST-HEARING BRIEF

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**RESPONDENT'S POST-HEARING BRIEF**

In accordance with the Chief Judge's April 18, 2012 Order Scheduling Post-Hearing Briefs, Liphatech, Inc. ("Respondent"), through its undersigned attorneys, respectfully submits the instant Respondent's Post-Hearing Brief, pursuant to section 22.26 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. § 22.26. For the reasons set forth below, Respondent respectfully requests that the Chief Judge find that Respondent did not violate section 12(a)(1)(B) of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") as alleged in Counts 2,141-2,231 of the Complaint and assess a fair and reasonable penalty, if any, based upon the actual gravity of Respondent's unintentional violation of FIFRA section 12(a)(2)(E).

## I. CASE OVERVIEW

The hearing in this case revealed that Complainant cannot meet its requisite burden of proof to support a liability finding as to Counts 2,141-2,231, nor can it support Complainant's requested penalty for any of the Counts charged. Complainant's theory of the case departs from the reality of both the facts and the law. As a result, Respondent

has already been penalized by continuing to incur substantial costs in defending against Complainant's untenable charges and grossly inflated proposed penalties. Respondent presents four general reasons to reject Complainant's requested relief: (1) Respondent's website is not an "offer for sale" and, therefore, no sale or distribution occurred as alleged in Counts 2,184-2,231; (2) Complainant has not established the requisite "nexus" between any allegedly substantially different claim and any sale or distribution of Rozol as set forth in Counts 2,141-2,183; (3) Complainant has not met its burden of proof to show that any of the statements made by Respondent are substantially different from the statement required as part of the registration of the products at issue; and (4) Complainant's proposed penalty fails to reflect the actual gravity of any violations that occurred. [1]

At the opening of the hearing on February 7, 2012, the Chief Judge offered the following general guidance regarding the scope of testimony that is relevant to this case:

> I would like to focus on, if we can ... Not on any big-picture issues, on whether pesticides are good or bad, on whether Rozol should have been registered ... whether it's better than any other pesticide out there. I want to focus on the narrow issues of the claims that were made, whether they were substantially different. What's an offer for sale. What is the unit of violation in this case, for example, on the website... What [is] a part of a distribution and sale... I know that the only issue in terms of penalty that remains is the issue of gravity. The penalty policy has certain factors that go into it that the agency relies on. But I am not bound by the penalty policy.

[1] For simplicity, unless specifically noted otherwise, Respondent will conform to Complainant's suggested abbreviations when referring to the pesticides at issue in this proceeding. (Compl.'s Posthrg. Br. 4). Respondent will use "Rozol Prairie Dog Bait" to refer generally to Rozol Prairie Dog Bait, EPA Reg. No. 7173-286, as well as the supplemental Special Local Needs registrations under FIFRA section 24(c). Respondent will use "Rozol Pocket Gopher Bait" to refer to Rozol Pocket Gopher Bait II (Alternate Name: Rozol Pocket Gopher Bait Burrow Builder Formula), EPA Reg. No. 7173-244. Finally, Respondent will use Rozol to refer to "Rozol Pocket Gopher Bait" and "Rozol Prairie Dog Bait," collectively.

(Niess Tr. 9:15-10:11).

Despite the Chief Judge's advice at the start of the hearing, Complainant transformed the hearing into a multi-day attack on Rozol generally and, through a series of overstatements regarding the U.S. Environmental Protection Agency's ("EPA's") regulatory authority, continues its attempt to use this penalty proceeding to expand EPA's limited jurisdiction under FIFRA section 12(a)(1)(B) to cover all pesticide advertising without the support of Congressional legislation or the administrative rulemaking process. In addition, based on a very limited investigation and without producing any probative evidence regarding the actual or potential for harm to human health or the environment, Complainant continues its attempt to levy an unprecedented multi-million dollar penalty on Respondent based on speculative assertions regarding the gravity of any FIFRA violations that occurred. Rather than focusing the hearing on filling the factual gaps identified in the Chief Judge's June 24, 2011 Order (for example, the relevant nexus between each shipment of Rozol and the direct mail package dated October 31, 2007 or the basis for Complainant's allegation that Respondent's website constituted 48 offers to sell Rozol), Complainant attempts to distract the finder-of-fact from the actual issues presented by this case.

This case is not about whether Rozol – containing chlorophacinone – is a pesticide designed to control – kill – prairie dogs. It is and it does. In fact, Rozol is a legally registered pesticide for that purpose. This case is not about whether Rozol was ever illegally sold or illegally applied by Respondent. It was not. In fact, this case is not about whether Rozol was illegally used by anyone.

This case is about: (a) the actual gravity of Respondent's inadvertent failure to include the words "Restricted Use Pesticide" in radio broadcasts and print advertisements published in niche trade journals during a limited period in 2007-2008; and (b) whether Respondent distributed or sold Rozol with claims made as part of its distribution or sale that substantially differ from claims made in connection with its registration and, if so, what is the actual gravity of that violation (particularly when the actual use of the product is always controlled by the product label and Rozol can only be sold to and used by certified applicators or used under their supervision). The actual gravity of any FIFRA violation that occurred is far lower than that suggested by Complainant's excessive penalty demand and is not reflected in Complainant's application of EPA's Enforcement Response Policy dated December 2009 ("2009 ERP"). Any penalty levied on Respondent must be based on the gravity of the violation that occurred, not the inherent characteristics of the pesticide.

As explained in more detail below, Counts 2,141-2,183 of the Complaint should be dismissed because Complainant has failed to establish the requisite nexus between any particular claim made by Respondent and any particular shipment of Rozol. Counts 2,184-2,231 of the Complaint should be dismissed because Complainant has failed to meet its required burden to prove that Respondent's website constitutes an offer to sell Rozol under FIFRA. In addition or in the alternative, all of Counts 2,141-2,231 should be dismissed because Complainant has failed to show that the claims that were made for Rozol were "substantially different" than the statement required as part of the product's registration. Furthermore, for any violation that occurred, the Chief Judge should

disregard the 2009 ERP in order to fashion an appropriate penalty, taking into account the totality of the circumstances of this case.

## II. STATUTORY AND REGULATORY BACKGROUND

As originally adopted, FIFRA "was primarily a licensing and labeling statute." *Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 601 (1991) (citing *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984)). Despite several amendments since its enactment that expanded the role of FIFRA to include regulation of "the manufacture, distribution or sale, and use of pesticides in the United States by means of a national registration system," FIFRA's role in the regulation of pesticide advertising remains limited to that narrow range described in FIFRA section 12(a)(2)(E) and that which falls within the narrower scope of FIFRA section 12(a)(1)(B). *In re Tifa Ltd.*, 9 E.A.D. 145, 2000 WL 739410, at *3 (EAB 2000).[2]

First, FIFRA section 12(a)(2)(E) makes it unlawful for any registrant "to advertise a product registered ... for restricted use without giving the classification of the product assigned to it." 7 U.S.C. § 136j(a)(2)(E).

Second, FIFRA section 12(a)(1)(B) prohibits selling or distributing "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 [FIFRA § 3]." *Id.* at § 136j(a)(1)(B). While FIFRA section 12(a)(2)(E) on its face applies to all pesticide advertisements, FIFRA section 12(a)(1)(B) only applies to a narrower subset of certain claims made by a

[2] All references to page numbers of cases reported on Westlaw are taken from the portable document format (pdf) printout of the case.

registrant "as part of" the distribution or sale of pesticides. While the phrase "as part of" does not require the claims and corresponding sales or distribution to be contemporaneous, there nevertheless must be some link between the two actions before they are brought within the ambit of FIFRA section 12(a)(1)(B). (Order Mots. For Accelerated Decisions Regarding Alleged Violations of FIFRA § 12(a)(1)(B), June 24, 2011) (hereinafter "6/24/2011 Order").

## III. PROCEDURAL BACKGROUND

Complainant filed its initial civil administrative complaint against Respondent on May 11, 2010. Pursuant to an Order on Prehearing Motions Related to Amending the Complaint dated December 29, 2010, Complainant filed its First Amended Complaint on January 6, 2011 (the "Complaint").[3] The Complaint includes three distinct sets of alleged FIFRA violations.

First, Counts 1-2,140 of the Complaint allege that Respondent advertised Rozol Prairie Dog Bait in radio broadcasts and niche trade journals without providing its restricted use classification as required by FIFRA section 12(a)(2)(E), 7 U.S.C. § 136j(a)(2)(E). Second, Counts 2,141-2,183 of the Complaint allege that, in the years 2007 and 2008, Respondent made claims as part of the *shipment* of Rozol that substantially differ from claims made for Rozol as part of the statement required in connection with its registration in violation of FIFRA section 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B). Finally, Counts 2,184-2,231 of the Complaint allege that, in the years 2009 and 2010, Respondent *offered to sell* Rozol on Respondent's website with claims

[3] In its First Amended Complaint, Complainant removed all allegations that Respondent made "false and misleading" claims for Rozol in violation of FIFRA section 12(a)(1)(E) and reduced its claim of economic benefit derived from the alleged violations to zero.

that substantially differ from the claims made for Rozol as part of the statement required in connection with its registration in violation of FIFRA section 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B).

On May 6, 2011, the Chief Judge issued an Order on Motions for Accelerated Decision Regarding Alleged Violations of FIFRA section 12(a)(2)(E) (the "5/6/11 Order") finding Respondent liable for Counts 1-2,140, but withheld decision on the appropriate unit of violation and penalty, if any, to be levied.

On June 24, 2011, the Chief Judge issued an Order on Motions for Accelerated Decision Regarding Alleged Violations of FIFRA section 12(a)(1)(B) denying Complainant's motions for accelerated decision as to Counts 2,141-2,183 and Counts 2,184-2,231. Among other things, the Chief Judge explained that: (a) Complainant's reliance on a legal theory that bases allegations of FIFRA liability on the "accepted label" is too narrow a formulation to justify a ruling in its favor as a matter of law because Complainant failed to show an absence of material fact as to Respondent's overall compliance with 7 U.S.C. § 136a(c)(1); (b) with respect to Counts 2,144 and 2,178, an evidentiary hearing was necessary to determine the precise nature of the recipients of those shipments in the context of the corporate structure of Respondent; (c) genuine issues of material fact remained with respect to whether a sufficient nexus existed between the claims made by Respondent and the sale or distribution of Rozol; (d) it is unclear that 40 C.F.R. § 168.22 actually governs in this case because it is specifically limited to five types of situations and pesticides; (e) even if 40 C.F.R. § 168.22 applies to Rozol and the claims made for it, it does not necessarily follow that EPA interprets FIFRA section 12(a)(1)(B) to define advertising as the equivalent of "offer for sale;" and

(f) a hearing was necessary to determine whether the literature found on Respondent's website constituted an offer to sell. (6/24/11 Order 23-27).

Therefore, the Chief Judge must now: (a) determine the appropriate unit of violation with respect to Counts 1-2,140; (b) determine liability with respect to Counts 2,141-2,183 and 2,184-2,231; and (c) based on the totality of the circumstances, determine a fair and reasonable penalty, if any, for the violations found.

## IV. FACTUAL BACKGROUND

Respondent is a pesticide manufacturer located in Milwaukee, Wisconsin. (Schmit Tr. 10:2-3, 12:11-16). Prior to the current proceeding, Respondent had a spotless compliance history dating back to the mid 1980's. (*Id.* at 11:18-12:5). This was, no doubt, due to the fact that Respondent exerts tremendous effort to maintain regulatory compliance. (*Id.* at 13:8-12).

Among other registrations, Respondent is the registrant of Rozol Pocket Gopher Bait, EPA Reg. No. 7173-184; Rozol Pocket Gopher Bait II (Alternate Name: Rozol Pocket Gopher Bait Burrow Builder Formula), EPA Reg. No. 7173-244; and Rozol Prairie Dog Bait, EPA Reg. No. 7173-286. (Joint Stips. at 2, 12). A brief discussion regarding the evolution of "Rozol" is helpful to understand the present case.

### A. The Background of "Rozol."

Rozol Pocket Gopher Bait, EPA Reg. No. 7173-184, was first registered in 1982 and is still used for the control of pocket gophers. (Schmit Tr. 17:17-18; RX 3). As a general use pesticide, use of the product is not restricted to certified applicators. (RX 3). In addition to its use on pocket gophers, Rozol Pocket Gopher Bait was also historically used to control black-tailed prairie dogs. (Schmit Tr. 18:9-19:25; RX3, RX_212-214).

The use of Rozol Pocket Gopher Bait to control black-tailed prairie dogs was permitted in accordance with FIFRA section 2(ee), which allows the use of a registered pesticide against an unregistered pest under some circumstances. 7 U.S.C. § 136(ee). In 2006, however, EPA requested that the label be modified so that its use was limited to "Pocket Gophers Only." (RX3, RX_212-214).

In order to fulfill the need of its constituents to control black-tailed prairie dog populations, the State of Kansas requested that Respondent submit an application to it under section 24(c) of FIFRA so that Rozol Pocket Gopher Bait could again be used to control black-tailed prairie dogs in Kansas. (Schmit Tr. 18:9-20:25). Respondent complied with that request and obtained a Kansas special local need ("SLN") registration and several other state-issued SLN registrations in this manner. (CX 2.b, EPA 12; CX 3.b., EPA 28-29; CX 4.b., EPA 36). All of the state-issued SLN labels classified the use of Rozol Pocket Gopher Bait to control black-tailed prairie dogs as restricted use despite the fact that the "parent" product (Rozol Pocket Gopher Bait, EPA Reg. No. 7173-184) was a general use pesticide. (*Id.*). According to Mr. Schmit, he suggested to the Kansas Department of Agriculture that the SLN be classified as restricted use because EPA generally requires field uses of pesticides to be classified as such. (Schmit Tr. 22:21-23:10).

About the same time that Respondent obtained its initial state issued SLN registrations permitting the use of the -184 pocket gopher bait product for the control of black-tailed prairie dogs, Respondent obtained a federal registration under FIFRA section 3 for Rozol Pocket Gopher Bait II, EPA Reg. No. 7173-244. (RX 2). Essentially, the -244 registration was the same as the -184 registration, except that it allowed Rozol to

be applied for the control of pocket gophers using a mechanical apparatus called a "burrow builder." (Schmit Tr. 24:16-18, 36:13-18; RX 2). As a result of the "burrow-builder" method of application, the -244 product was registered as a restricted use pesticide. (Schmit Tr. 37:17-38:12). Once the -244 registration was obtained, in order to avoid any confusion that could be caused by a restricted use SLN label being attached to a general use parent product, all of the prior SLN registrations were voluntarily modified to include the -244 product as the parent label. (*Id.* at 25:9-13).

As a result, during calendar years 2007 and 2008, Rozol Pocket Gopher Bait II, EPA Reg. No. 7173-244, was registered under the authority of section 24(c) of FIFRA to control black-tailed prairie dogs pursuant to SLN labels issued by the states of Kansas, Nebraska, Wyoming, Colorado, Texas and Oklahoma. (Joint Stips. 2; CX 2-7).

Due to the expanded use of the -244 product to control black-tailed prairie dogs under state SLN labels, Respondent applied for and was granted a federal registration by EPA under FIFRA section 3 for Rozol Prairie Dog Bait, EPA Reg. No. 7173-286. (Schmit Tr. 26:12-27:3; RX 1). Upon granting by EPA of the FIFRA section 3 registration on May 13, 2009, Respondent voluntarily cancelled the SLN registrations. (CX 108, EPA 2511-13). As the "Rozol" products evolved over time, Respondent showed its good stewardship by committing to hold informational meetings for potential users, some of which even met state continuing education requirements. (Schmit Tr. 13:13-15:14).

Importantly, the general use -184 product is exactly the same formulation as the -244 and -286 restricted use Rozol products. (*See* RX1, RX_140; RX 2.h., RX_188; RX3.g., RX_219 (indicating that Rozol is .005% of active ingredient chlorophacinone);

*see also* Hebert Tr. 133:19 ("the formulations are identical")). The only difference between the products is the method of application and the label. (Hebert Tr. 133:24-134:1).

B. The Pesticide Registration Process.

In connection with the registration of its pesticide products, both for registration under FIFRA section 3 (a "national" registration) and FIFRA section 24(c) (a "state specific" registration), Respondent submitted volumes of efficacy and toxicity data that was taken into account by EPA and individual states first in determining whether or not to register the products, but then in determining what, if any, mitigation measures might be necessary to make certain that, when used in accordance with the label, the product would not cause unreasonable adverse risk to human health and the environment. (*See, e.g.,* RX 1, RX_110-114).

By their very nature, pesticides may have inherent risks and EPA's Office of Pesticide Programs ("OPP") accounts for those risks as part of the registration process. (Hebert Tr. 134:23-135:6, 138:13-16). According to Mr. Hebert, in connection with the FIFRA section 3 registration of Rozol Prairie Dog Bait, OPP took into consideration publicly available documents like the EPA's "potential risks of nine rodenticides to birds and non-target mammals" (RX 12), the 2007 study conducted by Charles Lee (RX 10), and the other studies included on the data matrix submitted for the product in determining whether the product should be registered and what mitigation measures should be imposed on the label. (*See* Hebert. Tr. 135:7-21, 139:17-25, 141:4-148:24).

In contrast to a registration under FIFRA section 3, EPA's role in the FIFRA section 24(c) registration process is more limited. (Hebert. Tr. 141:15-17 ("We don't

register SLNs. We are given an opportunity to comment on the registration...")). As a result, in connection with SLN registrations, Respondent submitted its application and supporting documents directly to the relevant state regulators for a determination of whether the product should be registered. (*See* RX 4.a., 5.a., 6.a., 7.a., 8.a., 9.a.).

C. Rozol Product Information.

Prior to the time the -244 product was registered, only a handful of Respondent's products were classified as restricted use pesticides and of those pesticides that were classified for restricted use, Respondent didn't develop any product advertising. (Schmit Tr. 62:6-64:2). In fact, Respondent produced "very, very little or no advertising of ... field rodent control products." (*Id.* at 64:7-10).

After obtaining the SLN registrations for Rozol, however, Respondent's marketing department created four (4) versions of 30- and 60-second radio broadcasts and essentially two versions of print advertisements – a depiction to be printed in niche stockmen's and cattlemen's journals and a smaller "classified" type ad. (*See, e.g.*, CX 42-45, CX 14a, EPA 286-330). Respondent's radio broadcasts were aired on four different radio stations or radio station conglomerates. (*See* Compl.'s Posthrg. Br. 6-7). Respondent's print advertisements were included in six different niche publications. (*Id.* at 7-8).

While each of the radio scripts directed the listener to "ALWAYS FOLLOW AND READ LABEL DIRECTIONS," the advertisements inadvertently failed to include the words "restricted use pesticide." (CX 14a, EPA 361-362). Unfortunately, the advertisements were not reviewed for compliance and were aired or printed multiple times (Schmit Tr. 67:2-3). Promptly after being notified of the problem with its radio and

print ads, however, Respondent instituted a formal requirement and process so that all product literature and advertisements are now reviewed for compliance. (*Id.* at 68:8-25). As confirmed by Ms. Claudia Niess at the hearing, no further violation of FIFRA section 12(a)(2)(E) occurred following issuance of the initial SSURO. (Niess. Tr. 210:23-211:4; *see also* CX 28, EPA 512 (an example page from Respondent's website noting that Rozol is a restricted use pesticide)). In fact, Respondent's print and radio advertisements ended no later than April 26, 2008 – over a month prior to the date the initial SSURO was provided to Respondent. (*See* CX 14a, EPA 285-360; CX 46-49).

In addition to the radio broadcasts and print advertisements published in trade journals, Respondent prepared a direct mail package which was distributed in November of 2007. (CX 14a, EPA 150). The direct mail package included a two-page cover letter, a "Black-tailed Prairie Dog Control-Research Bulletin" (the "Research Bulletin"), a copy of the state specific FIFRA section 24(c) supplemental SLN label and a brochure. *Id.* In 2009 and 2010, according to the Complaint, Respondent also made certain product information available on its website. (CX 28).

In determining whether or not the information contained in this product information was acceptable, Mr. Schmit examined the material to determine (1) if the literature contradicted the product label and (2) whether it was supported by a study Respondent conducted, peer-reviewed public literature or documents published by the EPA. (Schmit Tr. 72:17-74:3).

D. EPA's Enforcement Action.

On June 2, 2008, Respondent received a Stop Sale, Use or Removal Order ("SSURO") in connection with the advertisement of a pesticide without giving the

classification of the product assigned to it in violation of FIFRA section 12(a)(2)(E). (CX 14a, EPA 140-145). Prior to June 2, 2008 no one from the EPA or any state agency contacted Respondent to alert it that its radio broadcasts and print advertisements may be in violation of FIFRA. (Schmit Tr. 189:25-190:8). Shawn E. Rich, an inspector for the Kansas Department of Agriculture, however, was made aware of the problem as early as November 21, 2007 by way of a statement he received from John Jenkinson of Rocking M Radio. (CX 8, EPA 67). In addition to receiving a transcript of the broadcast, Mr. Rich received a statement from Mr. Jenkinson that contained the following contact information for Respondent: "Charles Hathaway, 3600 W. Elm Street, Milwaukee, WI 53209." (*Id.*). In addition, Shawn Hackett was copied on an e-mail between radio personnel indicating that radio broadcasts were continuing to be run, but failed to notify Respondent of the issue. (*Id.* at EPA 72).

This information, including the contact information for Charles Hathaway and notification that the advertisements were continuing to be run, was referred to EPA Region 5 on January 10, 2008. (CX 8, EPA 59). Despite receiving the contact information for Charles Hathaway and notice of the problematic advertising in January 2008, EPA Region 5 did not request that the Wisconsin Department of Agriculture, Trade and Consumer Protection ("DATCP") issue a SSURO to Respondent until April 15, 2008. (CX 13, EPA 119). DATCP then did not issue the SSURO to Respondent until June 2, 2008. (CX 14a, EPA 140-145). While the Kansas Department of Agriculture and EPA Region 5 failed to notify Respondent of the problematic advertisements, hundreds of the violations which form the basis of Counts 1-2,140 occurred. (*See* CX 14a, EPA 285-360).

When the issue of potentially "substantially different/false and misleading" claims was brought to Respondent's attention in 2008, Respondent immediately cooperated with investigators by taking action to remove from the marketplace all product information Complainant had deemed to be in violation of FIFRA (Schmit Tr. 190:21-192:14; Niess Tr. 211:21-212:3). One of the all-inclusive actions Respondent took was to send a letter to its distributors advising them that all literature they may have access to regarding Rozol Prairie Dog Bait must be destroyed. (CX 17, EPA 371, 407).

