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October 28, 2010

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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

Michael It Simm

On behalf of Respondent, Liphatech, Inc., I enclose for filing an original and two copies of Respondent's Prehearing Information Exchange, together with true, accurate and complete copies of Respondent's Exhibits 1 through 88.

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

Respectfully submitted,

Michael H. Simpson

REINHART\5034438LNR:LC

Encs.

Honorable Barbara A. Gunning (w/encs., by courier) cc Ms. Nidhi K. O'Meara (C-14J) (w/encs., by courier) Mr. Carl Tanner (w/o encs., by courier)



REGIONAL HEARING CLERK U.S. ENVIRONMENTAL PROTECTION AGENCY

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 5

In the Matter of:	) Docket No. FIFRA-05-2010-0016	
Respondent, Inc. Milwaukee, Wisconsin,	) PREHEARING INFORMATION ) EXCHANGE OF RESPONDENT	
Respondent.	LIPHATECHTOEGEIVE	
	) OCT 2 9 2010	

REGIONAL HEARING CLERK

Pursuant to the Prehearing Order issued by the Presiding Officer on AGENCY.

June 30, 2010 and Section 22.19(a) of the Rules of Practice, 40 C.F.R. § 22.19(a),

Respondent Liphatech, Inc. ("Respondent") respectfully submits the following prehearing exchange information:

- I. The Names of Any Expert or Other Witness That Respondent Intends to Call at the Hearing Together with a Brief Narrative of Each Witness' Expected Testimony.
  - A. <u>Fact Witnesses</u>. Respondent may call the following persons to testify as fact witnesses at the hearing:
    - Carl Tanner,
       Alan Smith,
       Thomas Schmit and/or
       Charles Hathaway,
       Officers or Employees of Respondent.

Mr. Tanner is the Chief Executive Officer, Liphatech, Inc. Mr. Smith is the Business Director, Agricultural Division, Liphatech, Inc. Mr. Schmit is the Manager of Regulatory Affairs, Liphatech, Inc. Mr. Hathaway is the Senior

Market Manager – Agricultural Markets, Liphatech, Inc. The witness(es)' testimony may include, but may not be limited to the following:

Each witness may testify as to his own educational background, his relevant work experience and his role as an employee or officer of Respondent. Each witness may testify as to the history and use of chlorophacinone (the active ingredient in Rozol) as a rodenticide in general and, in particular, the development and use of Rozol to manage black-tailed prairie dogs and pocket gophers. Each witness may testify as to the pesticide registration process and the data and information that has been generated regarding the chemical characteristics and efficacy of Rozol. The witness(es) may also testify as to the specific registration process for Rozol at the state and federal regulatory levels. Each witness may also testify as to the documents submitted to state and federal regulatory agencies as part of the registration process.

Each witness may explain that the advertising material that is the subject of the Complaint is not labeling under FIFRA. Each witness may testify as follows: (a) the advertising material that is the subject of the Complaint was not attached to the Rozol product; (b) the advertising material that is the subject of the Complaint was not distributed with and never physically accompanied the product; (c) the advertising material that is the subject of the Complaint was not referenced on the label for the product; (d) the advertising material that is the subject of the Complaint was not referenced in literature accompanying the product; (e) the

advertising material that is the subject of the Complaint was intended to educate potential customers about the benefits of the product; (f) the advertising material that is the subject of the Complaint did not contain directions for use that were in any way intended to augment or supplement the label; (g) there was no intent on the part of Respondent to circumvent FIFRA, especially because Respondent's pesticides had EPA-approved labels which included detailed directions for use; and (h) the advertising material that is the subject of the Complaint was not intended to accompany the product user into the field during application. Each witness may also testify as to the purpose of Respondent's advertising and the nature of pesticide advertising in general.

Each witness may testify as to the content of the advertising that is the subject of the Complaint. Each witness may also testify that the advertising incorporated the terms of restriction of the pesticide. Each witness may further testify as to the scope of Respondent's advertising, the timing of advertisement placement, its targeted audience and the decision-making process employed to format and direct advertising to potential users. Each witness may testify as to the reach of Respondent's advertising material and the distribution of its advertising. The witness(es) may testify that Respondent has communicated with and educated potential product users by advertising in niche trade journals and on small radio networks.

Each witness may testify that the EPA does not require the review of advertising material as part of the pesticide registration process. The witness(es)

may testify that, while EPA reviews and approves statements for use on the product label or labeling as part of the registration process, EPA does not review advertising material.

Each witness may testify that Respondent's advertising material is truthful and not misleading. Each witness may testify that Respondent's advertising material is supported by scientific studies, reports, data and publicly available information. Each witness may testify that Respondent's advertising material is not substantially different from the registration materials submitted to EPA as part of the registration process.

Each witness may testify as to the content of Respondent's website at various points in time relevant to the Complaint. Each witness may testify that no pesticide products may be purchased on Respondent's website and that the website does not include product pricing information.

Each witness may testify that Jim Knuth and Mark Newman are representatives of Respondent. The witness(es) may testify as to the dates that the advertising that is the subject of the Complaint was created and the dates that the advertising was made available to the public.

Each witness may testify as to the nature of Respondent's prompt response to and cooperation with EPA's investigation of the alleged violations that are the subject of the Complaint.

Each witness may also testify to additional facts as necessary to respond to assertions or arguments raised by Complainant. To the extent deemed

necessary by the Presiding Officer, the witness(es) will provide testimony sufficient to authenticate the documents that he or they refer(s) to during his or their testimony at the hearing in this matter.

#### 2. Charles D. Lee.

Mr. Lee is an Instructor in the Department of Animal Sciences and Industry at Kansas State University in Manhattan, Kansas. Mr. Lee has a Bachelor of Science Degree in Fisheries and Wildlife Biology and a Master of Science Degree in Animal Science and Industry. He is a candidate for a Doctor of Philosophy Degree in Animal Sciences. Mr. Lee's factual testimony may include, but it will not be limited to, the following:

Mr. Lee may provide testimony as a fact witness on the scientific studies he has conducted and data he has generated on pesticides, and in particular Rozol. Mr. Lee may also testify to additional facts as necessary to respond to assertions or arguments raised by Complainant and provide testimony to authenticate the documents to which he refers during his testimony.

B. <u>Expert Witnesses</u>. Respondent may call the following persons to testify as expert witnesses at the hearing:

#### 1. Robert H. Fuhrman.

Robert H. Fuhrman is Principal and CEO of Seneca Economics and Environment, LLC, a consulting firm he founded in 2002 that is located in Germantown, MD. From 1977 to 1983, the U.S. Environmental Protection

Agency employed Mr. Fuhrman primarily as an economist at its headquarters in Washington, D.C., in its Office of Policy, Planning, and Evaluation, a component of its then existing Office of Planning and Management. Mr. Fuhrman left EPA as a GS-15 level economist. From 1987 through 2001, he was employed by two nationally-based, economic, financial and management consulting firms. His curriculum vitae is included at Respondent's Exhibit 40a.

Mr. Fuhrman's consulting practice focuses on economics, finance, and regulatory policy analysis. As a consultant, he has worked on many environmental civil penalty cases, performing economic benefit, ability-to-pay, and "gravity component" analyses. Analyses of the "gravity of violations" are based on the application of various statute-specific EPA civil penalty policies to case-specific situations. Mr. Fuhrman has published over 30 articles on issues related to environmental enforcement, including two on EPA civil penalty policies.

Mr. Fuhrman has provided expert testimony in federal district courts on, among other topics, the amounts of economic benefit that individual companies may have obtained due to alleged noncompliance with environmental requirements. He has provided expert testimony in hearings before EPA Administrative Law Judges on the application of statute-specific civil penalty policies, including the 1990 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Environmental Response Policy (ERP), to case-specific situations. Mr. Fuhrman qualified as an expert witness on the application of civil penalty policies

in the following cases: (1) In the Matter of Outboard Marine Corporation

[Docket No. V-W-91-C-123B (1995)] and (2) In the Matter of Rhee Bros., Inc.

[Docket No. FIFRA-03-2005-0028 (2006)]. Mr. Fuhrman has never been proffered as an expert witness and then not been allowed to testify as such by a trier-of-fact.

(a) Overview of Mr. Fuhrman's Potential Testimony.

In the administrative law hearing in this case, Mr. Fuhrman's testimony may include, but not be limited to, the matters discussed in the following paragraphs.

Mr. Fuhrman may testify that without going through public notice and comment rulemaking pursuant to the Administrative Procedure Act, EPA issued statute-specific civil penalty polices, including the 1990 and 2009 FIFRA ERPs, to guide EPA's internal decision-making related to the calculation of penalty amounts for violations of environmental requirements. He may testify that while the FIFRA ERPs were designed to deal with a wide variety of enforcement situations, EPA has not claimed that they are perfect or appropriate to deal with all potential circumstances that might arise in adjudicated cases.

He may testify that these policies were promulgated under the aegis of the Agency's 1984 Civil Penalty Policy, which has three stated goals: (1) deterrence; (2) fair and equitable treatment of the regulated community; and (3) swift resolution of environmental problems. He may testify that in discussing "fair and equitable treatment," the 1984 Policy stated, among other things, that "other

unique factors specific to the violator or the case" may be considered by EPA in civil penalty assessments.

Mr. Fuhrman may testify that the stated purposes of both the 1990 and 2009 FIFRA ERPs are "to provide fair and equitable treatment of the regulated community, predictable enforcement responses, and comparable penalty assessments for comparable violations." He may testify that according to the Agency's Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, ALJs are only required to consider a penalty policy or an ERP when they determine civil penalties based on evidence in the record and in accordance with the civil penalty criteria in the relevant statute, such as FIFRA.

Mr. Fuhrman may testify that applying some aspects of an ERP to case facts requires more use of subjective judgment than do others. He may testify that as a result of the need to apply subjective judgment to certain aspects of the FIFRA ERP, reasonable individuals may disagree about how some aspects of the ERP should be applied. He may testify that, as noted by the EPA Environmental Appeals Board,"... reasonable people may disagree over the amount of penalty in a particular case...."

