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October 14, 2011

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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 Prehearing 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,

Jeffrey P. Clark

Jeffrey P. Clark

REINHART\7881330

Encs.

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

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

CERTIFICATE OF SERVICE

I, Jeffrey P. Clark, one of the attorneys for the Respondent, Liphatech, Inc., hereby certify that I delivered one copy of the foregoing Respondent's Prehearing 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 Prehearing 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 14th day of October, 2011.

Jeffrey P. Clark

Jeffrey P. Clark
One of the Attorneys for Respondent
Liphatech, Inc.

REINHART\7902095LNR:JES 10/12/11

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	**Docket No. FIFRA-05-2010-0016**
	)	
Liphatech, Inc.	)	**Hon. Susan L. Biro**
Milwaukee, Wisconsin,	)	
	)	
Respondent.	)	
	)	
	)	

RESPONDENT'S PREHEARING BRIEF

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	**Docket No. FIFRA-05-2010-0016**
	)	
Liphatech, Inc.	)	**Hon. Susan Biro**
Milwaukee, Wisconsin,	)	
	)	
Respondent.	)	
	)	
	)	

RESPONDENT'S PREHEARING BRIEF

I. INTRODUCTION

This enforcement case is not about alleged harm to the environment. Nor is it about alleged harm to humans, harm to nontarget species or the chemical nature of chlorophacinone.[1] The Complainant does not allege that Rozol Pocket Gopher Bait Burrow Builder Formula, EPA Reg. No. 7173-244 ("Rozol"), or Rozol Prairie Dog Bait, EPA Reg. No. 7173-286 ("Rozol PD"), the lawfully registered pesticide products manufactured by Respondent, Liphatech, Inc., were misapplied, misbranded, misused, sold to unauthorized persons by Respondent, applied by unlicensed persons, or used in any way other than the manner authorized by the EPA-approved labels for such products. Instead, this case is about the words used by Respondent in communicating with distributors and potential customers.

Complainant has not alleged that Respondent's words caused actual harm to anyone or anything. Nonetheless, Complainant seeks to exact an unprecedented penalty of almost $2.9 million from Respondent. If such a penalty were levied

against Respondent, it would be by far the largest penalty ever levied in a reported case which was adjudicated to decision involving the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136-136y, ("FIFRA") of which counsel for Respondent is aware.[2, 3]

Complainant seeks to impose this substantial penalty on Respondent in the context of a statute and regulations that are vague and ambiguous when applied to critical aspects of this case. Furthermore, Complainant seeks to impose a penalty of this magnitude in a case involving legal issues of first impression and in an area of FIFRA involving alleged "differing claims" where EPA's statutorily-limited jurisdiction over advertising has never been clearly or definitively established and, to the contrary, where it has been seriously questioned and brought into considerable legal doubt.

In an Order on Motions for Accelerated Decision Regarding Alleged Violations of FIFRA § 12(a)(2)(E) dated May 6, 2011 (the "RUP Order"), the

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[1] Chlorophacinone is the active ingredient in Rozol and Rozol PD.

[2] In *E.I. Du Pont de Nemours & Co.*, Docket No. FIFRA-95-H-02 (ALJ 1998), *aff'd in part and remanded in part,* 9 E.A.D. 32, 2000 WL 356390 (EAB 2000), the Presiding Officer imposed a penalty of $1,895,000 as a result of finding Du Pont liable for 379 violations involving the shipment of misbranded pesticides. *Id.* The penalty was levied in part based upon a finding that the economic benefit derived by Du Pont from the violations was over $9.43 million. *Id.* The next largest penalty imposed under FIFRA of which counsel for Respondent is aware was levied in *99 Cents Only Stores*, Docket No. FIFRA-09-2008-0027, 2010 WL 2787749 (ALJ June 24, 2010), in the amount of $409,490 for sale of unregistered and misbranded pesticides. The next highest penalty of which counsel for Respondent is aware was levied in *Rhee Bros., Inc.*, Docket No. FIFRA-03-2005-0028, 2006 WL 2847398 (ALJ Sept. 19, 2006), *aff'd* 13 E.A.D. 261, 2007 WL 1934711 (EAB 2007) in the amount of $235,290 for the sale of an unregistered pesticide. Every other adjudicated FIFRA case of which counsel for Respondent is aware resulted in a penalty of less than $200,000.

[3] While Respondent has not made a comprehensive study of the highest penalty sought by EPA in a FIFRA civil penalty action, we are not aware of any FIFRA actions in which a higher penalty was sought. *See also* (footnote continued)

Presiding Officer determined that Respondent failed to disclose the "restricted use pesticide" ("RUP") classification of Rozol in certain advertisements run in the years 2007 and 2008 in violation of FIFRA section 12(a)(2)(E) (Counts 1-2140). The Presiding Officer, however, deferred decision on the appropriate unit of violation and the appropriate penalty based on the gravity of the violations until after a hearing. Complainant seeks a penalty of $2,268,500 for Counts 1-2140 of the First Amended Complaint (the "Complaint"). However, this proposed penalty far exceeds – by orders of magnitude – what is reasonable or appropriate for these RUP advertising violations. The appropriate unit of violation and a reasonable penalty for the failure to disclose the RUP classification of Rozol in accordance with section 12(a)(2)(E) of FIFRA are discussed in more detail in Section II. below.

Complainant also alleges that the words used by Respondent in its educational and marketing communications program are substantially different than claims made by Respondent as part of the registration of Rozol and Rozol PD (Counts 2141-2231). These allegations arise from a radical misinterpretation by Complainant of EPA's extremely limited regulatory jurisdiction over pesticide advertising. EPA's very narrow jurisdiction to regulate advertising of pesticides has never extended as far as the broad reach which Complainant now asserts.

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99 Cents Only Stores, 2010 WL 2787749 at *26 (citing a case where a penalty of $1,452,000 was sought and a penalty of $235,290 levied).

As explained in more detail in Section III. below, EPA lacks regulatory jurisdiction over the contested marketing statements because they were not part of the sale or distribution of the registered products. As a result, these allegations should be dismissed as a matter of law.

Even if it is determined that any of the statements fall within EPA's extremely limited regulatory jurisdiction over advertising under FIFRA, the evidence will show that Respondent's statements nevertheless fully complied with the requirements of FIFRA. If, however, the Presiding Officer should find that a violation of FIFRA did occur for one or more of these statements, then only a *de minimis* penalty should be imposed on Respondent. Each of these issues is discussed in more detail in Section III. below.

Given the immense magnitude of the penalty demanded by Complainant, a reasonable person can only assume that the alleged violations must have caused great harm, and that the alleged violations were a starkly clear and intentional breach of well-known, unambiguous legal standards readily accessible to the regulated industry and easy to apply. Yet analysis of the facts and law in this case reveals that neither assumption is correct – far from it.

In addition, the history of the registration of "Rozol" products is important to consider in evaluating the gravity of any violations that may have occurred. Rozol Pocket Gopher Bait, EPA Reg. No. 7173-184, was first registered on August 18, 1982. *See* RX 3, RX_000193-194. Rozol Pocket Gopher Bait is a general use pesticide that is still being sold and used today. This general use

pesticide is exactly the same product - containing the same chemicals in the same percentage - as Rozol, EPA Reg. No. 7173-244, and Rozol PD, EPA Reg. No. 7173-286, which are the subject of this enforcement action. *See* RX 1, 2 and 3.

There is no difference in these registered pesticide products other than the permitted method of applying the product to the target pest. Complainant's allegations of gravity must be assessed in light of the fact that exactly the same product (and active ingredient) is authorized by the EPA for unlimited use according to its label by the general public, without a "restricted use pesticide" classification, while the pesticides that are the subject of this action must be applied by certified applicators.

With respect to any harm caused by the failure of Respondent to adequately disclose the RUP classification of Rozol in advertisements in violation of FIFRA section 12(a)(2)(E) and the other statements alleged to be violations of FIFRA section 12(a)(1)(B), the Complainant:

(a) has not alleged that the words that are the subject of this action caused any actual adverse impact to human health or the environment;

(b) has not alleged that these words were improperly used on the label or in any labeling, as defined in FIFRA section 12(a)(1)(E) (which means that no misbranding could have occurred);[4]

[4] Complainant originally asserted multiple misbranding violations pursuant to FIFRA section 12(a)(1)(E), but later withdrew them when challenged by Respondent on statutory interpretation grounds. *See* Complainant's Motion for Leave to Amend the Complaint dated October 1, 2010 (where Complainant (footnote continued)

(c) has not alleged that the product was sold by Respondent to any person who was not authorized to purchase it;[5]

(d) has not alleged that Rozol or Rozol PD were used or applied contrary to the label; and

(e) has not alleged that Respondent obtained any economic benefit.[6]

In fact, the rationale offered by Complainant to explain its calculation of the proposed multi-million-dollar penalty is that the alleged violations "could reasonably create a false impression in consumers' minds, resulting in increased use/misuse of the product." *See* CX 55, EPA 001010. However, Complainant asserts this speculative statement without any proof to demonstrate that any such confusion occurred.[7]

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sought "to remove the paragraphs of the Complaint that allege violations of FIFRA section 12(a)(1)(E)") and First Amended Complaint.