EPA's initial SSURO was amended on August 22, 2008. (CX 21, EPA 436). Following issuance of the amended SSURO and the actions which Respondent took to ensure it was compliant with FIFRA, Complainant sent Respondent a Notice of Intent To File an Administrative Complaint on September 18, 2009, proposing a penalty of $1,280,500. (CX 24). In subsequent correspondence to Respondent's counsel dated October 2, 2009, Complainant explained that this penalty was based upon 148 alleged violations of FIFRA section 12(a)(2)(E) and 42 alleged violations of FIFRA section 12(a)(1)(B). (RX 39).

From November 18, 2009 to February 23, 2010, Ms. Niess of EPA Region 5 reviewed Respondent's website and identified additional materials that she believed were in violation of FIFRA section 12(a)(1)(B). (Niess Tr. 68:18-21, 68:25-69:2). Despite reviewing the website on November 18, 2009 and having sent Respondent a Notice of Intent to File an Administrative Complaint on September 18, 2009, Complainant did not alert Respondent to the alleged violations until sometime later and then only at the time Complainant informed Responding that it was issuing another SSURO. (CX 32, EPA 598-606). As it did in response to the earlier SSURO, Respondent immediately

took action to stop the sale of its product and, out of an abundance of caution, sent 48 distributors a letter to destroy/discard any literature, flyers and advertisements they may have had in their possession regarding Rozol. (CX 53, EPA 996-97). Respondent also undertook efforts to remove any product advertising material from its website. Ms. Niess confirmed at the hearing that Respondent promptly responded to each SSURO, cooperated with EPA enforcement and promptly took action to remove access to all product information deemed to be in violation of FIFRA. (Niess Tr. 211:21-212:3).

## V. BURDEN OF PROOF

### A. Standard.

"The complainant has the burdens of presentation and persuasion that the violation occurred as set forth in the complaint and that the relief sought is appropriate." 40 C.F.R. § 22.24(a). "The complainant must meet its burden by a preponderance of the evidence." *Id.* at § 22.24(b).

The term "burden of proof" encompasses two separate concepts. *In re Sandoz, Inc.*, 2 E.A.D. 324, 1987 WL 109662, at 7 n. 23 (EAB 1987). First, as a procedural matter, the complainant has the burden of going forward with the evidence by making out an affirmative case in favor of its position, which may be rebutted by the opposing party. *Id.* Second, the complainant has the burden of persuasion, which, as a matter of substantive law, always remains the burden of the complainant. *Id.*

While the complainant may, in some circumstances, meet its burden of going forward with the evidence by way of hypothetical or circumstantial proof, such evidence will in many cases fail to meet complainant's burden of persuasion. *Id.* at 7 (holding that under the circumstances of that case, complainant's presentation of a hypothetical

estimation regarding the benefit of non-compliance failed to meet its burden of persuasion); *In re L&C Servs., Inc.*, Docket No. VII-93-CAA-112, 1997 EPA ALJ LEXIS 113 (concluding that the failure to provide direct evidence was fatal to complainant's case). Importantly, the responding party bears no affirmative obligation to present evidence to rebut the complainant's position. *Sandoz*, 1987 WL 104662 at 7 n. 25 (stating "[a]lso disturbing is EPA's apparent belief that [the respondent], being in possession of the facts and in the best position to provide them, somehow has the burden of proof").

Where the Complainant requests the Chief Judge to draw an unsupported inference, the Complainant must nevertheless provide enough facts and circumstances to the trier of fact to establish with reasonable certainty the truth of the inference contended for. *Ford Motor Co. v. Mondragon*, 271 F.2d 342, 345 (9th Cir. 1959). "If the proven facts give equal support to each of two inconsistent inferences, then judgment must go against the party upon whom rests the necessity of sustaining one of these inferences. The essential inference cannot be left to conjecture and speculation." *Id.*

B. Complainant's Speculation Fails to Satisfy Its Burden of Proof.

As anticipated by counsel for Respondent in its opening argument at hearing, Complainant has failed to offer probative evidence on several key elements of FIFRA liability and has failed to meet its burden to show that the enormous penalty sought by it is appropriate. (Niess Tr. 17:18-23:25). Instead of conducting further investigation to support its case theory, Complainant resorts to speculation and asks the finder-of-fact to draw a number of unsupported inferences.

First, for purposes of Counts 2,184-2,231, Complainant asserts that liability should be found because Respondent's website allegedly is an offer to sell Rozol and that somehow 48 offers to sell were made because there is "circumstantial evidence showing that Respondent disseminated the New Slim Jim to a target audience of cattlemen, landowners, and farmers." (Compl.'s Posthrg. Br. at, 79-80).[4] Complainant could have easily conducted an investigation to determine whether any of these 48 distributors either actually viewed Respondent's website or received product literature from Respondent, but Complainant did not do so. Without such an investigation regarding Respondent's website, Complainant has offered no evidence supporting its allegation that 48 offers to sell Rozol were made as a result of the content on the website.

Second, for purposes of Counts 2,141-2,183, Complainant suggests that the appropriate "nexus" between Respondent's product literature and broadcasts, on the one hand, and shipments of the product, on the other hand, exists without providing any evidence that any of the persons who received shipments of Rozol ever received Respondent's product literature or listened to Respondent's radio broadcasts at any time (much less prior to the time the product was shipped to them). (*Id.* at 74-79). Complainant was provided both the names of Respondent's distributors (and names of specific contacts at those distributors) who received shipments of Rozol and who were authorized by Respondent to distribute Rozol Prairie Dog Bait SLNs (CX 17, EPA 378; CX 23). Complainant could also have investigated whether any of these parties received and read Respondent's product literature or listened to Respondent's radio broadcasts

[4] Importantly, Complainant asserts that Respondent's website was an offer to sell, but then bases the unit of violation on 48 theoretical mailings (in hard copy) of the same literature that was found on the website, (footnote continued)

prior to ordering Rozol by simply contacting these parties. Complainant apparently did not do so and as a result cannot establish any nexus between Respondent's product information and shipment of the product.

Third, with respect to the huge penalty proposed, Complainant failed to provide any evidence of any actual or potential harm resulting from the alleged FIFRA advertising violations. Instead, Complainant asserts that its proposed penalty is appropriate because "the violations subject to this enforcement action could result in unknown or potential serious or widespread harm." (CX 55.a., EPA 1010). Such speculative "unknown" harm cannot support a penalty when Complainant could have taken steps to establish whether any actual harm occurred.

As suggested by Respondent's counsel in opening argument at the hearing, there are three alternative inferences that can be drawn from EPA's failure to present this crucial evidence: (1) Complainant didn't conduct such investigations; (2) Complainant conducted the investigations and didn't like the results; or (3) Complainant conducted the investigations and withheld the results with the intent to ambush Respondent at hearing. (Niess. Tr. 22:15-24). Because Complainant failed to present any relevant evidence regarding its investigations at the hearing, Complainant's approach can only be explained by its failure to conduct such investigations or its failure to disclose the results. In any event, Complainant should not be rewarded for its failure to gather the information required to affirmatively prove a violation by allowing it to draw unsupported factual

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without providing any evidence that Respondent ever sent the literature in hard copy or that anyone ever actually received this literature or viewed the website. (Compl.'s Posthrg. Br. 19, 24, 26, 77-80.)

inferences, particularly when EPA has gathered similar information in past enforcement cases to support its position.

For example, in the case of *In re Behnke Lubricants, Inc.*, Docket No. FIFRA-05-2007-0025, 2008 EPA ALJ LEXIS 42, in which lead counsel for the EPA was Ms. Nidhi O'Meara, the EPA conducted field investigations in order to confirm that customers received and relied upon Behnke's labeling and advertising claims in purchasing the product at issue. In its post-hearing brief in *Behnke*, which can be found by searching on-line at http://yosemite.epa.gov/oa/rhc/epaadmin.nsf, the EPA described the level of investigation put forth in that case, which involved a proposed penalty of approximately $50,000. The EPA's field investigators not only conducted internet searches like the ones performed in the present case, but they also gathered the following type of information:

1. "On March 7 and 8, 2008, U.S. EPA conducted numerous follow-up investigations at facilities owned by some of Behnke's customers . . . . The purpose of these follow-up investigations was to verify that Behnke was making the labeling and advertising claims that were discovered at the Behnke facility on August 3, 2006 to [Behnke's] customers." (Compl.'s Posthrg. Br., *In re Behnke Lubricants, Inc.*, Docket No. FIFRA-05-2007-0025 at 16).

2. "On March 8, 2007 U.S. EPA conducted an investigation at American. . . . During that investigation Mr. Josh Rybicki of American gave the U.S. EPA inspector, Mr. Terrence Bonace, copies of purchase orders showing that American had ordered [the Behnke product] . . . . After the investigation, Mr. Rybicki sent Mr. Bonace three separate pieces of literature that American had received from

Behnke. . . . . Mr. Rybicki confirmed at the time of the hearing that he had received all three pieces of advertising literature from Behnke." (*Id.* at 16, 18, 19).

3. Mr. Rybicki testified at the hearing that he also relied upon this advertising literature to purchase Respondent's product. (*Id.* at 74-75).

4. Mr. Rybicki also testified at the hearing that he was never told by Behnke to "redact, destroy, or replace any of the advertising literature that Behnke had previously given to American." (*Id.* at 75).

In *Behnke*, the EPA conducted investigations at the facilities of distributors of the respondent's products, collected advertising from these distributors to establish they had received it and had at least one distributor testify at the hearing that he was induced to purchase Behnke's products based on the violative advertising.

In contrast, in the present case, Complainant only speculates about who received Respondent's product literature and asks the Chief Judge to infer both that literature was received prior to the distribution of Rozol to these parties in 2007-2008 and that literature was received by certain parties in 2009 and 2010.[5] Under the facts of this case, the inferences upon which Complainant's case rests cannot support a finding of liability for Counts 2,141-2,231 or support the unprecedented penalty demanded.

[5] Again, it is worth noting that while Counts 2,184-2,231 are based on Respondent's website, the unit of violation is based upon 48 theoretical distributions of the same literature found on the website.

VI. COMPLAINANT CANNOT ESTABLISH THAT RESPONDENT MADE CLAIMS AS PART OF THE SALE OR DISTRIBUTION OF ROZOL UNDER FIFRA § 12(A)(1)(B) THAT SUBSTANTIALLY DIFFER FROM THE STATEMENT REQUIRED AS ALLEGED IN COUNTS 2,141 THROUGH 2,231

A. Elements of Proof Under FIFRA § 12(a)(1)(B).

FIFRA section 12(a)(1)(B) provides that it is unlawful for any person in any state to distribute or sell to any person 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 FIFRA section 3. 7 U.S.C. § 136j(a)(1)(B). The Environmental Appeals Board ("EAB") articulated that the elements Complainant must prove to establish a violation of FIFRA section 12(a)(1)(B) are four-fold:

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

*In re Microban Prods. Co.*, 11 E.A.D. 425, 2004 WL 1658591, at 13 (EAB 2004) ("*Microban II*") (quoting *In re Microban Prods. Co.*, 9 E.A.D. 674 2001 WL 221611, at 11 (EAB 2001) ("*Microban I*").[6]

[6] In various briefs, Complainant has listed four or five elements required to establish liability under FIFRA section 12(a)(1)(B). (*See* Compl.'s Posthrg. Br. 15).

Complainant has alleged that Respondent violated FIFRA section 12(a)(1)(B) in two discrete time periods. First, Complainant alleged in Counts 2,141-2,183 that Respondent violated FIFRA section 12(a)(1)(B) by *shipping* Rozol Prairie Dog Bait on 43 occasions between October 1, 2007 and May 30, 2008. Second, Complainant alleged in Counts 2,184-2,231 that Respondent violated FIFRA section 12(a)(1)(B) by offering Rozol for sale on its website between November 18, 2009 and February 23, 2010.

For each set of alleged FIFRA violations, the disputed elements are the third and fourth elements articulated by the EAB in *Microban II*, namely: (a) whether Rozol was distributed or sold within the meaning of FIFRA; and (b) whether claims were made for Rozol as part of its distribution or sale that substantially differ from any claims made for it as part of the statement required in connection with its registration. In order to satisfy this last element, however, it must be affirmatively concluded that claims were made for Rozol by the Respondent, that such claims were made as part of the sale or distribution of Rozol and that such claims were substantially different from any claims made for Rozol as part of the statement required in connection with the registration for Rozol. Each of these disputed elements is reviewed in greater detail below.

B. Distribution or Sale.

"[T]o distribute or sell" is defined by FIFRA section 2(gg) as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver." 7 U.S.C. § 136(gg). The definition of "to distribute or sell" includes grammatical variations of these words. 40 C.F.R. § 152.3. Critically, even if the other elements of FIFRA section 12(a)(1)(B) are met, if no distribution or sale occurred, no

violation may be found. *Microban I*, 2001 WL 221611 at 10 ("Clearly, if the additional elements of paragraph (B) are met, but no distribution or sale of a registered pesticide occurred, Pesticide Enforcement could not prove a violation and a presiding officer could not conclude that the section had been violated.").

1. Distribution or sale – Counts 2,141-2,183. As noted above, for purposes of proving a violation of FIFRA section 12(a)(1)(B) as alleged in Counts 2,141-2,183, Complainant bases the "unit of violation" on 43 physical shipments of Rozol, including two shipments to employees of Respondent.

According to Counts 2,144 and 2,178 of the Complaint, Respondent sold Rozol to Jim Knuth and Mark Newman. Both individuals are employees of Respondent. (Schmit Tr. 204:23-205:17). Because internal operations of a corporate enterprise, with dispersed employees, must be judged as the conduct of a single actor, product transfers to employees of Respondent may not form the basis of a violation of FIFRA section 12(a)(1)(B). *See, e.g., Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 770 (1984).

Despite Complainant's argument to the contrary, a careful review of *In re Sultan Chemists, Inc.* confirms that the administrative law judge's decision in that case was driven, in part, based upon the respondent's failure to cite to the record to support its position that the individuals who received the product were Sultan's salespeople. *In re Sultan Chemists, Inc.*, Docket No. FIFRA-95-H-05, 1999 EPA ALJ LEXIS 46, at *10. In addition, there is no discussion of whether or not shipments of the product at issue in *Sultan* were to actual employees of Sultan's or to independent

contractors. Shipments to independent contractors would be more likely to fall within the scope of conduct subject to FIFRA section 12(a)(1)(B).

In the instant case, the two shipments of Rozol were made at the request of Respondent's employees. Even if such product transfers were to constitute "sales or distributions" for purposes of FIFRA section 12(a)(1)(B), which they do not, Complainant has failed to show that the requisite "nexus" existed between such transfers and any substantially different claim made by Respondent.

2. Distribution or sale – Counts 2,184-2,231. At the hearing, Ms. Niess, a key witness of Complainant, confirmed that Complainant does not allege that Rozol was physically sold or distributed for purposes of Counts 2,184-2,231:

> Q. Let's talk now about '09 to '10 counts. Now, for that period, you don't actually allege that there were actual sales or distributions of Rozol, rather, you say, Liphatech made offers to sell on [its] website. And that substantially different claims were made as part of the offers to sell, correct?
>
> A. Correct.
>
> . . .
>
> Q. Okay. So let's reask that question. Your allegations -- Do you allege that Liphatech made any actual sale of Rozol to any of the 48 distributors during the '09 to '10 time period?
>
> A. Not in the complaint, no.

(Niess Tr. 170:5-12, 172:3-7).

As a result, if Respondent's website is not an offer for sale under FIFRA, no violation of FIFRA section 12(a)(1)(B) can be found as alleged in Counts 2,184-2,231 of the Complaint. In fact, Respondent's website is not such an offer for sale.

The term "offer for sale" is not defined in FIFRA or any of its regulations and no legislative history provides guidance in this area. *In re Tifa Ltd.*, 2000 WL 739401, at *9. As Ms. Niess confirmed at the hearing, EPA has not issued any guidance as to what constitutes an "offer for sale:"

> THE COURT: And have you been provided any guidance by OPP or the enforcement attorneys on what an offer to sell is?
>
> THE WITNESS: I would say no formal guidance, and not in terms of advertisements.
>
> THE COURT: I am not talking in this particular case, I am talking about generally.
>
> THE WITNESS: Right. I can't think of anything right now. But certainly I haven't seen anything formal.

(Niess Tr. 240:18-241:2).

In *Tifa*, the EAB was asked to determine whether a pesticide manufacturer and distributor violated an EPA suspension order by offering its pesticide product for sale when it sent a facsimile to a potential customer stating the following: "Reference your telephone inquiry of yesterday afternoon regarding Rotenone. We are pleased to confirm our prices as follows." *Id.* In addition, the facsimile in *Tifa* stated, "Prices are all delivered Missouri. Material in stock available prompt shipment." *Id.*

In effect, the complainant in *Tifa* alleged that submitting a price list to a prospective customer and stating that the product was available in response to the

prospective customer's request for information about the pesticide constituted an "offer for sale" under FIFRA. *Id.*

Following an extensive analysis of contract law, including relevant cases and treatises, the EAB concluded in *Tifa* that "an offer must be definite and certain, and must be made under circumstances evidencing the express or implied intent of the offeror that its acceptance shall constitute a binding contract." *Id.* (internal citation omitted).

According to the EAB in *Tifa,* an offer to sell must be sufficiently certain such that all the recipient needs to do is accept an order to create a binding contract. *Id.* While prices are a fundamental component of an offer to sell, under the circumstances of that case, the EAB concluded in *Tifa* that sending a published price list to a potential purchaser of the product and stating the product was available did not constitute an offer for sale and, therefore, no violation of FIFRA occurred. *Id.*

a. Respondent's website does not constitute an "offer for sale" under *Tifa.* In order to determine whether Respondent's website rises to the level of an offer for sale for purposes of Counts 2,184-2,231, the evidence presented by Complainant must be examined in light of the EAB's interpretation of the statutory term in *Tifa.* Under the EAB's holding in *Tifa,* in order for an offer to sell to occur, a prospective buyer and seller must interact and exchange information at a level of detail which only requires the prospective buyer to say "yes" in order to create a binding contract. Analysis of Complainant's allegations and evidence in this case can only lead to the conclusion that no "offer to sell" Rozol was made on Respondent's website. As a result, no sale or distribution of Rozol occurred as alleged in Counts 2,184-2,231. Therefore, these counts must be dismissed. *See Microban I,* 2001 WL 221611 at 10 ("Clearly, if the additional

elements of paragraph (B) are met, but no distribution or sale of a registered pesticide occurred, Pesticide Enforcement could not prove a violation and a presiding officer could not conclude that the section had been violated.").

Ms. Niess' hearing testimony confirmed that Respondent's website did not contain product pricing information or any other relevant terms and conditions of sale:

> Q. Do you have – There's no evidence that any of the individuals associated with a particular distributor organization ever went to Liphatech's website, correct?
>
> A. Correct.
>
> Q. There's no evidence that Liphatech ever distributed a price list or the terms and conditions under which it would sell Rozol via the website; isn't that correct?
>
> A. Correct.
>
> Q. Therefore, those terms and conditions on the website are not available to the general public, correct?
>
> A. Correct.
>
> Q. Or anyone visiting the website for that matter, correct?
>
> A. I have not come across them.
>
> Q. There's no price list on Liphatech's website, correct?
>
> A. Correct. Not that I have seen.
>
> Q. There's no terms and conditions of sale of Rozol on Liphatech's website; isn't that correct?
>
> A. Correct.

(Niess Tr. 172:18-173:16).

Despite this critical void, Complainant goes on to assert that Respondent's website is identical to the situation where a pesticide sits on a store shelf waiting to be sold because the website allegedly is a "virtual shelf." (Compl.'s Posthrg. Br. 24). Complainant theorizes that, because a pesticide sitting on a store shelf may be an "offer for sale," the literature "sitting" on Respondent's website must also constitute an "offer for sale." This analogy simply does not work.

When a person goes into a store to purchases a pesticide, all the person needs to do is grasp the pesticide package, which is invariably marked to show the price at which it is offered, proceed to the checkout counter and pay for the product. Consequently, when a person grasps the pesticide package, he or she knows the price of the pesticide and is able to purchase it by paying that price.

On the other hand, Respondent's website is a passive website that does not contain product pricing information or any other relevant terms and conditions of sale. By its nature, a passive website cannot constitute an "offer for sale," because nothing can be purchased through such a website. The U.S. Sixth Circuit Court of Appeals has observed: "There are generally three levels of interactivity of websites, including: (1) passive sites that only offer information for the user to access; (2) active sites that clearly transact business and/or form contracts; and (3) hybrid or interactive sites that allow users to exchange information with the host computer." *See Inc. v. Imago Eyewear Party, Ltd.*, 167 F. App'x. 518, 522 (6th Cir. 2006). Respondent's website is of the least interactive type – it only offers information for the user to access.

Consequently, Complainant's purported analogy that Respondent's website is identical to a pesticide sitting on a store shelf ready for purchase is inherently flawed.[7]

Apparently realizing that Respondent's website does not constitute an "offer for sale," Complainant then attempts to bolster its argument by alleging that the same information that was available on Respondent's website in 2009 and 2010 was sent in "hard copy" to 48 distributors. (Compl.'s Posthrg. Br. 79-80). This argument fails for two reasons: (1) even if sent in hard copy, the literature still does not constitute an offer for sale under *Tifa*; and (2) Complainant has not established that any product literature

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[7] The following exchange between Complainant's counsel and the Chief Judge at the hearing confirms this:

> MS. O'MEARA: . . . That in and of itself, if it's sitting there, that's an offer for sale, okay. We don't call that a shipment. We don't call it distribution, just the fact that it sits on that shelf and is waiting to be bought is a violation. It's the same—
>
> THE COURT: If it sits there?
>
> MS. O'MEARA: Right.
>
> THE COURT: With a price, and the opportunity to take it off and take it to a salesperson is very different from the web.
>
> MS. O'MEARA: I would agree with that.
>
> THE COURT: And their website is very different from something like Amazon where, you know, one click and you buy something.
>
> MS. O'MEARA: I would agree with that as well, but with the internet progressing as it has over the years, it's like sitting on a virtual shelf. Anybody who gets the ads and says I want to give this 286 product a try, you just have to call Mark Newman or Tim Knuth and ask to buy it.
>
> THE COURT: Not anybody, a certified applicator.
>
> MS. O'MEARA: You are correct, and that's probably why there isn't a price list on the website, is because it isn't open to everybody.
>
> *****

(Steeger Tr. 117:2-118:2).

was ever sent to any of the 48 distributors. Instead, Complainant infers that the literature must have been sent because Respondent, in response to the second SSURO it received from EPA, sent a letter to its distributors requesting that they destroy certain literature if they had access to it. (CX 53). Respondent's response to the second SSURO was meant to be all-inclusive and does not in any way establish which distributors received what product information, when they may have received it or whether they ever read it or took action based on it.