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<sup>&</sup>lt;sup>1</sup> Courtney M. Price, EPA Assistant Administrator for Enforcement and Compliance Monitoring, "Environmental Protection Agency Civil Penalty Policy," February 16, 1984, copy published by the Bureau of National Affairs, S-698, at page 41:2992.

<sup>&</sup>lt;sup>2</sup> EPA, FIFRA Enforcement Response Policy, December 2009, page 4.

<sup>&</sup>lt;sup>3</sup> In re: Johnson Pacific, Incorporated [Docket No. FIFRA-09-0691-C-89-56; FIFRA Appeal No. 93-4 (1995), at 5 E.A.D. 696, 703].

Mr. Fuhrman may testify that to better inform his opinion about how ALJs and the EAB have interpreted and applied the FIFRA ERP in determining civil penalties, he reviewed the 1990 and 2009 FIFRA ERPs, read more than 30 ALJ and EAB decisions in FIFRA cases, and conducted additional research.

Mr. Fuhrman may testify that in calculating proposed penalties for use in pleadings, such as complaints, EPA enforcement staff members generally try to argue for high penalties within the broad guidelines of the applicable ERP, but they do not typically try to fill in gaps in an ERP that were left by its authors. He may testify that an ERP is a guidance document that lacks the force of law, and, as such, is open to challenge in individual cases. He may testify that an ALJ may deviate from an ERP if the reasons for doing so are "compelling" or "pervasive and convincing."

Mr. Fuhrman may testify that the 2009 FIFRA ERP does not state whether or how it should be applied retroactively to alleged violations that occurred prior to its promulgation. He may testify that ALJ J. F. Greene's initial decision (1996) and decision upon reconsideration (1997) in *In the Matter of Associated Products, Inc.* (Docket No. IF&R-III-412-C) appear to have considered this question in regard to the 1990 ERP and concluded that if retroactive application of that ERP would result in a higher penalty amount than would application of the 1974 FIFRA Civil Penalty Policy:

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"...it would appear to have been unreasonable and unfair to retroactively apply the 1990 policy" [quoting from the Initial Decision] where the violation occurred before it was issued, [and] penalty policies are not binding upon the trial judge in assessing a penalty.<sup>4</sup>

Mr. Fuhrman may testify that in the present case, if the Presiding Officer finds the Respondent liable for the violations alleged in Region 5's Complaint dated May 13, 2010, there may be "compelling" or "pervasive reasons" for the Presiding Officer to deviate from some or many of the aspects of the ERP the Presiding Officer chooses to employ.

Mr. Fuhrman may testify that FIFRA and the two ERPs provide no guidance as to how to treat circumstances where the penalty calculated under an ERP is highly disproportionate to the gravity of the violations in the view of the Presiding Officer. He may testify that Region 5's proposed penalty of \$2,941,456 in its Complaint, if accepted by the Presiding Officer, would place the gravity of the alleged violations in this case far above that of any FIFRA penalty determination by an ALJ during at least the last ten years and by the EAB since at least 1992. See Respondent's Exhibit 41, a document which Mr. Fuhrman created.

Mr. Fuhrman may testify that in several adjudicated FIFRA cases, ALJs have stated various reasons for deciding to depart from strict adherence to the penalty formulations embodied in the 1990 ERP. For example,

<sup>&</sup>lt;sup>4</sup> In the Matter of Associated Products, Inc. (Docket No. IF&R-III-412-C), Decision Upon Reconsideration, September 10, 1997, at 7.

<sup>&</sup>lt;sup>5</sup> The EAB made a similar statement in the last sentence of footnote 16 in its decision in *Rhee Bros., Inc.* [FIFRA Appeal No. 06-02 (2007)] at 13 E.A.D. 261, 271.

he may testify that individual ALJs have explained that they decided to deviate from the ERP in certain circumstances, including the following: (1) because the penalty proposed by the Complainant on the basis of the ERP overstated both the gravity of the harm and the gravity of the misconduct resulting from the violations; (2) because in the totality of the circumstances of a particular case, the penalty amount seemed unduly large<sup>7</sup> and the lesser amount determined by the ALJ reflected the ALJ's assessment of the gravity of the violations and was still sufficiently substantial to fulfill the basic purposes of civil penalty assessment, i.e., of punishment and deterrence when considering as a whole all the circumstances of the case; (3) because of equitable considerations in assessing a civil penalty: (4) because "[t]he simple multiplication of the penalty calculated under the ERP for one violation by the number of distributions yields a penalty which does not reflect the total circumstances of [that] case;"<sup>10</sup> (5) because of multiple factors, including (a) there was no evidence that Respondent's violative actions had an actual negative impact upon persons or the environment; (b) the total penalty calculated by the ALJ on the basis of the ERP, "as a result of the many counts

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<sup>&</sup>lt;sup>6</sup> In the Matter of Four Star Feed and Chemical [Docket No. FIFRA-06-2003-0318 (2004)], at 11.

<sup>&</sup>lt;sup>7</sup> In the Matter of Avril, Inc. [Docket No. IF &R III-441-C (1997)], [1997 EPA ALJ Lexis 176, at \*10.] <sup>8</sup> Ibid.

<sup>&</sup>lt;sup>9</sup> In the Matter of Johnson Pacific, Inc. [Docket No. FIFRA-09-0691-0-89-56 (1993), 1993 WL 32409, at \*9; FIFRA Appeal No. 93-4 (1995). See, in particular, 5 E.A.B. 696, 704, which states, "Although "fairness, equity, and 'other matters as justice may require' are not specifically mentioned in the penalty provisions of FIFRA, they are nonetheless fundamental elements of the regulatory scheme."

 $<sup>^{10}</sup>$  In the Matter of Rhee Bros., Inc. [Docket No. FIFRA-03-2005-0028 (2006), at page 47; FIFRA Appeal No. 06-02 (2007)].

alleged, also seems high,"<sup>11</sup> and (c) "the totality of the circumstances in this case, including the rather nominal amount of economic benefit" in comparison to the "high penalty calculated under the ERP;"<sup>12</sup> and (6) because, given the facts of a particular case, assessment of the penalty in accordance with the ERP would be "punitive rather than remedial."<sup>13</sup>

Mr. Fuhrman may testify that in an administrative penalty case the burden of proof is on the Complainant to show that the proposed penalty produced on the basis of an ERP is appropriate in light of the penalty criteria listed in Section 14(a)(4) of FIFRA, i.e., "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." However, Mr. Fuhrman understands that the size of the Respondent's business, Respondent's ability to remain in business and the potential adverse impact on the ability of Respondent to continue in business are not being contested in this litigation, so that the only relevant statutory penalty factor for the purpose of this proceeding is gravity.

Mr. Fuhrman may testify that the number of violations asserted by a Complainant that are upheld by an ALJ could lead to a penalty result that might be disproportionate to the totality of the circumstances in a particular case if the ALJ chose not to deviate from the ERP. He may testify that the rigidity

<sup>&</sup>lt;sup>11</sup> In the Matter of 99 Cents Only Stores [Docket No. FIFRA-09-2008-0027 (2010), at page 49.

<sup>12</sup> Ibid.

<sup>&</sup>lt;sup>13</sup> In the Matter of 4 Seasons Cooperative [Docket No. FIFRA-08-2006-0001 (2008), at page 19.

of the procedures embodied in an ERP is particularly obvious where, in a case such as this one, the Complainant has utilized its enforcement discretion to allege a huge number of violations, each of which Complainant asserts carry a maximum or very high per-violation penalty.

(b) Potential Testimony Related to the Alleged Violations under Section 12(a)(2)(E) of FIFRA.

Mr. Fuhrman may testify that FIFRA does not define what constitutes a single offense under Section 14(a)(1). He may testify that Section 12(a)(2)(E) states, in part, that it is unlawful for a registrant "to advertise a product registered under this Act for restricted use without giving the classification of the product assigned to it under section 3." He may note that FIFRA does not state whether for penalty purposes such offenses should be calculated on the basis of the *number of different* versions of broadcast and print ads for which the Respondent paid; the *total number of days* such advertisements were made on the air or in print publications; or *each time* such advertisements were broadcast or appeared in a separately dated issue of a print publication.

Mr. Fuhrman may testify that Ms. Claudia Niess, <sup>14</sup> who has been designated as a fact witness for Complainant in this case, calculated for the Complainant the number of alleged violations of Section 12(a)(2)(E) using different approaches at different points in time. For example, he may testify that in the Complainant's Prehearing Exchange dated September 28, 2010, Ms. Niess

<sup>&</sup>lt;sup>14</sup> Ms. Niess is an enforcement officer in the Pesticides and Toxics Compliance Section of EPA Region V.

based her penalty calculations related to Respondent's alleged violations of Section 12(a)(2)(E) on 2,140 instances in which Respondent allegedly advertised Rozol (EPA Registration No. 7173-244) without either stating that Rozol is a "Restricted Use Pesticide" or identifying its "terms of restriction." Furthermore, he may testify that Ms. Niess' name appears on a penalty calculation worksheet that Mr. Kevin C. Chow, Associate Regional Counsel, EPA Region 5, provided to Respondent's counsel Jeffrey P. Clark in a letter dated October 2, 2009, in which, based on the same facts discussed in the Complainant's Prehearing Exchange, only 132 "counts" of such advertising on radio and only 16 "counts" of such advertising in print publications were identified for purposes of calculating a penalty demand issued by Region 5 to Respondent related to these alleged violations of Section 12(a)(2)(E). Mr. Fuhrman may testify that the October 2, 2009 counting of alleged violations totals 148 violations, which is a vastly different number than the 2,140 alleged violations referred to in the Complainant's Prehearing Exchange.