[5] Because Rozol and Rozol PD are restricted use pesticides, they may only be sold to certified applicators. First Am. Compl. ¶¶ 28, 265; Answer to First Am. Compl. ¶¶ 28, 265. Respondent is aware of one settlement in which a penalty of $5,720 was levied against a company unrelated to Respondent for selling Rozol to an individual who did not have a valid certified applicator's license. *See* CX 102; RX 73. That case, however, did not involve Respondent and shows that FIFRA provides multiple layers of protection to prevent harm to human health and the environment as a result of the use of RUPs.

[6] Complainant initially sought to recover $50,256 for an alleged economic benefit obtained from all 2,231 counts alleged in its initial Complaint, but Complainant later reduced the alleged economic benefit to $0 in its First Amended Complaint. *See* Compl. at ¶ 649; First Am. Compl. at ¶ 649.

[7] It appears from the Complainant's pre-hearing exchange that Complainant is attempting to put the registered pesticides Rozol and Rozol PD and, more specifically, their active ingredient, chlorophacinone, on trial. The Presiding Officer will likely be asked to listen to statements from Complainant's witnesses and view documents which attempt to portray chlorophacinone as a dangerous chemical. However, most, if not virtually all, of this information was known to the EPA at the time the products were registered by the EPA. By registering the products, the EPA determined that the benefits of Rozol and Rozol PD outweigh any potential adverse impact on human health and the environment. *See* FIFRA § 3(c)(5)(C). Any such testimony and evidence offered by Complainant is irrelevant and not probative to the central issues in this case – which are whether the words complained of violated FIFRA and, if so, what was the gravity of the use by Respondent of these specific words? No adverse environmental or human health consequences flowed from the use by Respondent of these words.

Because Rozol is classified as a RUP, "then in all cases, by virtue of FIFRA, lawful use is only "'authorized by' or restricted to 'certified applicators', *i.e.*, those certified under FIFRA section 11. 7 U.S.C. § 136(a)-(c)." RUP Order at 11. In addition, according to the EPA itself, "the training and certification of applicators that is required for restricted use classification can significantly reduce the potential for adverse effects, whether from normal use or misuse" of RUPs. RX 60, RX_003300. There are strict protocols regarding the procedure required to sell RUPs to ensure that RUPs, such as Rozol, are only sold to licensed distributors. *See* CX 102; RX 73; FIFRA §§ 3(d)(1)(C)(i), (ii); FIFRA § 12(a)(2)(F).

Focusing on the legal standards to be applied in this case, FIFRA is a vague and ambiguous statute when viewed in the context of EPA's regulation of claims made in connection with the sale or distribution of pesticides. Statutes and regulations that are vague and ambiguous must be narrowly construed against a regulator such as the EPA when, as here, they are applied in a penalty enforcement context, *Pepsi Bottling Group, Inc. v. Thomas*, No. C10-54 MJP, 2010 WL 4622520, at *4 (W.D. Wash. 2010); *Fed. Comm'ns Comm'n v. Am. Broad. Co.,* 347 U.S. 284 (1954) (discussing the principle that statutes that impose a penalty must be construed strictly is well established), and particularly where a broad interpretation of the statutory and regulatory language would impinge on the right to commercial free speech under the First Amendment. *Thompson v.*

W. States Med. Ctr., 535 U.S. 357, 371 (2002) ("if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so."); *I.N.S. v. St. Cyr.*, 533 U.S. 289, 299 (2001) (if an otherwise acceptable construction of a statute would raise serious constitutional problems, and an alternative interpretation of the statute is 'fairly possible,' courts are obligated to construe the statute to avoid such problems); *Solid Waste Agency of Cty. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159 (2001) (whenever possible, an ambiguous statute should be construed to avoid constitutional questions).

Further, the extremely broad interpretations proposed by Complainant are a major departure from those commonly understood in the industry, and would, if accepted, lead to upheavals in an entire industry's advertising and marketing practices, as well as impose unreasonable restrictions on commercial free speech rights. No one could have reasonably predicted such an attempt by a regulator to so impact industry practices without legislation or administrative rulemaking.

Under such circumstances, assessing any penalty greater than a *de minimis* amount would be inequitable and contrary to law. *See CWM Chem. Servs., Inc.*, 6 E.A.D. 1, 1995 WL 302356, at *9 (EAB 1995) ("[I]t is not enough that the [agency's] interpretation of the regulation be reasonable, the regulation itself must provide the regulated community with adequate notice of the conduct required.").

Since the words used by Respondent caused no harm, and were used in a context in which the EPA's regulatory authority is ambiguous at best, a penalty, if any, should be *de minimis* in amount. Discussion of the gravity of the alleged

offenses and an appropriate penalty will be continued separately for each group of alleged offenses in Sections II. and III., respectively.

II. CALCULATION OF APPROPRIATE PENALTY FOR VIOLATION OF FIFRA SECTION 12(a)(2)(E)

A. Background.

Pursuant to the RUP Order, the Presiding Officer found that Respondent failed to adequately disclose the RUP classification for Rozol in 2140 instances of broadcast and print advertisements, but withheld decision on the appropriate unit of violation and appropriate penalty. The Presiding Officer now needs to determine what is a reasonable and fair penalty, if any penalty is to be imposed for this liability.[8]

Under FIFRA section 14(a)(4), 7 U.S.C. § 136l(a)(4), the penalty in this case is to be calculated based solely on the gravity of the violation.[9] However, neither the statute nor any promulgated regulations under FIFRA define "gravity."

B. EPA Proposed Penalty Calculation.

On September 18, 2009, Complainant sent Respondent a "Notice of Intent to File Administrative Complaint Against Liphatech, Inc." (the "Initial Notice"). *See* CX 24; RX 37 and Exhibit A attached hereto. The Initial Notice stated that

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[8] While the Presiding Officer must consider the applicable penalty policy, it may deviate from it where circumstances warrant. *Rhee Bros,* 2006 WL 2847398, at *30.

[9] FIFRA requires that the penalty be based upon the gravity of the violations and requires the Presiding Officer to take into account the impact the penalty may have on the ability of Respondent to remain in business and on the size of the business. 7 U.S.C. § 136l(a)(4). However, Respondent has waived its defenses related to the latter two points. Therefore, the penalty should be based solely on the gravity of any violation.

Complainant planned to seek a penalty of $1,280,500 against Respondent for various alleged violations of FIFRA. 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 per-violation penalty of $6,500 or a total penalty of $962,000.[10] *See* RX 39, Exhibit B (attached hereto).

The 148 counts related to FIFRA section 12(a)(2)(E) were determined 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 alleged RUP violations. *See* RUP Order at 10. Ms. Claudia Niess of EPA Region V 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.[11] *See* RX 32.

On April 1, 2010, Complainant issued an "Updated Notice of Intent to File an Administrative Complaint against Liphatech, Inc." (the "Updated Notice"). *See* RX 38, Exhibit C (attached hereto). Pursuant to the Updated Notice, Complainant dramatically increased the proposed penalty for all violations, including the failure

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[10] *See* the chart prepared by Ms. Claudia Niess that is attached to the October 2, 2009 Region V correspondence to Respondent. RX 39. Ms. Niess' penalty calculation worksheet alleged 16 print violations which conflicts with the First Amended Complaint. The First Amended Complaint alleges 23 print violations.

[11] The penalty calculation worksheet completed by Ms. Niess was based on Exhibit D-1 to the 1990 Penalty Policy. *See* RX 32.

to adequately disclose the RUP classification, from $1,280,500 to $2,941,456. *Id.* Pursuant to the First Amended Complaint, Complainant now alleges that the radio and print advertisements consist of 2140 violations of FIFRA section 12(a)(2)(E), not 148 as previously asserted in the Initial Notice. Complainant now asserts these alleged violations should result in a penalty of $2,268,500—more than double what was initially demanded by Complainant just six months earlier in the Fall of 2009. *See* First Am. Compl. ¶ 649.

The Complainant changed the basis of the alleged RUP violations from one count for each day a radio ad was broadcast (132) to one count for each time a radio ad was broadcast (2117), plus 23 print ads, resulting in a huge increase in the number of RUP counts from 148 in September 2009[12] to 2140 in April 2010. Complainant then used the EPA's FIFRA Enforcement Response Policy dated December 2009 ("2009 Penalty Policy") to calculate a proposed penalty of $2,268,500 for the 2,140 RUP counts, or an average of $1,060 per count. *See* CX 55, EPA 001012.

Even though nothing materially changed with respect to the facts which serve as the basis for the allegations related to the failure to adequately disclose the RUP classification of Rozol, Complainant more than doubled the proposed

[12] The chart that is attached to Region V's October 2, 2009 correspondence to Respondent referenced 16 alleged print RUP classification violations while the Complainant's First Amended Complaint references 23 alleged print RUP classification violations. *See* RX 39; First Am. Compl. Counts 2118-2140. This appears to reflect a counting error in the chart.

penalty between September 2009 and April 2010. The only significant event that occurred during this period is the fact that the parties were unable to settle.

While Complainant has some limited discretion to decide how to charge alleged violations under FIFRA, given the paucity of evidence explaining the unit of violation in Complainant's Prehearing Exchange, it can be reasonably inferred that Complainant tactically changed the alleged "unit of violation" in order to increase the risk to Respondent of litigating a higher proposed penalty because no "new" evidence has been presented by Complainant to justify the dramatic change. Or, perhaps this was done by Complainant with the view that if the Presiding Officer were to reduce the proposed penalty, for example, by cutting it in half, the final penalty would still be greater than the penalty demanded in Complainant's Initial Notice to Respondent.

