UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

IN THE MATTER OF	)	
	)	
	)	
STEVEN TUTTLE, TUTTLE TOOL ENGINEERING AND TUTTLE APIARY LABORATORIES	)	**Docket No. FIFRA 10-96-0012**
	)	
	)	
	)	
Respondent	)	

INITIAL DECISION

Federal Insecticide, Fungicide and Rodenticide Act. This proceeding involves a Complaint filed by the Environmental Protection Agency, seeking, $5,400 in civil penalties against respondent for 2 alleged violations of Section 12(a)(1)(A) of the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. Sec. 136j(a)(1)(A). An evidentiary hearing in this matter was held in Portland, Oregon on August 12, 1997. **Held:** Respondent is found liable for a civil penalty of $3,780, as he failed to demonstrate that his product was exempt under FIFRA Section 25(b), from the pesticide registration requirements of the Act.

Before: Stephen J. McGuire Date: September 30, 1997

Administrative Law Judge

APPEARANCES:

For Complainant: M. Socorro Rodriguez

Assistant Regional Counsel

Office of the Regional Counsel

U.S. EPA, Region 10

1200 Sixth Ave.

Seattle, Washington 98101

For Respondent: Steven Tuttle

Tuttle Apiary Laboratory

3030 Lewis River Road

Woodland, Washington 98674

I. INTRODUCTION

This is a civil administrative proceeding instituted pursuant to Section 14(a) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 l(a)), by issuance of a Complaint on March 22, 1996, by the United States Environmental Protection Agency, Region 10, Seattle, Washington (Complainant/EPA). The Complaint charges respondent, Steven Tuttle, Tuttle Tool Engineering and Tuttle Apiary Laboratories (Tuttle), with violations of FIFRA and regulations promulgated thereunder.

The Complaint specifically charges, in 2 separate counts, that respondent violated Section 12(a)(1)(A) of FIFRA, 7 U.S.C. Section 135j(a)(1)(A), which makes it unlawful "for any person in any State to distribute or sell to any person--(A) any pesticide that is not registered" under Section 136a of the Act.

Count 1 alleges that respondent violated Section 12(a)(1)(A)

by "offering for sale" *Mite Solution*, an unregistered pesticide.

Count 2 alleges that respondent violated Section 12(a)(1)(A) by "selling" *Mite Solution*, an unregistered pesticide. The Complaint sought a civil penalty in the amount of $2,700 per count for a total proposed penalty of $5,400.

On May 3, 1996, respondent filed an Answer denying the allegations contained in the Complaint and requested an evidentiary hearing in the matter. Subsequent to hearing, both parties supplemented the record. Respondent filed further documentation on August 27, 1997 and EPA filed supplements to Exhibits 15, 16, and 17 in accordance with instructions provided by the undersigned at hearing.[(1)]

II. FINDINGS OF FACT

1. On February 17, 1995, EPA's Office of Pesticide Programs notified respondent, Steven Tuttle/Tuttle Apiary Laboratories of Woodland, Washington that it had received his application for a new registration of a product manufactured by respondent known as "*Mite Solution*" (CX-1). Respondent has variously described this product during these proceedings as a "natural herbal miticide" (Tr. 39); a "miticide" (Tuttle Stipulation at Tr. 45); a "pesticide" (Tr. 47); and a "natural mite solution" (CX-4). *Mite Solution* was offered as an "*antiseptic and fungicide*" product to destroy mite infestation in bee-hives and is comprised of 95% petroleum jelly and 5% melaleuca alternafolia, or tea tree oil (Tr. 135).