Mr. Fuhrman may testify that while (1) Ms. Niess' calculations in the Complainant's Prehearing Exchange were allegedly based on the 2009 ERP and (2) the penalty calculation worksheet attached to Region 5's October 2, 2009 letter were clearly identified as having been based on the 1990 ERP, the use of the different ERPs in the two penalty analyses does not explain Ms. Niess' possible use of the two different approaches within a six-month period of time to counting alleged violations based on the same underlying facts. He may testify that Ms. Niess' possible use of two different approaches is problematic,

given that the same set of facts was used in each approach, particularly where the Complainant attempts to impose the maximum allowable penalty of \$6,500 per alleged violation.

Mr. Fuhrman may testify that although the 1990 and 2009
FIFRA ERPs include language attempting to address what constitutes
"independently assessable charges," over time EPA enforcement staff have
utilized a variety of different approaches to calculate the number of alleged
violations in different adjudicated cases. These range from exercising EPA's
"maximum" authority under FIFRA to charge a violation for each individual sale,
to charging just one count for each year in which an unregistered pesticide product
was sold.<sup>15</sup>

Mr. Fuhrman may testify that, as in *Rhee Bros., Inc.*, <sup>16</sup> a

FIFRA enforcement proceeding in which Mr. Fuhrman testified as an expert

witness, EPA has the authority to charge a Respondent with many more violations
than the number of violations EPA chooses to prosecute for penalty purposes. He
may testify that Region 5 has chosen not to do so in this case for no apparent
reason. This is unless, of course, the Complainant believes that the gravity of
Respondent's alleged violations in this case very substantially exceeds any other
known FIFRA cases decided by ALJs or the EAB in over at least the last decade

<sup>&</sup>lt;sup>15</sup> In the Matter of 99 Cents Only Stores [Docket No. FIFRA-09-2008-0027 (2010), at pages 41 and 42.]

<sup>&</sup>lt;sup>16</sup> In the Matter of Rhee Bros., Inc. [Docket No. FIFRA-03-2005-0028 (2006), at pages 2 and 10; FIFRA Appeal No. 06-02 (2007)].

and possibly for a longer period of time and exceeds by more than 50 percent the gravity of the violations in the single largest decision he is aware of during this period.<sup>17</sup>

Mr. Fuhrman may testify that in the penalty calculation analysis performed by Ms. Niess in support of the Complaint, <sup>18</sup> Ms. Niess incorrectly applied the "graduated penalty table" for Category I "Size of Business" Respondents to the alleged 2,140 Section 12(a)(2)(E) violations. <sup>19</sup> These alleged violations relate to radio and print advertisements for Rozol Prairie Dog Bait and Rozol Pocket Gopher Bait Burrow Builder Application ("Rozol," EPA Registration No. 7173-244) that according to the Complainant did not include the phrase "Restricted Use Pesticide" or, alternatively, did not state Rozol's "terms of restriction."

Mr. Fuhrman may testify that under a strict reading of the 2009 ERP the alleged Section 12(a)(2)(E) violations do not qualify for graduated penalty reductions according to Table 4 of the 2009 ERP because a plain English reading of pages 25 and 26 of that document indicates that such reductions are available only on a "per-distribution" basis. He may testify that both Table 4 and pages 25 and 26 do not discuss graduated penalty reductions related to alleged advertising-related violations not brought on a per-distribution basis.

<sup>&</sup>lt;sup>17</sup>See Respondent's Exhibit 41: In the Matter of E.I. Du Pont De Nemours & Co., [Docket No. FIFRA-95-H-02]; affirmed in part, remanded in part, FIFRA Appeal No. 98-2, (2000) (a \$1,895,000 penalty).

<sup>&</sup>lt;sup>18</sup> Bates pages EPA 001007-0001013.

<sup>&</sup>lt;sup>19</sup> Table 4 appears on page 25 of the 2009 FIFRA ERP.

In this same regard, Mr. Fuhrman may testify that he notes that in the first chart appearing on Bates page EPA 001012 of the Complainant's prehearing exchange, Ms. Niess substituted the phrase "Number of Violations" for the phrase "Number of Distributions" that appears in the three box charts on Table 4 of the 2009 ERP. Based on Mr. Fuhrman's understanding of the 2009 ERP and what Ms. Niess wrote regarding her penalty calculations on Bates page EPA 001012, he may testify that it appears that Ms. Niess deviated from the ERP by applying the "graduated penalty matrix" (Table 4) to the alleged advertising-related violations.

Mr. Fuhrman may testify that he believes it might be appropriate for the Presiding Officer to rule on whether the ERP binds the Complainant on (1) the general boundaries within which it can apply the ERP in calculating the proposed penalty in this case and (2) whether the Complainant may freely depart from the broad guidelines of the ERP by extrapolating its Table 4 to alleged violations that are not tied to the number of sales or distribution of a pesticide. Mr. Fuhrman may testify that if the authors of the 2009 ERP had envisioned that a Complainant might allege and a Respondent might be found liable for hundreds or perhaps thousands of advertising-related violations in a particular case, they might have created a very different graduated penalty matrix, with values very different than those on Table 4 that the Complainant wishes to apply to such alleged violations in this case.

Mr. Fuhrman may testify that strict adherence to the 2009 ERP might lead to a proposed penalty of \$13,910,000 for the alleged 2,140 advertising-related violations. He may testify that, in contrast to Ms. Niess' calculation of \$2,268,500 as the proposed penalty based on her "application" or "misapplication" of Table 4, such an absurdly high penalty for the alleged advertising-related counts highlights the rigidity of the ERP when large numbers of violations are alleged by the Complainant and a high "base penalty" (\$6,500) per alleged violation is used without reduction due to the "gravity adjustment criteria."

Assuming that the Presiding Officer finds the Respondent liable for the alleged 2,140 advertising-related violations, given the circumstances of this case, Mr. Fuhrman may testify that he believes that a penalty anywhere near \$2,268,500 for those alleged violations would be highly disproportionate to the gravity of the alleged violations, plus the amount of economic benefit allegedly obtained due to noncompliance in this case.<sup>21</sup>

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<sup>&</sup>lt;sup>20</sup> The references here are to pages 19, 20, 34, 35, and 37 of the 2009 ERP.

<sup>&</sup>lt;sup>21</sup> Although on page 103 of the Complaint, Region 5 alleged that the Respondent's "economic benefit" totaled \$50,256, Region 5 provided no support for this assertion. Mr. Fuhrman understands that the Complainant filed a Motion for Leave to Amend Complaint to Reduce Proposed Penalty and Memorandum in Support of Complainant's Motion, dated September 15, 2010, which would have the intended effect of reducing economic benefit to zero in an amended complaint. Further, he is aware that on October 1, 2010, an additional relevant document was filed, Complainant's Response to Motion of Respondent to Partially Dismiss the Complaint or in the Alternative for Partial Accelerated Decision on an Issue of Liability in Favor of Respondent with Respect the Alleged Violations of § 12(a)(1)(E) of FIFRA, which would also reduce economic benefit to zero in an amended complaint.

Mr. Fuhrman assumes that the following information is true for purposes of his testimony:

- (i) As a result of Rozol's classification as a restricted use pesticide, the product can only be sold to and be used by Certified Applicators or persons under the direct supervision of Certified Applicators, and only for uses specified on the label for the product.
- (ii) Respondent is prohibited from selling Rozol to a distributor unless the distributor provides to Respondent proof that the distributor has a valid license to use and/or to sell Rozol to individuals or entities covered by a Certified Applicator's license.
- (iii) Respondent's distributors are prohibited from selling Rozol to a dealer unless the dealer has a valid license to use or to sell Rozol to individuals or entities covered by a Certified Applicator's license.
- (iv) A dealer is prohibited from selling Rozol to a rancher or weed board unless that person or entity has a license to use Rozol in compliance with its terms of restriction as a restricted use pesticide.
- (v) Other than one settled case<sup>22</sup> in which the respondent Thomas County Noxious Weed Department in Colby, Kansas did not admit liability, there do not appear to be any other reported federal cases involving Rozol being sold or used contrary to the requirements set forth in items i-iv above.
- (vi) At the time Rozol is sold to an end user, the user must be handed both the label for the registered pesticide approved by EPA and the supplemental label approved by the relevant State in which the purchase is made. In the States of Texas and Colorado, sale and use of Rozol is lawful only in the counties identified on the approved supplemental labels.
- (vii) There are no reported cases of Rozol being sold or used in Texas or Colorado in counties not specified on Rozol's supplemental labels.

<sup>&</sup>lt;sup>22</sup> 2010 WL 2787715 (E.P.A.), July 1, 2010.

- (viii) During the relevant period of time, each State-approved supplemental label for Rozol included a statement that it is a "Restricted Use Pesticide" and a statement of the pesticide's "terms of restriction."
- (ix) The parties vigorously dispute whether the Respondent violated Section 12(a)(2)(E) of FIFRA.
- (x) The Complainant has not alleged that the Respondent acted in bad faith by attempting to satisfy the requirements of Section 12(a)(2)(E) by including in its broadcast advertisements for Rozol the spoken words

"Approved under a special local needs 24C label for the states of ... ALWAYS FOLLOW AND READ LABEL DIRECTIONS. SEE YOUR LOCAL AG CHEMICAL DEALER"

rather than just substituting the words "Restricted Use Pesticide."

- (xi) The cost of substituting in the radio advertisements the words "Restricted Use Pesticide" for the alternative, longer statements referenced in item 10 above would have been nil or *de minimis*.
- (xii) The Complainant has not alleged that the Respondent acted in bad faith by including in its print advertisements the words

"in order to use this product for the control of Black Tailed Prairie Dogs, you must have a 24(c) Prairie Dog label in your possession"

rather than substituting the words "Restricted Use Pesticide."

- (xiii) The cost of substituting the words "Restricted Use Pesticide" for the longer statements referenced in item (l) above would have been nil or *de minimis*.
- (xiv) The Complainant has not alleged that the Respondent either distributed or sold more units of Rozol because of the content of its radio and print advertising for the product.
- (xv) The Complainant has not alleged the Respondent distributed or sold Rozol to persons or entities not legally allowed to

purchase it because of the content of its radio and print advertising for the product.