The following three sections of this brief review the Complainant's use of the 2009 Penalty Policy and demonstrate that the 2009 Penalty Policy should not be employed in this case in order to determine an appropriate penalty that reasonably reflects the actual gravity and the totality of the circumstances for the failure of Respondent to disclose the RUP classification of Rozol in Respondent's advertisements.

C. Appropriate Unit of Violation.

The goal of the 2009 Penalty Policy is

> to provide fair and equitable treatment of the regulated community, predictable enforcement responses, and

> comparable penalty assessments for comparable violations.

2009 Penalty Policy at 4.

While this is a laudable statement, it clashes with reality for a number of reasons, including the arbitrary and capricious way in which EPA determines the alleged unit of violation. The Environmental Appeals Board ("EAB") has indicated that an Administrative Law Judge 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. *Chem. Lab Products, 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. U.S. 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 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 (emphasis added). *Chem. Lab Products*, 2002 WL 31474170 at *13 (citing *Titan Wheel Corp.*, 10 E.A.D. 526 (EAB 2002)). The "more" that would be needed has never been directly addressed by the EAB and

the tension between the EPA's two competing policies – one discouraging the examination of other cases and the other to provide comparable penalties for comparable violations – has not been resolved. *Id.*

Assuming the EAB is correct, the only conclusion that one can reasonably draw from the EAB's position is 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 disparate treatment of parties accused of violating FIFRA. However, this is far from the actual situation.

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

Number of units of violation	X	Penalty per unit	=	Total penalty[13]

Even assuming the penalty per unit of violation can be uniformly calculated under the 2009 Penalty Policy, 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).

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

While the penalty must be supported by the facts of the case, fairness, equity and other matters that justice may require are appropriate considerations in addressing civil penalties under FIFRA. *Id.* at *22. For example, in several cases it is clear that the EPA has manipulated the "unit of violation" variable in order to calculate a penalty it desires to achieve.[14]

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[14] "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 (ALJ Aug. 4, 1999), 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); *Green Thumb*, 6 E.A.D. 785-86 (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); *Johnson Pacific, Inc.*, 5 E.A.D. 696 (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); (d) number of customers (FRM *Chem, Inc., slip op.* at 2 (pesticide producer charged with three violations of FIFRA, one for each customer (municipality) to which it made two sales over four months)); and (e) 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 (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 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).

Consequently, as long as Complainant has almost unfettered discretion to arbitrarily and capriciously choose the number of units of violation which it will charge in a particular case, the application of the EPA penalty policy as an objective standard is virtually impossible. The facts of this case amply illustrate this point.

On the one hand, if Complainant chose to charge 2140 counts for the failure of Respondent to adequately disclose the RUP classification in advertising and charged those counts under the 1990 Penalty Policy, Complainant would have calculated a proposed penalty of over $13 million. On the other hand, if Complainant would have chosen to charge violations based upon the number of days on which the ads were broadcast (132), plus print ads (23), and applied the 2009 Penalty Policy (including the newly-created graduated adjustment formula), the penalty would have been substantially less than $1 million. A variation in a proposed penalty based upon this gulf between the high range and the low range makes the statement in the EPA penalty policy regarding predictability and comparability virtually meaningless.

Even if the Presiding Officer determines that this case does not provide the "more" referenced by the EAB in *Titan Wheel* in order to compare this enforcement action to a specific past penalty determination, the Presiding Officer may look to past reported adjudicated cases and the enforcement history of FIFRA to provide a context that appropriately informs the analysis of what is fair and equitable in a given case, keeping in mind the goal of the penalty policy to provide

"comparable penalty assessments for comparable violations." 2009 Penalty Policy at 4. As indicated earlier, counsel for Respondent is only aware of 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 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 in this historical context that one should decide what is a reasonable and appropriate penalty in this case in light of the totality of the circumstances presented.

As Complainant has indicated, this case represents the first time a tribunal will hear a case involving a party alleged to have violated FIFRA section 12(a)(2)(E). RUP Order at 13. FIFRA and its regulations do not address what constitutes an independently assessable violation for purposes of section 12(a)(2)(E). In addition, the ERP, "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. Moreover, "the determination of whether an act of proscribed conduct constitutes multiple offenses under a statutory provision is not a matter of enforcement discretion; it is,

rather, a matter of statutory interpretation." *McLaughlin Gormley King Co.*, 6 E.A.D. 339, 1996 WL 107270, at *6 (EAB 1996).

While FIFRA provides that violations under section 12(a)(1), 7 U.S.C. § 136j(a)(1), are to be based on each sale or distribution, that analysis does not apply to Section 12(a)(2)(E), 7 U.S.C. § 136j(a)(2)(E). Section 12(a)(2)(E) simply states that it is unlawful to "advertise a product registered under this subchapter for restricted use without giving the classification of the product. . . ." The legislative history provides no guidance on the appropriate unit of violation for purposes of section 12(a)(2)(E).

Importantly, when determining the unit of violation under section 12(a)(1), 7 U.S.C. § 136j(a)(1), the agency considers an act independent if it results from an act which is not the result of any other violation. "Consistent with the above criteria, 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. § 136j(a)(1). 2009 Penalty Policy at 16.

Because EPA would not count individual containers in a single distribution of a product as separate violations under section 12(a)(1), individual advertisements within an advertising contract should not be counted as separate violations for purposes of section 12(a)(2)(E). As a result, the appropriate unit of violation for purposes of section 12(a)(2)(E) should, at most, be the number of different advertising contracts into which Respondent entered for the production of

advertisements that failed to adequately disclose the RUP classification of Rozol. Therefore, the maximum number of alleged RUP violations in this case is 12.[15] See RX 81; CX 14a, EPA 000285-EPA 000360.

D. Fundamental Problems with Calculation of Penalty Under 2009 Penalty Policy.

Under its 2009 Penalty Policy, Complainant is required to undertake the following steps to calculate the penalty once the number of violations has been determined:

1. Determine the size of the business;

2. Determine the gravity of the violation;

3. Determine the base penalty amount;

4. Determine the adjusted penalty amount based upon case-specific factors using the gravity adjustment criteria in Appendix B;

5. Calculate the economic benefit of noncompliance;

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

[15] Alternatively, the Presiding Officer could reasonably find that one (1) violation occurred based on the single act of failing to adequately disclose the RUP classification in advertising, or that the unit of violation should be based on the number of versions of violative advertisements (6), or the number of states where violative ads were broadcast or distributed (6). *See 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 (EAB 1996) (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).

7. Consider further modifications in accordance with Section IV.B.1.-3. of the 2009 Penalty Policy.

In this case, there is no disagreement over how Complainant applied the 2009 Penalty Policy in Steps 1-3[16] and 5-6.[17] This leaves Step 4, including application of the gravity adjustment factors from Appendix B and Table 3, and Step 7. Respondent strongly disagrees with Complainant's analysis as to the application of the 2009 Penalty Policy to the facts of this case with respect to these issues.

The 2009 Penalty Policy 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.

2009 Penalty Policy at 19-20.

The adjustment factors relate to very specific issues. The "specific characteristics of the pesticide involved" obviously relates to the toxicity of the

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[16] Respondent does not agree that this case invokes violations of high gravity, but it does not dispute that Complainant determined the correct gravity rate as directed by the 2009 Penalty Policy.

[17] Respondent does not dispute the size of its business and agrees that the Category I classification is the default position under the 2009 Penalty Policy. Complainant alleges the 2009 Penalty Policy 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 Penalty Policy 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 dispute Step 6 regarding the impact of the penalty on the ability of Respondent to continue in business.

applicable pesticide. "Compliance history and culpability of the violator" obviously relate to the violator itself.

"Harm to human health and/or harm to the environment" relate to the potential or actual harm caused by the violation. Complainant, however, bases 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 likelihood of actual violation to cause harm. This is an incorrect legal interpretation.[18]

The 2009 Penalty Policy must be construed to require that these two gravity adjustment criteria be based on the harm to human health and/or harm to the environment caused or threatened by the actual acts alleged. To hold otherwise would require the entire harm to human health and harm to environment gravity adjustment factors to be determined by the chemical composition of the pesticide rather than the actual gravity of the offense.

Importantly, the EAB has referred to witnesses who testify as to the calculation of a proposed penalty as "experts." *Strong Steel Prods., LLC,* Docket Nos. RCRA-5-2001-0016, CAA-5-2001-0020, MM-5-2001-006, 2003 EPA ALJ LEXIS 191, at *15 (ALJ 2003) (internal citation omitted). The person calculating

[18] *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 the gravity of the violation."

the penalty must be shown to have expertise as to penalty assessments and may be required to submit a curriculum vitae. *Id.*

Ms. Claudia Niess, Complainant's proposed penalty "expert," however, has not been shown to have any relevant experience with the pesticide products at issue in this case that would allow her to accurately determine the gravity of the alleged offenses. Nor has Complainant submitted a CV for Ms. Niess. As a result, Ms. Niess' opinions regarding the proposed penalty assessment are unreliable and should not be admitted in evidence.

The subsections below analyze the gravity adjustment criteria in Appendix B of the 2009 Penalty Policy.

(a) Pesticide. The Complainant concluded that the value was "3" because the product in question is a restricted use pesticide. This conclusion is erroneous.