2. *Mite Solution* first came to the attention of EPA through a complaint filed by a Mr. Jack Thomas of Mann Lake Supply, Ltd., of Hackensack, Minnesota, which referenced a competitor selling a "non-registered miticide" (Tr. 34). On March 23, 1995, Thomas faxed a copy of respondent's literature on the product to Mr. Lyn Frandsen, a senior official at EPA's pesticide enforcement program (Tr. 19, 35-37). This material contained 2 international symbols of circles with drawings of mites and slashes through them representing "no mites" (Tr. 38), along with the statement that the product was a "*natural herbal miticide*" . Also contained in the flyer was the statement "*applications should be a month apart in both spring and fall to kill mites in cells as well as those on bees and comb"(CX-11; Tr. 39-41).*

3. In response to the Thomas complaint, on April 25, 1995, an investigator from the Washington Department of Agriculture conducted an inspection of respondent's facilities to collect appropriate documentation of any sale or distribution of the product(CX-10; Tr. 53, 57).

4. By letter dated May 11, 1995, respondent was notified by EPA that he was mistaken in his belief that on the basis of the February 17, 1995, letter that the registration process for *Mite Solution* was complete. Respondent was therein advised that his application was still under review by EPA and warned that any sale of *Mite Solution* before it was registered would be a violation of Section 12(a)(1)(A) of FIFRA (CX-2).

5. After deciding to discontinue registration attempts over the cost of fees, respondent, on September 20, 1995, was notified by Glen Williams of EPA that no mention of *Mite Solution* as a

"miticide" or "fungicide" could be made in advertisement or literature about the product until it was registered (CX-15).

6. Similarly, on October 12, 1995, respondent was advised by Mr. Williams that any advertisements for *Mite Solution* "should not make or imply pesticidal claims for a product that is not registered as a pesticide....to do so would be a violation of FIFRA....what has been faxed to us as an ad/proof does not appear to have any claims which place this material under our jurisdiction. If your product is an antiseptic or antibiotic that promotes healthy bees that are able to handle their mite problems, then I again recommend that you contact Dr. Woods of the FDA's center for Veterinary Medicine and briefly review your product with her to receive guidance on how you should proceed".

[Emphasis added][(2)]

7. On October 16, 1995, Williams again contacted respondent and stated:

If your product is an antiseptic or antibiotic

that promotes healthy bees that are then able to

handle their mite problems, then I again recommend

you contact [the FDA]

If your product is a pesticide, then I recommend

that you....get your product registered as soon as possible. (CX-15).

8. By letter dated November 24, 1995, respondent was notified by the Food and Drug Administration (FDA) that upon review of the most current label for *Mite Solution,* no CFR reference listed "tea tree oil" as an approved food additive. Respondent was also informed that the label represented the product as a pesticide subject to the jurisdiction of FIFRA and provided: "The fact that component ingredients are approved by FDA for other purposes can not be used as evidence of the safety and effectiveness of the specific combination of ingredients for the stated intended use."(Emphasis supplied)(CX-3).

9. On December 13, 1995, an invoice signed by respondent indicated the sale of 35 1 oz. packs of *Mite Solution to* Blossumland Bee Supply of Berrien Center, Michigan in the amount of $1,071.00. This invoice continued to display graphics of encircled dead mites and referred to *Mite Solution* as a "natural herbal miticide" (CX-5; Tr. 70).

10. Thereafter, an advertisement offering *Mite Solution* for sale appeared in the January 1996 Bee Culture Magazine (Stipulation 1; CX-12). Unlike previous literature, the advertisement no longer contained graphics of encircled dead mites and described the product as a "natural mite solution", with ingredients containing "petroleum jelly and natural botanical extract". The advertisement also contained the following statements:

All ingredients are FDA approved.

Healthy bees naturally remove chalk

brood,, EFB, AFB, sacbrood, tracheal

mites, and varroa mites.

Mite Solution is not yet registered

with the U.S. EPA as a Miticide and

until it is it cannot be sold as a

Miticide by law. (CX-4).

Tuttle Apiary Labs, 3030 Lewis River Rd., Woodland, Washington, was the address listed in the January 1996 Bee Culture Magazine advertisement as the place to send orders for *Mite Solution* (Stipulations 2; CX-12). In January 1996, *Mite Solution* was not registered with the U.S. Environmental Protection Agency as a pesticide (Stipulation 3; CX-12).