In conclusion, the product information found on Respondent's website in the years 2009 and 2010 was not an offer to sell pursuant to the definition set forth by the EAB in *Tifa* and therefore Counts 2,184-2,231 must be dismissed because Complainant has failed to meet its burden to show that a sale or distribution occurred during such time period.

b. Complainant misinterprets and misapplies 40 C.F.R. § 168.22. Despite the binding precedent set forth in *Tifa*, Complainant suggests that the EAB's analysis must be disregarded because EPA's interpretive rule set forth at 40 C.F.R. § 168.22 (which was in effect at the time *Tifa* was decided by the EAB) somehow controls the definition of "offer to sell" under FIFRA section 12(a)(1)(B). Interpretive rules, themselves, however, are non-binding. *Vietnam Veterans of Am. v. Sec'y of the Navy*, 843 F.2d 528, 537 (D.C. Cir. 1988) (interpretive rules do not have binding effect). Moreover, Complainant's argument misses the mark.

First, Complainant misinterprets 40 C.F.R. § 168.22. Complainant asserts that section 168.22 should be read to confirm that any pesticide advertisement that is available to the general public automatically rises to the level of an "offer for sale" and

therefore a "distribution or sale" under FIFRA section 12(a)(1)(B). However, even assuming "that section 168.22 applies to Rozol and the claims that Respondent made, the language of the regulation does not unambiguously extend the definition of 'distribution or sale' to *mean* all forms of advertising. Rather, it states that EPA 'interprets these provisions as extending to all advertisements.'" (6/24/11 Order 27). "This does not mean that EPA interprets section 12(a)(1)(B) to define advertising as the equivalent of 'offer for sale.'" (*Id.*).

In fact, Ms. Niess confirmed at the hearing that the term "offer for sale" is, at most, a subset of advertising, which undercuts Complainant's attempt to equate all advertising that is available to the general public with the term "offer for sale" under FIFRA section 12(a)(1):

> THE COURT: Okay, now, you would agree with me that an offer to sell would be a subset of advertising in general?
>
> THE WITNESS: Yes.

(Niess Tr. 239:16-19).

Complainant's interpretation of 40 C.F.R. § 168.22 would effectively replace the word "advertising" for the words "offer for sale" within the statutory definition of "sale or distribution" in section 136(gg) of FIFRA. If Congress had intended section 12(a)(1) of FIFRA to extend to all advertising, rather than only a subset of advertising – an offer for sale – it could have easily done so. Rather, Congress's use of the word advertising in one other section of FIFRA but omission of the word "advertising" from the definition of "to sell or distribute" suggests that Congress did not

intend for EPA's authority to extend to all advertising. *See e.g.* FIFRA § 12(a)(2)(E) (making it a violation to *advertise* a pesticide without providing its classification).

Second, even if Complainant was correct in asserting that for purposes of 40 C.F.R. § 168.22, EPA interprets all advertisements available to the general public to be offers for sale, that section is specifically limited to five types of situations and pesticides, none of which are alleged in this case.[8] Nothing in 40 C.F.R. § 168.22 or in the proposed rule suggests that it was intended to apply to all pesticide advertising.

Even a cursory examination of the title of 40 C.F.R. § 168.22 readily reveals that the primary purpose of this interpretive regulation is to control advertising for five different types of pesticides and situations, and its scope is limited to the following:

- Any pesticide for a use under a FIFRA section 5 experimental use permit;
- Any pesticide for a use authorized under a FIFRA section 18 emergency exemption;
- Any pesticide for any use authorized only by a FIFRA section 24(c) special local need registration, unless certain notice requirements are met;
- Any unregistered pesticide for any use; and

[8] While in the years 2007 and 2008, several state SLN labels were issued for Rozol Pocket Gopher Bait Burrow Builder Formula, EPA Reg. No. 7173-244, all of the alleged violations set forth in Counts 2,184-2,231 relate to the federally registered Rozol Prairie Dog Bait, EPA Reg. No. 7173-286, and Rozol Pocket Gopher Bait, EPA Reg. No. 7173-244, during the 2009 and 2010 time period. This analysis may also explain the EAB's failure to address 40 C.F.R. § 168.22 in its opinion in *Tifa*. *Tifa* did not involve the offer for sale of a pesticide that fell within any of the five categories of products or situations described in 40 C.F.R. § 168.22(b) so it was not applicable to the facts of that case.

- A registered pesticide product for an unregistered use.[9]

Going beyond the title of 40 C.F.R. § 168.22, nowhere does the proposed or final interpretive rule give any indication that its reach may extend beyond the five situations specifically listed. The background information published in the Federal Register regarding the purpose of 40 C.F.R. § 168.22 supports a narrow interpretation of that section:

> EPA proposes to treat as unlawful under FIFRA Section 12 the advertising of [1] any pesticide for a use authorized under FIFRA Section 5 Experimental Use Permit; [2] any pesticide for uses authorized under a FIFRA Section 18 emergency exemption, . . . ; [3] any pesticide for a use authorized by FIFRA Section 24(c) special local need registration . . .; [4] any other unregistered pesticide . . .; and [5] any registered pesticide for any other use not registered under FIFRA Section 3 or 24(c).

Pesticide Advertising, 51 Fed. Reg. 24393 (proposed July 3, 1986) (to be codified at 40 C.F.R. Pts. 153, 166); s*ee also* Advertising of Unregistered Pesticides, Unregistered Uses of Pesticides and FIFRA Section 24(c) Registrations, 54 Fed. Reg. 1122 (Jan. 11, 1989) (to be codified at 40 C.F.R. Pts. 166, 168).[10]

c. FIFRA does not grant EPA plenary authority to regulate advertising. Complainant's interpretation of the scope of 40 C.F.R. § 168.22 is an unlawful attempt to extend the EPA's authority beyond that granted to it by Congress and beyond what the EPA itself originally intended. In fact, EPA acknowledged that its

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[9] The regulation exempts some advertisements from coverage under the regulation that are not applicable to the present case. *See* 40 C.F.R. § 168.22(b).

[10] It is noteworthy that EPA received comments on the proposed rule from only nine parties. Not a single comment discussed the scope of 40 C.F.R. § 168.22(a) and whether it applied to all pesticides under EPA's jurisdiction. If the regulated community believed that this provision was intended to expand EPA's jurisdiction to cover all advertising, one would assume that EPA would have received additional comments.

authority was limited by statute when it stated in the proposed rule that the "proposed regulation would address only advertisements that, in EPA's view, make unlawful offers to sell..." 51 Fed. Reg. 24395. Thus, even in drafting this narrow interpretive regulation, the EPA acknowledged that it only applies to advertisements that ultimately constitute "offers to sell."

EPA also acknowledged its limited authority to regulate advertising in a memorandum published by the Office of General Counsel in 1973. According to the memorandum:

> In comparison to the FTC's statutory mandate to regulate false, misleading, or deceptive advertising, EPA's authority to control advertising of pesticide products rests upon a weak (or perhaps non-existent) reed.

Authority to Regulate Advertising of Pesticide Products, 1 Op. Off. Gen. Counsel 439, 1973 WL 21961, at 1 (1973) (hereinafter "1973 OGC Memorandum").[11] In that memorandum, the Office of the General Counsel of EPA discussed two different theories under which EPA might argue that it has authority to regulate pesticide advertising. One is a "claims approach" under FIFRA section 12(a)(1)(B) and the other is a "labeling approach" under FIFRA section 12(a)(1)(E). *Id.* Complainant is attempting to advance the claims approach in this case.

The Office of General Counsel of EPA stated with respect to the claims approach that if claims made for a pesticide as part of the sale or distribution of the pesticide differed substantially from the claims included in the registration statement,

[11] A copy of the EPA's General Counsel's Memorandum is included at RX 78, which was not admitted into evidence at the hearing, but is publicly available.

the EPA could seek sanctions against the manufacturer. *Id.* The Memorandum then stated:

> This provision may apply to "claims" made in advertising. Congress, however, uses the words "distribution or sale" instead of the word "advertising" in Section 12(a)(1)(B). Section 12(a)(2)(E) provides that it is unlawful for any person who is a registrant, wholesaler, dealer, retailer, or other distributor to advertise a pesticide product registered for restricted use without giving its classification. The negative implication of the use of the word "advertising" in one section and not in the other perhaps indicates that the words of art "distribution or sale" should be read more narrowly than advertising in general.

*Id.* The Memorandum concluded:

> Hopefully the upshot of this memorandum will be a refined consideration of the remaining legal questions in a thorough policy consideration of the thorny practice ramifications the various alternatives for regulating pesticide product advertising with or without FTC participation. . . . A coherent regulation would well serve all parties, including the pesticide consumer.

*Id.* at 5. The only regulation that has been adopted by the EPA regarding pesticide advertising following the 1973 Office of General Counsel Memorandum is 40 C.F.R.§ 168.22. The EPA did not, as it could have done and as was suggested in 1973, seek specific legislative authority from Congress to clarify its regulatory jurisdiction over advertising or issue a coherent regulation that would thoroughly explain EPA's authority with respect to advertising. Instead, almost 40 years after the EPA General Counsel's Memorandum was written, Complainant seeks to extend its limited authority to regulate pesticide advertising by radically re-imagining the scope of

40 C.F.R. § 168.22 – a narrowly-drafted 23-year-old interpretative regulation that has never been applied this way in the past.

While Complainant attempts to portray both *Microban II* and *Sporicidin* as supporting its application of 40 C.F.R. § 168.22(a), a careful analysis of those cases reveals that Complainant's assertion is overstated.

In a footnote, without commenting on its validity, enforceability or applicability to the facts of that case, the EAB in *Microban II* acknowledged the existence of 40 C.F.R. § 168.22, but the EAB's statement was not necessary to support its decision. *Microban II*, 2004 WL 1658591, at 16 n.26. Similarly, in *Sporicidin*, the EAB noted the existence of 40 C.F.R. § 168.22 in dicta, but did not clarify or specify its scope and application. *In re Sporicidin*, 3 E.A.D. 589, 1991 WL 155255, at 9 (EAB 1991).[12]

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[12] Complainant's synopsis of *Sporicidin* in its post-hearing brief is an egregious misstatement of that case. In its overzealous effort to penalize Respondent, Complainant alleges that *Sporicidin* acknowledged the existence of 40 C.F.R. § 168.22 and then asserts that *Sporicidin* held

> that "distribution [which includes an offer for sale, 7 USC Section 136(gg)] includes both marketing and merchandising a commodity" and that "merchandising means 'sales promotion as a comprehensive function. . . .

(Compl.'s Posthrg. Br. 23-24). Let's look at what *Sporicidin* actually said. The EAB in *Sporicidin* stated:

> I note, however, that Section 12(a)(1)(B) extends to claims made as part of either the distribution or sale of the pesticide. "Distribution" includes both marketing and merchandising a commodity. [FN 38] Merchandising means "sales promotion as a comprehensive function" and includes "coordination of manufacture and marketing an effective advertising and selling." [FN 39]. I also note that, after issuance Initial Decision, EPA published a rule confirming Agency enforcement personnel interpret the provision in Section 12(a)(1)(B) as extending to "advertisements in any medium to which pesticide users or the general public have access." 40 C.F.R. Section 168.22(a). . . .

*Sporicidin*, 3 E.A.D. at 605. Surely, the above-quoted language cannot be treated as the "holding" of *Sporicidin*, as asserted by Complainant. It is simply dicta.

Complainant's reliance on *Sporicidin* is made even more tenuous based on the presiding officer's initial decision in *Sporicidin*. As noted by the EAB, the presiding officer in the initial *Sporicidin* decision questioned the EPA's claim that it had general authority over pesticide advertising. *In re Sporicidin*, Docket FIFRA 88-H-02 1988 WL 236319 at 8 (ALJ Nov. 1, 1988). In the initial decision in the *Sporicidin* case, the presiding officer stated that the Order it issued on February 22, 1988 concluded that FIFRA (footnote continued)

As a result, no weight should be given to the statements in Complainant's post-hearing brief regarding the application of *Microban II* or *Sporicidin* to the interpretation, application or effectiveness of 40 C.F.R. section 168.22(a) because those cases failed to review or analyze that section.

C. Claims Were Not Made "As Part of" the Distribution or Sale of Rozol.

The FIFRA section 12(a)(1)(B) statutory phrase "as part of" requires that "a nexus exist between the unapproved claims and the distribution or sale of the pesticide." *Microban I*, 2001 WL 221611, at 12.

> While the phrase "as part of" does not require the claims and corresponding sales or distributions to be contemporaneous . . . there nevertheless must be some link between the two actions before they are brought within the ambit of Section 12(a)(1)(B).

(6/24/11 Order 24). As explained in *Sporicidin*, the word "part" is defined by the dictionary as "an integral element" and, therefore, in order for a substantially different

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section 12(a)(1)(B) was not a general proscription on advertising claims for a pesticide. *Id.* at 12. The presiding officer in *Sporicidin* stated that the primary reason for this conclusion was that effect must be given to the qualifying words in FIFRA section (12)(a)(1)(B) "as part of its [the pesticide's] distribution or sale." *Id.* at 13.

In the initial *Sporicidin* decision, the presiding officer rejected EPA's assertion that claims made for a pesticide as part of its distribution or sale encompasses claims made in promotional literature and advertising. *Id.* The EPA in that case argued that the plain meaning of the statute supported its interpretation and even cited to the initial Federal Register which, by that time, had published the proposed rule now set forth at 40 C.F.R. § 168.22. The presiding officer went on to state that he had difficulty with EPA's argument because "part" is defined, *inter alia*, as an "essential portion" or an "integral element" and that:

> [i]t may be questioned whether any advertising, let alone that shown here, is an essential portion or an integral element of the pesticide sales at issue. . . . Moreover, under complainant's view, the statute appears to have the same meaning with or without the phrase "as part of its distribution or sale." . . . . *Id.*

In effect, the presiding officer was of the view in that case, as Respondent contends in this case, that Complainant's position renders the nexus requirement of FIFRA section 12(a)(1)(B) meaningless.

claim to be "as part of" the sale or distribution of the product, the claim must be an integral part of that sale or distribution. *Sporicidin*, 1991 WL 155255, at 7.

In *Microban II*, the EAB determined that, based on the facts and circumstances of that case, a presentation (which contained substantially different claims) made by Microban to Hasbro followed by 32 shipments of the product from Microban to Hasbro was sufficient to show that the substantially different claims made in the presentation were "part of" the subsequent shipments. *Microban II*, 2004 WL 1658591, at 14-17. Importantly, in that case, the EAB "did not consider" a Microban brochure and a Microban fact sheet "as part of" the sale or distribution of the product stating that "there is insufficient evidence in the record establishing when Hasbro received them." *Id.* at 16, 20 ("Shipments made prior to Microban's furnishing these documents to Hasbro obviously cannot be considered as linked to the unapproved claims . . .").

The EAB went on to state in *Microban II* that "without a time frame establishing 'receipt' of the documents containing the unapproved claims, it is possible that Microban sent them to Hasbro after the 32 shipments at issue in this case" and "consequently, there is inadequate evidence to demonstrate that the unapproved claims were linked with the distribution or sale of the pesticide." *Id.* Importantly, the EAB made it clear that the elements of FIFRA section 12(a)(1)(B) must be satisfied with respect to each shipment of the product in order for a violation to be found. *Id.*

As a result, in order to establish a violation of FIFRA section 12(a)(1)(B), the Complainant must prove, by a preponderance of the evidence, that each person to whom the product in question was sold or distributed actually received the literature containing

the substantially different claim prior to the sale or distribution of the product.[13] Here, Complainant failed to establish these critical facts.

1. Counts 2,141-2,183. For purposes of Counts 2,141-2,183, Complainant asserts that a "sufficiently close link" exists between 43 shipments of Rozol by Respondent based on the alleged dissemination of certain direct mail packages and radio broadcasts.

Applying the analysis set forth in *Microban II*, Complainant must show, at a minimum, that each person who received one or more of the shipments of Rozol as alleged in Counts 2,141-2,183 received the shipment following "receipt" of material containing a substantially different claim and that the substantially different claim was an "integral part" of that shipment. No such showing was made by Complainant here.

At the outset, it is important to note that during the 2007 and 2008 time period (the time period in which the alleged violations set forth in Counts 2,141-2,183 occurred), Rozol Pocket Gopher Bait, EPA Reg. 7173-244, was registered under the authority of FIFRA section 24(c) for use to control prairie dogs in certain states. (Joint Stips. 2). As a result, Rozol Pocket Gopher Bait, when used in accordance with a state approved SLN label, could legally be applied to prairie dogs. When Rozol Pocket Gopher Bait was shipped from Respondent's warehouse, there was no way of determining whether the product was ultimately going to be applied on pocket gophers or prairie dogs (the parent product could be used to control pocket gophers in accordance with the

[13] Even if it is shown that the literature was received prior to the sale or distribution, this alone is insufficient to establish the requisite "nexus" under FIFRA section 12(a)(1)(B). There still must be some "link" between the literature and the sale or distribution.

EPA-approved FIFRA section 3 label or if a supplemental special local needs label was provided to the purchaser at the point of sale, the purchaser could use the product to control prairie dogs). (CX 23 (indicating shipment of EPA Reg. No. 7173-244); *see also* Schmit Tr. 23:11-24:13 (ultimate use of the product could have been for use on pocket gophers or prairie dogs). In order to show a violation of FIFRA section 12(a)(1)(B) during the 2007-2008 time period, Complainant would need to show, among other things, that a substantially different claim was made for Rozol Prairie Dog Bait and that the product was purchased for use on black-tailed prairie dogs. Complainant has not shown that any of the 43 shipments made during 2007 and 2008 were intended to be used for the control of prairie dogs or pocket gophers. All of the shipments could have involved use of the product against either pest. Even if Respondent made a substantially different claim about use of the product on prairie dogs, a shipment of the product that was purchased for the control of pocket gophers could not be "linked" to the differing claim.

Furthermore, Complainant has not shown that any person who purchased Rozol ever received Respondent's product literature or listened to one of its radio ads. As an example, Complainant alleges in Count 2,172 that McCoy Farms located at HC 72 Box 1, Crookston, Nebraska 69212 received a shipment of Rozol on March 24, 2008. In order for a violation of FIFRA section 12(a)(1)(B) to be found based on the shipment to McCoy Farms, Complainant must, at a minimum, show that McCoy Farms received the material containing the substantially different claim for a specific pest (pocket gophers or prairie dogs) prior to March 24, 2008 and that the material was an integral part of the shipment for use on that pest. The record in this case is devoid of any such evidence.

In addition, Counts 2,141-2,144 allege that Respondent distributed or sold Rozol on four separate occasions on October 1, 8, 19 and 29, 2007. (Compl.'s Posthrg. Br. 471-86). Complainant asserts that these shipments of the product are somehow linked to the broadcasts of radio advertisements by Respondent. (Compl.'s Posthrg. Br. 75). The record in this case is devoid of any evidence that any of the shipments set forth in Counts 2,141-2,144 of the Complaint were to persons who heard Respondent's radio broadcasts before receiving shipments of Rozol. Because the Complainant has not shown that any of the individuals that received shipments of Rozol as alleged in Counts 2,141-2,144 ever heard Respondent's radio broadcasts, much less heard them prior to receiving shipments of Rozol, Complainant has failed to show that the "radio" broadcasts were an "integral part" of the shipment of the product.

Complainant goes on to assert that "Respondent's shipment of Rozol to United Suppliers Inc. located in Eldora, Iowa was to a different location of one of Respondent's 'authorized' distributors of Rozol, and occurred after the February 17, 2006 version of the 'slim jim' was in the marketplace." (Compl.'s Posthrg. Br. 75). None of the violations alleged in Counts 2,141-2,183, however, are based on claims made in the version of the "slim jim" dated February 17, 2006.[14] In fact, Ms. Niess admitted this at hearing. (Niess Tr. 158:4-7 (confirming that the "slim jim" has nothing to do with the "first set of violations")). As the EAB did in *Microban II*, it must be concluded that any allegations based on the version of the "slim jim" dated February 17, 2006 are untimely raised and therefore barred. *Microban II*, 2004 WL 1658591, at 20 (concluding that only

[14] Complainant sometimes refers to this piece of product literature as the "Old Slim Jim" (see Compl.'s Posthrg. Br. 8).

claims made in material referenced in the complaint could be considered to form the basis of a violation). Even if the allegations herein were timely raised, however, the record in this case is devoid of any evidence showing that United Suppliers Inc. received the version of the slim jim dated February 17, 2006 prior to receiving a shipment of Rozol on October 1, 2007.

In addition, Complainant asserts other theoretical links between companies that received shipments of Rozol and product information that allegedly included substantially different claims, including: shipments of Rozol to states where Respondent distributed its direct mail packages (without any evidence in the record that any particular company in those states received the product information prior to being shipped the product); and shipments of Rozol to companies that were authorized by Respondent to distribute Rozol when it was registered under FIFRA section 24(c) (again without any record evidence that any particular company received the product information prior to being shipped the product). (Compl.'s Posthrg. Br. 76-77).

Going further, Complainant asserts that "all of the 21 shipments to the distributors authorized to distribute Rozol were received after the direct mail packages were sent and after Respondent's radio advertisements for Rozol Prairie Dog Bait were broadcast in Nebraska and Texas." (*Id.* at 77). Complainant makes this assertion without providing any evidence of which companies were sent the direct mail packages or that any of the 21 distributors ever received a direct mail package or heard a radio ad. Complainant, however, speculates that certain individuals (concerning which Complainant has provided no evidence confirming that they received any of Respondent's product information) "contacted their respective company's other branches after receiving

the direct mail packages from Respondent." *Id.* Such speculation by Complainant cannot support a finding of FIFRA liability.

The EAB in *Microban II* confirmed that in order to find a violation of FIFRA section 12(a)(1)(B), the Complainant must show, at a *minimum*, that each person who received a shipment of Rozol also received product information containing substantially different claims prior to the time that the shipment was made. Complainant has failed to meet this burden here. As a result, Counts 2,141-2,183 must be dismissed.

2. Counts 2,184-2,231. Complainant asserts that the requisite nexus exists between Respondent's product literature and the "offers for sale" alleged in Counts 2,184-2,231 because the allegedly violative claims were made as part of the offers themselves. (Compl.'s Posthrg Br. 79). While not decided by the Administrative Law Judge in *Sporicidin*, the judge in that case was troubled by a similar argument made by the EPA before him because such an interpretation would render the phrase "as part of" meaningless. *In re Sporicidin Int'l*, Docket No. FIFRA-88-H-02, 1988 WL 236319, at 12-13 (ALJ Nov. 1, 1988) (*aff'd* 1991 WL 155255 (EAB 1991)). As suggested by the judge in that case, under Complainant's view, the statute would appear to have the same meaning with or without the phrase "as part of its distribution or sale." As a result, Complainant's position that FIFRA section 12(a)(1)(B) applies to all advertising is clearly overstated.