- (xvi) The Complainant has not alleged that the Respondent somehow economically benefited because of the content of its radio and print advertising for Rozol.
- (xvii) The Complainant has not alleged that the Respondent continued to advertise Rozol after it received notification from EPA that the Agency considered its previous radio advertising to violate Section 12(a)(2)(E).
- (xviii) The Complainant has not alleged that the Respondent continued to advertise Rozol in print advertising after it received notification from EPA that the Agency considered its previous print advertising of Rozol to violate Section 12(a)(2)(E).

Based on the eighteen points listed above, Mr. Fuhrman may testify that if the Respondent is found liable for the alleged advertising-related violations, he does not believe that a penalty even remotely approaching \$2,268,500 would (a) appropriately reflect the actual gravity of the alleged violations, (b) equate to "fair and equitable" treatment of a member of the regulated community, (c) be necessary to achieve deterrence by Respondent and/or the regulated community, or (d) be remedial rather than highly punitive.

Mr. Fuhrman may testify in greater depth on his penalty analysis concerning the alleged advertising-related violations, which appears in a separate document titled "Civil Penalty Analysis re: Docket No.

FIFRA-05-2010-0016" that is located at Respondent's Exhibit 42 in its prehearing exchange information.

(c) <u>Potential Testimony Related to the Alleged Violations</u> under Section 12(a)(1)(B) of FIFRA.

Mr. Fuhrman may testify that he noted that in pages 69 through 102 of the Complaint, Region 5 pled 91 counts<sup>23</sup> alleging that Respondent made claims "for the product as part of distribution or sale that substantially differed from claims approved in the March 2, 2005 'accepted label,'" <sup>24</sup> or, additionally or in the alternative by distributing or selling Rozol "which was misbranded..." <sup>25</sup>

Mr. Fuhrman may testify that in the two adjudicated cases that he read in which "differing claims" violations were discussed, the cited differences were between "claims" made to induce sale of a particular pesticide and claims made as part of its registration statement, 26,27 as contrasted with claims on an "accepted label."

In regard to Counts 2141 through 2231 of the Complaint,

Mr. Fuhrman may testify that he is aware that the Respondent disagrees with the

Complainant's interpretation of certain statutory and regulatory provisions and

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<sup>&</sup>lt;sup>23</sup> The 91 include Counts 2141 to 2231 in the Complaint dated May 13, 2010.

<sup>&</sup>lt;sup>24</sup> See, for example, paragraph number 472, which appears on page 69 of the Complaint dated May 13, 2010.

<sup>25</sup> Ibid.

<sup>&</sup>lt;sup>26</sup> In the Matter of Sporicidin International [Docket No. FIFRA-88-H-02; FIFRA Appeal No. 88-2; 1991 WL 155255 (E.P.A.), at \*2: "On May 28, 1986, EPA issued an Amended Policy Statement announcing that sellers of antimicrobial pesticides may no longer make claims for their products that substantially differ from claims accepted by EPA in connection with their registrations."]

<sup>&</sup>lt;sup>27</sup> In re: Microban Products Company [Docket No. FIFRA-98-H-01; FIFRA Appeal No. 02-07, 2004 WL 1658590, at \*1: "Section 12(a)(1)(B) makes it unlawful to distribute or sell a pesticide if any claims made as part of its distribution or sale substantially differ from claims made for it as part of its registration statement."]

that Respondent has contended that (1) Respondent's advertisements are not labeling; (2) labeling requirements under FIFRA do not apply to the Respondent's advertising claims; (3) violations did not occur where no nexus existed between the Respondent's advertising and the sale or distribution of Rozol; and (4) the Complainant's claims are barred due to lack of "fair notice."

Mr. Fuhrman may testify on his penalty analysis concerning the alleged "differing claims" violations that appears in a separate document titled, "Civil Penalty Analysis re: Docket No. FIFRA-05-2010-0016" that is located at Respondent's Exhibit 42 in its prehearing exchange information.

(d) <u>Potential Testimony Related to the Alleged Violations</u> <u>Under Section 12(a)(1)(E) of FIFRA.</u>

Should the Presiding Officer grant either the pending motion of the Respondent or that of the Complainant to essentially eliminate the alleged violations for distribution or sale of a misbranded pesticide from consideration in the hearing, <sup>28</sup> Mr. Fuhrman may not testify regarding such alleged violations. Otherwise, he may.

Mr. Fuhrman may also testify to additional facts or opinions as necessary to respond to assertions or arguments raised by Complainant. To the

<sup>&</sup>lt;sup>28</sup> Respondent and Complainant cited different reasons for asking that the Presiding Officer not adjudicate the counts in the Complaint related to "misbranding." In the Respondent's Motion dated September 16, 2010, it requested that the Presiding Officer dismiss from the Complaint the charges that it allegedly misbranded pesticides, or, alternatively, that accelerated decision on liability for these charges be granted in favor of the Respondent. In the Complainant's Motion for Leave to Amend the Complaint, dated October 1, 2010, Complainant moved to amend the complaint to remove the paragraphs of the Complaint concerning the "misbranding" allegations for reasons including "judicial economy."

extent deemed necessary by the Presiding Officer, Mr. Fuhrman will provide testimony sufficient to authenticate the documents to which he refers during his testimony at the hearing in this matter.

#### 2. Charles D. Lee.

Mr. Lee is an Instructor in the Department of Animal Sciences and Industry at Kansas State University in Manhattan, Kansas. Mr. Lee has a Bachelor of Science Degree in Fisheries and Wildlife Biology and a Master of Science Degree in Animal Science and Industry. He is a candidate for a Doctor of Philosophy Degree in Animal Sciences. Mr. Lee is a Certified Applicator and regularly teaches at training seminars for certified applicators. His curriculum vitae is included at Respondent's Exhibit 43a. Mr. Lee's testimony may include, but it will not be limited to, the following:

Mr. Lee may provide testimony as an expert witness on prairie dogs and pocket gophers, prairie dog and pocket gopher control, toxicants for the use of wildlife control, pesticide application, and the training of certified applicators.

Mr. Lee may testify as to his prairie dog-related scientific research and the scientific studies he has conducted and data he has generated on Rozol. He may testify as to the content of Respondent's advertising statements, the application of Rozol and the minimal impacts to non-target species posed by Rozol. In particular, Mr. Lee may testify as to: (a) the efficacy of Rozol in eradicating prairie dogs when applied in accordance with the EPA-approved label; (b) pesticide safety; and (c) the impact of the regulatory scheme on the use of Rozol.

Mr. Lee may testify that the empirical research he conducted established that Rozol is effective with a single application. He may testify that Rozol poses low primary poisoning potential to birds and other non-targets. He may testify as to the qualities and characteristics of Rozol and other toxicants used to control Black Tailed Prairie Dogs and the application of such toxicants.

Mr. Lee may also testify that Rozol is applied under the surface and that his research showed that few prairie dog carcasses were found above ground. Mr. Lee may testify as to the secondary poisoning potential of Rozol and other toxicants.

Mr. Lee may testify that certain toxicants require pre-baiting and retreatment. Mr. Lee may testify as to the weatherability of Rozol and other toxicants. Mr. Lee may testify that the application of Rozol does not require that the target rodent be in the burrow at the time of application, as is the case with many alternative toxicants. Mr. Lee may testify as to the directions contained on the product label for Rozol and the application requirements for other toxicants.

Mr. Lee may also testify to additional facts or opinions as appropriate to respond to assertions or arguments raised by Complainant. To the extent deemed necessary by the Presiding Officer, Mr. Lee will provide testimony sufficient to authenticate the documents that he refers to during his testimony at the hearing in this matter.

### 3. <u>James F. Hobson, Ph.D., DABT.</u>

Dr. Hobson has over 20 years of experience as an Environmental Toxicologist evaluating the exposure, effects and risks posed by pesticides and

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industrial chemicals to human health and the environment. He has a B.Sc. in Biology, a M.Sc. in Toxicology, and a Ph.D. in Biology. He is Board Certified in General Toxicology. Dr. Hobson has extensive experience managing professional staff with responsibilities for testing programs in support of new and existing chemical product registrations under FIFRA, TSCA and FDA, and regulation under State, EU, and Canadian statutes and laws. He has held senior-level positions with major chemical companies, including FMC Corporation and Rhône-Poulene, and three industry-focused consulting firms, Technology Sciences Group Inc., ARCADIS Geraghty & Miller, Inc and MorningStar Consulting, Inc. Dr. Hobson is currently president of MorningStar Consulting, Inc., an independent, Maryland-based, consulting firm providing Scientific and Regulatory Support Services to industrial clients and trade associations. His curriculum vitae is included at Respondent's Exhibit 44 in its prehearing exchange information. Dr. Hobson's testimony may include, but shall not be limited to, the following:

Dr. Hobson will testify as an expert toxicologist. He may testify on the primary and secondary poisoning potential of Rozol on non-target species. He may testify that the predicted low level of secondary risk associated with Rozol is supported by the low observed frequency of chlorophacinone-related incidents. He may also testify that the ecological risk of using Rozol to control prairie dogs is minimal. Dr. Hobson may testify that the characteristics of chlorophacinone (the active ingredient in Rozol) and factors related to the prairie dog use pattern combine to provide a safe control agent for prairie dogs and that a combination of

mitigating factors serves to keep the primary and secondary hazards to non-target species minimized.

Dr. Hobson may testify that Rozol was first registered by the EPA as a pesticide in 1971. Dr. Hobson may also testify that chlorophacinone-related incidents are recorded in EPA's Environmental Incident Information System ("EIIS"). Dr. Hobson may testify to the contents of EIIS regarding the application of Rozol and the anticoagulant chlorophacinone in general..

Dr. Hobson may also testify to additional facts or opinions as appropriate to respond to assertions or arguments raised by Complainant. To the extent deemed necessary by the Presiding Officer, Dr. Hobson will provide testimony sufficient to authenticate the documents that he refers to during his testimony at the hearing in this matter.