11. On March 22, 1996, an administrative complaint was filed against respondent by EPA for the assessment of civil penalties.

The Complaint alleged 2 violations of Section 12(a)(1)(A) of FIFRA for "selling or distributing an unregistered pesticide". Violation 1 for "offering for sale *Mite Solution"*, an unregistered pesticide; and Violation 2 for "selling *Mite Solution"*, an unregistered pesticide, to Blossumland Bee Supply(CX-6).

12. By letter to the Regional Hearing Clerk on March 26, 1996, respondent replied to the administrative complaint asserting that since *Mite Solution* was proven "safe for the environment" that it was exempted from coverage of FIFRA, which deprived EPA of jurisdiction to issue the Complaint(CX-7A). Respondent wrote a similar letter which constituted his answer to the administrative complaint on May 3, 1996(CX-7).

13. In response to respondent's inquiries for an exemption from registration under FIFRA, on May 9, 1996, Mr. Williams informed respondent that "it sounds to me as if it is less difficult to register a product than to receive an exemption since exemption requires a rule-making" [Emphasis supplied](RX-2).

14. Despite this admonition, by invoice dated July 12, 1996, respondent sold *Mite Solution* to Davco Bee Supply in Maine (Tr. 160, 162-164). EPA has introduced a disputed label which allegedly accompanied this sale which purports to show that of this date, respondent also continued to make "pesticidal claims" by depicting encircled dead mites on his sales literature(CX-17).

15. On April 30, 1997, respondent sold yet again, *Mite Solution* to Draper's Super Bee (Tr. 156-159). The invoice from the sale was allegedly accompanied by a disputed flyer which purportedly showed that respondent, at the time of the sale, continued to make "pesticidal claims" by marketing the product as a "natural miticide"(CX-16).

16. By memorandum dated March 6, 1996 and penalty calculation worksheet dated March 20, 1996, Case Reviewer Michele L. Wright of the EPA Pesticides Unit, described the process by which she deduced the total proposed civil penalty of $5,400 for the two violations contained in the Complaint (CX-13, 14).

17. On August 12, 1997, an evidentiary hearing was held in Portland, Oregon, before the undersigned in the U.S. Bankruptcy Court. Respondent, appearing pro se, filed post-hearing evidence on August 27, 1997, while EPA sought to supplement the exhibits previously filed with Declarations of Glenn Williams (CX-15); Jeffrey Bastian (CX-16); and John Kenney (CX-17).

II. APPLICABLE LAW

40 C.F.R. Section 152.15--Pesticide products required to be registered.

No person may distribute or sell any pesticide product that is not registered under the Act, except as provided in 152.20, 152.25 and 152.30. A pesticide is any substance (or mixture of substances) intended for a pesticidal purpose, i.e., use for the purpose of preventing, destroying, repelling, or mitigating any pest or use as a plant regulator, defoliant, or desiccant. A substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if:

(a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise):

(1) The substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or

(2) That the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or.....

(c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.

FIFRA Section 25-(b)-Exemption of Pesticides

The Administrator may exempt from the requirements of this subchapter *by regulation* any pesticide *which the Administrator determines* either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this subchapter in order to carry out the purposes of this subchapter [Emphasis supplied].[(3)]

FIFRA Section 2--Definitions

(p) Label and Labeling

(1) Label--The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) Labeling-- The term "Labeling" means all labels and all other written, printed or graphic matter--

(A) accompanying the pesticide.....; or

(B) to which reference is made on the label or in literature accompanying the pesticide......

(gg) To distribute or sell

The term "to distribute or sell" means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment,, or receive and (having so received) deliver or offer to deliver.

III. DISCUSSION

A. Liability

The record in this proceeding establishes, through evidence and stipulation, that *Mite Solution* has been advertised and sold by Tuttle Apiary Labs and that this product was not registered with the agency as a pesticide as required by 40 CFR Section 152.15 (FOF 5,9,10,11,14; Stipulations at CX-12). The testimony of Lyn Frandsen, an expert witness from EPA's pesticide enforcement program, clearly demonstrates, that at various times in this proceeding, respondent made "pesticidal claims" in its advertisement and accompanying literature in violation of Section 152.15 (Tr. 21-23,39-44,48-51,63,109).