The regulatory authority granted to EPA by Congress should be interpreted narrowly because Congress intentionally limited EPA's authority in FIFRA section 12(a)(1)(B). In contrast, Congress granted EPA broad authority to regulate advertising that fails to include the restricted use classification of a pesticide pursuant to

FIFRA section 12(a)(2)(E). "Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *INS v. Cardoza-Fonseca*, 480 U.S. 421 (1987). As a result, FIFRA section 12(a)(1)(B) should not be interpreted in a manner that renders the phrase "as part of" meaningless. If Congress intended FIFRA section 12(a)(1)(B) to apply to all advertising, it could have easily stated so.

D. Claims Were Not Made For "It."

FIFRA section 12(a)(1)(B) logically limits the scope of that provision to claims made only for the registered pesticide itself. As set forth in FIFRA section 12(a)(1)(B), it is unlawful for any person in any state to distribute or sell to any person "any registered pesticide if any claims made for *it* as part of its distribution or sale substantially differ." 7 U.S.C. § 136j(a)(1)(B) (emphasis added). As a result, the word "it" does not refer to other products or things made in product literature. Statements such as "Kaput-D Prairie Dog Bait (25 PPM) achieved only 53% to 56% control" and "Kaput-D Pocket Gopher Bait* (50 PPM) 2X the rate of active ingredient, achieved only 56% to 57% control. *Not labeled for Black-Tailed Prairie Dog" are not claims for "Rozol" and as a result don't fall within the scope of FIFRA section 12(a)(1)(B).

E. Any Claims That Were Made for Rozol Did Not Substantially Differ from the Statement Required.

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 grant EPA plenary authority to regulate pesticide advertising, allegations that advertising claims violate FIFRA must be reviewed in light of FIFRA

section 12(a)(1)(B). FIFRA section 12(a)(1)(B) makes unlawful the distribution or sale of any registered pesticide if any claims made for it as part of its sale or distribution substantially differ from any claims made for it as part of the statement required in connection with its registration. 7 U.S.C. § 136j(a)(1)(B). "Substantially differ" is not defined in FIFRA or its implementing regulations.

Importantly, the scope and application of FIFRA section 12(a)(1)(B) must be reviewed in light of the First Amendment to the United States Constitution. In proposing the interpretive rule regarding pesticide advertising set forth at 40 C.F.R. § 168.22, EPA expressly acknowledged that restrictions on pesticide advertising must be scrutinized to determine whether they comply with 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.

51 Fed Reg. 24393, 24395 (July 3, 1986). In the proposed rule, EPA also acknowledged that the four-part test set forth by the Supreme Court in *Central Hudson Gas and Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980) would apply to any restrictions placed on pesticide advertising. *Id.* In *Central Hudson*, the Supreme Court stated:

> 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 more expansive than is necessary to serve that interest.

*Central Hudson*, 477 U.S. at 566.

Courts are particularly critical of bans against truthful speech that is not inherently misleading. *44 Liquormart v. R.I*, 517 U.S. 484, 503 (1996). In order to avoid the constitutional concerns raised by the First Amendment, the Chief Judge should adopt a narrow construction of FIFRA section 12(a)(1)(B) that is consistent with its legislative history and prior case law rather than the expansive interpretation suggested by Complainant.

A review of existing case law shows that violations of FIFRA section 12(a)(1)(B) have been found where a pesticide manufacturer claimed that its product was effective against a pest other than that for which its use was approved by the EPA in violation of the Agency's policy set forth at 40 C.F.R. § 168.22(b)(5).[15] In *Microban*, the administrative law judge found a violation of FIFRA § 12(a)(1)(B) where a pesticide manufacturer claimed that its antimicrobial pesticide was effective against microorganisms infectious to man, when the product was registered by EPA for use only against non-health related organisms. *Microban II*, 11 E.A.D. 425. Similarly, in *Sporicidin*, the administrative law judge found a violation of FIFRA § 12(a)(1)(B) where a pesticide manufacturer claimed that its antimicrobial product was effective against the AIDS virus, when the product was not registered for that purpose. *In re Sporicidin Int'l*, 1988 WL 236319.

[15] Section 168.22(b)(5) explains that as a matter of policy, the EPA will not regard as unlawful the advertisement of uses of pesticides permitted by FIFRA section 2(ee) provided that the product is not an antimicrobial pesticide.

No adjudicated decision has interpreted the scope of FIFRA section 12(a)(1)(B) as broadly as advocated by Complainant in the proceeding.[16]

1. Determining the Basis of Comparison – the Statement Required.

The next step in determining whether a claim is substantially different from the "statement required" is to determine the universe of documents that form the basis of the comparison – that is, what registration documents are part of the "statement required." FIFRA section 3, 7 U.S.C. § 136a provides, in pertinent part:

> (c) Procedure for registration
>
> (1) Statement required. 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;
> (F) except as otherwise provided in paragraph 2(D), if requested by the Administrator, a full description of the tests 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 and that the Administrator may consider in accordance with the following provisions . . . .

[16] In addition to the arguments set forth herein, Respondent's position is supported by the 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 dated January 5, 2011 (the "Non-party Brief"). In particular, the Non-party Brief provides a detailed analysis of how Complainant's position is incompatible with the legislative history concerning EPA's waiver of efficacy data under FIFRA section 3(c)(5) and the considerable practical problems raised by Complainant's strained construction of FIFRA section 12(a)(1)(B). In lieu of repeating the arguments raised by Rise and Croplife America, Respondent incorporates them herein by reference.

FIFRA § 3(c)(1), 7 U.S.C. § 136a(c)(1)(A)-(F).

The testimony of Mr. John Hebert of the EPA at the hearing in response to the Chief Judge's line of questioning to him regarding the scope of the "statement required" is informative:

> Q. Just to begin, when an applicant submits their package to EPA to try and obtain registration, the statute says they submit a registration statement. What do you consider is part of a registration statement? What are the various, you know, documents that make up a registration statement?
>
> A. It would include the form we require, the application form, the confidential statement of formula, which is the actual ingredients that are in the information. It would include any type of data compensation forms that we might require -- associated with a data matrix.
>
> Q. I don't understand. What is the data matrix?
>
> A. Registrants can either fulfill data requirements by selectively citing data or doing -- or citing-- selectively citing their own data or citing someone else's data, and the data comp. form relates to that.
>
> ...
>
> Q. Is efficacy data part of that statement?
>
> A. It can be, yes. If the product is labeled for public health pests, a structural pest like termites, a quarantine pest.
>
> Q. If an application to be a registrant submits efficacy data, do you consider it part of the statement?
>
> A. Sure, yes.

(Hebert Tr. 182:20-183:23, 189:19-189:25 (confirming that the Lee and Hyngstrom study submitted by Respondent to EPA was part of the Section 3 registration for Rozol Prairie

Dog Bait)). Mr. Hebert's testimony is consistent with FIFRA section 3(c)(1) in that the registration statement required by FIFRA 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 § 3(c)(1)(F), 7 U.S.C. § 136a(c)(1)(F).

According to Mr. Hebert's hearing testimony, the "statement required" by FIFRA section 3 is not limited to the pesticide label and a discrete affirmative statement of claims for the product, if one is submitted. (Hebert Tr. 182:20-183:23); *see also In re Roger Antkiewicz*, Docket No. IF&R-V-002-95, 1998 WL 830758, at 11 (ALJ, Nov. 20, 1998) (rev'd on other grounds) (where the EPA noted "that it submitted into evidence the [pesticide] label, which comprises at least one component of the product's registration statement"); (Niess Tr. 234:13-235:7 (confirming that efficacy data is part of the statement required)).

Despite Mr. Hebert's testimony in the record that the "statement required" includes efficacy and other data submitted for the pesticide as set forth on the data matrix and the Chief Judge's pretrial ruling explicitly to the contrary, Complainant continues to assert, contrary to the statute, that the sole basis for comparison in determining whether a substantially different claim was made is the product label and Notice of Pesticide Registration. (*See e.g.*, Compl. ¶ 620 ("Respondent violated section 12(a)(1)(B) of FIFRA . . . by distributing or selling Rozol . . . with claims made for the product as part of distribution or sale that substantially differed from the claims approved in the March 2, 2005 "accepted label"); Compl.'s Posthrg. Br. 4). Complainant asserts that comparing claims made to the accepted labels is supported by (1) the text of FIFRA, (2) the manner

in which EPA's Office of Pesticide Programs has historically implemented FIFRA's registration provisions and (3) certain EPA policy documents. Complainant's assertions are erroneous.

a. The text of FIFRA. FIFRA section 12(a)(1)(B) states, in pertinent part, that claims made as part of the sale or distribution of a pesticide may not "substantially differ from any claims made for it as a part of the *statement required* in connection with its registration under section 136a." 7 U.S.C. 136j(a)(1)(B) (emphasis added). Complainant's argument that the "statement required" is limited to the label and a discrete statement of claims set forth in FIFRA section 3(c)(1)(C) is not persuasive. (Compl.'s Posthrg. Br. 37-38).

If Congress had intended the "statement required" to be limited to the material set forth at FIFRA section 3(c)(1)(C), Congress could have easily narrowed the scope of FIFRA section 12(a)(1)(B) by explicitly referencing that section and referring to the basis of comparison as the "accepted label" or the "statement of claims." Instead, FIFRA section 12(a)(1)(B) references the "statement required" which directly matches the language set forth in FIFRA section 3(c)(1). This evidences Congress's intent to include all of the information set forth in subparts (A)-(G) as part of the statement and therefore the basis of comparison for determining if a differing claim was made.

b. EPA's course of conduct. Relying on the testimony of Mr. Hebert, Complainant asserts that EPA's course of conduct justifies its strained interpretation of the statute. (Compl.'s Posthrg. Br. 39-43). Mr. Hebert explained, among other things, that his registration team does not "typically see a separate document in the registration package labeled statement of claims," but if such a document was submitted,

his team would ask the applicant to include the statement of claims on the proposed label. (Hebert Tr. 17:3-18:18). If the EPA required all claims made for a pesticide to be included on the label and limited its review of claims made as part of the sale or distribution of a pesticide to whether the claims appear on the approved label, the EPA's course of conduct, contrary to the statute, would essentially require all pesticide advertising claims to be pre-approved by EPA. This would directly contradict the statute.

While deference is sometimes given to an agency's interpretation of a statute, an agency may not hide behind a long-standing interpretation that is inconsistent with the statute or that is against the underlying policy behind the statute. *Horrer v. Jeffrey*, 823 F.2d 1521, 1531-32 (Fed. Cir. 1987); *Coca-Cola v. Atchinson, T. & S.F.Ry. Co.*, 608 F.2d 213, 222 (5th Cir. 1979) ("[D]eference to an agency's interpretation of its statute is limited by the court's obligation to 'honor the clear meaning of the statute, as revealed by its language, purpose and history.'").

As the Chief Judge explained in the June 24, 2011 Order, "nothing in 7 U.S.C. § 136a(c) requires claims about a registered pesticide to be affirmatively approved by the EPA." (6/24/11 Order 24). This is supported by the fact that as part of the registration process, the Administrator of EPA may waive the data submission requirement for efficacy data and register a pesticide without the Agency providing an exhaustive list of approved claims. *Id.* Beyond this, the Agency has confirmed that it does not "routinely review advertising." (CX 88, EPA 1572).

Complainant then explains the process by which a registrant can submit optional marketing claims for use on the product label, cites two instances where Respondent submitted optional marketing claims for use on the label, and refers to the

process by which a registrant can amend a pesticide label. (Compl.'s Posthrg. Br. 40-41, 43). Again, Complainant confuses the requirements for pesticide labeling on the one hand, and pesticide advertising on the other. (Schmit Tr. 76:2-7 ("We all know that labeling must be specifically approved. Every word that appears on the label, has to be approved and appear on the stamped label. And that's the reason why you see the alternate marketing statements."). If statements are made on a pesticide label which have not been approved by the EPA, the pesticide may be considered misbranded in violation of FIFRA section 12(a)(1)(E), 7 U.S.C. § 136j(a)(1)(E). The submission of optional marketing claims for use on the label and the fact that a label can be amended have no direct relationship to what claims can be made in advertising.

Moreover, Complainant's analysis of the statement required as applied to the facts of this case (in particular Counts 2,141-2,183 during the 2007-2008 time period) ignores the fact that EPA's role in the registration of SLN labels under FIFRA section 24(c) is extremely limited. In the case of a FIFRA section 24(c) registration, the application is submitted to a specific state – not EPA – and the state determines if the product should be registered. (*See, e.g.*, RX 8.g., RX_590-597). 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), EPA waives 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). This is important, because the claims in Respondent's advertisements during the 2007-2008 time period concerned a special local

use of Rozol Pocket Gopher Bait to control black-tailed prairie dogs. As a result, the "statement required" was submitted by Respondent to individual states pursuant to each specific state's requirements. EPA has provided absolutely no evidence regarding what was submitted to each state during the "special local need" registration process and therefore can't possibly show that the statements made by Respondent during this time period "substantially differ."

c. EPA policy on pesticide advertising claims. In an attempt to support its restrictive interpretation of FIFRA section 12(a)(1)(B), Complainant cites several EPA policy documents. (Compl.'s Posthrg. Br. 44-47). First, Complainant cites a single paragraph in EPA's 225-page Label Review Manual which, without any statutory support, indicates that statements made in advertising may violate FIFRA section 12(a)(1)(B) if they substantially differ from any claims made on the label or labeling. (CX 88, EPA 1572).

Second, Complainant selectively cites a portion of the EPA's website entitled "Pesticide Labeling Questions & Answers." (Compl.'s Posthrg. Br. 44-45). The entire discussion follows:

> Section 12(a)(1)(B) of FIFRA makes unlawful any sale or distribution of "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." The statement required for registration must *include* "a statement of all claims to be made for the [pesticide]." FIFRA 3(c)(1)(C). *EPA has generally not allowed the use of "safe" in labeling because it has been considered to be false or misleading. 40 C.F.R. § 156.10(a)(5)(ix). False and misleading claims make a product misbranded and sale or distribution of the product unlawful. See FIFRA §§ 2(q)(q)(A); 12(a)(1)(E).* If use of the term

> "safe" has not been allowed in labeling and use of the term hasn't been otherwise approved, use of "safe" in advertising the sale or distribution of a pesticide product would generally be considered to substantially differ from what was approved in the registration and sale or distribution of the pesticide would be unlawful under section 12(a)(1)(B) of FIFRA.

(CX 136, EPA 3264).

Third, Complainant references a letter from EPA to a trade group known as Responsible Industry for a Sound Environment ("Rise"). (Compl.'s Posthrg. Br. 45-47). A careful review of that letter to Rise reveals that EPA's analysis focuses on "why EPA finds use of 'Professional Grade' in . . . products' labeling and marketing to be a false or misleading claim and therefore unacceptable." (CX 135, EPA3261).

The Agency's policy guidance cited by Complainant does nothing more than confirm that EPA is attempting to apply the standards for pesticide labeling found at 40 C.F.R. § 156.10(a)(5) (the standards used by EPA during the registration process to determine what claims are acceptable for use on a product label) to claims made as part of the sale or distribution of the product. Complainant previously took this position when it sent Respondent a highlighted version of certain statements in Respondent's Research Bulletin which Complainant erroneously deemed to be false and misleading under 40 C.F.R. § 156.10(a)(5). (CX 20, EPA430). Examining the actual case review from which that excerpt was pulled shows that OPP would consider certain of the claims to be "false or misleading" if they "received [the] Research Bulletin as labeling to accompany a product to control prairie dogs." (CX 19, EPA416 (emphasis added)). The product information at issue in this case is not labeling and therefore not subject to 40 C.F.R. § 156.10(a)(5).

Complainant's interpretation of FIFRA has not been upheld by any court and blurs the clear distinction created by FIFRA between labeling and claims made as part of the sale and distribution of the product. *See Sporicidin*, 1991 WL 155255, at 7 n. 25 ("I note that, at the hearing, EPA counsel refers to 'false and misleading claims,' thereby obscuring the distinction between sections 12(a)(1)(B) and 12(a)(1)(E) . . . Section 12(a)(1)(B) prohibits claims that differ substantially . . . Section 12(a)(1)(E) prohibits false or misleading statements or graphic representations in pesticide labeling. EPA enforcement staff makes the same mistake in a June 30, 1986 letter to respondent, stating that 'Section 12(a)(1)(B) prohibits the promotion of false and misleading claims made on behalf of a registered pesticide.'") Whether a claim may be false or misleading has no bearing on whether the claim is substantially different from the statement required as part of the pesticide registration process.

2. Even if the basis of comparison is the pesticide label – the statements made by Respondent are not substantially different. Even if the appropriate basis of comparison for determining whether a violation of FIFRA section 12(a)(1)(B) occurred was limited to the approved product label – a concept the Chief Judge rejected in her June 24, 2011 Order – the claims made by Respondent are not substantially different. (6/24/2011 Or. at 24). Complainant has offered several unsupported interpretations of what it means for a claim to be substantially different.

First, through a series of dictionary definitions, Complainant suggests that the phrase substantially different must mean "substantively or materially unlike." (Compl.'s Posthrg. Br. 36). Apparently abandoning its "substantively or materially unlike" approach, Complainant goes on to say that "[i]n this case, Respondent is liable under

FIFRA section 12(a)(1)(B) because the claims at issue contradict or undermine the approved label." *Id.*

There is no case law or regulation to aid the Chief Judge or a registrant in determining what a substantially different claim is. According to Mr. Hebert, if a registrant wants clarity on what can and can't be included in a statement made as part of the sale or distribution of a pesticide, the registrant should contact EPA. (Hebert. Tr. 187:20-188:7).

EPA, however, is not always consistent in its approach. On one hand, Mr. Hebert testified that generalizations such as "easy to use" are never allowed on product labels and, on the other hand, the same phrase is found on a label approved by his registration team. (Hebert Tr. 192:1-193:9). Ultimately, it seems that whether a statement is acceptable to EPA turns on nothing more than the opinion of the person reviewing it. Obviously, the regulated community must be provided with clearer guidance before a penalty can be imposed for such an alleged violation of FIFRA.

Notably, EPA's "Protocol for Conducting Environmental Compliance Audits under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)" dated September 2000 provides absolutely no guidance regarding compliance with FIFRA section 12(a)(1)(B). EPA "Office of Compliance, Protocol for Conducting Environmental Compliance Audits Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)" (Sept. 2000), available at http://www.epa.gov/compliance/resources/policies/incentives/auditing/apcol-fifra.pdf.

While none of Complainant's interpretations add sufficient clarity to the term "substantially differ," the most reasonable construction of the phrase is that claims made

as a part of the sale or distribution of the product may not materially contradict the label. This interpretation finds support in the testimony of both Mr. Hebert of EPA and Mr. Schmit of Respondent and is the most plausible construction to survive First Amendment scrutiny. According to Mr. Hebert's testimony:

> Q: Where is the line, in your view, realizing that the law has its own idea of that?
>
> A: If the claim could possibly contradict the label, present information that may confuse the user about how to properly use the label – use the product.

(Hebert Tr. 161:14-18). Similarly, Mr. Schmit testified that the first test that he uses to determine if a claim can be made is whether the claim contradicts the product label. (Schmit Tr. 72:17-21).

Turning to the actual statements made by Respondent, Complainant divides it analysis into two categories of claims: statements regarding toxicity and statements regarding efficacy.

a. Toxicity claims. Complainant asserts that certain statements made by Respondent allegedly contradict the labels for Rozol because: (a) the labels state that Rozol is a restricted use pesticide due to potential secondary toxicity to non-target organisms; (b) "the fact that the FIFRA section 3 accepted labels for Rozol state that '[d]ogs and other predatory scavenging mammals and birds might be poisoned if they feed upon animals that have eaten the bait means that, contrary to Respondent's claims, some black-tailed prairie dogs do die aboveground;" (c) claiming that Rozol is not hazardous or less hazardous to birds contradicts the reasons why Rozol is classified as a restricted use pesticide; (d) these statements contradict the following statement on the labels: "This product is toxic to fish and wildlife. Dogs and other predatory

scavenging mammals and birds might be poisoned if they feed upon animals that have eaten the bait;" (e) the labels instruct users to "not apply bait on the ground or above ground level. Treat only active burrows."; and (f) such claims conflict with specific mitigation measures required by the accepted labels, including follow-up, bait collection, and storage of bait. (Compl.'s Posthrg. Br. 48-51).

In contrast to Complainant's assertions:

a. a product may have a low primary toxicity profile or a lower risk profile when compared to alternatives and still be classified as a restricted use pesticide (Niess Tr. 236:3-12 (indicating that a study could show what the risk to non-target animals is of different pesticides); RX 89, RX_4293 (Respondent asserts that Rozol is safer for non-target birds and mammals than zinc phosphide, because the LD50 dose for chlorophacinone is much larger));

b. the fact that the label warns that mammals and birds may be poisoned if they feed upon animals that have eaten the bait discloses nothing about whether black-tailed prairie dogs may die aboveground – furthermore, Respondent has not claimed that black-tailed prairie dogs never expire aboveground;

c. comparisons of the relative hazard level of two pesticides does not contradict a restricted use classification (one may still be lower risk than the other);

d. a pesticide may be toxic to fish and wildlife and still be less toxic than alternatives;

e. Respondent has made no assertion that Rozol should be applied other than below ground to active burrows; and

f. Respondent has made no assertion that Rozol should be applied in a manner other than as set forth on the label.

b. Efficacy claims. Complainant also asserts that certain efficacy claims made by Respondent allegedly contradict the reapplication directions on the pesticide labels. (Compl.'s Posthrg. Br. 53-54). Importantly, Complainant mischaracterizes the label directions which instruct users to make 2-3 treatments per burrow system for the control of pocket gophers. This is not a mandatory requirement for reapplication, but an instruction on how many initial treatments to make in each burrow system for the control of pocket gophers. (*See* CX1, EPA 2). In addition, the application directions on the label for Rozol Pocket Gopher Bait is not applicable to claims made for Rozol Prairie Dog Bait and it is not clear how a statement made by Respondent regarding the relative efficacy of Rozol contradicts the reapplication directions on the product label. (Niess. Tr. 229:4-231:17).

The following exchange between the Chief Judge and Ms. Niess highlights the difficulty with Complainant's position:

> THE COURT: When this says 85 percent effectiveness, doesn't that suggest that if you want to get rid of 100 percent, you are going to have to do something else?
>
> THE WITNESS: It does. I understand that the EPA's efficacy standard is 70 percent. So if something is going to be considered effective by EPA, it's got to meet at least 70 percent effective.
>
> THE COURT: In this case, in connection with the reregistration, subsequent registration, did Liphatech ever provide efficacy data showing that in a first treatment it was 85 percent effective?

> THE WITNESS: I believe they submitted efficacy data. But I am not sure exactly what that data said. That's not something that we would review in the region.
>
> THE COURT: But wouldn't you consider that material you provided -- the efficacy data -- that you provide ... part of the registration statement, and that a claim made therein, in the efficacy data, would then be a part of that statement?
>
> THE WITNESS: Yes.