### 4. Henry Jacoby.

Mr. Jacoby is a staff member of the ACTA Group, L.L.C.. From 1991-1997 Mr. Jacoby was the Branch Chief, Environmental Fate and Effects Division, Office of Pesticide Programs at EPA. From 1974-1991, Mr. Jacoby held various positions within EPA's Registration Division, Office of Pesticide Programs. His curriculum vitae is included at Respondent's Exhibit 45. Mr. Jacoby's testimony may include, but it will not be limited to, the following:

Mr. Jacoby may testify as to his educational background, his work experience handling pesticide registrations and his duties when employed at EPA.

Mr. Jacoby may testify as to the Registration Division's role in the pesticide

registration process. Mr. Jacoby may also explain the review and approval process that occurs when a registrant submits an application to register a pesticide. Mr. Jacoby may also testify as to the decision-making process regarding the classification of a pesticide as a Restricted Use Pesticide. Mr. Jacoby may testify that a pesticide registrant is required to develop, and in some cases submit, various data as part of the pesticide registration process. Mr. Jacoby may also testify as to the role of the Environmental Fate and Effects Division (EFED) of the Office of Pesticide Programs in the registration of a pesticide. Mr. Jacoby may testify that label changes are often required as a result of EPA's review of a pesticide application and associated data in order to mitigate potential adverse risks to human health and the environment.

Mr. Jacoby may testify as to what constitutes labeling under FIFRA compared to advertising. Mr. Jacoby may also testify as to the statutory requirements for a pesticide label versus labeling. He may testify that the claims a company makes regarding its pesticide products in advertising should be reviewed in light of all of the information that a company is required to develop and submit as part of the pesticide registration process and that it is inappropriate to only compare a company's advertising claims to the claims that were approved for use on the label.

Mr. Jacoby may also testify to additional facts or opinions as appropriate to respond to assertions or arguments raised by Complainant. To the extent deemed necessary by the Presiding Officer, Mr. Jacoby will provide

testimony sufficient to authenticate the documents to which he refers during his testimony at the hearing in this matter.

### 5. Dennis Estenson.

Dennis Estenson is the Director of Account Services at Integre

Advertising by Design, Inc. Mr. Estenson has over 15 years of business-toconsumer communication and marketing strategy experience. Mr. Estenson's
curriculum vitae is included at Respondent's Exhibit 88. Mr. Estenson's testimony
may include, but it will not be limited to, the following matters:

Mr. Estenson may testify as to the purpose and content of advertising. He may testify that the purpose of advertising, including Respondent's advertising, is to inform and educate potential product users. He may also testify as to the content of Respondent's advertising and its relationship to other pesticide advertising.

Mr. Estenson may also testify to additional facts or opinions as necessary to respond to assertions or arguments raised by Complainant. To the extent deemed necessary, Mr. Estenson will provide testimony sufficient to authenticate the documents that he refers to during his testimony at the hearing on this matter.

## II. Copies of All Documents and Other Exhibits Which Respondent Intends to Introduce.

Respondent expects to offer the following documents and other exhibits into evidence either during or prior to the hearing. Respondent may also make

reference to these documents in any motions, post-hearing briefs or oral arguments. Copies of some portions of the exhibits may be presented at the time of hearing in enlarged poster size to allow for easy reference for the witness and the judge. The exhibits are numbered as RX 1 through RX 88.

RX NO.	Title of Document	Date of Document	Bates No.
1	Packet For "Rozol Prairie Dog Bait," EPA Reg. No. 7173-286		
	a. Letter From Liphatech to U.S. EPA regarding application for registration of Rozol Prairie Dog Bait, EPA Reg. No. 7173-286	January 23, 2008	1-5
	b. Registration Application Documents Regarding Rozol Prairie Dog Bait, EPA Reg. No. 7173-286: Transmittal Document; U.S. EPA Application for Pesticide; Data Matrix; Certification With Respect to Citation of Data; Proposed Label	January 23, 2008	6-22
	c. Letter to Liphatech From U.S. EPA to Liphatech Indicating Compliance of Registration Application	February 1, 2008	23-25
	d. Data Package Bean Sheets	March 3, 2008; May 4, 2009; and May 4, 2009	26-34
	e. Ecological Risk Assessment Evaluating Expanded Uses for Rozol Black Tailed Prairie Dog Bait Conducted by U.S. EPA Environmental Fate and Effects Division	November 6, 2008	35-103
	f. "Final Questions and Answers for Topics for Rozol Prairie Dog Bait, EPA Reg. No. 7173-EIA (286)Big Question: Are restrictions enough to mitigate against secondary poisoning?"	May 3, 2009	104- 108
	g. Email Correspondence from Dan Peacock of U.S. EPA to John Hebert of U.S. EPA, including Table Titled "Justification for RD Mitigation Responses to EFED Risks Concerns, Rozol Prairie Dog Bait, EPA File Symbol 7173-RIA (286)"	May 13, 2009	109- 114
	h. Various Internal U.S. EPA Email Correspondence Regarding Registration of Rozol Prairie Dog Bait, EPA Reg. No. 7173-286	May 7, 2009 – May 15, 2009	115- 133
	i. Accepted Label With Comments	May 13, 2009	134- 142

	j. Various Internal U.S. EPA Email	May 29, 2009 –	143-
	Correspondence Regarding Endangered Species	June 1, 2009	147
	Considerations		
	k. Updated Accepted Label for Rozol Prairie Dog	September 10,	148-
	Bait, EPA Reg. No. 7173-286	2009	149
2	Packet for "Rozol Pocket Gopher Bait II," EPA		
	Reg. No 7173-244		
	a. Letter From Liphatech to U.S. EPA Regarding	August 2, 2004	150-
	Registration Application for Rozol Pocket Gopher	, ====	158
	Bait II, EPA Reg. No. 7173-244		
	b. Letter from U.S. EPA to Liphatech Regarding	January 12, 2005	159-
	Registration of Rozol Pocket Gopher Bait II, EPA		161
	Reg. No. 7173-244		
	c. Letter from Liphatech to U.S. EPA Regarding	January 21, 2005	162-
24	Registration of Rozol Pocket Gopher Bait, EPA	Juliuary 21, 2003	164
1	Reg. No. 7173-244	#.	10.
	d. Notice of Pesticide Registration and Accepted	March 2, 2005	165-
	Label for "Rozol Pocket Gopher Bait II," EPA Reg.	Wiatem 2, 2003	167
	No. 7173-244		107
	e. Notification of an Alternate Name for Rozol	April 14, 2005	168-
	Pocket Gopher Bait II, EPA Reg. No. 7173-244	April 14, 2003	170
	f. Letter From Liphatech to U.S. EPA Regarding	November 14,	171-
	Label Amendment for Rozol Pocket Gopher Bait II,	2008	177
	EPA Reg. No. 7173-244	2008	1//
	g. Letter From U.S. EPA to Liphatech Regarding	February 12,	178-
	Requested Label Amendment	2009	183
	h. Letter From Liphatech to U.S. EPA and U.S.	July, 2009	184-
	EPA Acceptance of Label Amendment for Rozol	July, 2009	190
	-		190
3	Pocket Gopher Bait II, EPA Reg. No. 7173-244		
3	Packet for "Rozol Pocket Gopher Bait," EPA		
	Reg. No. 7173-184	August 10 1002	101
	a. Accepted Label for "Rozol Pocket Gopher Bait,"	August 18, 1982	191-
	EPA Reg. No. 7173-184	A	194
	b. Accepted Label with comments	August 27, 2003	195-
	A	T 4 0004	197
	c. Accepted Label with comments	June 4, 2004	198-
			202
	d. Accepted Label with comments	April 17, 2007	203-
			206
	e. Application for Pesticide Notification and	June 18, 2007	207-
	Notification	<u></u>	210

	f. Letter from U.S. EPA to Liphatech and Prior	November 16,	211-
	EPA Correspondence Regarding Application of	2006	214
	Rozol Pocket Gopher Bait, EPA Reg. No. 7173-184		
	To Control Prairie Dogs		
	g. Accepted Label with comments	September 29,	215-
		2008	219
4	Kansas Special Local Needs Registration Packet		
	for Rozol Prairie Dog Bait		
	a. Letter from Liphatech to Kansas Department of	March 11, 2004	220-
	Agriculture Regarding State Registration of a	,	226
	Pesticide To Meet a Special Local Need		
İ	b. Approval of SLN Label from Kansas Dept. of	April 1, 2004	227-
	Agriculture dated April 1, 2004 and Decision and	1 ,	235
	Order Regarding SLN KS-040004		
	c. Email Correspondence Between Gary Meyer, KS	April 2, 2004 –	236-
	Dept. of Ag., Liphatech and Bill Jacobs of U.S.	April 7, 2004	239
	EPA	,	
	d. Letter from Liphatech to John Hebert, U.S. EPA	April 14, 2004	240-
	Regarding SLN Reg. No. KS-040004	, , , , , , , , , , , , , , , , , , , ,	241
	e. Letter from U.S. EPA to Kansas Department of	July 30, 2004	242-
	Agriculture	,,	245
	f. Letter from Kansas Dept. of Agriculture to	December 6,	246-
	Liphatech, including Letter from U.S. EPA to	2006	249
	Kansas Dept. of Agriculture		
	g. Letter from Liphatech to Kansas Dept. of	January 15, 2007	250-
	Agriculture		253
	h. Letter from Liphatech to Kansas Dept. of	January 24, 2007	254-
	Agriculture		257
	i. Letter from Liphatech to Kansas Dept. of	August 2, 2007	258-
	Agriculture		260
	j. Letter from Kansas Dept. of Agriculture to U.S.	August 29, 2007	261-
	EPA		269
5.	Nebraska Special Local Needs Registration		1
	Packet for Rozol Prairie Dog Bait		
	a. Letter from Liphatech to Nebraska Department	November 18,	270-
	of Agriculture Regarding Registration of a Pesticide	2005	275
	For Special Local Needs		
	b. Community Support Letters In Favor of SLN	n/a	276-
	Registration		291
}		Navionalion	292-
	c. Nedraska Section 24(c) Reduest Checklist and	i November –	1 292-
	c. Nebraska Section 24(c) Request Checklist and Correspondence from Liphatech to Nebraska Dept.	November – December, 2005	292-