The appropriate category is "1." The label provides that the pesticide is a restricted use pesticide but the EPA required only 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 "value" is also in line with the fact that the same pesticide, Rozol Pocket Gopher Bait, EPA Reg. No. 7173-184, is a general use pesticide.

When a document is ambiguous it should be construed against the drafter, and this is particularly true in an enforcement case. *Pepsi Bottling Group*, 2010 WL 4622520, at *4 (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). Therefore, the value of "1" should be applied to the pesticide prong of the Gravity Adjustment Criteria.

(b) Harm to Human Health. The Penalty Calculation Analysis by Ms. Claudia Niess of Region V (*see* CX 55, EPA 001010) 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 001010.

Ms. Niess' assertion is erroneous for several reasons. First, the Complainant has dropped all allegations that the sale or distribution of Rozol took place with 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). *See* First Am. Compl. 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* RX 1, 2. Third, Complainant simply "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. This statement is simply sheer speculation by Complainant. This is no proof that any harm to human health occurred.

Further, the Rozol products at issue in this case could only be sold to certified applicators of pesticides and there is no allegation in the First Amended Complaint that any of the Rozol products were sold by Respondent to anyone other than to certified applicators.[19] In addition, there is no allegation in the First Amended Complaint or any evidence in Complainant's pre-hearing exchange to support a conclusion that the Rozol products were ever misused, applied contrary to the label or to land other than what was allowed by the label. Therefore, the value of the harm to human health prong of the Gravity Adjustment Criteria should be zero.

The application of the value of "0" to this prong is also supported by the 2009 Penalty Policy which states that a value of "0" should be applied in those cases where "negligible harm to human health [is] anticipated." 2009 Penalty Policy at 34-35. The footnote associated with this quote explains "negligible" as meaning "no actual or potential harm or actual or potential harm which is insignificant and has no lasting effects or permanent damage or monetary loss."

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

2009 Penalty Policy at 35 n.3. Complainant has offered no evidence in its pre-hearing exchange to enable the Presiding Officer to distinguish between the basis for ascribing the value of one or zero to this prong other than Complainant's conclusory assertions. *See also Martex Farms, S.E.*, Docket No. FIFRA-02-2005-5301 (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. U.S. EPA,* 559 F.3d 29 (1st Cir. 2009) ("the evidence does not reveal any actual injuries or adverse health effects resulting from these violations").

(c) Environmental Harm. Ms. Claudia Niess asserts 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 001010.

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. There is no evidence in the record that the failure to use the words "restricted use pesticide" resulted in any actual or threatened harm to the environment. In addition, there is no evidence in the record that the sales of Rozol increased because of the advertising of this product without the RUP classification or that any misuse of the product occurred as a result of advertising this product without the RUP classification. The assertions by Ms. Niess are sheer speculation.

Such conjecture, like Complainant's speculation regarding possible human harm, cannot serve as the basis for imposing a penalty on Respondent. *See* 40 C.F.R. § 22.24 ("The Complainant has the burdens of presentation and persuasion that the violations occurred as set forth in the complaint and that the relief sought is appropriate"). Because no harm to the environment could have occurred as a result of the violations alleged and Complainant simply offers speculative assertions to support its allegation, the value for the environmental harm prong of the Gravity Adjustment Criteria from the failure to use the words "restricted use pesticide" in these radio and print advertisements should be "zero."

Furthermore, EPA was well aware of 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. There is no

evidence in the record that this lawfully registered product was ever misused, applied contrary to the label or applied in a manner other than what was allowed by the label as a result of the violation of FIFRA section 12(a)(2)(E).

The sale of restricted use pesticides is also rigorously controlled by FIFRA and applicable state laws. FIFRA § 12(a)(2)(F); RX 34, 35. These laws prohibit such a product from lawfully being sold to individuals other than those who are certified applicators.

In addition, Respondent has strict controls in place to ensure that Rozol is not sold to anyone who is not lawfully permitted to purchase it. *See, e.g.*, RX 92. Consequently, even if the advertisement did not adequately disclose the RUP classification and somehow piqued the interest of someone who was not a certified applicator of pesticides, 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.

(d) Compliance History. Respondent agrees with Complainant's position that the compliance history value is "zero."

(e) Culpability. In this section of her analysis, Ms. Claudia Niess refers to the June 2008 Stop Sale, Use or Removal Order for violations of section 12(a)(2)(E) of FIFRA ("2008 Stop Sale Order"). CX 55, EPA 001011. She states that based on that June 2008 Stop Sale Order and

allegations of violations in November of 2009 the company's culpability has been evaluated as unknown or violations resulting from negligence.

According to the First Amended Complaint, all violations for failure to adequately state the RUP classification occurred before June of 2008. First Amended Compl., ¶¶ 369-470. Therefore, the allegations in November of 2009 are not relevant to the 2007-2008 RUP classification issue for purposes of culpability. At most, the culpability value for this RUP liability, which occurred in 2007-2008, should be "1" based on negligence.

The description of this "1" value in the 2009 Penalty Policy states that it should apply if the "violator instituted steps to correct the violation immediately after discovery of the violation." 2009 Penalty Policy at 34. This is exactly what occurred once the 2008 Stop Sale Order was received by Respondent. Therefore, at most, the value of "1" should be applied to the culpability prong of the Gravity Adjustment Criteria.

Adding all of these adjustment factors together results in a total of "2." Using Table 3 of the 2009 Penalty Policy, the enforcement remedy is

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

2009 Penalty Policy at 20. Given the nature of the conduct alleged in the First Amended 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 commencing an enforcement action.

See Sporicidin Int'l, Docket FIFRA 88-H-02, 1988 WL 236319, at *3 (ALJ 1988), *aff'd*, 3 E.A.D. 589, 1991 WL 155255 (EAB 1991) (referencing copies of letters sent to respondent "informing Respondent that claims made in collateral literature for the effectiveness of sporicidin against Hepatitis B and HTLV III/LAV (AIDS) viruses were unacceptable).[20]

Respondent acknowledges that EPA has the legal right to issue a Stop Sale Order without first issuing a Notice of Warning. However, the investigators knew of these allegations in November 2007 and at that time also had telephone contact information for Respondent. *See* CX 8, EPA 00067 (including contact information for Respondent's employee Charles Hathaway). As a result, Complainant could have easily alerted Respondent to this problem. Respondent is raising this point simply to point out that the long delay in contacting Respondent before issuing the 2008 Stop Sale Order in June of that year is an indication of the lack of significant gravity which the EPA attached to these allegations at the time they were occurring. 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 2009 Penalty Policy, the per-penalty amount would be reduced to $2,600.

After calculating the per-unit penalty amount, Complainant then calculated its proposed penalty by applying the discount formula in Section IV.B.1. of the

[20] 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* 8 EPA 00067, EPA 00072 (e-mail informing Shawn Hackett of KDA that the advertisements would continue to be run).

2009 Penalty Policy.[21] The discount formula in this penalty policy provides that the per-unit penalty amount for violations exceeding 100 should be 25% of the per-penalty amount for the first 100 violations. 2009 Penalty Policy at 25. Applying this discount to this proposed penalty amount of $2,600, as Complainant did to its proposed per-unit penalty, would reduce the penalty for violations above 100 to $650.

If a penalty were based on the unit of violation originally asserted by Complainant – the number of days an advertisement was broadcast rather than the number of times the advertisement was broadcast – the resulting penalty calculated under the 2009 Penalty Policy would have been $291,200 – $2,600 for the first 100 violations and $650 for the next 48 violations. A further 20% reduction in this amount for good faith efforts during penalty discussions would result in a proposed total penalty for the RUP classification issue of $232,960. Respondent believes that even this amount exceeds what is reasonable and appropriate for these alleged RUP violations considering the totality of the circumstances – including the total lack of evidence of any harm whatsoever to humans or the environment caused by the violations. This unreasonably high amount is driven by the Complainant's legal interpretation of the "unit of violation" and its application of the 2009 Penalty Policy, which is unsupported by

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

facts in the record. As noted above, the maximum reasonable unit of violation for this issue is 12, based on the number of different advertising contracts Respondent entered into. Applying the 2009 Penalty Policy to this number of violations results in a penalty of $31,200.

E. Complainant's Analysis of the Penalty Policy Must Be Disregarded.

For the reasons set forth above, Complainant's analysis under the 2009 Penalty Policy should be ignored in determining an appropriate penalty for the violation of FIFRA section 12(a)(2)(E). But in addition, Complainant has also misinterpreted the 2009 Penalty Policy regarding the application of the discount formula in Section IV.B.2. of this policy to alleged advertising violations.

This misinterpretation also makes it inappropriate to apply the 2009 Penalty Policy, including the discount matrix, to the facts of this case. The discount formula in Section IV.B. of the 2009 Penalty Policy applies only to the "multiple sales or distributions for the same violations." 2009 Penalty Policy at 25. This section of the 2009 Penalty Policy does not address in any fashion what type of discount should be applied, or how a discount should be applied, to advertising violations.

In order to apply the discount to "advertising" violations, Ms. Claudia Niess simply substituted in Table 4 the term "Number of Distributions" in the first column with "Number of Advertisements." *Compare* 2009 Penalty Policy at 25 *with* CX 55, EPA 001012. Section IV.B.2. of the 2009 Penalty Policy not once mentions the word "advertising," or references the RUP classification requirement

under FIFRA section 12(a)(2)(E), or suggests that the discount should be applied in all multi-violation cases. It specifically refers to multiple-violation cases involving "sales" or "distributions."