(Niess Tr. 233:17-234:22).

In fact, Respondent did submit efficacy data to EPA in connection with the registration of Rozol Prairie Dog Bait that confirmed that the pesticide showed a population decrease of 94% when comparing pre- and post-treatment plots using the visual observation method. (RX 10, RX_653).

Complainant also asserts that statements indicating that using Rozol is less costly than zinc phosphide allegedly "undermine" the specific carcass search and disposal instructions on the labels for Rozol Prairie Dog Bait. Rozol may require search and disposal instructions and still be less costly than zinc phosphide.

The EPA has even confirmed that when an applicator chooses a bait from an economic standpoint that they take into account more than the "sticker price" of the product. "EPA understands that when an applicator chooses a bait from an economic standpoint, they may prefer Rozol even though it costs more than the zinc phosphide products. Eliminating the skilled labor requirement for prebaiting with zinc phosphide is apparently a relevant factor for such applicators. Prebaiting necessitates observation to ensure that the black-tailed prairie dogs consume the untreated oats... Thus, the

prebaiting requirement [associated with zinc phosphide products] may be time consuming and labor intensive." (RX 89, RX_4299).

Rather than address each of Complainant's arguments regarding the supportability and truthfulness of Respondent's statements herein, Respondent attaches as Exhibit A hereto a chart which includes the alleged substantially different claim and support for that claim. Respondent notes, however, as did the court in *Sporicidin*, that Complainant's continued reference to "false and misleading claims" is not relevant for purposes of determining whether a violation of FIFRA § 12(a)(1)(B) occurred. *See Sporicidin*, 1991 WL 155255, 7 n. 25 ("I note that, at the hearing, EPA counsel refers to 'false and misleading claims,' thereby obscuring the distinction between sections 12(a)(1)(B) and 12(a)(1)(E) . . . Section 12(a)(1)(B) prohibits claims that differ substantially . . . Section 12(a)(1)(E) prohibits false or misleading statements or graphic representations in pesticide labeling. EPA enforcement staff makes the same mistake in a June 30, 1986 letter to respondent, stating that 'Section 12(a)(1)(B) prohibits the promotion of false and misleading claims made on behalf of a registered pesticide.'").

Finally, apparently recognizing that the statements made in Respondent's literature are supported by factual data, Complainant undertakes a significant attack on the scientific validity of the studies themselves. Complainant takes this position despite the fact that some of the documents were created by EPA and others were reviewed and relied upon by EPA in registering the products at issue in this case.

First, Complainant suggests that Respondent's reliance on the EPA's own Comparative Risk Assessment somehow "directly or indirectly implies that EPA recommends or endorses the use of Rozol for the control of black-tailed prairie dogs and

pocket gophers" in violation of the labeling regulation set forth at 40 C.F.R. § 156.10(a)(5)(v). (Compl.'s Posthrg. Br. 59). Again, Complainant confuses the requirements for pesticide labeling with the standard set forth in FIFRA section 12(a)(1)(B). Moreover, the citation of factual data from a publicly available document does not in any way imply that EPA recommends or endorses the product.

Second, Complainant devotes substantial effort to reviewing and critiquing the Lee and Hyngstrom study and goes as far as to say that unrecorded deviations from the study protocol make the data unreliable. (Compl.'s Posthrg. Br. 62). Complainant, however, fails to mention that Mr. Schmit testified that additional quality assurance review documentation was not introduced at hearing. (Schmit Tr. 375:2-3).

Complainant also ignores the fact that EPA relied upon this study in registering Rozol, even going as far as to state:

> The efficacy report by Lee and Hyngstrom (2007: MRID No. 473336-02) suggests that single applications of 1/4 cup of bait effectively controlled black-tailed prairie dogs under the conditions of use. The census method involved in the study overlapped in time and were conducted for shorter periods of time than is typical for field efficacy trials of rodenticides on farm and rangelands. However, the trials were adequate to support the fundamental label claim.

(RX 29, RX_1880 (emphasis added)). Furthermore, Mr. Hebert's testimony revealed that he also relied upon the study:

> Q: So when you went to approve it for all ten, was there data you relied on to expand the right to use the prairie dog bait killer in ten states, prairie dog bait?
>
> A: We referred to the Lee and Hyngstrom study that we talked about. That was part of that registration application...

(Hebert Tr. 189:19-24). After a pesticide has been registered, the Complainant cannot back-track and claim that the Registrant is prohibited from citing the data upon which Complainant relied to register the product.

After critiquing several other studies relied upon by Mr. Schmit in reviewing product information for Rozol, Complainant concludes that the studies could not have been relied upon by Mr. Schmit in reviewing the claims made for Rozol because some of the studies "commenced after Respondent made the same or similar claims in the February 17, 2006 version of the slim jim." (Compl.'s Posthrg. Br. 70). As mentioned previously, however, the February 17, 2006 version of the slim jim is not referenced in the Complaint and does not form the basis of any of the violations alleged in this case. As a result, Complainant's analysis in this regard should be given no weight – Respondent was not given fair notice prior to trial that it would be asked to provide justification for the claims made in any document other than those referenced in the Complaint.

In conclusion, the issue presented for the Chief Judge to determine is whether or not the statements made by Respondent substantially differ from the statement required in connection with the registration of the pesticides at issue in this case. Because that analysis in no way requires one to determine the scientific validity of any studies submitted to EPA as part of the statement required, the Chief Judge should disregard the Complainant's arguments in this regard.

## VII. COMPLAINANT'S PROPOSED PENALTY SHOULD BE IGNORED AND THE CHIEF JUDGE SHOULD CALCULATE A FAIR AND REASONABLE PENALTY FOR ANY FIFRA VIOLATIONS THAT OCCURRED BASED UPON THE ACTUAL GRAVITY OF THE VIOLATION.

### A. Penalty Factors.

The assessment of civil administrative penalties is governed by the Consolidated Rules, which provide in pertinent part that:

> If the Presiding Officer determines that a violation has occurred and the complaint seeks a civil penalty, the Presiding Officer shall determine the amount of the recommended penalty based upon the evidence in the record and in accordance with any penalty criteria set forth in the Act. The Presiding Officer shall [also] consider any civil penalty guidelines issued under the Act.

40 C.F.R. § 22.27(b).

FIFRA section 14(a)(4) provides, in pertinent part, that:

> In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. Whenever the Administrator finds that the violation occurred despite the exercise of due care or did not cause significant harm to health or the environment, the Administrator may issue a warning in lieu of assessing a penalty.

7 U.S.C. § 136l(a)(4). The Complainant bears the burdens of presentation and persuasion to show that the relief sought in this case is "appropriate." 40 C.F.R. § 22.24(a).

In this case, Respondent has waived any argument regarding the "size of the business" or "ability to continue in business." (Joint Stips., p. 16). As a result, the only statutory criteria that is relevant to this case is the "gravity of the violation."[17]

While the Complainant calculated the proposed penalty utilizing the 2009 ERP, this policy has never been put out for public notice and comment, lacks the force of law and is only "a non-binding agency policy whose application is open to attack in any particular case." *In re McLaughlin Gormley King Co.*, 6 E.A.D. 339, 1996 WL 107270 (EAB 1996). Even a proposed penalty calculated in accordance with the ERP can be excessive. *In re 99 Cents Only Stores*, Docket No. FIFRA-09-2008-0027, 2010 WL 2787749, at 28 (ALJ June 24, 2010).

"It has been held that fairness, equity and other matters as justice may require are appropriate considerations in assessing civil penalties under FIFRA, even if not specifically mentioned in the penalty provisions of FIFRA." *In re Rhee Bros., Inc.*, Docket No. FIFRA-03-2005-0028, 2006 WL 2847398, at 35 (ALJ Sept. 19, 2006) (*aff'd* 2007 WL 1934711 (EAB 2007) (citation omitted). "The matter of concern is...whether the penalty is appropriate in relation to the facts and circumstance at hand." *99 Cents Stores Only*, 2010 WL 2787749, at *40 (citation omitted). The totality of circumstances includes, among other things, whether any actual harm to human health or the

[17] Complainant continues to refer to information in its post-hearing brief regarding the size of the business and the effect on the ability to continue in business which is inaccurate, incomplete and, most certainly, irrelevant. As Respondent pointed out to Complainant previously, the statements that Complainant gratuitously inserted in its post-hearing brief regarding Respondent's business are inaccurate. (*See* Compl.'s Posthrg. Br. 113-114). Information regarding DeSangosse is also irrelevant. DeSangosse is a separate and distinct corporate entity and the relationship between DeSangosse and Respondent has never been litigated in this case. The Chief Judge should ignore all financial information regarding Respondent and any purportedly related entity.

environment occurred, the respondent's good faith and the economic benefit obtained, if any, as a result of any violations found. *Id.* at *40-41.

Even a cursory review of the facts of this case reveals that Complainant's penalty demand is excessive in light of the fact that no harm to human health or the environment occurred as a result of Respondent's advertising, Respondent always acted in good faith[18], and no economic benefit was derived from the alleged violations.[19] Moreover, if Respondent's conduct was as egregious as the Complainant suggests, why didn't enforcement personnel immediately notify Respondent of the fact that its radio broadcasts did not include the words "restricted use pesticide" instead of waiting at least 6 months to issue a SSURO? The delay in taking action to remedy the alleged violation of FIFRA supports the fact that the violations are not of high gravity.

B. Gravity of the Violation.

Throughout the entire course of this case, Complainant has acted as if the inherent characteristics of Rozol and its active ingredient, chlorophacinone, are on trial. FIFRA, however, requires that any penalty imposed be based on the "gravity of the violation." The statute does not speak in terms of the inherent toxicity of the underlying pesticide or chemical composition of that pesticide. The allegations advanced by Complainant in this

[18] Ms. Niess confirmed at hearing that Respondent promptly responded to each SSURO, cooperated with EPA enforcement and promptly took action to remove access to all product information deemed to be in violation of FIFRA. (Niess Tr. 211:21-212:3)..

[19] In the original Complaint filed May 14, 2010, Complainant alleged that Respondent received an economic benefit of $50,256 from the alleged acts. Complainant later amended its Complaint to drop this claim stating in paragraph 649 of the Amended Complaint filed January 6, 2011: "Economic Benefit: 'REDUCED TO ZERO IN AMENDED COMPLAINT.'" Importantly, according to the 2009 ERP, "The Agency's Policy on Civil Penalties (EPA General Enforcement Policy #GM-21), dated February 16, 1984, mandates the recapture of any significant economic benefit of noncompliance (EBN) that accrues to a violator from noncompliance with the law." 2009 ERP at 20. As a result, if Respondent did receive any economic benefit as a result of the alleged violations, Complainant was "mandated" to recapture it.

case are about certain words used or not used by Respondent in advertising its product and the harm, if any, that occurred as a result. The gravity of any violation that occurred is separate and distinct from any testimony or information related to chlorophacinone or Rozol generally, particularly inherent risks of the pesticide products that were known to EPA at the time the products were registered.

In fact, the inherent risks regarding the use of Rozol and potential impacts on non-target species were well known to the EPA when Rozol was registered by EPA and label modifications were required by EPA in order to mitigate those risks. (*See, e.g.,* RX 1.g., RX_111-114). Because the risks identified by Complainant's witnesses at the hearing were known to the EPA and taken into account when Rozol was registered by EPA, their testimony adds nothing to the analysis of the gravity of the alleged advertising violations. Ms. Niess, who developed the proposed penalty calculation for Complainant, admitted that the EPA was aware of the inherent risks of Rozol at the time it was registered:

> Q. EPA was well aware of the potential risks to non-target species when this product was registered by EPA as a restricted use pesticide, and when its chemically identical twin was registered as a general use pesticide; isn't that correct?
>
> A. That is one of the categories that EPA considers when registering pesticides. I was not personally involved in registering either of these – any of these pesticides.
>
> Q. Well, presumably you looked at the historical data and found that they were well aware of these potential risks to non-target species when they registered it; isn't that correct?
>
> A. Correct.

> Q. And they know that the risk exists for numerous general use pesticide products that contain chlorophacinone; isn't that correct?
>
> A. Correct.
>
> Q. You stated that you discovered – EPA discovered evidence of fatal secondary poisoning of a non-target species from the application of, you said, Rozol; isn't that correct?
>
> A. Yes.
>
> Q. Now, you know, of course, that discovery was made before EPA registered the RUP Rozol; isn't that correct?
>
> A. Yes.

(Niess Tr. 207:16-208:2-23).

Moreover, Complainant has not provided any evidence that Rozol was ever illegally sold by Respondent; that any misuse of Rozol in the field can be attributed to any acts of Respondent; or that the acts alleged in the Complaint caused any actual or potential harm to human health or the environment. Also, Complainant introduced no evidence that Respondent increased its sales of Rozol as a result of the alleged violations or derived any economic benefit from those alleged acts. These facts were confirmed by Ms. Niess at the hearing.

1. There is no evidence of misuse of Rozol as a result of Respondent's failure to adequately disclose the restricted use classification of Rozol in certain product advertising.

> Q. There's no evidence of any misuse of the product that occurred as a result of advertising this product without the RUP classification; isn't that correct?

A. Yes.

(Niess Tr. 207:11-15).

2. There is no evidence of actual or threatened harm to the environment from Respondent's failure to adequately disclose the restricted use classification of Rozol in certain product advertisements.

> Q. There is no evidence that the failure to use the words "restricted use pesticide" resulted in any actual or threatened harm to the environment; isn't that correct?
>
> A. Correct.

(*Id.* at 207:1-5).

3. There is no evidence that any of Respondent's product advertising increased sales of Rozol.

> Q. There's no evidence in the record that the sales of Rozol increased because of the advertising of this product without the RUP classification; isn't that correct?
>
> A. That's correct.

(*Id.* at 207:6-10).

4. There is no evidence of actual harm to the environment or human health from the alleged violation of FIFRA section 12(a)(1)(B).

> Q. And with respect to any harm caused by the allegations of differing claims, you have no evidence that shows that the alleged violations, which are the subjects of this enforcement action, caused any actual adverse impact to human health or the environment; isn't that correct?
>
> A. Correct.

(*Id.* at 199:3-9).[20]

5. The restricted use classification of Rozol does not support an increased gravity adjustment factor for harm to human health.

> Q. In your analysis of the harm to human health component on EPA 1010 in front of you, you indicate that EPA classified both Rozol Prairie Dog Bait and Rozol Pocket Gopher Burrow Builder Formula as RUP due to a risk of potential poisoning to non-targeted organisms; isn't that correct?
>
> A. Yes.
>
> Q. How does a potential secondary poisoning to non-target organisms, that may be inherent to the product, support an increased gravity adjustment factor for the harm to human health factor?
>
> A. It doesn't.

(*Id.* at 199:25-200:12).

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[20] Ms. Niess attempted to describe how the failure to disclose RUP or presenting "differing" claims could harm human health by stating:

> A. Again, the failure to provide these products' restricted use classification and the failure – or not the failure – the making of these claims that contradict the safety of the product that undermines the label requirements and informs the consumer or the user that the product is less toxic, less risky, can be done in a single application, could result in that consumer feeling that the product was not as harmful as it is. And they may be less careful. They may fail to use chemical resistant gloves. Those claims provide a picture for the consumer that the product is less risky. And that represents a potential harm.

(Niess Tr. 202:14-203:1).

But she then conceded that the only people who can buy this product are certified applicators.

> Q. But the consumer is licensed – The distributor is licensed applicators only; isn't that correct?
>
> A. That's correct.

(*Id.* at 203:2-5).

Moreover, the EPA has recognized that restricting the sale of Rozol to certified applicators lessens the risk to humans, because certified applicators are trained in how to follow label directions and apply the product. (RX 60, RX_3300).

6. Respondent did not sell Rozol to anyone who was not a certified pesticide applicator.

> Q. Only certified applicators can legally purchase restricted use pesticides; isn't that correct?
>
> A. Correct.
>
> Q. There is no allegation in the first amended complaint that any Rozol products were sold by Liphatech to anyone other than a certified applicator; isn't that correct?
>
> A. That's correct.
>
> Q. And so no unlicensed person could purchase Rozol Prairie Dog Bait or Rozol Pocket Gopher Bait Burrow Builder Formula from a dealer without the dealer violating FIFRA; isn't that correct?
>
> A. That is correct.

(*Id.* at 200:13-201:1).

7. The inherent toxicity of Rozol is not related to Complainant's allegations regarding Respondent's product advertising.

> Q. And how is toxicity in any way relevant to advertising-related violations?
>
> A. Pesticide toxicity is a factor that is incorporated into every violation of FIFRA.
>
> Q. But once again, these – This is not relevant conduct to your determination. Is it an assessment of – an aggressive one, I might add – of the product itself only, nothing [to] do with the conduct here; isn't that correct?
>
> A. Yes. For pesticide toxicity, yes.

(*Id.* at 197:17-198:1).

Furthermore, much of the testimony from Complainant's witnesses regarding potential harm to human health or the environment was based on the faulty assumption that Rozol would either be illegally sold or illegally used by third parties outside the control of Respondent. (Compl's Posthrg. Br. 97-101). For example, Complainant theorizes, without any evidence to support its theory, that Respondent's radio ads would cause customers to purchase Rozol Pocket Gopher Bait and illegally apply it to control prairie dogs. (Compl.'s Posthrg. Br. 98-99). Complainant attempted to elicit similar testimony from its expert witness, Dr. Steeger, at hearing. (Steeger Tr. 100:6-23). The Chief Judge, however, sustained Respondent's objection to such testimony as being unreliable and speculative. (*Id.*)[21]

In effect, Complainant is bringing this enforcement action against Respondent based, in large part, on the erroneous assumption that Respondent's advertising caused individuals to illegally use Rozol. Complainant, however, provides no support for this theory other than conjecture on the part of its witnesses.

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[21] Q. Are you aware of a general use Rozol product that's available on the market to a consumer who developed this want through advertising or whatever, are you aware of a general use Rozol product that would be available to someone who wanted to kill prairie dogs?

MR. CAMELI: Same objection.

THE COURT: Overruled.

THE WITNESS: I think that if I was told as a general – as a member of the general public that Rozol is effective to kill prairie dogs and that it has limited secondary effects and that the animals will die in the ground and all the claims that have been made and I couldn't get Rozol prairie dog bait, I would simply use pocket gopher bait because I could get it.

MR. CAMELI: Your Honor, move to strike. It's totally speculative, unreliable.

THE COURT: Can you find a foundation for what you base that on? Sustained.

(Steeger Tr. 100:6-23).

None of Complainant's witnesses provided facts or information to substantiate Complainant's theory that the words used in advertising by Respondent had the potential to cause confusion in the marketplace. Ms. Niess simply said it caused potential confusion without giving any further explanation or support. For example, Complainant never undertook any field studies to determine if the theories it advanced were supported. Ms. Niess testified:

> Q. And the rationale, which you have lobbied in explaining your calculation of this proposed multimillion-dollar penalty, is that the alleged violation of Liphatech, quote, "could reasonably create a false impression in consumers' minds resulting in increased use or misuse of the product;" isn't that correct?
>
> A. Yes.
>
> Q. There's no evidence to support that any such alleged confusion actually occurred, correct?
>
> A. Correct.
>
> Q. In fact, you never commissioned a survey or other study to support this kind of a conclusion; isn't that correct?
>
> A. Correct.

(Niess Tr. 199:10-24).

Complainant simply relied upon the unsupported opinions of its witnesses, none of whom were qualified as experts in marketing analysis, advertising or how the words used in advertising impact the general public or certified pesticide applicators. As a result, their testimony in this regard must be disregarded. *Calhoun v. Yamaha Motor Corp.*, 350 F.3d 316 (3rd Cir. 2003) ("An expert may be generally qualified but may lack qualifications to testify outside his area of expertise.").

In its post-hearing brief, Complainant advances seven situations that it believes relate to gravity. (Compl.'s Posthrg. Br. 84-107). The first three situations identified by Complainant (field use of Rozol, the restricted use pesticide status of Rozol and the labeling requirements of Rozol) are merely a recitation of facts as to how Rozol and its underlying chemical compound, chlorophacinone, work to control prairie dogs, and the steps the EPA has taken in labeling Rozol to mitigate these risks.

The fourth point made by Complainant, that Respondent's failure to include the restricted use language in advertising undermines the protection afforded non-target wildlife under FIFRA section 12(a)(2)(E), is overstated. (*Id.* at 97). Complainant speculates that the failure to include "RUP" in advertising could adversely impact non-target wildlife in two ways: (1) a potential customer who is not a certified applicator may buy the product and misuse it; or (2) someone may use the general use pesticide (Rozol Pocket Gopher Bait, 7173-184) to control black-tailed prairie dogs.[22] These two examples are pure speculation and assume without any proof that the people engaging in these acts will willingly violate FIFRA to obtain and use Rozol in a manner other than set forth on its label. *See, e.g.,* FIFRA § 12(a)(2)(G) (it is a violation of FIFRA to use a

[22] Complainant also argues that Respondent's conduct may "cause harm to the regulatory scheme." This rationale – harm to the regulatory program – is typically applied to conduct that occurs outside the regulatory scheme – such as selling unregistered pesticides. *In re Chempace*, 2000 WL 696821, at *16 ("Given the number of sales, and the number of unregistered and misbranded pesticides at issue, the pesticides regulatory program, lacking data on these transactions, would be significantly harmed if any environmental or human health problems were to result"); *In re 99 Cents Stores Only*, 2010 WL 2787749, at *5 (courts have consistently concluded that the sale or distribution of unregistered pesticides is harmful or potentially harmful to human health and the environment, as well as harmful to the regulatory program). In those cases the EPA does not know of the activity that Congress wanted to regulate – for example, distributing pesticides in commerce only after they are registered. Congress determined that it was important for the EPA to know that these activities existed so they could be regulated. Any potential harm to the regulatory scheme from the alleged advertising violations is substantially less than, for example, selling an unregistered pesticide, because of the additional steps already built into the regulatory scheme for the products once they have been registered. For example, the product can only be sold to certified
(footnote continued)

registered pesticide in a manner inconsistent with its labeling); FIFRA § 12(a)(2)(F) (it is a violation of FIFRA to sell a restricted use pesticide to a person other than a certified applicator or to a person who is not a certified applicator for use by a certified applicator). This speculation also assumes that the user will not follow and read the label, even though in its radio broadcasts, Respondent urged the user to "read and follow the label." (See, e.g., CX 45).

With respect to the potential sale of Rozol to non-licensed applicators, no evidence was ever introduced by Complainant that Respondent sold Rozol illegally. Moreover, in the 29 years that Rozol has been sold, Complainant can point to only one instance where the product was sold to a party who was not a certified applicator and this was by someone not related to Respondent and is, therefore, irrelevant to this proceeding. (Compl.'s Posthrg. Br. 97-98). Complainant attempts to tie this one isolated sale to Respondent by suggesting that because radio ads were aired within the region where this one illegal sale took place, these ads "could have influenced the purchase . . . ." (Compl.'s Posthrg. Br. 98). Again this suggestion is pure speculation and, like many other assertions by Complainant in this case, Complainant decided to rely upon speculation rather than doing its own investigation to verify its assertions.[23]

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applicators who are licensed by the state in which that product is sold and are trained to use restricted use pesticides.