	d. Handwritten Note "From the Desk of: Tim	December 16,	295-
	Creger" of Nebraska Department of Agriculture	2005	296
	Indicating Stability of Rozol		
	e. Memorandum from Tim Creger of Nebraska	December 19,	247-
	Dept. of Agriculture Regarding Rozol SLN Request	2005	300
	Packet		
i	f. Correspondence from Nebraska Cattlemen to	December 21,	301-
	Nebraska Dept. of Agriculture	2005	303
	g. Letter from Liphatech to Nebraska Department	January 20, 2006	304-
	of Agriculture		308
	h. Nebraska SLN registration request for Rozol	January 25, 2006	309-
	(Chlorophacinone) prairie dog bait	•	312
	i. Application for/Notification of State Registration	February 14,	313-
	of a Pesticide to Meet a Special Local Need For	2006	317
	Rozol Prairie Dog Bait, SLN No. NE-060001 and		
	Supplemental Label		
	j. Email correspondence from Tim Creger of	May 17, 2006	318-
	Nebraska Dept. of Agriculture to Liphatech		319
	k. Letter from U.S. EPA to Nebraska Dept. of	November 16,	320-
	Agriculture	2006	321
	Letter from Liphatech to Nebraska Dept. of	May 1, 2007	322-
	Agriculture Regarding Application for Section 24(c)		327
	"Special Local Needs" Registration for Rozol		
	Prairie Dog Bait		
	m. Letter from Nebraska Dept. of Agriculture to	June 21, 2007	328-
	U.S. EPA		330
	n. Letter from Liphatech to Nebraska Dept. of	March 25, 2008	331-
	Agriculture		334
	o. Letter from Liphatech to Nebraska Dept. of	April 28, 2008	335-
	Agriculture	,	337
	p. Memorandum to Nebraska Pesticide Board From	May 12, 2008	338-
	Tim Creger		343
	q. Letter from Nebraska Dept. of Ag. to U.S. EPA	July 1, 2008	344-
	renewing SLN	, , -	346
6	Wyoming Special Local Needs Packet For Rozol		
	Prairie Dog Bait		
	a. Letter from Liphatech to Wyoming Department	April 10, 2006	347-
	of Agriculture Regarding Application for Special		353
	Local Needs Registration for Rozol Prairie Dog Bait		
	b. Application for/Notification of State Registration	May 23, 2006	354-
	of a Pesticide to Meet a Special Local Need, SLN	<b>,</b>	355
	WY-06-0004		
			•

	c. FIFRA § 24(C) Supplemental Label for Rozol Prairie Dog Bait, EPA Reg. No. 7173-184; SLN No. WY-06-0004	n/a	356- 357
	d. Memorandum from Wyoming Department of Agriculture to U.S. EPA Regarding SLN Registration of Rozol Prairie Dog Bait	May 23, 2006	358- 359
	e. Letter from U.S. EPA to Wyoming Department of Agriculture	November 16, 2006	360- 362
	f. Email Correspondence Between Wyoming	March 13, 2007	363-
	Department of Agriculture and Liphatech	Wiarch 13, 2007	364
	g. Letter from Liphatech to Wyoming Department	May 1, 2007	365-
	of Agriculture	1viuy 1, 2007	370
	h. Memorandum from Wyoming Department of Agriculture to U.S. EPA	July 30, 2007	371- 372
	i. Application for/Notification of State Registration	July 30, 2007	373-
	of a Pesticide To Meet a Special Local Need, EPA Reg. No. 7173-244; SLN NO. WY 07-0005		374
	j. FIFRA § 24(c) Supplemental Label, EPA Reg. No. 7173-244; SLN No. WY-070005	n/a	375- 376
	k. Community Letters Supporting Registration of	Various	377-
	Rozol Prairie Dog Bait		380
	Letter from Wyoming Department of Agriculture to Weed and Pest Districts	August 1, 2007	381- 382
	m. Email Correspondence Between Poly Cross, Wyoming Department of Agriculture, Liphatech and Kim Dickerson, U.S. Fish & Wildlife Regarding Requested Label Modifications	November 11, 2008	383- 384
7	Colorado Special Local Needs Packet for Rozol		
	Prairie Dog Bait		
	a. Letter from Liphatech to Colorado Department of Agriculture	September 6, 2006	385- 392
	b. Letter from Colorado Department of Agriculture	September 22,	393-
	to Colorado Division of Wildlife	2006	396
	c. Email correspondence between U.S. Fish &	October 2, 2006	397-
	Wildlife and Colorado Department of Agriculture		400
	d. Letter from Liphatech to Colorado Department of Agriculture	October 4, 2006	401- 410
	e. Email Correspondence from Colorado	October 23, 2006	411-
	Department of Agriculture to Liphatech		416
	f. Email Correspondence from Colorado	October 26, 2010	417-
	Department of Agriculture to Liphatech		421
	g. Memorandum to Division Director, Colorado	October 30, 2006	422-
	Department of Agriculture		433

h. Facsimile from Colorado Department of	November 1,	434-
Agriculture to Liphatech	2006	438
i. Application for/Notification of State Registration of a Pesticide to Meet a Special Local Need for Rozol Prairie Dog Bait, EPA Reg. No. 7173-244; SLN No. CO 060009	November 1, 2006	439- 441
j. FIFRA § 24(c) Supplemental Label for Rozol Prairie Dog Bait, EPA Reg. No. 7173-244; SLN CO-060009	November 1, 2006	442- 443
k. Letter from Colorado Department of Agriculture to U.S. EPA	November 2, 2006	444- 452
l. Letter from Colorado Department of Agriculture to Colorado Division of Wildlife and US Fish and Wildlife Service	December 26, 2006	453- 456
m. Email Correspondence Between Colorado Division of Wildlife, William Erickson of U.S. EPA and Colorado Department of Agriculture	Various	457- 462
n. Letter from Colorado Department of Agriculture to U.S. EPA	January 23, 2007	463- 466
o. Email Correspondence between Liphatech and Colorado Department of Agriculture	Various (March, 2007)	467- 480
p. Email Correspondence between Liphatech and Colorado Department of Agriculture	Various (January, 2007)	481- 484
q. Letter from Colorado Department of Agriculture to Liphatech	July 9, 2007	485- 487
r. Letter from Liphatech to Colorado Department of Agriculture	August 2, 2007	488- 491
s. Letter from Colorado Department of Agriculture to U.S. Fish and Wildlife Service and Colorado Division of Wildlife	August 22, 2007	492- 509
t. Letter from Colorado Department of Agriculture to Liphatech	September 11, 2007	510- 511
<ul><li>u. Email Correspondence between Colorado</li><li>Department of Agriculture and U.S. EPA</li></ul>	September 12, 2007	512- 513
v. Letter from Colorado Department of Agriculture to U.S. EPA	September 21, 2007	514- 515
w. Revised FIFRA § 24(c) Supplemental Label for Rozol Prairie Dog Bait, EPA Reg. No. 7173-244; SLN No. CO-060009	n/a	516- 517
x. Email Correspondence from Liphatech to Colorado Department of Agriculture	May 14, 2009	518- 519

8	Texas Special Local Needs Packet For Rozol Prairie Dog Bait		
	a. Letter from Liphatech to Texas Department of	March 16, 2007	520-
	Agriculture regarding Application for Section 24(c)	10, 2007	532
	registration for Rozol Prairie Dog Bait		
	b. Letter from Liphatech to Texas Department of	April 6, 2007	533-
	Agriculture regarding community support for 24(c)		573
	Registration		
	c. Email Correspondence from Liphatech to Texas	Undated	574-
	Department of Agriculture		576
	d. Internal Correspondence from Texas Department	April 17, 2007	577-
	of Agriculture Regarding Rozol	•	584
	e. Special Local Need (SLN) – FIFRA 24(c)	April 17, 2007	585-
	Review		586
	f. David T. Villarreal, Ph.D., Summary ecological	April 24, 2007	587-
	risk assessment and environmental fate of the	-	588
	rodenticide chlorophacinone.		
	g. Letter from Texas Department of Agriculture to	April 27, 2007	589-
	U.S. EPA	_	597
	h. Letter from Texas Department of Agriculture to	March 24, 2008	598-
	U.S. EPA		599
9	Oklahoma Special Local Needs Packet For Rozol Prairie Dog Bait		
	a. Letter from Liphatech to Oklahoma Department	October 5, 2007	600-
	of Agriculture, Food & Forestry	3, 2007	608
	b. Handwritten Memorandum of Sandra Morgan,	January 7, 2008	609-
	Veterinary Toxicologist Oklahoma Animal Disease	,,	610
	Diagnostic Lab		
	c. Letter from Oklahoma State University –	January 9, 2008	611-
	Division of Agricultural Sciences and Natural		612
	Resources to Oklahoma Department of Agriculture		
	d. Letter from Oklahoma Department of Agriculture	January 15, 2008	613-
	to U.S. EPA	,	621
	e. Application for/Notification of State Registration	January 15, 2008	622-
	of a Pesticide to Meet a Special Local Need for		623
	1		
	Rozol Prairie Dog Bait, EPA Reg. No. 7173-244;		
	Rozol Prairie Dog Bait, EPA Reg. No. 7173-244; SLN No. OK-080002		
		n/a	624-
	SLN No. OK-080002	n/a	624- 625
	SLN No. OK-080002  f. FIFRA § 24(c) Supplemental Label for Rozol Prairie Dog Bait, EPA Reg. No. 7173-244; SLN No.	n/a Undated	1