As complainant correctly argues, a product is "intended" for preventing and destroying pests if the seller claims, states or implies by labeling or otherwise that the product can or should be used as a pesticide (Tr. 21-23,51).

Respondent, in fact, stipulates that Mite *Solution* and it's accompanying literature was originally marketed as a "miticide",[(4)] and at that time was "offer[ed] for sale as a 'pesticide' as it is defined under FIFRA" (Tr. 45-50,139; FOF 1,2,9). These admissions, without more, would establish liability as violations of Section 12(a)(1)(A) of FIFRA by "selling or distributing an unregistered pesticide".

However, respondent asserts that under FIFRA Section 25(b), he is exempt from pesticide registration requirements on the grounds that 1) his product was "adequately regulated" by another federal agency; and 2) his product did not pose an unreasonable risk to human health or the environment. Respondent also alleges that he made a good faith attempt to cease making any pesticidal claims once he was notified that they were in violation of the statute (Tr. 15, 18, 130-132, 136, 138, 144, 146, 152).

It is well-settled that the burden of proving a product is exempt is on the respondent. In the Matter of Ashland Chemical

Co., Division of Ashland Oil Inc., Docket No. RCRA-V-W-86-R-13, 1987 RCRA LEXIS 50 (Initial Decision, June 22, 1987). Respondent has failed to meet that burden.

Respondent first argues that the active ingredient in *Mite Solution*, tea tree oil, is "adequately regulated" by another federal agency under 40 CFR 152.20, by being approved under Food and Drug Administration (FDA), guidelines as a food additive. Given such approval, respondent asserts that tea tree oil should also be exempt for use under FIFRA as a pesticide (CX-7, 7A; Tr. 131-136, 138, 144). This argument however, if not factually inaccurate (See FOF 8), is contrary to law and therefore of no merit.

FIFRA not only excludes any "pesticidal chemical" as a food additive in or on an agricultural commodity (See, 40 CFR Section 177.3), but the respondent was placed on notice that even were tea tree oil regulated as a food additive, it would not exempt EPA registration of the ingredient for use as a pesticide. (FOF 8; See also, Frandsen testimony at 77-78).

FDA warned respondent that "the fact that component ingredients are approved by FDA for other purposes can not be used as evidence of the safety and effectiveness of the specific combination of ingredients for the stated intended use" (FOF 8). "While you reference 21 CFR 171 to support the label claim that the ingredients are approved, there are no approved uses for petrolatum in bees or contact surfaces for beekeeping")."The name *Mite Solution* coupled with the graphics of dead bugs and the universal symbol of a circle and a slash establish the intended use of this product as a miticide" (CX-3).

FDA's warning followed Glen Williams admonition to respondent that he contact FDA if his product was determined to be an antiseptic or antibiotic, but if *Mite Solution* was deemed to be a pesticide by FDA, "I recommend that you...get your product registered as soon as possible" (FOF 7). This dual administrative determination of product "purpose" and "use" was precisely the procedure noted by witness Frandsen in describing a seller's responsibility to determine how and by what agency a product would be regulated (TR. 73-77). Here, respondent readily admits and the record demonstrates, that *Mite Solution* was intended and sold for use as a pesticide (Tr.45-47).

The evidence thus clearly refutes respondent's first argument and establishes that *Mite Solution* was not exempt from registration as a pesticide, as any regulation of tea tree oil

by the FDA did not constitute the "adequate regulation by another Federal agency" contemplated in 40 CFR 152.20 and FIFRA Section 25(b).

Respondent's second claim, that *Mite Solution* should be exempt from FIFRA registration because it poses no threat to the environment, is similarly unpersuasive. 40 CFR 152.25, issued under the authority of FIFRA Section 25(b), exempts classes of pesticides "of a character not requiring regulation under FIFRA".