If the discount formula in the 2009 Penalty Policy is, in fact, not applicable to advertising, one must seriously question Complainant's ability to use the 2009 Penalty Policy in this case. 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, 2009 Penalty Policy at 20, and (ii) application of a discount matrix for multiple sale/distribution violations. 2009 Penalty Policy at 25.[22] 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.

As a result, the 2009 Penalty Policy is fatally flawed when applied to a case involving an allegation of multiple units of violation of FIFRA section 12(a)(2)(E) and should not be employed to calculate a penalty in this case. The penalty generated by the 2009 Penalty Policy, as interpreted and applied by Complainant, grossly overstates the actual gravity of this case. Importantly, the 2009 Penalty Policy 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).

[22] The discount penalty matrix contains no explanation of why the break points for discounting the penalty for a Category I business should be 100 distributions and 400 distributions. In addition, Complainant is erroneously equating an advertisement to a sale or distribution for applying the discount matrix and there is no justification set forth in the 2009 Penalty Policy for doing so.

Because even a penalty calculated under the applicable Enforcement Response Policy can be excessive, the true matter of concern "is whether the penalty is appropriate in relation to the facts and circumstances at hand." *99 Cents Only*, 2010 WL 2787749, at *27-28. In this case, the Presiding Officer should not utilize the penalty policy and should instead fashion an equitable and fair penalty based on the "totality of circumstances." *Id.* at *28.

III. ALLEGED VIOLATIONS OF FIFRA SECTION 12(a)(1)(B).

A. Introduction and Overview.

Counts 2141-2231 of the First Amended Complaint involve allegations by Complainant that Respondent violated FIFRA section 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B), during two different periods of time – from October 1, 2007 to May 13, 2008 (involving 43 alleged violations) and from November 18, 2009 to February 23, 2010 (involving 48 alleged violations).

FIFRA section 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B), provides that it is unlawful 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 from any claims made for it as a part of the statement required in connection with its registration under Section 136a of this title.

In order for Complainant to establish that a violation of FIFRA section 12(a)(1)(B) occurred as alleged, it must establish, among other factors, that (1) claims made by Respondent for "it" (the pesticide product in question) were substantially different from the claims made for "it" in connection with its

registration statement ("Substantially Different Claim"); (2) that a sale or distribution of a pesticide occurred; and (3) that the Substantially Different Claim was made as part of a particular sale or distribution ("Nexus").[23]

Therefore, the Presiding Officer must determine whether a "Substantially Different Claim" was made, whether a "sale or distribution" of Rozol occurred and whether a Nexus existed between the Substantially Different Claim and the sale or distribution.

While Complainant's allegations for each of the Counts 2,141-2,231 involve the same statutory section of FIFRA, the basis of the allegations for the 2007-2008 time period is substantially different than for the 2009-2010 time period.

During the 2007-2008 time period, Complainant alleges that Substantially Different Claims were made in connection with the actual sale or distribution of Rozol. The record indicates that sales or distributions of Rozol occurred during this period to 41 distributors of Respondent, First Amended Compl. ¶¶ 213-215, 217-249, 251-255; Answer ¶¶ 213-215, 217-249, 251-255, and two product transfers were made to employees of Respondent. Answer ¶¶ 216, 250. However, Respondent vigorously disputes that (a) Substantially Different Claims were made

[23] There are other factors that must be established in order for Complainant to prove a violation of this section of FIFRA, but these other factors are not at issue in this case: for example, Respondent admitted that Rozol is a registered pesticide and that Respondent is a person.

and (b) that a Nexus exists between any allegedly Substantially Different Claim and the actual sale or distribution of Rozol for any of these sales or distributions.

For the 2009-2010 time period, rather than alleging that there were actual sales or distributions of Rozol, Complainant asserts that Respondent made "offers to sell" Rozol and that Substantially Different Claims were made as part of the offers to sell. Consequently, if there was no "offer to sell" Rozol during the 2009-2010 time period, no violation of FIFRA section 12(a)(1)(B) could have occurred even if Substantially Different Claims were made by Respondent. *In re Microban Prods. Co.*, 9 E.A.D. 674, 2001 WL 221611, at *10 (EAB Feb. 23, 2001) (". . . 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"). If it is determined that an "offer to sell" Rozol occurred, Respondent strongly disputes that Substantially Different Claims were made by Respondent during this time period. Respondent further disputes that a Nexus existed between any alleged Substantially Different Claim and any "offer to sell."

However, if the Presiding Officer finds that violations of FIFRA Section 12(a)(1)(B) occurred during either or both the 2007-2008 and the 2009-2010 time periods, any resulting penalty should be *de minimis*. Critical issues that need to be resolved in order to find that Respondent violated FIFRA section 12(a)(1)(B) are legal issues of first impression that must be decided by the Presiding Officer – for example:

1. What is the statement required in connection with pesticide registration under Section 136a?

2. What claims are subject to FIFRA section 12(a)(1)(B)?[24]

3. If claims made by Respondent are subject to FIFRA section 12(a)(1)(B), when do such claims rise to the level of a claim that is "substantially different?"

4. What constitutes a sufficient nexus between claims that are alleged to be substantially different and the sale or distribution (including an offer to sell) to find a violation of FIFRA section 12(a)(1)(B)?

5. What is the extent of the EPA's limited legal authority to regulate pesticide advertising under FIFRA section 12(a)(1)(B), especially when compared to the broad statutory authority of the Federal Trade Commission to regulate advertising and the clear authority given by Congress to other federal agencies to regulate advertising in their particular regulatory areas? and

6. To what extent can Complainant – through a broad interpretation of FIFRA section 12(a)(1)(B) – limit or curtail a pesticide manufacturer's constitutional right to make truthful statements about its product to its distributors and potential customers?[25]

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[24] For example, can statements about another pesticide product be the basis of a "differing claim?"

[25] "FIFRA does not grant EPA plenary authority to regulate advertising as such." 54 Fed. Reg. 1122, 1124 (Jan. 11, 1989).

Because of the numerous legal issues of first impression presented by the facts of this case and the lack of potential or actual harm caused by the alleged violations, if any violations of FIFRA section 12(a)(1)(B) are found by the Presiding Officer, only a *de minimis* penalty should be applied for Counts 2,141-2,231. Based on the totality of the circumstances of this case, the gravity of the alleged violations is minor.

The following sections discuss the allegations made by Complainant during each of the two respective time periods.

B. 2007-2008 Allegations.

1. Introduction. In order for Complainant to establish a violation of section 12(a)(1)(B) based on events that occurred during the 2007-2008 time period, Complainant must demonstrate that (a) the claims made by Respondent for Rozol were substantially different from the claims made for it as part of the statement required in connection with its registration; (b) a sale or distribution of Rozol occurred; and (c) there was a nexus between the substantially different claim and the particular sale or distribution.

In this case, Complainant alleges that there were 43 violations. In other words, there allegedly were 43 sales or distributions to various distributors of Respondent and, as part of each sale or distribution, Respondent made a Substantially Different Claim for Rozol.

2. Requisite Nexus Does Not Exist.

a. Standard for Determining Whether "Nexus" Exists.

FIFRA section 12(a)(1)(B) is not an absolute prohibition on the ability of a pesticide manufacturer to make claims that are substantially different from the statement in connection with the product's registration. *Sporicidin Int'l*, 1988 WL 236319, at *12. Even if Complainant could show that a Substantially Different Claim was made by Respondent, no violation of FIFRA section 12(a)(1)(B) could occur unless the differing claim can be linked to a particular sale or distribution of Rozol. *Microban*, 2001 WL 221611, at *10. A Nexus must exist between the substantially different claim and the distribution or sale of the pesticide. Order on Motions for Acc. Decision Regarding Alleged Violations of FIFRA § 12(a)(1)(B) dated June 24, 2011 ("Differing Claims Order") at 24.

b. Application of Nexus Standard to Facts of the Case.

The 43 distributors can be placed into several categories with respect to Nexus.

(i) Employees of Respondent. Two of the parties who are reported to have purchased or received a distribution of Rozol thereby resulting, according to the Complainant, in a violation of FIFRA, were employees of Respondent. *See* First Am. Compl. ¶¶ 216, 250; Answer ¶¶ 216, 250;

RX 94-95. As stated by Respondent in an earlier brief,[26] a corporation and its employees are one enterprise and there cannot be any sale or distribution of product within the enterprise that would result in a violation of FIFRA. *See, e.g.*, *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 770 (1984) (operations of a corporate enterprise, with dispersed employees, must be judged as the conduct of a single actor); *Saucier v. Coldwell Banker JME Realty*, 644 F. Supp. 2d 769, 784 (S.D. Miss. 2007) (holding that in the context of conspiracy law, a corporation cannot conspire with itself). Therefore, any distribution of Rozol to an employee of Respondent cannot constitute a violation of FIFRA.

(ii) Sales/distributions prior to the distribution of direct mail package. There were four sales/distributions of Rozol prior to the time the Respondent first distributed the Direct Mail Packages. *See* First Am. Compl. ¶¶ 213-216; CX 14, EPA 000171. Since distribution of Rozol to these four distributors occurred before the Direct Mail Packages were transmitted, Complainant cannot establish that the requisite Nexus existed between the literature and sale/distribution.