10	Charles D. Lee and Scott E. Hygnstrom, Field Efficacy and Hazards of Rozol Bait for Controlling Black-Tailed Prairie Dogs	July 26, 2007	646- 946
11	Charles D. Lee, In-burrow Application of Rozol to Manage Black-tailed Prairie Dogs	April 22, 2005	947- 962
12	William Erickson and Douglas Urban, Potential Risks of None Rodenticides to Birds and Nontarget Mammals: A Comparative Approach	July 2004	963- 1193
13	John Baroch, Secondary Hazard Study Using Chlorophacinone-Killed Laboratory Rats Fed to Black-billed Magpies ( <i>Pica pica</i> )	June 4, 1997	1194- 1271
14	Md. Sayed Ahmed, Ph.D., et al., Secondary Hazard Study Using Chlorophacinone-Killeed Laboratory Rats Fed to Domestic Ferrets ( <i>Mustela putorus furo</i> )	October 22, 1996	1272- 1356
15	Ronald L. Baron, Ph.D., Secondary Hazard Evaluation of Chlorophacinone in Raptors and Chlorophacinone Residue Levels in Hawk, Owl and Vole Tissues from Pullman, Washington	October 9, 1990	1357- 1364
16	Eric M. Silberhorn, et al., Ecological Risk Assessment for Grain-Based Field-Use Anticoagulant Rodenticides Registered by the California Department of Food and Agriculture for Special Local Needs	June 2, 2003	1365- 1474
17	James Hobson, Ph.D., Chlorophacinone use to control prairie dogs: An environmental review with comparison to Zinc phosphide	Undated	1475- 1491
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19	David J. Horn and George Keeney, Assessment of the Potential Impact of Chlorophacinone on Burying Beetles	March 28, 2007	1579- 1594
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23	R. C. Meyers and S. M. Christopher, Rozol Pellets: Cutaneous Irritancy Testing Using the Rabbit	November 3, 1993	1698- 1726
24	R. C. Meyers and S. M. Christopher, Rozol Pellets: Dermal Sensitization Study in the Guinea Pig Using the Buehler Technique	January 7, 1994	1727- 1770

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## III. Respondent's Statement Explaining Why the Proposed Penalty Should Be Eliminated or Reduced.

A. The Penalty Proposed by Complainant Must be Eliminated Because Respondent Did Not Violate FIFRA.

As Respondent set forth in its Answer to Complaint, the penalty proposed by Complainant must be eliminated because Respondent complied with FIFRA and the applicable regulations at all times relevant to the Complaint. (Answer to Compl. ¶ 650).

1. Counts 1 through 2,140 of Complaint. Each of Respondent's radio and print advertisements included a statement of the terms of restriction of the pesticide in accordance with FIFRA § 12(a)(2)(E) and 40 C.F.R. § 152.168.

Therefore, the proposed penalty for these counts must be eliminated. If the Presiding Officer finds that any of Respondent's radio and print advertisements did not comply with FIFRA, then Respondent asserts that Complainant incorrectly determined the appropriate unit of violation under FIFRA § 12(a)(2)(E) and, therefore, the number of violations and the penalty must be substantially reduced accordingly. Please see Section III.B. below and Respondent's Exhibit 42 for further explanation of Respondent's reasoning why the proposed penalty must be substantially reduced if it is not eliminated.

2. Counts 2,141 through 2,183 of Complaint. None of Respondent's advertisements contained claims as part of the sale and distribution of the pesticides that differed substantially from claims that were made for the products in connection with their registration under FIFRA. Therefore, Respondent did not violate FIFRA § 12(a)(1)(B). In addition, Respondent's advertisements are not "labeling" under FIFRA § 12(a)(1)(E) and, as a result, could not have caused the pesticide to be misbranded. Furthermore, because Respondent's advertising is not labeling the prohibition under the FIFRA regulation regarding "false or misleading" labels and labeling information (40 C.F.R. § 156.10(5)) is not applicable. Complainant apparently agrees with this conclusion because it has filed a Motion to Amend its Complaint in order to eliminate the allegations relating to misbranding. Even though this labeling standard does not apply to Respondent's advertisements, Respondent will demonstrate at the hearing that its advertisements were not false or misleading,

should that be necessary. As a result, the proposed penalty for these counts must be eliminated.

3. Counts 2,184 through 2,231 of Complaint. Respondent's website does not constitute an "offer for sale" under FIFRA and, therefore, Respondent could not have violated FIFRA as alleged in Counts 2,184-2,231 of the Complaint. Alternatively, if the Presiding Officer finds that Respondent's website constitutes an "offer for sale," then Respondent asserts that none of the advertisements on the website contained claims as part of the sale and distribution of the pesticide that differed substantially from claims that were made for the product in connection with its registration under FIFRA. Therefore, Respondent did not violate FIFRA § 12(a)(1)(B). In addition, Respondent's website advertisements are not "labeling" under FIFRA § 12(a)(1)(E) and, as a result, could not have caused the pesticide to be misbranded. Furthermore, because Respondent's advertising is not labeling the prohibitions under the FIFRA regulation regarding "false or misleading" labels and labeling information (40 C.F.R. § 156.10(5)) is not applicable. Complainant apparently agrees with this conclusion because it has filed a Motion to Amend its Complaint in order to eliminate the allegations relating to misbranding. Even though this labeling standard does not apply to Respondent's advertisements, Respondent will demonstrate at the hearing that its advertisements were not false or misleading. should that be necessary. As a result, the proposed penalty for these counts must be eliminated.

If the Presiding Officer determines that Respondent did not comply with FIFRA §§ 12(a)(1)(B) or 12(a)(1)(E), then Respondent asserts that Complainant incorrectly determined the appropriate unit of violation and, therefore, the number of violations and the penalty must be substantially reduced accordingly.

For the reasons set forth above, Respondent did not violate FIFRA and/or Complainant incorrectly determined the number of violations. Therefore, the penalty proposed by Complainant must be eliminated or must be substantially reduced accordingly. Please see Section III.B. below and Respondent's Exhibit 42 for further explanation of Respondent's reasoning why the penalty must be substantially reduced if it is not eliminated.

B. <u>If It Is Determined That Respondent Violated FIFRA, the Proposed Penalty Must be Very Substantially Reduced.</u>

If Respondent is determined by the Presiding Officer to have violated FIFRA, then the penalty proposed by Complainant must be very significantly reduced because the proposed penalty is grossly disproportionate to the gravity of any violations.

The assessment of civil administrative penalties is governed by the Consolidated Rules of Practice, 40 C.F.R. Part 22, which provide in pertinent part:

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 civil penalty based upon the evidence in the record and in accordance with any penalty criteria set forth in

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the Act. The Presiding Officer shall [also] consider any civil penalty guidelines issued under the Act.

40 C.F.R. § 22.27(b). 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 determining an appropriate penalty, FIFRA § 14(a)(4) requires that the Presiding Officer consider the appropriateness of the penalty to the size of the business of the person charged and the effect on the person's ability to continue in business. Pursuant to the Response of Respondent to Complainant's Request for Voluntary Production of Financial Information, Respondent does not contend that it is unable to pay the proposed penalty or that payment will adversely affect its ability to continue in business. In addition, Respondent does not contest that its sales are greater than \$10 million per year. Therefore, the only statutory factor that is relevant to establishing an appropriate penalty in this case should the Presiding Officer determine that one or more violations occurred is the gravity of the violation.

Importantly, FIFRA also authorizes the issuance of a warning to the respondent in lieu of assessing a penalty against the respondent upon a finding that the violation did not cause significant harm to health or the environment. FIFRA § 14(a)(4).

With regard to civil penalty guidelines, Complainant purports to calculate the proposed penalty in this case utilizing the FIFRA Enforcement Response

Policy dated December 2009 (the "2009 ERP"). See CX 55. Importantly, the 2009 ERP recommends a 60% reduction in the matrix rate for each violation where a respondent is charged with multiple count violations. Complainant, however, has not applied that reduction to the facts of this case. However, even when properly applied, the 2009 ERP did not undergo public notice and comment, lacks the force of law and is "a non-binding agency policy whose application is open to attack in any particular case." *In re: 99 Cents Only Stores*, No. FIFRA-09-2008-0027 (ALJ June 24, 2010) (citation omitted). The most important inquiry in any penalty proceeding is whether the penalty is appropriate to the "circumstances at hand." *Id.* A penalty may be excessive even if it was assessed in accordance with the FIFRA penalty policy. *Id.* 

In this case, Complainant's selection, interpretation and application of the 2009 ERP are arbitrary and capricious. The ERP fails to properly take into account the actual gravity of the alleged violations. As a result, the ERP should be disregarded under the facts and circumstances of this case in order to fashion a more appropriate penalty if the Presiding Officer finds any violation of FIFRA.

The remainder of this statement explains why the 2009 ERP is not applicable in this case, how Complainant has misapplied the ERP and why the facts and circumstances of this case do not support the unprecedented and draconian penalty proposed by Complainant.

1. <u>Complainant's actions undermine the credibility of the 2009 ERP.</u>

At the outset, it is not necessary to analyze the 2009 ERP in detail to illustrate that it should not be followed in this case. With minor exception, the violations alleged by Complainant occurred at the time the Enforcement Response Policy For The Federal Insecticide, Fungicide, and Rodenticide Act dated July 2, 1990 (the "1990 ERP") was in effect. The 2009 ERP (used by Complainant to calculate the multi-million-dollar penalty proposed in this case), was not adopted until December 2009.<sup>29</sup>

The 2009 ERP revised the 1990 ERP by requiring, among other things, that any significant economic benefit realized by Respondent be recovered and that Complainant could use a graduated penalty calculation matrix for certain cases involving multiple violations based on multiple sales or distributions of a product. 2009 ERP at 20, 25. Complainant's actions in this case have undermined each of these revisions and demonstrate that the 2009 ERP is inherently flawed and should be disregarded in this case.

(a) The huge disparity in Complainant's proposed penalties illustrates that the 2009 ERP is inherently flawed.