It is clear however, that exemption pursuant to FIFRA Section 25(b), must specifically be made by "*the Administrator ....by regulation*" [Emphasis supplied]. See, In the Matter of Hosho-Somerset Corporation, Docket No. IF&R III-345-C (May 19, 1989). This is the formal "rulemaking" requirement that Glen Williams notified respondent of in his May 9, 1996 correspondence (FOF 13).

Confirmation of this requirement came from by EPA witness Frandsen when he noted that even a natural product or one of low toxicity does not by itself exempt it from the requirement of registration (Tr. 42,72). "A person cannot [simply] declare his product as minimal risk....it has to be reviewed by EPA and they

make the determination". Such an exemption must be "proposed as a rule.... finalized and published in the regulation (Tr. 27-29)...through the rule-making process" (Tr.112). As of the date of the Complaint, no application for exemption had been made by the respondent.

FIFRA Section 25(b), as implemented by 40 CFR Part 152, has recently been supplemented by a final rule listing certain additional pesticides that "will not pose unreasonable risks to public health or the environment and will, at the same time, relieve producers of the burden associated with regulation. Pesticidal products that do not meet the conditions of this final rule will continue to be regulated under FIFRA." (61 Federal Register 8876, March 6, 1996).[(5)]

The regulations thus clearly and concisely state which conditions manufacturers must meet to obtain exempted status for certain low-risk pesticides. As tea tree oil (Melaleuca alternifolia), is not included on the list of low risk pesticides exempted by the Administrator under 40 CFR 152.25, it is not "of a character not requiring regulation under FIFRA".

Having failed to demonstrate entitlement to an exemption under Section 25(b), it is concluded that *Mite Solution,* given its component makeup and intended use, was a regulated pesticide requiring registration under FIFRA.

Respondent's last argument, i.e., that he attempted to cease making pesticidal claims once he was aware that they were in violation of the statute, speaks essentially, to respondent's culpability, which will be addressed more fully in the penalty portion of this discussion.

That respondent made changes to his literature and advertisement of the product after warnings from both EPA and the FDA (FOF 10; Tr. 48, 138, 141, 146-147), does not preclude *Mite Solution's* regulation under FIFRA. The fact that respondent was aware inter alia, of the product's "intended use" and that he never changed the component parts of the product, were sufficient, of themselves, to subject the product to FIFRA registration as a pesticide (Tr. 147-148, 155, 167-169, 171).

Having failed to meet the criteria for exemption under Section 25(b), respondent is thus found to have committed two violations of FIFRA Section 12(a)(1)(A), 7 U.S.C. Section 1136j(a)(1)(A) by having 1) "sold" and 2) "offered for sale", an unregistered pesticide.

B. Penalty

Respondent's liability having been established, the remaining issue is determination of an appropriate penalty.

Section 14(a)4 of FIFRA directs that the following factors be taken into consideration when determining a penalty: the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. Section 14(a)4 also states that, if the violation occurred despite the exercise of due care or did not cause significant harm to the environment, the Administrator may issue a warning in lieu of assessing a penalty.

On its face, FIFRA thus vests the Agency with discretion,

to issue a warning in lieu of a penalty. See, In re Kay Dee Veterinary, 2 E.A.D. 649, n. 7. Such discretion also would allow the Administrator to assess a penalty if either of the requisite conditions for issuing a warning were found to exist. To implement this statutory responsibility, the Agency on July 2,

1990, issued the FIFRA Penalty Policy, which pursuant to Section 22.27(b) of the Consolidated Rules of Practice (Rules), should be utilized to determine an appropriate penalty.

EPA has set forth its calculation worksheet and accompanying

memorandum for its proposed penalty assessment in this case at CX-13 and 14. Moreover, its witness testified at the evidentiary hearing what factors were utilized in determining the proposed penalty (Tr. 81-89). Respondent disputes only the culpability

(gravity) rating of 4 assessed against him for knowingly violating the statute, stating he did make an effort to comply (Tr. 113, 142).