Complainant may introduce evidence that Respondent's website contained copies of marketing information at the time of these sales/distributions or that

[26] Memo. of Resp. Opposing Mot. of Complainant for Accelerated Decision on Liability for Counts 2,141 through 2,183 of the Compl. dated Dec. 3, 2010 at 13-14.

differing claims were made in radio advertisements, thereby arguing that the requisite Nexus occurred. However, there is no evidence that any individual associated with any of these four distributors either looked at, read or acted upon any information that was contained on Respondent's website or that any such individual heard a radio advertisement. This attempted link by Complainant stretches the meaning of "nexus" well beyond what has been the state of the law to date. Under these circumstances, no penalty should be imposed on Respondent.

(iii) The remaining sales/distributions of the product for the 2007-2008 period occurred after the direct-mail packages were distributed. However, there is no evidence in the record that any of the individuals associated with a particular distributor organization which may have received this literature, either actually received it, read the literature or acted upon the literature.[27] Again a determination that the mere sending of literature creates the requisite Nexus, without more, for these sales/distributions will expand the concept of "nexus" far beyond what is currently permitted by case law.

For these reasons alone, all 43 counts for the alleged advertising violations under FIFRA section 12(a)(1)(B) during the 2007-2008 period should be dismissed.

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[27] The Complainant has the burden of presentation and persuasion that the violation occurred as set forth in the Complaint. 40 C.F.R. § 22.24. Respondent has no such burden of proof in disputing Complainant's allegations.

3. No Substantially Different Claim for It. To establish a violation of FIFRA section 12(a)(1)(B), Complainant must also prove that claims made by Respondent for "it as 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 . . . ." FIFRA § 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B). Respondent does not have the burden to establish that its claims were not substantially different. Complainant has the burden to show that the claims were substantially different. *See* 40 C.F.R. § 22.24 (Complainant has the burden of presentation and persuasion). There is no evidence that the claims the Respondent made for Rozol as part of its sale or distribution differed substantially from the claims made as part of the statement required in connection with its registration.

In prior briefs, Complainant argued that the "statement required" as used in FIFRA was the Notice of Pesticide Registration, which contains the "Accepted Label."[28] On the other hand, Respondent argued that the "statement required" consists of all documents and data that were submitted to the EPA in the

[28] According to Complainant, the "Accepted Label" is the label approved by EPA as part of the pesticide registration process. *See* Complainant's Motion for Accelerated Decision on Liability for Counts 2,141 through 2,183 of the Complaint at 11 and Complainant's Motion for Accelerated Decision on Liability for Counts 2,184 through 2,231 of the Complaint and Memo. in Support at 17-18.

registration application or that is publicly available at the time of the registration.[29] In her order dated June 24, 2011, the Presiding Officer rejected both suggested legal formulations but concluded

> Complainant's reliance on a legal theory that bases allegations of liability on the "accepted label" is too narrow a formulation to justify a ruling in its favor as a matter of law. In focusing solely on the "accepted label" argument, Complainant has not established sufficient evidence showing an absence of material fact as to Respondent's overall compliance with 7 U.S.C. § 136a(c)(1).

Differing Claims Order at 24.

Based on this decision, the statement required must be something more than the Notice of Pesticide Registration and the Accepted Label. But what is it? The fact that the requisite legal standard could not be articulated in a decision on Complainant's motions for accelerated decision on Counts 2,141-2,231 indicates that whatever the standard is, the underlying statutory language is vague and ambiguous. As a result, any penalty that may be imposed for having ultimately

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[29] Complainant may argue that Respondent knew some type of "statement of claims" had to be submitted with the registration of a pesticide by referring to Complainant's Exhibits 137-138 which show that Respondent submitted "optional marketing statements" to EPA for approval. *See* CX 137-138. However, what Complainant does not disclose is that these statements were statements that Respondent might have wanted to make on the label for a different pesticide product. Statements made on a pesticide label must be approved by EPA (*see* 7 U.S.C. § 136(a)(c)(5)(B)), and labeling claims are subject to the misbranding prohibitions under FIFRA section 12(a)(1)(E). Therefore, claims to be made on the label or in labeling must be submitted to and approved by the EPA. But as the Presiding Officer pointed out in her June 24, 2011 decision, advertising claims, not appearing on the label, do not need to be approved by EPA. Differing Claims Order at 24. The fact that registrants may, in some cases, submit "optional marketing statements" to EPA so that such statements may be reviewed and approved for use on the label does not control what statements, if any, can be made by a registrant in a manner other than on the product label or as labeling.

violated this vague and ambiguous section of FIFRA should be, at most, *de minimis*.

Moreover, before any type of penalty may be imposed, not only does the Presiding Officer have to determine what the legal standard is, but the Presiding Officer must also determine that Complainant has carried its burden of proof that whatever claims were made by Respondent for "it" were "substantially different" from what was submitted by Respondent to EPA. In other words, the apparently "different" claims must not only have been "substantially different," they must also have been for "it."

As set out in earlier briefs, no reported case law has defined either the word "substantially" or "it" as used in this section of FIFRA. Webster's dictionary defines "substantial" as "important, essential." Webster's Ninth New Collegiate Dictionary 1176 (1988). The plain meaning of the word "it" in the statute must refer to the pesticide product itself, which in this case is Rozol. If Congress had wanted to apply this statute to any claim made by a pesticide manufacturer, Congress could simply have deleted the words "for it" in FIFRA section 12(a)(1)(B).

A number of allegedly illegal claims made by Respondent were about a competitor's product. Complainant has argued that these statements actually need to be construed as statements "for it" under the statute. However, the word "it" does not mean "anything." "It" means "it" – the pesticide product in question.

If one accepts the Complainant's line of reasoning, then no pesticide manufacturer could ever truthfully point out in any of its communications any flaws or deficiencies that existed in a competitor's products without first submitting that information to the EPA as part of a "statement of claims" for the product to be registered by the EPA. This absurd result cannot be what Congress intended, nor is it what even the EPA currently states is its intent (much less authority) to regulate advertising; namely, the EPA does not routinely review advertising claims. *See* CX 88, EPA 001572 ("OPP does not routinely review advertising in connection with the registration . . ."); *see also* RX 97; *Compton Unified Sch. Dist. v. Addison*, 598 F.3d 1181 (9th Cir. 2010) ("In construing a statute, courts read the statute as a whole and avoid interpretations that would produce absurd results").

As discussed above, the Presiding Officer must determine what constitutes the "required statement" under FIFRA section 12(a)(1)(B). Whatever the "required statement" means, it cannot be extended to preclude Respondent or any other pesticide manufacturers from making truthful statements about their products. *United States ex rel. Attorney Gen. v. Delaware &. Hudson Co.*, 213 U.S. 366 407 (1909) ("when the constitutionality of a statute is assailed, if the

statute be reasonably susceptible of two interpretations . . . it is our plain duty to adopt the construction which will save the statute from constitutional infirmity").[30]

This would be akin to a pesticide manufacturer making an efficacy claim about its product without having submitted efficacy data to the EPA and the EPA subsequently alleging a FIFRA Section 12(a)(1)(B) violation over efficacy claims even though they are true, merely because the supporting data was not submitted to EPA.[31] Again, Respondent is not arguing that FIFRA Section 12(a)(1)(B) is unconstitutional. Respondent is arguing that the expansive interpretation that Complainant ascribes to FIFRA section 12(a)(1)(B) results in an infringement of Respondent's right to commercial free speech, so to the extent the statute is ambiguous, a narrow rather than broad construction of this FIFRA provision should be adopted by the Presiding Officer in this penalty context. *I.N.S.*, 533 U.S. at 299.

The statements of Respondent that Complainant objects to were either (a) contained in or supported by the materials submitted with the product registration; (b) were claims made for products other than Rozol and, therefore, were not

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[30] While in *Sporicidin*, 3 E.A.D. 589, 1991 WL 155255 at *7, the EAB mentions that truthfulness is not a defense for a violation of Section 12(a)(1)(B), the EAB appears to base its statement on the mistaken impression that the EPA must pre-approve advertising claims. As the Presiding Officer has already determined, nothing in 7 U.S.C. § 136(a)(c) required claims about a registered pesticide to be affirmatively approved by the EPA. Differing Claims Order at 24. As a result, the statement made by the EAB, and the legal standard for determining a violation of FIFRA section 12(a)(1)(B), will need to be clarified in this proceeding.

[31] Pursuant to FIFRA section 3(c)(5), Congress has allowed EPA to waive the review of such efficacy data as part of registration. 7 U.S.C. § 136(a)(c)(5).

claims for "it;" or (c) were not substantially different based upon the foregoing legal standard.

C. 2009-2010 Advertising Allegations.

1. Introduction.

The same analysis for Nexus and Substantially Different Claims set forth above for the 2007-2008 allegations also applies to Complainant's allegations for the 2009-2010 time period – namely Counts 2184-2231 of the First Amended Complaint. That is, the evidence in the record does not and cannot demonstrate the requisite Nexus that the alleged Substantially Different Claims were made as part of a sale or distribution. Furthermore, Complainant will not be able to establish that the statements made by Respondent were Substantially Different Claims.