On September 18, 2009, Complainant issued a Notice of Intent to File An Administrative Complaint against Respondent for the alleged

To the extent that the 2009 ERP would result in a higher penalty than that calculated from the penalty policy in effect at the time of the alleged violations, it would be unreasonable and unfair to retroactively apply the new penalty policy to Respondent. See In re: Associated Products, Inc., No. IF&R-III-412-C, 1996 WL 691495, 13 n.37.

violation of FIFRA §§ 12(a)(2)(E) and 12(a)(1)(B) and proposed a penalty of \$1,280,500 (the "Initial Notice"), presumably based on the 1990 ERP. Compl. ¶ 357; Answer to Compl. ¶ 357, Exh. A. On April 1, 2010, Complainant arbitrarily and capriciously issued an Updated Notice of Intent to File an Administrative Complaint against Respondent for the alleged violation of FIFRA §§ 12(a)(2)(E), 12(a)(1)(B) and 12(a)(1)(E) and proposed a wildly excessive penalty of \$2,941,456 (the "Updated Notice") based on the 2009 ERP. See Respondent's Exhibits 37-39.

The only discernable difference between the violations of FIFRA alleged in the Initial Notice and those alleged in the Updated Notice is the addition by the Complainant of 48 alleged violations set forth in Counts 2184-2231 of the Complaint for which Complainant is seeking \$343,200 that relate to the 2009/2010 period. Therefore, for the same alleged violations of FIFRA (namely Counts 1-2,183) for which Complainant proposed a \$1,280,500 penalty under the 1990 ERP, it now seeks a \$2,548,000 penalty under the 2009 ERP.

Both proposed penalties of \$1,280,500 and \$2,548,000 are based on the same underlying facts and were calculated by the Complainant within approximately six months of each other. For the same facts to yield such dramatically disparate penalty calculations, one can only conclude that either the ERPs are seriously flawed or the manner in which they have been applied in this case by Complainant is seriously flawed.

(b) Complainant no longer asserts that Respondent received an economic benefit of \$50,256 as a result of the alleged non-compliance.

In its Motion to Amend Complaint to Reduce Proposed Penalty ("Motion to Amend"), Complainant asserts: "[B]ased on new guidance that is currently being developed by the United States Environmental Protection Agency on how to calculate the economic benefit in FIFRA cases, Complainant seeks to reduce the proposed penalty by the amount of the economic benefit calculated in this matter." Compl. Mot. to Amend, 2.

The addition of an economic benefit component to the 2009 ERP was one of the significant revisions to the 1990 policy. The 1990 ERP was in effect for 19 years. The 2009 ERP was issued less than one year ago, but EPA is apparently in the process of revising it already. The Presiding Officer should not rely on a penalty policy that EPA continues to modify at will.

2. The violations of FIFRA alleged by Complainant are of low gravity and do not warrant the proposed unprecedented and draconian penalty.

The penalty proposed by Complainant is wildly excessive, grossly disproportionate and not supported by the facts of this case.

(a) Complainant ignores regulatory controls that prevent any harm to human health and the environment resulting from the alleged violations.

When calculating a proposed penalty for the alleged violations, Complainant ignores the pervasive regulatory controls on the handling, distribution, sale and use of the restricted use pesticides that are the subject of the

Complaint. Restricted use pesticides can only be used by Certified Applicators, Rozol's labeling expressly reflects that it is a restricted use pesticide and FIFRA prohibits applying pesticides in a manner inconsistent with their labeling.

Significant FIFRA penalties must 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 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." *In re: Rhee Bros., Inc.,* No. FIFRA-03-2005-0028, 2006 WL 2847398, \*31 (ALJ Sept. 19, 2006), *aff'd* 2007 WL 1934711 (EAB May 17, 2007).

No such situation exists here. There is no allegation by Complainant that the alleged violations of FIFRA resulted in the sale of the restricted use pesticide to anyone who was not legally entitled to purchase it. Complainant has made no allegation that the product was ever misapplied or misused as a result of the alleged violations. Complainant has made no allegations that any labeling information was incorrect or that there were any issues with Respondent's labels. In fact, what Complainant is alleging is that several pieces of Respondent's literature may have contained some inaccuracies which "would create a false impression in consumers' minds, resulting in increased use/misuse of the product." Complainant's Exhibit 55, EPA 001010.

(b) Complainant's delay in notifying Respondent of the alleged violations illustrates that they were not of high gravity.

Complainant's several month delay in notifying Respondent of the alleged violations of FIFRA illustrate that these allegations were not a priority for Complainant and demonstrate that they are clearly not of high gravity. If the Kansas Department of Agriculture or EPA would have simply issued Respondent a warning letter to Respondent in November 2007 when the regulators first became aware of the alleged violations, the vast majority of the acts which Complainant alleges are violations would not have occurred.

Moreover, in January of 2008, the Toxics and Pesticides
Branch, EPA Region 7, requested that the Chemicals Management Branch, EPA
Region 5, investigate potential violations of FIFRA involving Respondent.
Compl. ¶ 33. Complainant did not have an inspector from its agent, the State of
Wisconsin, Bureau of Agricultural Management, Compliance Section conduct an
inspection at Respondent's place of business until June 2, 2008. At that time, the
Federal SSURO was served on Respondent even though this SSURO was dated
April 11, 2008. Compl. ¶ 34; CX 15. If the alleged violations could have resulted
in significant harm to human health and the environment, then it would be difficult

to understand why Complainant would delay its enforcement action against Respondent for such a significant period of time.<sup>30</sup>

#### 3. Complainant has incorrectly applied the 2009 ERP.

Respondent's Exhibit 42 (a) sets forth Respondent's analysis of the Complainant's penalty calculation under the 2009 ERP and (b) sets forth Respondent's position explaining in further detail its objection to the proposed penalty and why it believes the Complainant has misinterpreted and misapplied the 2009 ERP. This analysis was prepared by Robert H. Fuhrman, Respondent's expert witness who will testify to these matters at the hearing.

# IV. Respondent's Statement As to the Appropriate Place of Hearing and the Estimated Amount of Time Need to Present Respondent's Case.

The supplemental rules governing administrative penalty actions filed under the authority of FIFRA provide that

the prehearing conference and the hearing shall be held in the county, parish, or incorporated city of the residence of the person charged, unless otherwise agreed in writing by all parties.

40 C.F.R. § 22.35(b).

Respondent is a corporation with its business located in Milwaukee,
Wisconsin. Therefore, the hearing in this matter should be held in Milwaukee,
Wisconsin. Complainant has suggested that the hearing could be held at either the
Federal Courthouse for the United States District Court for the Eastern District of

<sup>&</sup>lt;sup>30</sup> Respondent is not saying that Complainant should be barred from bringing these allegations after a significant passage of time, but instead contends that the significant passage of time certainly demonstrates that the allegations must not have been viewed by EPA as having high gravity.

Wisconsin, located at 517 East Wisconsin Avenue, Milwaukee, Wisconsin 53202, or at the Milwaukee County Courthouse, located at 901 North 9th Street, Milwaukee, Wisconsin 53233. Respondent agrees that either of these locations would be suitable for the hearing.

Respondent estimates that its case-in-chief will be presented within two to three full days. Respondent notes, however, that it may need significantly less time to present its case-in-chief after resolution of the outstanding motions and if Complainant agrees to stipulate to certain facts in this case.

#### V. Description of Respondent Representative for Purposes of the Hearing.

In Complainant's Prehearing Exchange, Section VIII, it requested that all witnesses who have not been designated as expert witnesses be excluded from the courtroom in which the hearing takes place while other witnesses are testifying, with the following exceptions:

- 1. Expert witnesses should be allowed to remain in the courtroom and listen to testimony.
- 2. The witness designated by counsel for either party as a representative of the party who is an officer or employee of a party which is not a natural person should be allowed to remain in the courtroom at all times and to listen to testimony.

Complainant then cited legal authority for this position and asks the Presiding Officer to allow Ms. Claudia Niess to act as the representative of Complainant for purposes of being in the courtroom during the testimony of

Complainant's other witnesses and during the testimony of Respondent's witnesses.

Respondent has no objection to Complainant's request.

Respondent is also a non-natural person and should be accorded the same rights. Respondent hereby respectfully requests that either Carl Tanner, Alan Smith, Charles Hathaway or Thomas Schmit (or a combination of them, but with only one individual at a time in attendance at the hearing) be allowed to be present in the courtroom during the testimony of Respondent's other witnesses and during the testimony of Complainant's witnesses. Prior to the hearing, Respondent will designate which of these four individuals will be the person(s) acting as Respondent's representative at the hearing. The reason Respondent wants to wait until prior to the hearing to designate the specific individual is that the hearing dates have not been scheduled and the schedule of each of these individuals may prevent the same individual from appearing at the entire hearing. The parties anticipate the hearing will potentially last for six to eight days or longer given Respondent's and Complainant's respective estimate of time it will take to present its case-in-chief.

### VI. Reservation of Rights.

Respondent respectfully reserves the right to supplement its list of witnesses and/or its list of exhibits upon reasonable notice to the Presiding Officer and the Complainant, or by order of the Presiding Officer. Respondent respectfully reserves its right to introduce in evidence any of Complainant's

exhibits identified in its prehearing exchange. Respondent intends to defend itself against Complainant's allegations by way of presenting direct evidence, presenting rebuttal evidence and through cross-examination of Complainant's witnesses at the hearing.

Dated this 28th day of October, 2010.

Respectfully submitted,

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Inc.



Answer 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 Prehearing Information

Exchange of Respondent and Respondent's Exhibits 1 through 88, to the persons designated below, by depositing it with a commercial delivery service, postage prepaid, at Milwaukee, Wisconsin, in envelopes addressed to:

Honorable Barbara A. Gunning 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



REGIONAL HEARING CLERK
U.S. ENVIRONMENTAL
PROTECTION AGENCY

I further certify that I filed the original and one copy of the Prehearing Information Exchange of Respondent, the original of this Certificate of Service and true, accurate and complete copies of Respondent's Exhibits 1 through 88 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 28th day of October, 2010.

Michael H. Simpson

One of the Attorneys for Respondent

Liphatech, Inc.