The gravity of any violation is a function of 1) the potential that the act committed has to injure man or the environment; 2) the severity of such potential injury; 3) the scale and type of use anticipated; 4) the identity of the persons exposed to a risk of injury; 5) the extent to which the applicable provisions of the Act were in fact violated; 6) the particular person's history of compliance and actual knowledge of the Act; and 7) evidence of good faith in the instant circumstances.

Respondent's original position that he believed *Mite Solution* to be registered when it wasn't (Tr. 15-16, 70; FOF 4), does not excuse his actions. His contention that he attempted to comply with the statute by changing his sales literature after subsequent warnings by both EPA and FDA that he was making pesticidal claims (FOF 4-8), only partially mitigates the fact that he continued to sell the product to Davco and Draper (FOF 14,15).

At the time of these sales, respondent no doubt knew that apart from any labeling disputes, the intended use, purpose and product components were such as to render *Mite Solution* a registerable pesticide (Tr. 21, 146-148, 150, 155, 167). This not only speaks to his actual knowledge of the Act but establishes a certain lack of good faith in complying with its provisions.[(6)]

The facts and circumstances surrounding the violations in the instant case therefore weigh heavily in favor of assessing a civil penalty and preclude issuance of a warning. The context of respondent's violations however, suggest that a lesser civil penalty than proposed by the Agency is adequate to achieve deterrence. "FIFRA's civil penalty provisions must be viewed as

remedial in nature and not punitive." In the Matter of South Coast Chemical, Inc., FIFRA Appeal No. 84-4, Order Reversing and Remanding Initial Decision (March 11, 1996), at 5 n. 5.

Under Section 22.27(b) of the Rules, the presiding judge may impose a penalty that is different in amount from the penalty recommended in the Complaint, provided certain conditions are met. First, he must set the penalty amount "in accordance with any criteria set forth in the Act relating to the proper amount of penalty....". Second, he must consider "any civil penalty guidelines issued under the Act". Finally, if he decides to impose a penalty that is different in amount than that recommended in the Complaint, the presiding judge must "set forth in his initial decision the specific reasons for the increase or decrease". In the Matter of High Plains Cooperative, Inc., FIFRA Appeal No. 87-4, Final Decision, 1990 FIFRA LEXIS 8; 3 E.A.D. 228, 229 (July 3, 1990).

The undersigned has considered the 1990 penalty guidelines and determines that based on applicable criteria, no harm to human health or the environment resulted from the violations at issue. The record further shows no evidence of respondent's prior non-compliance with the statute; that any potential injury would be severe; or that the use or identity of persons exposed to risk was significant.

Moreover, EPA has failed to establish that respondent's culpability is as severe as alleged in the gravity portion of its penalty calculation. The specific reasons for this conclusion follow.

First, EPA's attempt to establish respondent's lack of good faith through testimony regarding the altering of documents to mislead the editor of Bee Culture Magazine (Tr. 124-126) is inadequate. The record shows that respondent had in fact telephoned the individual to advise him that the fax in question was compiled from two letters and thus speaks against any intent respondent may have had to mislead (Tr. 127).

Similarly, EPA's claim that respondent continued to ship literature/labels as late as April 1997, which made pesticidal claims to both Draper and Davco is unsupported by the record (FOF 14,15). Respondent asserts, with some persuasiveness, that the labels in question were actually flyers sent to these companies long before the sale of product which were then gathered during inspections of these facilities on July 26, 1996 and May 22, 1997 (Tr. 157-163, 166). Unsworn declarations

offered by EPA post- hearing do not establish that the subject labels were indeed part of any literature which accompanied such later sales. Thus, EPA's allegations pertaining to these issues remain unproven(CX-16,17).