[23] For example, without too much difficulty Complainant could have contacted the parties involved in this enforcement case and interviewed them (or perhaps even talked with the EPA enforcement officers who were involved in the case) to determine the impact, if any, Respondent's advertising had on that transaction. Without these facts one is left to speculate – perhaps the clerk selling the product in that case was newly hired and not fully trained in the procedures for selling restricted use pesticides. As stated earlier in this brief, when a litigant asks a court to infer a conclusion from an underlying fact, the court cannot grant that request when there are other plausible conclusions that can be drawn from that fact. *Ford Motor Co.*, 271 F.2d at 345. Here there are several "conclusions" as to why the Rozol product was sold, in this one instance, to someone who was not a certified applicator. Based on *Ford*, the Chief Judge cannot draw the (footnote continued)

The second scenario presented by Complainant is the situation where someone purchases the general use version of Rozol and uses it to control prairie dogs. (*Id.* at 98). For this to happen, the purchaser of the product would have to violate FIFRA by using the pesticide in a manner other than set forth on the product label and there is no evidence in the record to support that this ever occurred. As mentioned above, this type of testimony was found to be speculative and unreliable at the hearing and should not be given any weight. (Steeger Tr. 100:6-23).

The fifth and sixth points raised by Complainant assert that Respondent's claims contradicted or undermined the Rozol label and allegedly were based upon studies that did not support those claims. (Compl.'s Posthrg. Br. 101-105). As discussed above, the statements made by Respondent are truthful and supported by empirical research. To the extent studies were submitted by Respondent to EPA to support the registration of Rozol, Complainant cannot now attack those studies in a subsequent enforcement case when the EPA never informed Respondent that the Agency might have had issues with those studies at the time the product was registered. As far as Respondent knew, these studies had been submitted to and accepted by the EPA to support the registration of the product.[24] Respondent also reasonably assumed that the EPA had reviewed the submitted

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inference (Respondent's advertising caused the illegal sale) from the underlying facts presented by Complainant.

[24] In its brief, Complainant makes much of the fact that a review of the Lee and Hyngstrom Study (RX 10) by EFED concluded that it was insufficient for evaluating non-target secondary exposure. (Compl.'s Posthrg. Br. 66). The date of EFED's review, however, is September 3, 2009 - well after the conduct occurred which forms the basis of Counts 2,141-2,183 and well after Rozol Prairie Dog Bait, EPA Reg. No. 7173-286 was registered by the EPA on May 13, 2009. (*See* CX 81; RX 1, RX_000129). Even after EFED's review, no evidence was presented that Respondent was notified of EFED's conclusion. (Schmit Tr. 424:2-5).

studies at the time of registration as vigorously as it did for this case. At least this is the position the EPA publicly takes regarding its analysis of registration applications.

> Under FIFRA Section 3, EPA registers a pesticide only after conducting an extensive scientific review of the risks, and when appropriate, benefits of the proposed use of the pesticide to determine whether the use of the pesticide causes "unreasonable adverse effects" to human health or the environment.

(RX 89, RX_4279).

In the seventh point, Complainant alleges that Respondent continued to violate FIFRA during and after the hearing. (Compl.'s Posthrg. Br. 106-107). In response to each SSURO that Complainant issued to Respondent, Respondent immediately directed its employees and its outside vendors to remove all advertising literature from Respondent's website and the marketplace. (*See, e.g.,* Schmit Tr. 192:11-14). Respondent acted to rid its website of all advertising material just as it acted to rid the marketplace of any material that could have been available by sending a "please destroy" letter to all distributors authorized to sell Rozol regardless of whether they had actually received this literature. (*See* CX 53). Respondent believed this was done.

However, one page that Respondent removed from its website apparently remained accessible on a limited basis. (Niess Declaration June 6, 2012). This single "Rozol-Overview" page could not be accessed through the menu on Respondent's website.[25] Complainant refers to this as an alleged continuing violation after the hearing. (Compl.'s Posthrg. Br. 107). Attached hereto as Exhibit B is a Declaration from Mr. Pierre Payne, President of MGI Communications, Inc., Respondent's third party website

provider, describing the efforts of Respondent to remove these advertisements from Respondent's website and explaining how this one page may have remained accessible on a very limited basis to Ms. Niess following the hearing.[26] Based upon this Declaration, it is clear that this was an inadvertent and isolated situation and should be given no weight when determining the appropriate penalty.

C. Calculation of Fair and Reasonable Penalty for Any FIFRA Liability Determined to Exist.

Complainant calculated its proposed penalty of $2,891,200 using the 2009 ERP. As indicated above, the ERP is a "non-binding agency policy whose application is open to attack in any particular case." *McLaughlin Gormley King Co.*, 6 E.A.D. 339, 350 (EAB 1996). While the ERP must be considered, the Chief Judge is free to ignore the penalty policy and instead fashion an equitable and fair penalty based upon the "totality of circumstances." *99 Cents Only*, 2010 WL 2787749, at 28. The ultimate goal of any penalty calculation is to make certain that the "penalty is appropriate in relation to the facts and circumstances at hand." *Id.* at 27-28.

The proposed penalty demanded by Complainant under the 2009 ERP is grossly in excess of what is warranted by this case. For the reasons set forth below, the Chief Judge should disregard the 2009 ERP in order to calculate a fair and equitable penalty for any FIFRA liability that is found.

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[25] The page that Complainant identifies, apart from being removed from Respondent's website, arguably does not even need to say "restricted use pesticide." This page simply provides an overview of Rozol products without identifying any specific product.

[26] Respondent provides this Declaration only as a response to the Declaration of Ms. Niess attached to Complainant's Posthearing Brief.

1. Background to calculation of proposed penalty by Complainant.

On September 18, 2009, Complainant sent Respondent a "Notice of Intent to File Administrative Complaint Against Liphatech, Inc." (the "Initial Notice"). (*See* CX 24). The Initial Notice stated that Complainant planned to seek a penalty of $1,280,500 against Respondent for various alleged violations of FIFRA sections 12(a)(2)(E) and 12(a)(1)(B). (*Id.*) In explaining this demand in subsequent correspondence to Respondent dated October 2, 2009, Complainant asserted that, among other allegations, there were 148 instances where Respondent failed to adequately disclose the RUP classification of Rozol in violation of FIFRA section 12(a)(2)(E), warranting, according to Complainant, a penalty of $962,000. (RX 39).

The 148 counts related to FIFRA section 12(a)(2)(E) were apparently determined by Complainant by adding the number of days that at least one radio broadcast advertisement was aired, 132 days, to 16 print advertisements, for a total of 148 counts. (*Id.* at RX_2858); (Niess Tr. 153:9-11)).[27]

On April 1, 2010, Complainant issued an "Updated Notice of Intent to File an Administrative Complaint against Liphatech, Inc." (the "Updated Notice"). (RX 38). Pursuant to the Updated Notice, Complainant dramatically increased the proposed penalty for all alleged violations, including the failure to adequately disclose the RUP classification, from $1,280,500 to $2,941,456. (*Id.*) Pursuant to the Complaint, Complainant then alleged that the radio and print advertisements consist of 2,140 counts of FIFRA section 12(a)(2)(E), not 148 as previously asserted. (Compl. ¶ 649).

[27] Ms. Niess used the calculation worksheet contained in EPA's July 2, 1990 Enforcement Response Policy for the Federal Insecticide, Fungicide and Rodenticide Act (the "1990 Penalty Policy") to calculate Complainant's proposed penalty.

Complainant then asserted that the 2,140 counts should result in a penalty of $2,268,500 – more than double what was initially demanded by Complainant just six months earlier. (*Id.*)

The Complainant changed the basis of the FIFRA section 12(a)(2)(E) violations from one count for each day a radio ad was broadcast (132) to one count for each time a radio ad was broadcast (2,117), plus 23 print ads, resulting in a drastic increase in the number of counts.

Even though nothing changed with respect to the relevant facts which serve as the basis for the allegations related to the failure to adequately disclose the restricted use classification of Rozol, Complainant more than doubled the proposed penalty between September 2009 and April 2010. (Niess Tr. 154:2-17). Complainant's attempt to more severely punish Respondent for the violation of FIFRA section 12(a)(2)(E) (Counts 1-2,140) based on subsequent conduct alleging violation of a different section of FIFRA is misplaced and inappropriate.

2. Appropriate unit of violation.

a. § 12(a)(2)(E) – Counts 1-2,140. This is the first case to address the issue of the appropriate "unit of violation" under FIFRA section 12(a)(2)(E) regarding the failure to adequately disclose the RUP classification in advertising. (*See* Compl.'s Posthrg. Br. 108). As a result, there is no precedent for determining the appropriate unit of violation in this case. In fact, Ms. Niess testified at the hearing:

> THE COURT: Okay. So just to clarify, you are unaware of any EPA guidance or documents that talks about what independent violations would be in the context of advertising?

THE WITNESS: Correct.

THE COURT: And in terms of violations on a website, there's no EPA guidance or documents talking about how to calculate violations in regard to statements or claims made on the website for a pesticide:

THE WITNESS: Not that I can think of, no.

THE COURT: And there's nothing that talks about calculating for advertising, whether it would be the number of versions, the number of contracts for advertising, the number of ads, the number of companies that you placed the ads with, no guidance in regards to that?

THE WITNESS: No.

(Niess Tr. 238:23-239:15).

Complainant relies on *In re Chempace Corp.*, 9 E.A.D. 119, 2000 WL 696821 (EAB 2000), to argue that the unit of violation should be each time an advertisement is aired. (Compl.'s Posthrg. Br. 109). Complainant argues that since the EAB in *Chempace* found that each sale or distribution of a pesticide is a violation, each advertisement should likewise be a separate violation. In effect, Complainant argues that "to advertise" equates with "to sell or distribute." Complainant cites no authority to support this flawed assertion. Its analysis is erroneous.

The EAB in *Chempace* interpreted FIFRA section 12(a)(1)(A) which states that it is unlawful to distribute or sell to any person any pesticide that is not registered. FIFRA § 12(a)(1)(A). The EAB noted that the applicable penalty policy also stated that each sale or distribution should be a violation. For example, the 2009 ERP states "the Agency considers violations that occur from each sale or shipment of a product (by product registration number, not individual containers) or each sale of a

product to be independent violations" for purposes of Section 12(a)(1), 7 U.S.C. § 13j(a)(1). 2009 ERP at 16. Based on the language of the statute and the statements in the applicable ERP, the EAB concluded that the term "to any person" required that each individual sale or distribution be a unit of violation. *Chempace*, 9 E.A.D. at 129-30.

However, FIFRA section 12(a)(2)(E), which is applicable to Counts 1-2,140, simply states that it is a violation of FIFRA "to advertise" a restricted use pesticide without providing its classification. The language in this section does not indicate what it means "to advertise" and the 2009 ERP provides no guidance.[28] In addition, the legislative history provides no guidance on the appropriate unit of violation for purposes of FIFRA section 12(a)(2)(E). Therefore, Complainant's argument that "to advertise" in FIFRA section 12(a)(2)(B) is analogous to "to sell or distribute" in FIFRA section 12(a)(1) lacks merit. *Chempace* provides no guidance for determining the unit of violation for pesticide advertising.

Because EPA would not count individual containers in a sale or distribution of a product as separate violations under FIFRA section 12(a)(1), *see* 2009 ERP at 16, individual advertisements should not be counted as separate violations for purposes of FIFRA section 12(a)(2)(E). As a result, the appropriate unit of violation for purposes of FIFRA section 12(a)(2)(E) should, at most, be the number of different contracts that Respondent entered into as evidenced by the number of radio stations/radio station conglomerates or publications that contained advertisements that failed to

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[28] The failure of EPA to address the "unit of violation" in the ERP has also been noted in other cases. "The Agency's . . . guidance document on assessing FIFRA penalties provides no instructions or criteria to be used by the enforcement staff in determining the number of violations to be charged in a particular case." *99 Cents Only*, 2010 WL 2787749, at 24.

adequately disclose the RUP classification of Rozol. The term "contract" in the context of advertising is akin to the term "sale" or "distribution" and individual advertisements are akin to the number of individual containers in a "sale" or "distribution." Therefore, the maximum number of alleged RUP violations in this case should be 10 which is based on the four different radio stations or radio station conglomerates and six different print publications that contained or aired the advertisements at issue. (*See* Compl.'s Posthrg Br. 6-8).

Alternatively, the Chief Judge could reasonably find that (i) one (1) violation occurred based on the single act of failing to adequately disclose the RUP classification in advertising, or (ii) that the unit of violation should be based on the number of versions of violative radio and print advertisements (essentially 6, 4 radio broadcasts and 2 print), or (iii) the number of states where violative ads were broadcast or distributed (6); or (iv) two (2) violations based on one print ad and one broadcast ad. (*See* RX 81; CX 14a, EPA 285-EPA 360).[29]

The unreasonableness of EPA's penalty position is made further evident by comparing it to the sanction prescribed by the United States Sentencing Commission for individuals criminally prosecuted for such offenses. *See United States Sentencing Commission, Guideline Manual* (Nov. 2011) ("USSG"). Of course, one would presume that criminal violations under FIFRA would, and should, be treated

[29] *See In re Associated Prods., Inc.,* Docket No. IF & R-111-412-C, 1996 WL 691495 (ALJ May 31, 1996) (only one violation of FIFRA § 12(a)(2)(L) was found for failing to register a pesticide producing establishment even though more than one pesticide was produced there); *McLaughlin Gormley King Co.,* 6 E.A.D. 339 (a compliance statement which covered a single study could account for no more than one violation of FIFRA section 12(a)(2)(Q), even if the compliance statement was false for several independent reasons).

substantially more seriously than civil violations. This is not the case with respect to Complainant's position in this case.

In short, the guidelines instruct that multiple criminal counts of conduct violative of FIFRA – if prosecuted here – would be "grouped" under the guidelines. Specifically, as a unit of violation, they would be combined to form a single count, as the RUP violations and differing claims violations are among acts connected as part of a common "scheme" or plan.[30]

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[30] The resulting fine in such criminal cases would be a small fraction of the monetary penalty sought to be imposed here. The recommended period of incarceration (0-6 months) would likely yield a period of probation. Thus, while Respondent's conduct could never be characterized as criminal, EPA seeks sanctions far out of proportion to the penalties even recommended for individuals criminally charged, providing yet another independent reason to reject Complainant's requested penalties outright.

The guideline calculation begins with referencing the appropriate section in Chapter 2 of the USSG – Offense Conduct. Specifically, section 2Q.1.2 applies. (*See USSG* at 2Q.1.2, "Statutory Provisions.") Under the provision, a base offense level of eight is prescribed (*USSG* at 2Q.1.2). As with most guideline provisions, specific offense characteristics which result in aggravation of the conduct are considered. None apply under the facts of this case. (*Id.*) But arguably, a mitigating factor – the offense involving simple recordkeeping – would actually result in a <u>decrease</u> by two levels to a level six. (*Id.* at (b)(6).) Moreover,

> Except when the adjustment in subsection (b)(6) for simple recordkeeping offenses applies, this section assumes knowing conduct. In cases involving negligent conduct, a downward departure may be warranted.

*Id.* at Application Note, n.4.

Certainly the RUP violations are supported in the record as a negligent oversight by Respondent, at most. (Schmit Tr. 65:5-68:25). Likewise, one cannot argue that the differing claims allegations involve a knowing violation particularly given the substantial legal and factual shortcomings of the EPA's theory of prosecution. This leads to an inescapable conclusion that the base offense level under the guidelines would be reduced further.

Section 3.D.1.2 sets forth the circumstances in which counts "involving substantially the same harm" be grouped together into a <u>single</u> group. (*See USSG* at Section 3.D.1.2). As Ms. Niess testified, and as the evidence made abundantly clear, the RUP violations are a "textbook" example of counts that should be grouped together under this section, as are the differing claims violations, thus resulting in two violation groups not the 2,183 advocated here. *See USSG* at section 3.D.1.2(b) and (d). (Niess Tr. 160:20-161:6 (agreeing that Counts 2,141-2,2,31 all derived from a common fact that statements were made that allegedly differed from the "statement required" and that the first 2,140 counts all derived from the single fact that Liphatech failed to include the RUP classification in advertisements)).

(footnote continued)

Moreover, the EPA has used a wide variety of rationales for determining the "unit of violation,"[31] which obviously impacts the amount of any proposed penalty and, in some cases, does so dramatically.

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Section 3.D.1.4 prescribes adding two levels for the two (units) in this action. At most this results in a base level of eight, but for reasons noted above, the negligent nature of the alleged conduct would result in further departures downward. For the sake of simplicity here, we presume an offense level of eight. But *see* Section 3.E.1.1 (acceptance of responsibility) which clearly would reduce the base level again to six or lower. Further, Section 5, Part A shows a 0-6 months sentence.

Of course there is no history of violations contemplated under the guidelines "Criminal History." Finally, under Section 5.E.1.2, the prescribed total fines would be $500 to $5,000. It should be noted, as stated above, that these calculations are for individuals. Corporations under this particular statutory scheme are not subject to the sentencing guidelines. But even if such guidelines were used as a compass for determining a corporate fine, the guidance given with respect to the grouping of counts (i.e., the unit of violation) would still advise for a fine for a small fraction of the civil penalties sought by Complainant in the instant case.

[31] "The Agency has utilized a variety of different methods to calculate the number of violations. For example, on some occasions, the Agency has exercised its maximum authority under FIFRA and charged a violation for each individual sale. *See 99 Cents Only,* 2010 WL 2787749 at 24; *Sultan Chemists, Inc.*, 1999 EPA ALJ LEXIS 46 at *4, 2000 EPA App. LEXIS 24 (EAB 2000), *aff'd Sultan Chemists, Inc. v. U.S. EPA* 281, F.3d 73 (3d Cir. 2002) (manufacturer/distributor charged with 89 violations for 89 individual sales of four types of unregistered pesticides); *Super Chem Corp,* EPA Docket No. FIFRA-9-2000-0021, 2002 EPA ALJ LEXIS 25 (ALJ April 24, 2002) (manufacturer charged with 15 violations, one for each sale over a one-year period). In most instances however, EPA has exercised its discretion and, utilizing several different approaches, charged fewer violations than the maximum permitted. For example, EPA has limited the number of violations charged to (a) months of sale (*Avril, Inc.,* EPA Docket No. IF&R III-441-C, 1997 EPA ALJ LEXIS 176 (ALJ March 24, 1997) ("Chemical blender" charged with five counts of violation by combining sales (22 sales over 13 days) within calendar months into single counts – total proposed penalty of $17,500)); (b) years of sale (*Hanlin Chemicals-West Virginia, Inc.*, EPA Docket No. IF&R III-425-C, 1995 EPA ALJ LEXIS 91 (ALJ Nov. 9, 1995) (chemical manufacturer charged with one count for each year it sold approximately 171,000 gallons of unregistered pesticide after cancellation - total proposed penalty $10,000); (c) number of different unregistered products (*Hing Mau, Inc.*, 2003 EPA ALJ LEXIS 63 (ALJ Aug. 25, 2003) (retailer charged with one count of violation for each of the two types of unregistered mothball products sold (total packages sold 32) – total proposed penalty of $9,900); *Sporicidin International,* 3 E.A.D. 589 n.26 (EAB 1991) (pesticide manufacturer/distributor charged with two violations for each unregistered product despite evidence of at least three sales and three corresponding shipments of one pesticide product and one shipment of another pesticide product); *In re Green Thumb Nursery, Inc.*, 6 E.A.D. 782, 1993 WL 131978 (EAB 1997) (pesticide producer charged with one violation for one registered pesticide despite sale of thousands of gallons in multiple sales over a multi-year period, and knew that the respondent continued to sell the product for a year even after it was specifically advised by its supplier of the need for registration); *In re Johnson Pac., Inc.*, 5 E.A.D. 696, 1995 WL 90174 (EAB 1995) (retailer charged with one violation for one unregistered product sold to inspector despite many units of the product available for sale); *Sav Mart, Inc.*, 5 E.A.D. 732, 1995 EPA App. LEXIS 13, at *1-5 (EAB 1995) (retailer charged with one violation for selling an unregistered pesticide although evidence indicated that it produced and offered for sale ten bottles of unregistered pesticide and made one sale of two bottles to the inspector); and (d) portion of invoices (*Microban Products Co.*, FIFRA Appeal No. 02-07, 2004 EPA App. LEXIS 13 n. 30 (EAB 2004) (EPA charged 32 violations in the complaint although it had evidence (footnote continued)

Consequently, as long as Complainant has almost unfettered discretion to choose the number of units of violation which it will charge in a particular case (in the name of prosecutorial discretion), the application of the ERP as an objective standard is virtually impossible. The facts of this case amply illustrate this point.

b. § 12(a)(1)(B) – Counts 2,141-2,231. As discussed earlier in this brief, Respondent's records for the 2007-2008 alleged violations (Counts 2,141-2,183) show that Respondent sold or distributed Rozol to 41 persons, plus two employees. Complainant alleges that the two internal shipments to Respondent's employees should be additional distributions, but Complainant's analysis is flawed as discussed earlier in this brief. The facts of this case do not establish that the transfers to Respondent's employees constituted distributions under FIFRA, and, even if they did, Complainant has failed to establish any nexus between an allegedly substantially different claim and the shipment of the product.

As far as the 2009-2010 alleged violations (Counts 2,184-2,231) are concerned, Complainant alleges that Respondent's website was an offer for sale and that somehow 48 offers to sell were made. While Complainant alleges that the website was an offer for sale, it bases the number of violations on the fact that Respondent sent 48 distributors a "please destroy" letter in response to the second SSURO. Complainant has not produced any evidence to connect the website to any of the 48 distributors for these counts other than through the "please destroy" letter. Moreover, since Complainant

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(invoices) of at least 54 shipments to the same company). Sometimes, as was seen in the *Rhee* case, the Agency took a middle ground and charged the wholesaler/distributor with 467 *violations* based upon the number of cases or cartons sold *but* only sought a penalty for 264 "*distributions*" by consolidating "one shipment or distribution" all the sales or shipments of products to a customer on a certain day, regardless of (footnote continued)

alleges that the website constituted the "offer for sale" for these counts, if the Chief Judge finds that a violation occurred, then the "unit of violation" must relate to the website.