In addition, Complainant cannot establish that Respondent made an "offer to sell" Rozol to any of the 48 distributors during the 2009-2010 time period. Complainant has not produced any evidence to establish that the direct-mail literature that Complainant alleges was sent to each of the 48 distributors was, in fact, sent to them or was ever read by a particular distributor or that the particular distributor acted upon that literature or that literature induced or even influenced any one of the 48 distributors to purchase Rozol.[32]

[32] Importantly, Counts 2184-2231 allege differing claims were made on Respondent's website. Complainant, in prior briefs, has argued that Respondent also sent this information to 48 distributors because Respondent contacted the distributors when responding to a SSURO.

2. No "Offer to Sell" Was Made in Connection with the 2009-2010 Allegations.

Complainant alleges that Respondent offered to sell Rozol to each of the 48 distributors named in Attachment I to the First Amended Complaint. The legal standard for what constitutes an "offer to sell" and application of this legal standard to the facts preclude a finding that Respondent made an "offer to sell" Rozol to any one of the 48 distributors.

a. Legal Standard. The term "offer for sale" is not defined in FIFRA or in any regulation promulgated under FIFRA. No legislative history that discusses the meaning of the term "offer for sale" exists. *Tifa Ltd.*, 9 E.A.D. 145, 2000 WL 739401, at *9 (EAB 2000). Apart from *Tifa*, a decision by the EAB, Respondent's counsel is not aware of any final judicial decision interpreting this term.

FIFRA section 12(a)(1) utilizes the term "distribute or sell" in four different places. The relevant language of FIFRA section 12(a)(1) (emphasis added) follows:

> (1) . . . It shall be unlawful for any person in any State to **distribute or sell** to any person –
>
> > (A) any pesticide that is not registered . . . or whose registration has been cancelled or suspended, except to the extent that **distribution or sale** otherwise has been authorized by the Administrator under this subchapter;
> >
> > (B) any registered pesticide if any claims made for it as part of its **distribution or sale** substantially differ from any claims made for it as part of the

> statement required in connection with its registration . . .;
>
> (C) any registered pesticide the composition of which differs at the time of its **distribution or sale** from its composition as described in the statement required in connection with its registration . . . (Emphasis added.)

Tifa examined the meaning of the term "distribution or sale" under FIFRA section 12(a)(1)(A). This term "distribution or sale" is identical to the term that is used in the other three places in FIFRA section 12(a)(1), including FIFRA section 12(a)(1)(B), which is the section Complainant alleges that Respondent violated.

When Congress uses the same term in multiple places in the same section of a statute, a court must conclude that Congress intended to ascribe the same meaning to that term throughout that section. *Arrnett v. Comm'r*, 473 F.3d 790, 798 (7th Cir. 2007) (absent evidence of Congress's intent to the contrary, courts assume that Congress intended the same words used close together in a statute to have the same meaning). Since the term "offer for sale" is a subset of "distribution or sale," the same meaning has to be ascribed to the term "offer for sale" throughout FIFRA section 12(a)(1).

In 2000, the EAB stated in *Tifa* that it had not been able to find any reported decision that discussed the meaning of the term "offer for sale." *Tifa*, 2000 WL 739401, at *9. Respondent's counsel's research has not disclosed any case that has discussed the meaning of this term since that time. Therefore, the

EAB decision in *Tifa* is the only authority of which counsel for Respondent is aware to have discussed the meaning of this term throughout the history of FIFRA. Since the term "offer for sale" that was discussed in *Tifa* is the same term in the statutory section that Complainant alleges Respondent violated, the discussion of this term by the EAB in *Tifa* is directly relevant to the case at hand.

In *Tifa*, the EAB was asked to determine if 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 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." *Id.* Because the registration of the pesticide in *Tifa* had been suspended, complainant alleged the respondent had violated FIFRA section 12(a)(1)(A). *Id.*

Following an extensive analysis of contract law, including 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 offer or 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. While prices are a fundamental component of an offer to sell, under the circumstances of that case, the EAB concluded 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.*

In order to determine whether Respondent's product information rises to the level of an offer to sell, the Presiding Officer must examine the material 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 accept the contract. Analysis of Complainant's allegations in this case, and the facts herein, do not constitute such an "offer to sell." As a result, no sale or distribution of Rozol occurred as alleged in the First Amended Complaint, and therefore no violation of FIFRA section 12(a)(1)(B) can be found.

Moreover, a passive website cannot constitute an "offer for sale." 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 Fed. App'x. 518, 522 (6th Cir. 2006). A passive website such as Respondent's that did not contain product pricing information or other relevant terms of sale cannot constitute an "offer to sell."

b. Facts Alleged by Complainant Do Not Constitute an "Offer to Sell."

The legal standard for what constitutes an "offer to sell" is based upon the controlling reasoning of the EAB in *Tifa*. There is no evidence that Respondent ever distributed a price list or the terms and conditions under which it would sell Rozol to any of the 48 distributors set forth in Attachment I of the First Amended Complaint. Therefore, based on *Tifa*, it follows that no "offer to sell" was made by Respondent.

In other words, even if Complainant shows that each and every one of the 48 distributors received the literature contained on Respondent's website and this literature induced them to buy Rozol, it does not constitute an "offer to sell." Moreover, there is no evidence that the direct-mail package was ever received by any one of the 48 distributors other than Complainant's allegation that this literature must have been received because Respondent contacted each of the distributors in response to a SSURO. Sending a letter to each of the distributors requesting that they destroy any allegedly violative literature shows only

Respondent's desire to cooperate with the EPA in the event any of the distributors had received the literature.

Nor is Complainant able to demonstrate that the website literature induced any of the 48 distributors to purchase Rozol. In addition, Respondent had a specific price list for Rozol, and this price list was not available on the website or sent in conjunction with the literature to any one of the 48 distributors. *See* RX 91. Furthermore, there is no evidence that this price list was ever available for review by the general public. The price list was never posted on Respondent's website.

Respondent also had a specific document detailing the terms and conditions that each purchaser of Rozol had to accept before Rozol could be sold to a particular party. RX 91. Again, there is no evidence that these terms and conditions were ever distributed to any one of the 48 distributors in conjunction with the direct-mail literature. Also, these terms and conditions were never posted on Respondent's website. Consequently, these terms and conditions were not available to the general public. Finally, before Rozol could be sold to any one of these distributors, the distributor had to provide Respondent with its certified applicator's license number. *See* RX 92.

c. An Advertisement Does Not Constitute an "Offer to Sell" Unless It Meets the *Tifa* Standard.

As discussed in previous briefs and orders, EPA promulgated 40 C.F.R. § 168.22(a) in which the EPA asserts that any advertisement that is available to the

general public constitutes an "offer to sell." This is an interpretive regulation, and a legally incorrect interpretation at that, which is not binding on a Presiding Officer. *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). In addition, 40 C.F.R. § 168.22(a), according to its title and content, only applies with regard to the advertisement of unregistered pesticides, unregistered uses of registered pesticides and Section 24(c) registrations, none of which is at issue for the alleged 2009-2010 violations. *See* Differing Claims Order at 26. However, even assuming that the direct-mail material that Complainant complains about constitutes "advertising that was available to the general public," there is no legal support for Complainant's aggressive position under any statute, regulation or reported case that this type of literature constitutes an "offer to sell." In fact, the *Tifa* case provides otherwise.[33]

Code of Federal Regulations title 40 section 168.22 was promulgated in 1989. At that time, there was even consternation within the EPA as to whether EPA had the legal authority to regulate advertising. For example, a legal memorandum from the EPA Office of General Counsel stated, "In comparison to the FTC's statutory mandate to regulate false, misleading or deceptive advertising,

[33] The marketing material that is the subject of the alleged violations of FIFRA section 12(a)(1)(B) has been referred to as advertising in some cases, *see* Am. Compl. ¶¶ 145, 273; Am. Answer ¶¶ 145, 273, and as educational material. *See* Memo. of Respondent Opposing Motion of Complainant for Accelerated Decision on Liability for Counts 2,141 Through 2,183 of the Complaint at 17. The material could also just as easily have been referred to as product information or educational material. The analysis used in *Tifa* to determine whether an offer for sale was made depends on the content of the material, not on the label used to describe it.

EPA's authority to control advertising rests upon a weak (or perhaps non-existent) reed." RX 78. See Exhibit D attached hereto.

In this EPA Memorandum, the General Counsel of EPA raised serious concerns and questions to the effect that the EPA does not have the legal authority to regulate advertising. After this Memorandum was issued, EPA did not, as it could have done, seek specific legislative authority from Congress to clarify its regulatory jurisdiction over advertising. Instead, Complainant seeks to extend its authority pursuant to this proceeding.

No case before or after this interpretive regulation was published has ever squarely addressed the issue of the EPA's extremely limited statutory authority to regulate advertising. In fact, EPA's own labeling manual provides that the EPA does not routinely review advertising. CX 88, EPA 001572. Respondent respectfully asks the Presiding Officer to take judicial notice of the entire EPA manual on labeling and to view the depth and scope of information set forth in that manual regarding EPA's regulatory jurisdiction over labeling. *See* Label Review Manual Table of Contents, available at http://www.epa.gov/oppfead1/labeling/lrm/. The labeling regulatory jurisdiction of EPA is clear and has been confirmed by courts. *See, e.g.*, CX 57-88; 109-11.

On the other hand, there is no separate EPA manual on how the EPA regulates advertising, and the Presiding Officer can view the paucity of information in the EPA labeling manual that the EPA uses to attempt to justify its narrow and limited authority to regulate advertising. Just as importantly, the

labeling manual of EPA specifically states that the EPA will not routinely review advertising material. Therefore, the EPA's own practical position in the real world conflicts with Complainant's aggressive legal position in this proceeding. If the EPA does not "routinely review advertising material," then how can Complainant reasonably contend that every advertisement must be submitted to EPA for review for substantially differing claims, whatever the latter are determined to be?