Considering all the evidence in this case, the undersigned finds that the respondent ahould be assessed a civil penalty in the amount of $3,780. This conclusion is based primarily on the gravity of respondent's actions in continuing to knowingly sell an unregistered pesticide after being warned of such violation.(7)

This assessment does however, represent a 30 percent reduction of the proposed penalty of $5,400 and acknowledges, in part, respondent's efforts to remove all indicia of pesticidal claims from his literature. The assessed penalty should be enough to inspire respondent to attend carefully to his compliance obligations in the future.

DECISION

Accordingly, Steven Tuttle, Tuttle Tool Engineering and Tuttle Apiary Laboratories are ordered to pay a civil penalty of $3,780, pursuant to Section 14(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. Section 136j(a)(1)(A).

Payment of this penalty shall be made within 60 days of the date of this decision. Payment shall be made by mailing, or presenting, a cashier's or certified check made payable to the

Treasurer of the United States, to the Regional Hearing Clerk, U.S. EPA Region 10, Mellon Bank, P.O. Box 360903, Pittsburgh, PA 15251-6903.(8)

Stephen J. McGuire

Administrative Law Judge

1. Hereinafter, references to the official record in this case shall be typically referenced as follows: Official Hearing Transcript, page 114 (Tr. 114); Complainant's Exhibit 3 (CX-3); Respondent's Exhibit 2 (RX-2); Finding of Fact No. 12 (FOF 12).

2. It is not clear from the record what was faxed to Mr. Williams. However, the record does indicate that it is unknown whether *Mite Solution* actually kills mites or whether it creates

a pheromonal effect which provides for cleaner, healthier hives where the bees kill the mites themselves (Tr.173-174).

3. The pesticides exempted by EPA regulations from FIFRA's registration requirements are primarily contained in 40 CFR Sections 152.20 and 152.25 and include..... inter alia, certain biological control agents, 40 CFR Section 152.20(a); new drugs within the jurisdiction of the Food and Drug Administration under the FFDCA, id at 152.20(b); pheromones used in pheromone traps, 152.25(b); articles or substances treated with, or containing pesticides intended to protect the articles or substances themselves, id at 152.25(a); preservatives for biological specimens, id at 152.25(c); vitamin hormone products, id at 152.25(d); and foods (without active ingredients) used to attract pests, id 152.25(e); natural cedar products, id. at 152.25(f); and "minimum risk pesticides" listed at 152.25(g).

4. Respondent has also stipulated that mites are a "pest" in a beehive (CX-12).

5. "EPA has determined, with the conditions imposed by this rule, that use of the listed pesticides poses insignificant risks to human health or the environment in order to carry out the purposes of the Act, and the burden imposed by regulation is, therefore, not justified. The Agency, in promulgating this rule, is responding to society's increasing demand for more natural and benign methods of pest control, and to the desire to reduce governmental regulations and ease the burden on the public. The regulatory steps required to register any pesticide substance are formidable, not only for the Agency but for the applicants, who often are small businesses......

.....Supporters of the final rule commented that deregulation of low risk substances would encourage the development and use of "safer" pesticides and that the exemptions would benefit business, especially small business and the organic industry. Many supporters felt that EPA should more fully implement the proposal by greatly expanding the lists of exempted active ingredients and permitted inerts. Approximately 80 additional active ingredients and 50 inerts were proposed for future consideration. The Agency will evaluate each active ingredient and will include those it feels qualify for exemption in its next proposal" (61 Federal Register 8876).

6. Respondent's knowledge of the Act is displayed in his January 1996 advertisement disclaimer: *"Mite Solution* is not yet

registered with the U.S. EPA as a Miticide and until it is it cannot be sold as a Miticide by law"(FOF 10).

7. As noted earlier, respondent's sale of *Mite Solution* to Draper and Davco occurred even after issuance of the Complaint (FOF 11, 14, 15).

8. Unless this decision is appealed to the Environmental Appeals Board (EAB) in accordance with 40 CFR Section 22.30, or unless the EAB elects to review this decision *sua sponte*, it will become the final order of the EAB. 40 CFR Section 22.27 (c).