If the Chief Judge were to accept Complainant's argument that the website was a "virtual shelf" and find Respondent liable, it would be appropriate to find only one violation. *See In re Johnson Pacific, Inc.*, 5 E.A.D. 696 (EAB 1995) (retailer charged with one violation for unregistered product sold to inspector despite more units of the product available for sale); *Sav Mart, Inc.*, 5 E.A.D. 732, 1995 EPA App. LEXIS 13, at *1-5 (EAB 1995) (retailer charged with one violation for selling an unregistered pesticide although evidence indicated that it produced and offered for sale ten bottles); *99 Cents Only Stores*, 2010 WL 278749 ("In other words, she suggested that regardless of the number of bottles of the illegal pesticide found available for sale on store shelves on the day of inspection, the Agency would charge only one count related thereto").

3. Analysis of Complainant's calculation of the proposed penalty under the 2009 ERP.

a. Introduction. Under the 2009 ERP, Complainant is required to undertake the following steps to calculate the proposed penalty once the number of FIFRA violations has been determined:

(i) Determine the size of the business;

(ii) Look up the "gravity" of the alleged violation in Appendix A of the ERP;

(iii) Determine the base penalty amount;

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how many cartons were sold or if the shipment contained various sizes or types of products. *Rhee Bros., Inc.*, EPA Docket No. FIFRA-03-2005-0028, 2006 EPA ALJ LEXIS 32 *88-90 (ALJ Sept. 19, 2006).

(iv) Determine the adjusted penalty amount based upon case-specific factors using the gravity adjustment criteria in Appendix B;

(v) Calculate the economic benefit of noncompliance;

(vi) Consider the effect that payment of the total penalty amount will have on the Respondent's ability to pay/continue in business; and

(vii) Consider further modifications in accordance with Section IV.B.1.-3. of the ERP.

In this case, there is no disagreement over how Complainant applied the ERP in Steps (i)-(iii)[32] and (v)-(vi).[33] This leaves Step (iv), including application of the gravity adjustment factors from Appendix B and Table 3, and Step (vii). Complainant's analysis of the 2009 ERP as applied to the facts of this case with respect to Steps (iv) and (vii), however, is fundamentally flawed.

The ERP states:

> The Agency has assigned adjustments, based on the gravity adjustment criteria listed in Appendix B, for each violation relative to the specific characteristics of the pesticide involved, the harm to human health and/or harm to the environment, compliance history of the violator, and the culpability of the violator.

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[32] Step (i) is irrelevant to this case. For step (ii), this case does not involve violations of high gravity, but Complainant determined the correct gravity rate as directed by the 2009 ERP.

[33] Respondent does not dispute the size of its business and agrees that the Category I classification is the default position under the ERP. Complainant alleges the ERP would classify the RUP classification violation as a Level 2 violation thereby resulting in a "base" penalty in the amount of $6,500. However, the "base" penalty amount under the 2009 ERP for a Category I business is listed as $7,500 for a Level 1 violation and $7,150 for a Level 2 violation. Therefore, it would seem that when using the correct inflation adjustment for the time period of the alleged violations, the "base" penalty amount should be less than $6,500 for a Level 2 violation. Respondent also does not dispute Step 5 – the calculation of the economic benefit. Complainant initially demanded a penalty which included an economic benefit of $50,256 but amended its Complaint to provide "Economic Benefit: REDUCED TO ZERO IN AMENDED COMPLAINT." First Am. Compl. ¶ 649. Likewise, Respondent does not raise any issues under Step 6 regarding the impact of the penalty on the ability of Respondent to continue in business.

2009 ERP at 19-20.

Three of the adjustment factors clearly relate to specific issues. The phrase "specific characteristics of the pesticide involved" obviously relates to the toxicity of the applicable pesticide. "Compliance history and culpability of the violator" obviously relate to the violator itself.

However, the ERP does not distinguish between whether "harm to human health and/or harm to the environment" relate to the potential or actual harm caused by the violation or the underlying pesticide. These adjustment factors must relate to the violation, not to the underlying pesticide. Complainant, however, based its evaluation of the harm to human health and harm to the environment factors, in large part, upon the characteristics of the pesticide involved rather than on the alleged violation. This is an incorrect interpretation and could lead to double-counting. For example, Ms. Niess testified at the hearing as follows:

> THE COURT: When you were going through your analysis of the penalty, you said you always take into account pesticide toxicity. But how you describe what the pesticide toxicity is is the impact that it has, or may have, on human health or the environment. And aren't those two other categories in your evaluation? So aren't you basically repeating the same issues, pesticide toxicity and then you have another factor of human health and the environment, human health, and then you have impact on the environment. So doesn't that duplicate the same issues twice over?
>
> THE WITNESS: I think they can. The pesticide toxicity gravity portion is there to capture the inherent toxicity of a product. The remaining factors, harm to human health and harm to the environment, would take into account the action and . . .

(Niess Tr. 241:3-19).[34] This testimony is clearly an admission by Complainant that these two adjustment factors relate to the alleged violations (the "action," to use Ms. Niess' words) rather than to the underlying pesticide.

If these two criteria were based only on the pesticide and underlying chemical ingredient, as Complainant suggests, then the 2009 ERP would never permit an adjustment to the penalty based on the impact that the actual advertising words would have on harm to human health or the environment. Under Appendix A, all advertising violations are considered a "level 2" violation, but if these two adjustment factors relate to the pesticide then "innocent" mistaken words used in advertising would be treated the same as "deliberate" falsehoods. For example, two different "illegal" phrases may have substantially different impact (or no impact) on consumers but, if the toxicity, harm to human health and harm to the environment adjustment factors are based on the pesticide, then there is no way to weigh one set of words more heavily under the 2009 ERP than another set of words.

In addition, if these two criteria are based on the pesticide and underlying chemical ingredient as Complainant suggests, the 2009 ERP would not permit the size of the market in which the advertisements were placed or the amount spent on advertising to be taken into account in determining the gravity of an advertising violation. In fact, Ms. Niess ignored these factors in calculating her proposed penalty for the alleged advertising violations. For example, Ms. Niess testified as follows:

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[34] *See* FIFRA section 14(a)(4), 7 U.S.C. § 136l(a)(4): "In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the . . . gravity of the violation" (emphasis added).

> Q. . . . Did you ever take into consideration the small number of people that would likely hear any radio ad that's a subject of this action?
>
> A. No.
>
> Q. Radio ads were being done in very small, low population density areas of the country; isn't that correct?
>
> I am not aware of the population density of the states in which these products were being advertised in.
>
> . . .
>
> Q. Again, we are dealing now with the number of people likely to hear these ads and to act upon them. And you - - It's still your testimony that in low population density areas, that is not a mitigating factor for any sort of violation here?
>
> A. Yes.
>
> Q. Of the small number of people that overheard this ad, did you ever try to determine what percentage would have even been interested in the advertised products?
>
> A. No.

(Niess. Tr. 193:10-19; 194:25-195:11).

Complainant also alleges that Respondent entered into a "large-scale" advertising campaign when the Rozol FIFRA section 3 registration became effective, but the advertising campaign involved no more than $32,000. (See Compl.'s Posthrg. Br. 6; CX 14a. EPA 285-360 (including advertising invoices)). Yet, Complainant seeks a total penalty of over 90 times the cost of the entire "large-scale advertising campaign."

Based on Complainant's analysis, the penalty for advertising violations under the ERP would be based simply on the size of the Respondent's business, its ability to continue in business, and the pesticide being advertised. But surely significant consideration must be given to the actual words used in the advertisement when evaluating an alleged advertising violation. There is no guidance in the 2009 ERP as to how this should be done.

It even appears that Complainant concurs with this analysis. In its Post-Hearing Brief, it states:

> At the hearing, the Chief Judge questioned Ms. Niess about the connection between the "toxicity" value and the "harm to human health" value and the "harm to the environment" value in the penalty policy, inquiring whether or not assessing a value for both criteria might somehow be "double counting." . . . As Ms. Niess indicated, the toxicity value goes to the inherent toxicity of the pesticide. . . . In contrast, the "harm to human health" and the "harm to the environment" values address a specific violation's potential or actual harm to human health and the environment.

(Compl.'s Posthrg. Br. 116)

As a result, the 2009 ERP must be construed to require that these two gravity adjustment criteria – harm to human health and harm to the environment – be evaluated based on the acts alleged to violate FIFRA, which, in this case, are the words Respondent used in advertising Rozol.

b. Toxicity. Ms. Niess concluded that the appropriate value for toxicity was "3" because the product in question is a restricted use pesticide. This conclusion should be rejected for three reasons:

(i) The Chief Judge should ignore the testimony of Ms. Niess for this adjustment factor because Ms. Niess demonstrated through her testimony that she is not qualified to evaluate the toxicity of Rozol.[35] As a result, Ms. Niess' characterization of the gravity of the alleged violation must be given no weight, particularly because, as she testified, she alone calculated the proposed penalty. (Niess Tr. 99:24-100:4).

In addition, Ms. Niess admitted that she did not have any work experience with chlorophacinone, which is the active ingredient in Rozol, or "zinc phosphide," which is a competitor product.

> Q. Do you have any relevant work experience or technical knowledge regarding chlorophacinone?
>
> A. No.
>
> . . .
>
> Q. Why don't you look at 3128, RX 3128. I'll draw your attention to the third bullet point. This is for zinc phosphide. Do you know what zinc phosphide is by the way?
>
> A. Yes.
>
> Q. What is it?
>
> A. Zinc phosphide is a registered pesticide.
>
> Q. How does it act? Do you know how it works or anything; is that within your expertise?
>
> A. No, it's not.

[35] Ms. Niess may be capable of calculating a proposed penalty in other circumstances, but, in this case for this adjustment factor, she is not. *See In the Matter of Strong Steel Products, LLC*, 203 EPA ALJ Lexis 191 at *61.

> Q. So comparative to chlorophacinone, you wouldn't be able to tell us which is more toxic, dangerous, things of this sort?
>
> A. No, I wouldn't.

(Niess Tr. 133:17-19, 180:7-21).

Ms. Niess also demonstrated very little understanding of the distinctions between Rozol, as a restricted use pesticide, and its companion product which is a general use pesticide. Testimony established that these two products have identical chemical ingredients and the only distinction between the two products is the method of application. (Niess Tr. 237:20-238:22). Ms. Niess testified as follows as to her failure to understand the application method for Rozol:

> THE COURT: Okay. And I think that you were asked on redirect why two products that have exactly the same ingredient, one could be a general use product and one could be a restricted use product. And you said it's primarily a different method of application; is that correct?
>
> THE WITNESS: Yes.
>
> THE COURT: And what makes one application method cause it to be restricted versus another?
>
> THE WITNESS: In this instance, it was the burrow builder application. And I'm not that familiar with how those work –
>
> THE COURT: I don't even understand the term "burrow builder." Do you know what that term means?
>
> THE WITNESS: From my understanding, it is a piece of machinery that actually creates a burrow. So if you can see where – that kind of picture or graphic on the right-hand side – that's indicating the hand-baiting method that you would insert a probe directly into the natural burrow of the pocket gopher.

> If you want to apply it using the burrow builder application, you don't do that at all. You use this piece of machinery and it creates the burrow itself. And that's really – The use of that product, of that machinery, is apparently very complicated; that's my understanding.

(Niess Tr. 237:20-238:22).

(ii) Besides Ms. Niess' admitted lack of knowledge regarding the toxicity adjustment factor, the toxicity adjustment factor should not even apply to advertising claims. This adjustment factor is irrelevant to words used in advertising. Without citing any authority, Complainant asserts:

> The gravity of a violation should always be higher for a high toxicity chemical than for a low toxicity chemical. If the violation were one related to a recordkeeping requirement, for example, complainant believes that the gravity of such a violation should be higher for a chemical that is inherently more toxic than for a chemical with a lower toxicity.

(Compl.'s Posthrg. Br. 117).

Complainant's position is simply wrong. First, Complainant cites no authority for its proposition. Second, EPA requires pesticide manufacturers to annually report the amount of pesticides that are produced. *See* FIFRA § 7. In conjunction with this "record keeping" requirement, the EPA has created an enforcement response policy specifically for this section of FIFRA (see "Enforcement Response Policy for FIFRA § 7(c) Establishing Reporting Requirements updated May 2010"), of which Respondent respectfully asks the Chief Judge to take judicial notice. Nowhere in this penalty policy does the EPA levy a penalty with respect to this requirement based upon the toxicity of the pesticide that is the subject of the reporting requirement. Consequently, Complainant's position as stated in its post-hearing brief is

directly contradicted by the EPA's penalty policy for the reporting requirements under FIFRA section 7(c).

Complainant will no doubt argue in its reply brief that this is a separate section of FIFRA and a different penalty policy, which it is. However, the above point is made in order to contradict the Complainant's unsupported assertion in its brief that every FIFRA violation must be adjusted for the toxicity of the pesticide involved. That simply is not true.

(iii) The label provides that the pesticide is a restricted use pesticide. However, the EPA only required that the warning word of "caution" be placed on the label because Rozol is a Category III pesticide. (RX 1, 2, 48a, 48b). The signal word "caution" results in a value of "1." This creates an ambiguity in the level of "toxicity" for Rozol. When a document is ambiguous it should be construed against the drafter, and this is particularly true in an enforcement case. *Pepsi Bottling Grp., Inc. v. Thomas*, No. C10-54, 2010 WL 4622520 at *4 (W.D. Wash. Nov. 4, 2010) (recognizing the general rule that penalizing statutes must be construed strictly and with lenience exercised in favor of the party who may be the object of the penalty).

Since Ms. Niess admittedly didn't understand the chemical "chlorophacinone," much less the differences between chlorophacinone and zinc phosphide and didn't understand the machinery that is used to apply Rozol, her testimony on the "pesticide" adjustment factor should be ignored. She cannot credibly assign a value of "3" to this adjustment factor based on her admitted lack of knowledge. *Calhoun*, 350 F.3d at 322 ("An expert may be generally qualified but may lack qualifications to testify outside his area of expertise.").

As indicated above, this adjustment factor should not apply to words used in advertising a pesticide. However, if the Chief Judge should nevertheless decide to apply this adjustment factor to this case, a substantially lower adjustment should be applied to this factor.

c. Harm to human health. In her Penalty Calculation Analysis, Ms. Niess asserts with respect to the harm to human health gravity adjustment factor:

> both the failure to disclose the products' restricted use classification and the sale or distribution of the product with false or misleading claims could reasonably create a false impression in consumers' minds, result in increased use/misuse of the product. EPA considers this potential for harm to either be of an unknown or minor extent. For the purposes of this calculation, it will be assumed that any harm to human health would have been minor, i.e., of short duration, no lasting effects or permanent damage, easily reversible, and would not result in significant monetary loss. The appropriate Gravity Adjustment Level for minor potential or actual harm to human health is 1, per the ERP.

(CX 55, EPA 1010).

Ms. Niess' assertion is erroneous for several reasons. First, the Complainant has dropped all allegations regarding false and misleading claims (*i.e.*, that the products were misbranded pursuant to FIFRA section 12(a)(1)(E), 7 U.S.C. § 136j(a)(1)(E)). Second, the Rozol products involved in this case were not listed as restricted use pesticides due to a potential risk of "harm to human health." (*See, e.g.*, RX 1, 2). Third, Complainant "assumed that any harm to human health would have been minor" without even attempting to explain what type of impact to human health would have occurred or why it would have been minor, other than reciting the label restrictions.

Ms. Niess' statements in this regard are sheer speculation on her part. There is no evidence that any harm to human health occurred or could have occurred from the alleged acts.

In addition, Ms. Niess attempts to support her position regarding the potential for harm to human health by referencing a letter written by Charles Lee. (Niess Tr. 113:15-114:14 (referencing CX 140, EPA 3345-46)). Mr. Lee's argument in that letter is obvious and can be explained very simply. Less human contact with a pesticide is always better, regardless of the pesticide involved. His letter indicates nothing about the actual potential for Rozol to cause harm to human health and, going further, indicates nothing about the gravity of the violations of FIFRA alleged in this case.

Further, the Rozol products at issue in this case could only be sold to certified applicators and there is no allegation in the Complaint that any of the Rozol products were sold by Respondent to anyone other than to certified applicators, or that the advertising words about which Complainant complains resulted in any illegal sales or that the advertisements that are the subject of this case caused any confusion in the marketplace.[36] And no evidence was introduced at the hearing to establish that any actual harm to human health occurred. The assertions regarding potential harm to human health were nothing but the personal opinions of Complainant's witnesses. Their views on how the market would perceive the words Respondent used in advertising are speculative

[36] The act of selling a restricted use pesticide to an individual who is not a certified pesticide applicator is a separate violation of FIFRA. *See* FIFRA § 12(a)(2)(F); CX 102; RX 73.

musings. None of Complainant's witnesses were qualified as experts in marketing or advertising. See *Calhoun*, 350 F.3d at 322.

In addition, there is no information in Complainant's pre-hearing exchange and no evidence was provided at the hearing to support a conclusion that Rozol was ever misused, applied contrary to the label or to land other than what was allowed by the label which could have harmed human health as a result of any of Respondent's advertisements.

For these reasons, the value of the harm to human health prong of the Gravity Adjustment Criteria in the ERP should be zero. The application of the value of "0" to this prong is supported by the 2009 ERP which states that a value of "0" should be applied in those cases where "negligible harm to human health [is] anticipated." 2009 ERP at 34-35. The footnote associated with this quotation explains "negligible" as meaning, among other things, "actual or potential harm which is insignificant and has no lasting effects or permanent damage or monetary loss." 2009 ERP at 35 n.3. *See also In re Martex Farms, Inc.*, Docket No. FIFRA-02-2005-5301 2006 WL 1582510 (ALJ Jan. 19, 2007), *aff'd in part and rev'd in part* 13 E.A.D. 464, 2008 WL 429631 (EAB 2008), *aff'd Martex Farms, S.E. v. EPA,* 559 F.3d 29 (1st Cir. 2009) ("the evidence does not reveal any actual injuries or adverse health effects resulting from these violations"). Therefore, the value of "0" should be applied to this adjustment factor.

d. Harm to the Environment. Ms. Claudia Niess asserted that the:

> violations subject to this enforcement action could result in unknown or potential serious or widespread harm to the environment. EPA has discovered evidence of the fatal secondary poisoning of

> non-target species from applications of Rozol. The extent of such incidents is not known to EPA at this time, nor is it known if this poisoning occurred due to improper sale or use of the product. However, EPA considers this to be an indication of the potential serious threat of harm to the environment of the product. Actions minimizing the toxicity or danger of the product (i.e., not disclosing the product's restricted use classification or making false and misleading claims about the safety of the product) would reasonably create a false impression in consumers' minds, resulting in increased use/misuse of the product. The appropriate Gravity Adjustment Level for unknown or potential or serious widespread harm is 3, per the ERP.

(CX 55, EPA 1010).

As discussed above, Complainant is erroneously mixing apples and oranges when analyzing this gravity adjustment factor. In evaluating this criterion, it is the acts that are alleged to violate FIFRA – not the subject products – that have to be analyzed for their potential danger to the environment; otherwise there is double-counting of the pesticide's toxicity in those cases where toxicity is relevant. (Niess Tr. 241:3-19).

Besides Complainant's speculative assertions regarding potential harm to the environment from Respondent's advertising words, EPA knew of potential risks to non-target species when EPA registered this product as a restricted use pesticide. There is no evidence in the record that the advertising words in question led to this lawfully registered product ever being misused, applied contrary to the label or applied in a manner other than what was allowed by the label, or that the sales of Rozol increased as a result of Respondent's use of these advertising words.

The sale of restricted use pesticides is also rigorously controlled by FIFRA and applicable state laws. *See, e.g.,* FIFRA § 12(a)(2)(F). These laws prohibit

such a product from legally being sold to individuals other than those who are certified pesticide applicators and require the sellers of restricted use pesticides to keep records of these sales, including the name and license number of the certified applicators.[37]

Consequently, even if the advertisements in question somehow piqued the interest of someone who was not a certified applicator, that individual would not be legally able to buy or use the product. Moreover, there is no evidence in the record that the product was ever sold by Respondent to individuals who were not authorized to purchase the product. There is also no evidence in the record that the general public attempted to buy Rozol or that licensed sellers of Rozol had to turn away customers from buying this product as a result of Respondent's advertisements or for any other reason.

Because the Complainant simply offers speculative assertions to support its theory, the value for the environmental harm prong of the Gravity Adjustment Criteria from the allegations in the Complaint should be "zero."[38]

e. Compliance history. The compliance history adjustment is "zero." (Compl.'s Posthrg. Br. 123).

f. Culpability.

(i) Counts 1-2,140 (RUP classification). Ms. Claudia Niess stated that, based on the first SSURO and the allegations of violations in November of 2009, Respondent's culpability has been evaluated as unknown or violations resulting

[37] Given the extensive recordkeeping for the sale of restricted use pesticides, Complainant could have readily produced evidence of whether Respondent's advertising words caused any potential harm to human health or the environment by simply canvassing some of these easily identified purchasers.

[38] Complainant argued in its brief that these alleged advertising violations may have harmed the regulatory scheme. Responded addressed this argument previously.

from negligence. She assigned a value of "2" to this factor. (CX 55, EPA 1011). However, when she calculated the penalty previously, she assigned a value of "0" to this factor. (RX 39, RX_002858).

According to the Complaint, all violations for failure to state the RUP classification for Counts 1-2,140 occurred before June of 2008. (Compl., ¶¶ 369-470). Consequently all these violations ceased prior to the issuance of the first SSURO in 2008. Ms. Niess concurred.

> Q. Well, according to the first amended complaint, all alleged violations with failures that state an RUP classification occurred before June of '08, correct?
>
> A. Correct.
>
> Q. You did not allege that Liphatech violated 12(a)(2)(E) following issuance of the first stop sale order, have you?
>
> A. No.
>
> Q. So there's no continuing violation of this section, correct?
>
> A. Correct.

(Niess Tr. 210:18-211:4).

Moreover, the allegations in 2009 are after the time in which Counts 1-2,140 occurred. Therefore, they are not relevant to the culpability of Respondent for these earlier counts.

For purposes of this adjustment factor, the fact that Respondent ceased publication and airing of advertisements without the RUP classification prior to issuance of the 2008 SSURO must be viewed as the same as

"having instituted steps to correct the violation immediately after discovery of the violation." For Counts 1-2,140 the culpability factor should be, at most, "1." The only question is whether the failure to use "RUP" resulted from "negligence," meriting a "1," or was "neither knowing nor willful," meriting a "0." The hearing testimony by Respondent's witness, Mr. Schmit, supports the fact that the failure to use "RUP" was neither "knowing nor willful" and should be assigned a value of "0." (Schmit Tr. 66:5-67:8).

In addition, the advertising allegations for 2009/2010 are not relevant to establishing culpability for earlier and different violations. Even Ms. Niess agreed with this. (Niess Tr. 210:3-2:11:4, 213:3-12). Therefore, the culpability value for this RUP liability, which occurred in 2007-2008, should be "0" based on it being neither "knowing" nor "willful."