Respondent reserves the right to also challenge whether the material that is the subject of Complainant's First Amended Complaint is even "advertising" that is subject to 40 C.F.R. § 168.22.

D. Advertising Is Regulated by the Federal Trade Commission.

The regulatory jurisdiction of the EPA over advertising under FIFRA is extremely limited. It is strictly limited to prohibiting the use of Substantially Different Claims as part of the sale or distribution of the pesticide (FIFRA § 12(a)(1)(B)) and to requiring pesticide manufacturers to state that a pesticide is a restricted use product (or otherwise describe the terms and conditions of its use) in their advertising (FIFRA § 12(a)(2)(E)). However, this narrow and limited jurisdiction by the EPA to regulate advertising does not mean that advertising of pesticides is not regulated by the federal government.

In stark contrast to the EPA's "weak (or perhaps non-existent)" statutory authority to regulate pesticide authority, the Federal Trade Commission has clear legislative authority to regulate false and misleading advertising of pesticides. *See e.g., Orkin Exterminating Co.*, 117 F.T.C. 747, 1994 WL 16011001 (1994) (FTC

challenging deceptive claims that company's lawn pesticides are "practically non-toxic" and pose no significant risk to human health or environment). The fact that the FTC did not bring any enforcement action over the facts alleged in this case does not give the regulatory authority to the EPA to bring such an enforcement action against Respondent. Such grants of regulatory powers are for Congress to make.

E. Fundamental Problems With Calculation of Reasonable Penalty Under 2009 Penalty Policy.

The discussion in Section II.D. above with respect to the calculation of a reasonable penalty under the 2009 Penalty Policy for the RUP calculation issue apply with equal force to the calculation of an appropriate penalty if any of the allegations in Counts 2141-2231 of the First Amended Complaint are determined to constitute violations of FIFRA. Complainant has seriously misinterpreted the 2009 Penalty Policy relating, in particular, to the gravity adjustment factors, as discussed in Section II.D. above. This includes the discussion of the adjustment for pesticide toxicity and adjustments for harm to human health, the environment and culpability.

Although there are unique reasons as to why culpability for the RUP classification issue should be, at most, a "value" of 1, that "value" of 1 is also the appropriate value for culpability with respect to any violations which are found to exist for the 2009-2010 time period for the FIFRA section 12(a)(1)(B) allegations.

This is because Respondent ceased its challenged activities immediately upon the issuance of the EPA's 2010 Stop Sale Order to Respondent.

While a warning letter should have been issued by Complainant to Respondent with respect to these allegations rather than commencing a multi-million dollar enforcement action, Respondent understands that Complainant has the legal right to issue a "Notice of Intent to File Administrative Complaint." However, if the Presiding Officer determines that violations with respect to certain distributions of Rozol or Rozol PD did occur, the question remains as to what the appropriate and reasonable penalty should be given the totality of the circumstances of this case. Within the context of the ERP, the specific questions would be (a) what is the proper unit of violation; and (b) what per-unit-of-violation penalty amount should be assessed for these violations.

Any per-violation penalty amount that approaches the maximum per-violation penalty amount that Complainant asserts should be levied is unreasonable and exceeds, by orders of magnitude, what is warranted when considering the totality of the circumstances of this case. Finally, as a matter of law there could not have been any violations of FIFRA with respect to the 2009-2010 allegations because there was no "offer to sell" Rozol during this time period.

IV. SUMMARY OF RESPONDENT'S DEFENSES, WHICH, AMONG OTHERS, WILL BE FURTHER DEVELOPED AT HEARING AND IN POSTHEARING BRIEFING

With respect to the violation of FIFRA section 12(a)(2)(E) as determined by the Presiding Officer in the RUP Order as a result of the failure of Respondent to adequately disclose the restricted use classification of Rozol in advertising, Respondent contends that: (a) Complainant has not applied the correct unit of violation; and (b) Complainant has misapplied the applicable Penalty Policy and, even if correctly applied, the Penalty Policy grossly overstates the gravity of the violation because (i) the Penalty Policy compresses violators and violations into a few select categories, (ii) simple multiplication of the "unit of violation" by the per-unit penalty determined by the Penalty Policy overstates the gravity of the actual violation when a large number of counts are sought for penalty purposes; (iii) the Penalty Policy provides no guidance on when a Notice of Warning should be issued before seeking a monetary penalty; (iv) the violation of FIFRA section 12(a)(2)(E), in and of itself, could not lead to the illegal sale and distribution of a restricted use pesticide because the sale of a restricted use pesticide to an individual who is not licensed is a violation of FIFRA section 12(a)(2)(F); (v) when Complainant chooses to allege a large number of violations for penalty purposes, the Penalty Policy is not flexible enough to determine a penalty that is consistent with the gravity of the violations, particularly in a case such as this, where the majority of the violations can be traced to four versions of a radio

advertisement that was broadcast multiple times; and (vi) Respondent received no economic benefit as a result of the violations.

Because the Penalty Policy is non-binding agency guidance that has never undergone public notice and comment, the Presiding Officer should disregard the Penalty Policy in order to determine a penalty that accurately reflects the low gravity when considering the totality of circumstances surrounding the violation of section 12(a)(2)(E) of FIFRA in this case. In determining an appropriate penalty, "[t]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *99 Cents Stores*, 2010 WL 2787749, at *25 (internal citation omitted). In this case, no such rational connection can be made to the penalty proposed.

With respect to the alleged violation of FIFRA section 12(a)(1)(B) during the 2007-2008 and 2009-2010 time periods, Respondent contends that: (a) during the 2009-2010 time period, Respondent's website was not an offer to sell under the standard set forth by the EAB in *Tifa* and the fact that Respondent sent letters to 48 distributors in response to the EPA's SSURO is irrelevant; (b) the statements made in Respondent's literature and on its website are not substantially different than those made in connection with its product registration; (c) not all of the statements made on the website or product literature are claims made for Rozol or Rozol PD; and (d) there is no "nexus" between the allegedly violative literature or the website and any particular sale or distribution of Rozol or Rozol PD.

Respondent further contends that Complainant's interpretation of the "statement" required in connection with the registration of a pesticide is too narrow – the pesticide label is only a part of the statement. Complainant's position that all data upon which statements made in advertising are based must be submitted to EPA is inconsistent with EPA's waiver of the requirement to submit efficacy data as part of the registration process. EPA has waived the requirement to submit efficacy data as part of the pesticide registration process, with a few limited exceptions which do not apply here. *See* FIFRA § 3(c)(5), 7 U.S.C. § 136(a)(c)(5); 40 C.F.R. § 158.400(e)(1); *see also* Declaration of James V. Aidala attached hereto as Exhibit E.

In addition, Complainant's position cannot be reconciled with FIFRA section 2(ee), 7 U.S.C. § 136(ee) and 40 C.F.R. § 168.22(b)(5), which collectively, state EPA's policy that, with limited exceptions not applicable to this proceeding, a pesticide manufacturer can advertise its registered pesticide product for use against a target pest for which it was not registered. It would be illogical to authorize in 40 C.F.R. § 168.22(b)(5) the advertisement of a pesticide's use on a pest for which it has not been approved – even if that use is not authorized on the label – and then prohibit a manufacturer from making truthful statements about a product's effectiveness when used according to the label against the pest for which the product was registered.

If the Presiding Officer determines that any violations of FIFRA section 12(a)(1)(B) occurred as set forth in the First Amended Complaint, Respondent

contends that: (a) Complainant incorrectly determined the unit of violation for the 2009-2010 time period; (b) Complainant has incorrectly applied the applicable Penalty Policy and, (c) even if properly applied, the Penalty Policy overstates the actual gravity of the alleged offenses and should be disregarded in order to fashion a penalty that is appropriate considering the totality of the circumstances of this case and the vague and ambiguous legal standards surrounding it.

V. CONCLUSION.

It has been determined that Respondent violated the RUP provision of FIFRA. Given that determination, an appropriate and reasonable penalty needs to be calculated for the RUP issue. As discussed above, EPA's Penalty Policy, and Complainant's application of it, are fundamentally flawed when applied to the facts of this case. Applying a "totality of the circumstances" standard to this case, as would be appropriate and reasonable, yields a *de minimis* penalty for the violation of FIFRA section 12(a)(2)(E).

Complainant cannot prove that Respondent violated the "Differing Claims" provision of FIFRA. FIFRA § 12(a)(1)(B). Under the controlling analysis of the EAB in *Tifa*, no "offer to sell" existed. In addition, Section 12(a)(1)(B) is vague and ambiguous and must be narrowly construed in an enforcement context where the government seeks a penalty. Such a narrow construction is also necessary to avoid impinging on Respondent's constitutional right of commercial free speech to truthfully advertise its lawfully registered pesticide products. Therefore, the "Differing Claims" allegations in the First Amended Complaint should be

dismissed because the challenged claims are not substantially different from the statement submitted as part of the products' registration. If it is determined that any "Differing Claims" violations occurred, however, then a *de minimis* penalty would be appropriate and reasonable for any such violations of FIFRA.

Dated this 14th day of October, 2011.

Respectfully submitted,

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