(ii) Culpability for Counts 2,141-2,183. Respondent took steps to immediately correct the alleged violations after Complainant brought the regulators' concerns to Respondent's attention. (*Id.* at 211:21-212:3). Respondent immediately sent a "please destroy" letter to its authorized distributors regardless of whether they actually had received the sales literature. Therefore, the adjustment factor for this set of violations for culpability should be either "0" or "1" because each of those adjustment factors apply in the event that the "violator instituted steps to correct the violation immediately after discovery of the violation." ERP at 34.

However, at the hearing, Ms. Niess placed a value of "2" on culpability based on her conclusion that Respondent's culpability was unknown. Ms. Niess, however, had previously determined that the appropriate value was "0." (RX 39,

RX_002858). At the hearing she then testified that she became aware of the fact that Respondent had filed "optional marketing claims" with the EPA for review and based on this fact she concluded that Respondent could have submitted any of its claims in its advertising or on its website to EPA for review." (Niess Tr. 122:13-124:8). However, this analysis is misplaced. First of all, pesticide advertising does not need to be submitted to the EPA for preapproval or any approval before it is used by a registrant, and, in fact, the EPA has stated that it routinely does not review advertising. (*See* CX 88, EPA 1572). Secondly, Ms. Niess again mixes labeling requirements with advertising. The optional marketing claims to which she is referring are actually marketing claims that Mr. Schmit testified were for use on the label and, as Mr. Schmit testified, anything that is stated on the label must be preapproved by the EPA. (Schmit Tr. 76:2-5). Mr. Schmit also stated that it was his understanding that pesticide advertising did not need to be preapproved by the EPA. (*Id.* at 65:1-4). Therefore, Ms. Niess' conclusion regarding culpability should be ignored.

Whether culpability ought to be "0" or "1" for Counts 2,141-2,183 depends on whether Respondent's acts were "negligent" or "neither knowing nor willful." With respect to the alleged advertising violations in Counts 2,141-2,183, Respondent's conduct was "neither knowing nor willful." As demonstrated at the hearing, there are no guidelines on what constitutes "substantially different" claims.[39]

[39] For example, EPA's "Protocol for Conducting Environmental Compliance Audits under the Federal Insecticide, Fungicide and Rodenticide Act" ("Audit Protocol") never mentions the issue of substantially different claims and the only mention of advertising in the entire 100+ page document is a reference on one page to the FIFRA section 12(a)(2)(E) requirement to specify the restricted use classification of the pesticide in advertising. (Audit Protocol 44). And this is the protocol that the EPA developed "to provide regulated entities with specific guidance in periodically evaluating their compliance with federal environmental requirements. (*Id.* at ii). This is the document Ms. Niess stated she was unfamiliar with at the hearing. (Niess. Tr. 216:12-216:18, 218:8-219:23).

Respondent had no prior FIFRA violations relating to advertising claims or otherwise before this time. Also, Ms. Niess' analysis that was sent to Respondent in November 2008 was after the alleged violations had been identified.[40] Therefore, the culpability factor for this set of alleged violations should be "0," should the Chief Judge find Respondent liable for these counts.

(iii) Culpability for Counts 2,184-2,231. Again, Respondent took immediate steps to rid the marketplace and its website of allegedly violative material as soon as the Complainant raised the issue with Respondent. (Niess Tr. 211:21-212:3). Therefore, this culpability factor should be either a "0" or a "1." The facts in the record and the evidence produced at hearing, particularly related to the lack of guidance on what constitutes substantially different claims should be considered factors in concluding that the literature that was posted on Respondent's website in 2009 and 2010 resulted from "neither knowing nor willful" conduct.

g. Summary of adjustment factors. Adding all of these adjustment factors together results in a total of "3" or less for each set of violations. Using Table 3 of the ERP, the enforcement remedy is

> No action or Notice of Warning (60% reduction of matrix value recommended where multiple count violations exist).

ERP at 20. Given the nature of the conduct alleged in the Complaint, Complainant should have first given Respondent a Notice of Warning before issuing the 2008 Stop Sale Order. On many occasions, EPA will give the respondent a warning letter before

[40] It should also be noted that her November 2008 analysis was based on what Complainant considered to be "false and misleading;" not what was considered to be "substantially different" claims.

commencing an enforcement action. *See Sporicidin Int'l*, 1988 WL 236319, at 3 (referencing copies of letters sent to respondent in that case "informing Respondent that claims made in collateral literature for the effectiveness of sporicidin against Hepatitis B and HTLV III/LAV (AIDS) viruses were unacceptable).[41]

Respondent acknowledges that EPA has the legal right to issue a SSURO without first issuing a Notice of Warning. However, the regulatory investigators knew of the RUP allegations in November 2007 and at that time also had telephone contact information for Respondent. (CX 8, EPA 67 (including contact information for Respondent's employee Charles Hathaway)). As a result, Complainant could have easily alerted Respondent to this problem. The long delay in contacting Respondent before issuing the 2008 SSURO in June of that year is an indication of the lack of significant gravity which the EPA attached to the RUP allegations in Counts 1-2,140. Nonetheless, if a 60% reduction in the matrix value is applied to the per-unit penalty of $6,500, as provided by Table 3 of the ERP, then the per-penalty amount would be reduced to $2,600.

h. Complainant's interpretation of the 2009 ERP discount policy is strained. After calculating the per-unit penalty amount, Complainant applied the discount provided in Section IV.B.1. of the 2009 ERP to Counts 1-2,140.[42] The discount formula in Section IV.B. of the 2009 ERP, on its face, however, only applies to the

[41] If Complainant would have issued such a notice of warning to Respondent on November 21, 2007 when Kansas Department of Agriculture Inspector Shawn Rich first became aware of the alleged violations, many of the violations could have been prevented. (*See* CX 8 EPA 00067, EPA 00072 (e-mail informing Shawn Hackett of KDA that the advertisements would continue to be run)).

[42] The Complainant did not make any further adjustments to the proposed penalty based on the factors in Section IV.B.3 of the 2009 ERP. For example, Respondent acted in good faith during the penalty discussions and the penalty should have been reduced another 20%.

"multiple sales or distributions for the same violations." 2009 ERP at 25. This section of the 2009 ERP provides that the per-unit penalty amount for violations involving sales or distributions that exceed 100 should be discounted to 25% of the per-penalty amount for the first 100 violations. It does not on its face apply to pesticide advertising violations. 2009 ERP at 25. Nowhere does the 2009 ERP explain how any type of discount should be applied in a case involving multiple advertising violations.[43] If the drafters of the 2009 ERP had considered the potential for FIFRA section 12(a)(2)(E) to result in thousands of violations based on individual radio broadcasts, it is quite possible that a more significant discount would have been applied.

Nevertheless, Complainant applied this discount to the alleged advertising violations in Counts 1-2,140 and hides behind its application to support counting each individual radio broadcast as a separate violation. (*See* Compl.'s Posthrg. Br. 126-127). Because Complainant assumed each airing of an advertisement constituted a separate violation of FIFRA § 12(a)(2)(E), it had to creatively interpret the 2009 ERP by applying the discount for sales and distributions to "advertising" violations. Ms. Claudia Niess testified that she arbitrarily substituted the term "Number of Advertisements" in the first column of Table 4 in the 2009 ERP for the term "Number of Distributions" to achieve Complainant's desired result. *Compare* 2009 ERP at 25 *with* CX 55, EPA 001012. She confirmed this fact at the hearing:

> Q. And on the graduated penalty calculations, the discount formula under the '09 penalty policy applies

[43] It should be noted that this "discount" policy was one of the main reasons the EPA issued this ERP to replace the prior ERP, which did not address "multiple-violation" penalty situations at all. To Respondent's knowledge, this is the first case to ever consider how and on what basis this "discount" policy should be interpreted and applied.

> to multiple sales or distributions for the same violations; isn't that correct?
>
> A. I believe that is the wording in that section.
>
> Q. And that does not address, in any fashion, what type of discount should be applied, but how discounts should be applied to advertising violations that are not based on the number of sales or distributions, correct?
>
> A. Correct. But it does go on to say that it is at EPA's discretion or – well, discretion to implement that in other cases.
>
> Q. So what you did to apply the discount to advertising violations, those that you believe were advertising violations, was you set the substituted in table for the term "number of distributions" in the first column with "number of advertisements, didn't you?
>
> A. Yes.

(Niess Tr. 214:12-215:8).

Section IV.B.2. of the 2009 ERP does not once use the word "advertising," or reference the RUP classification requirement under FIFRA section 12(a)(2)(E), or suggest how or even if the discount should be applied in multi-violation "advertising" cases. It specifically refers to multiple-violation cases involving "sales" or "distributions."

As a result, as it routinely does, EPA modifies the unit of violation and, as demonstrated by this case, selectively applies its own 2009 ERP in order to achieve the result it desires rather than the result that is supported by the totality of circumstances of the case. In this case, Complainant's selective application of the 2009 ERP can be shown by its failure to allege any economic benefit (which is mandated by the ERP), failure to apply any good faith adjustment for Respondent's cooperation during

this proceeding (including responding to SSURO's and stipulating to the vast majority of factual issues presented by this case) and its modification of the gravity adjustment scheme set forth in the 2009 ERP to apply to violations of FIFRA § 12(a)(2)(E).[44]

i. The 2009 ERP should be ignored in calculating a fair and reasonable penalty for Counts 1-2,140. The goal of the 2009 ERP is

> to provide fair and equitable treatment of the regulated community, predictable enforcement responses, and comparable penalty assessments for comparable violations.

2009 ERP at 4.

While this is a laudable statement, it clashes with reality for a number of reasons, including the way in which EPA determines the alleged unit of violation as discussed above. The EAB has indicated that a presiding officer generally cannot look at the penalty levied in other enforcement cases because such cases are sufficiently fact-intensive as to make any comparison difficult and inefficient. *In re Chem. Lab Prods., Inc.*, 10 E.A.D. 711, 2002 WL 31474170 (EAB 2002); *see also Valimet, Inc.*, Docket No. EPCRA-09-2004-0021, 2008 EPA ALJ LEXIS 38, at 32-33 (ALJ Nov. 6, 2008).

On the other hand, some federal circuit courts of appeal have indicated that penalties in previous EPA cases may be relevant. *See, e.g., Katzson Bros., Inc. v. EPA*, 839 F.2d 1396, 1401 (10th Cir. 1988) (indicating, when reviewing a penalty, that "EPA has shown greater temperance in the past"). In addition, the EAB has

[44] Notably, the failure of the 2009 ERP to address multiple violations of FIFRA § 12(a)(2)(E) could be the result of the fact that individual advertisements should not be counted as separate violations of that section. Rather the failure to include the restricted use classification of a pesticide in advertising should only result in one violation.

indicated that "[v]ariations in the amount of penalties assessed in other cases, even those `involving violations of the same statutory provisions or regulations, do not, without more, reflect an inconsistency" with the EPA policy of fair and equitable penalties. *Chem. Lab Products*, 2002 WL 31474170 at *13 (citing *In re Titan Wheel Corp.*, 10 E.A.D. 526, 2002 WL 1315600 (EAB 2002)) (emphasis added). The "more" that would be needed has never been directly addressed by the EAB and the tension between the EPA's two competing enforcement policies – one discouraging the examination of other cases and the other attempting to provide comparable penalties for comparable violations – has not been resolved. *Id.*

The federal district court decision in *Titan Wheel* indicates that a comparison of penalty cases may be appropriate where the complainant has misapplied the applicable penalty policy. *Titan Wheel Corp. v. United States Environmental Protection Agency*, 291 F. Supp. 2d 899, 918 (S.D. Iowa 2003). That is the point Respondent is making in this case, because when the penalty that is proposed by Complainant in this case is compared to the body of FIFRA penalty cases, the proposed penalty is "in a league of its own." *Monieson v. Commodity Futures Trading Commission*, 996 F.2d 852, 864 (7th Cir. 1993).

However, if this case also does not provide the "more" that the EAB in *Titan* felt was necessary before other penalties could be considered, then one is led to the conclusion that the applicable penalty policy is so clear and is applied so uniformly and consistently by EPA that one cannot reasonably imagine that it results in widely disparate treatment of parties accused of violating FIFRA. However, this is far from the actual situation.

A major flaw in the 2009 ERP is illustrated by looking at the formula for calculating penalties. The deceptively simple formula is:

| | | | | |
|---|---|---|---|---|
| Number of units of violation | X | Penalty per unit | = | Total penalty[45] |

Even assuming the penalty per unit of violation can be uniformly calculated under the 2009 ERP, which it cannot, prior cases have given the EPA significant latitude to charge whatever number of units of violation it cares to charge up to the maximum permitted by law. *See Rhee Bros.*, 2006 WL 2847398, at 20 (recognizing that where there are many units of violation, penalties may become out of proportion to the gravity of the offense and the agency retains discretion to seek less than the maximum penalty). This unchecked discretion may also result in a miscarriage of justice.

The Chief Judge should look to past reported adjudicated cases and the enforcement history of FIFRA to provide a context that appropriately assists the analysis of what is fair and equitable in a given case, keeping in mind the goal of the 2009 ERP is to provide "comparable penalty assessments for comparable violations." 2009 ERP at 4.

Counsel for Respondent is aware of only three adjudicated enforcement cases in the entire history of FIFRA in which a penalty has exceeded $200,000. Importantly,

> [T]he maximum penalty allowed by law . . . should normally be reserved for the most horrific violator, who has committed the most horrific violations such as a respondent with a long history of committing serious FIFRA violations, who then commits other

[45] The 2009 Penalty Policy also contains a formula for discounting the "penalty per unit," which is discussed below in Section II.D. *See* 2009 ERP at 25-26.

> egregious violations which were knowing and willful, involving a pesticide of the highest toxicity, and/or which caused actual serious or widespread harm to human health and the environment.

*Rhee Bros.*, 2006 WL 2847398, at 30-31. It is within this historical context that a reasonable and appropriate penalty should be calculated here.

Complainant's ability to use the 2009 ERP in this case must be seriously questioned.[46] Applying the 2009 ERP as proposed, the penalty proposed by Complainant would be the largest penalty ever assessed under FIFRA as admitted by Ms. Claudia Niess:

> Q. Sure. So if such a penalty of 2.9 is levied against Liphatech here, it would be the largest penalty ever levied in a reported case which was adjudicated, isn't that correct, in a FIFRA action?
>
> A. To my knowledge.

(Niess Tr. 138:7-12).

Without the discount, the penalty in this case using the 2009 ERP could range anywhere from being *de minimis* (or simply the issuance of a warning letter) to over $13 million depending on how the "unit" of violation is calculated. (*See* Compl.'s Posthrg. Br. 126-127). It is hard to see how a penalty policy that allows for this wide range of penalties can be viewed as a document that results in "fair and reasonable" and "equitable" penalties. Under the facts of this case, the 2009 ERP becomes a cloak to hide the Agency's arbitrariness and capriciousness by labeling it "prosecutorial discretion."

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[46] The major distinctions as far as the facts of this case are concerned between the 1990 and 2009 Penalty Policies are (i) the requirement in the new policy to recover significant economic benefit, and (ii) application of a discount matrix for multiple sale/distribution violations. 2009 Penalty Policy at 20 and 25. Complainant dropped its attempt to recover any economic benefit in its First Amended Complaint. In addition, it now has been demonstrated that the discount matrix does not apply to advertising.

The 2009 ERP is fatally flawed when applied to a case involving allegations of multiple units of advertising violations under FIFRA section 12(a)(2)(E) and should not be used to calculate a penalty in this case. The penalty generated by the 2009 ERP, as interpreted and applied by Complainant, grossly overstates the gravity of the Respondent's conduct in this case and would result in a miscarriage of justice.

Because the proposed penalty calculated by Complainant under the 2009 ERP is excessive, the goal of this proceeding must be to determine a penalty that "is appropriate in relation to the facts and circumstances at hand." *99 Cents Only*, 2010 WL 2787749, at 27-28. In this case, the Chief Judge should not utilize the penalty policy for these counts and should instead fashion an equitable and fair penalty based on the "totality of circumstances." *Id.* at 28.

In large part, the unreasonably high penalty demanded by Complainant for Counts 1-2,140 is driven by its interpretation of the "unit of violation," by a flawed application of the 2009 ERP by Complainant and by Complainant's prosecutorial zeal. As demonstrated above, the maximum reasonable unit of violation for this RUP issue is, at most, 10, based on the number of different radio stations or radio station conglomerates and trade journals with which Respondent contracted for the advertisement of Rozol. Applying the 2009 ERP to this number of violations results in a maximum sanction ranging from issuance of a warning letter up to a financial penalty of $26,000 based on a per unit violation amount of $2,600 with a maximum of 10 violations (see Sections VII.C.2. and 3.g. above).

j. 2009 ERP should be ignored for calculating a proposed penalty for Counts 2,141-2,231 should FIFRA liability be found to exist. Most of the

reasoning discussed in the previous section regarding the application of the 2009 ERP to Counts 1,-2,140 (other than the discount discussion) also applies to any proposed penalty that is assigned to the alleged violations in Counts 2,141-2,231 should the Chief Judge find Respondent liable for any of these acts. With respect to the unit of violation issue, the unit of violation for Counts 2,184-2,231 should be based on Respondent's website and, as discussed above, there is no guidance on the number of units of violation for alleged website advertising violations. As discussed previously, the unit of violation should be "1" based upon the material posted on Respondent's website.

Moreover, Complainant failed to show any link between the claims made by Respondent, even assuming they are substantially different, and any actual or potential damages to human health or the environment resulting from these advertising claims. While there was much testimony about Rozol, chlorophacinone and Rozol's use in the field by Complainant's witnesses, Complainant has not established any link between that testimony and the alleged violations set forth in the Complaint. Only a minimal penalty is warranted should any FIFRA liability be found by the Chief Judge with respect to these counts.

## VIII. CONCLUSION

For the reasons set forth above, Respondent believes that the Chief Judge must calculate a fair and reasonable penalty for Counts 1-2,140 based upon the "totality of the circumstances" relating to this case, not the 2009 ERP. Furthermore, Complainant has failed to carry its burden of persuasion necessary to establish any liability for Counts 2,141-2,231 and these counts should be dismissed.

The failure of Complainant to introduce contrary evidence can lead only to the following conclusions for purposes of this case: (1) Rozol was never sold illegally by Respondent; (2) no misuse of Rozol can be attributed to the acts of Respondent alleged in the Complaint; (3) Respondent's sales were not increased as a result of the alleged violations; (4) Respondent received no economic benefit from the acts alleged by Complainant to have violated FIFRA; (5) no actual harm to human health or the environment occurred as a result of the acts alleged by Complainant; and (6) Complainant failed to link any potential instances of harm to human health or the environment to the advertising words that are the subject of this action.

Complainant was not able to establish the requisite nexus between any claims made by Respondent and the sale or distribution of Rozol to any particular person with respect to Counts 2,141 through 2,183. The record also demonstrates that Complainant cannot establish that an offer for sale occurred with respect to Counts 2,184-2,231. Finally, Respondent has provided evidence establishing that the claims made by Respondent were supported by scientific evidence and were truthful. As a result, even if the claims made by Respondent were substantially different than the statement required, no harm could have occurred as a result.

Moreover, Complainant's reliance on the 2009 ERP and its interpretation of the 2009 ERP is misplaced and leads to a penalty that is devoid of any relationship to fairness or equity. Using the purely formulaic approach set forth in Complainant's post-hearing brief, the 2009 ERP fails to take into account myriad factors related to the uniqueness of this case. For example,

(a) The application of the 2009 ERP discount formula for sales and distributions is misplaced when it comes to alleged "advertising" violations. There is no discussion in the 2009 ERP explaining how and on what basis this discount is to be applied to words used in advertising; nor does Complainant make any attempt to explain this in its post-hearing brief. One of the many anomalies with this approach is that a discount that does not apply until 100 illegal sales/distributions of, for example, an unregistered pesticide results in a disproportionate penalty when applied to 100 alleged violations of advertising words where there is no link between those words and any evidence of harm introduced by Complainant in this case.

(b) The 2009 ERP does not contain any discussion of how Complainant should evaluate the importance or impact of advertising words as far as the gravity of the violation is concerned; nor does it discuss whether and to what extent the amount of dollars spent on an advertising campaign, the size of the advertising market or the concentration of ads aired within a market are to be evaluated for purposes of determining the gravity of advertising violations.

(c) In determining the gravity of advertising words, a critical component would be the impact of those words on the consuming public or, more importantly in this case, on certified applicators. Complainant produced no one who could testify on these impacts. Complainant's witnesses may be knowledgeable about the biology and science of chlorophacinone and Rozol, but that does not translate into expertise with respect to advertising and potential confusion created in the marketplace by alleged advertising words.

(d) The flaws in the 2009 ERP can also be seen from the fact Complainant's penalty analysis would result in the largest penalty ever levied under FIFRA and this case does not involve any egregious conduct such as sale of unregistered pesticides, illegal labeling of registered pesticides or actual harm to human health or the environment. Something is fundamentally wrong with its application when the 2009 ERP leads to this proposed result.

Complainant has used this case as a first impression test of its authority over advertising and it is inevitable that this case will have profound effect on both the EPA and the regulated community. It will have an impact on the EPA because if the Chief Judge determines that the extent of authority over advertising is as Complainant asserts, then the EPA will have enormous new burdens to sort through a deluge of requests from the regulated community to review and approve advertising material (whether or not it is considered to be part of the label). At the same time, the regulated community would be faced with the previously unimagined prospect that its advertising will also be subject to EPA scrutiny on a level beyond that applied by the Federal Trade Commission, even for advertising that is not connected to any actual sale or distribution of a pesticide. Under Complainant's theory, any advertising that is available to the general public would now be subject to EPA preapproval, scrutiny and enforcement, even absent any actual sale or distribution of the advertised product. This theory is contrary to the intent of the applicable language in FIFRA and the Chief Judge should not open the door to that type of interpretation.

Dated this 13th day of August, 2012.

Respectfully submitted,

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

**CERTIFICATE OF SERVICE**

I, Michael H. Simpson, one of the attorneys for the Respondent, Liphatech, Inc., hereby certify that I delivered one copy of the foregoing Respondent's Post-hearing Brief, to the persons designated below, by depositing it with a commercial delivery service or First Class Mail, postage prepaid, at Milwaukee, Wisconsin, in envelopes addressed to:

Honorable Susan L. Biro
Office of the Administrative Law Judges
Franklin Court Building
1099 14th Street, NW, Suite 350
Washington, D.C. 20005; and

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

I further certify that I filed the original and one copy of the Respondent's Post-hearing Brief and the original of this Certificate of Service in the Office of the Regional Hearing Clerk, U.S. EPA, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, by depositing them with a commercial delivery service, postage prepaid, at Milwaukee, Wisconsin, on the date below.

Dated this 13th day of August, 2012.

Michael H. Simpson
One of the Attorneys for Respondent
Liphatech, Inc.