UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

IN THE MATTER OF:	)	
	)	
MICROBAN PRODUCTS COMPANY	)	DOCKET NO. FIFRA-98-H-01
	)	
Respondent	)	

ORDER DETERMINING NUMBER OF VIOLATIONS AND RULING ON RESPONDENT'S MOTION FOR ACCELERATED DECISION AS TO PENALTY

I. Order Determining Number of Violations.

On September 18, 1998, the Court issued an Order granting Complainant EPA's Motion for Partial Accelerated Decision in this matter. In that Order the parties were directed to submit briefs on an issue raised by the Court: Whether it is appropriate to view the number of violations involved as thirty-two (32) independently assessable violations or rather as five violations, reflecting the five offending Defendant Microban documents set forth in the Complaint.

The parties have submitted their briefs on this issue. As Microban's brief was included within a Motion for Accelerated Decision As To Penalty, the Motion required an independent response from EPA. Both matters are addressed in this Order.

The statutory provision under consideration is Section 12(a)(1)(B) of FIFRA. Subsection (B) is within Section 12(a)(1) which, as pertinent to the interpretation involved here, provides:

> [I]t shall be unlawful for any person in any State to distribute or sell to any person

(A) any pesticide that is not registered . . . ;

(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 a part of the statement required in connection with its registration under Section 136a of this title;

(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 under Section 136a of this title;

(D) any pesticide which has not been colored or discolored pursuant

pursuant to the provisions of section 136w(c)(5) of this title;

(E) any pesticide which is adulterated or misbranded; or

(F) any device which is misbranded.

7 U.S.C. § 136j(a)(1) (emphasis added).

EPA's Position on the Number of Violations.

In EPA's view, *each separate sale* constitutes an independently assessable violation of Section 12(a)(1)(B). Complainant's Brief at 1. EPA believes that the statute, case law, and the July 2, 1990, FIFRA Enforcement Response Policy ("ERP"), all support this view. Statutorily, EPA believes that the plain language of the section makes *each* act of selling or distributing a violation for any of the six subsections of Section 12(a)(1) and it observes that the Respondent did not challenge that it made the 32 shipments set forth in the Second Amended Complaint. Complainant also points to the ERP's statement that ". . . the Agency considers violations that occur from each shipment of a product . . . or each sale of a product . . . to be independent offenses of FIFRA."

Last, EPA refers to several decisions to support its position: In the Matter of Chempace Corporation, Docket No. 5-FIFRA-96-017 (October 15, 1997), 1997 FIFRA LEXIS 32 at *10 ("Chempace"); In the Matter of E.I. DuPont de Nemours & Co., Inc., Docket No. FIFRA 95-H-02 (April 30, 1998) ("DuPont"); In the Matter of Scotts-Sierra Crop Protection Company, Docket No. FIFRA-09-0864-C-95-03 (February 11, 1997) ("Scotts-Sierra"); In the Matter of Accuventure, Inc., Docket No. FIFRA-1092-07-01-012 (May 25, 1994) ("Accuventure"); In the Matter of Cole Chemical Company, FIFRA Docket No. VII-322C/347C (October 30, 1980) ("Cole Chemical"); In the Matter of Bio-Tek Industries, Inc., Docket No. FIFRA-92-H-06 (April 13, 1993), 1993 FIFRA LEXIS 160, ("Bio-Tek"); and In the Matter of Hawk Industries, Inc., Docket No. FIFRA II-120C (December 21, 1976), 1976 FIFRA LEXIS 30 at *18-19 ("Hawk Industries").

Microban's Position on the Number of Violations.

Microban recognizes that the Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act, July 2, 1990, ("ERP"), is used as a guide by EPA in determining the number of violations and that it measures the number of independent violations on the basis of the number of shipments. While acknowledging that the number of shipments may be a reasonable basis for determining the number of independent violations for some parts of Section 12 of FIFRA, Microban maintains that, under the facts of this case, such a basis is inappropriate for determining the number of Section 12(a)(1)(B) violations involved here.

Referring to the decision of the Environmental Appeals Board ("EAB" or "Board") In

the Matter of: Sporicidin International, 1991 EPA App. LEXIS 3; 3 E.A.D.589, June 4, 1991 ("Sporicidin"), in which the respondent there was charged with one violation of Section 12(a)(1)(B), even though it had made three shipments of the product, Microban asserts that neither the Presiding Judge nor the Chief Judicial Officer associated the Respondent's offending literature with any particular shipment, and it maintains that the shipments were viewed collectively as one sale or distribution. Respondent's Memorandum at 11. On this basis Microban asserts that its five offending documents should be viewed as "having a sufficiently close link with only one sale or distribution of Microban Additive B resulting in only one violation of Section 12(a)(1)(B)." Id. In its view, separate violations under this section can only be made out where it can be shown that "the claims made in the five documents induced or encouraged 32 independent sales or distributions of Microban Additive B to Hasbro." Id. at 12 (emphasis in original).

The Court's Resolution of the Issue.

The most significant observation to be made about the cases cited by EPA is that *none* of them deal with the particular subsection at issue here and EPA itself recognizes that Section 12 "enumerates six *distinct* statutory violations." Complainant's Brief at 1 (emphasis added). Chempace, for example, dealt with Subsections (A) and (E). Unlike Subsection (B), Subsections (A) and (E) are straightforward, with the former plainly and directly prohibiting the distribution or sale of any unregistered pesticide and the latter plainly banning the distribution or sale of any pesticide which is adulterated or misbranded. These sections, when violated, manifestly present a distinct harm with each new sale, distribution, adulteration or misbranding.

Although the Respondent in Chempace nominally challenged the number of separate violations alleged, it offered no argument to support the challenge. In DuPont, which challenged Section 12(a)(1)(E) violations, no issue was raised concerning the appropriateness of the 379 separate violations charged, and in upholding the violations, the judge noted the *harm* addressed by Subsection (E), observing that the misbranded labels could pose risks to those who handle the pesticide. Unlike the present case, *each* shipment carried forth the misinformation set forth on the misbranded labels. For similar reasons, neither Scotts-Sierra, nor Accuventure or Cole Chemical add anything to the discussion at hand.

EPA also refers to Bio-Tek and Hawk Industries for the proposition that the number of shipments is controlling in determining the number of offenses. As mentioned, neither case involved the section in issue here. Section 12 (a)(2) was involved in Bio-Tek, while Hawk Industries dealt with Section 12(a)(2)(A). In Bio-Tek the judge rejected EPA's claim that each false statement constituted a separate count, finding instead that with only two studies and two compliance statements involved, only two penalties could be assessed. The judge noted that where the Act does not clearly specify whether multiple penalties may be imposed, ambiguities are to be resolved in favor of lenity. Bio-Tek at 1993 FIFRA LEXIS 160, *23.

Although EPA has referred to the ERP's statement that ". . . the Agency considers violations *that occur* from each shipment . . . or each sale of a product . . . to be independent offenses of FIFRA," ERP at 25 (emphasis added), this begs the question as to whether violations occur here from each shipment or sale of the product. In the criteria which supports this statement, the ERP recognizes that a separate penalty requires an independent violation, which in turn must be based upon an act which is not the result of any other charge. However, the examples in the ERP do not specifically address or otherwise answer the question here as to what constitutes an independent violation. In fact, the ERP implicitly acknowledges in Appendix A, FIFRA Charges And Gravity Levels, that the thrust of the violation is about false *claims*, not the number of sales or distributions.

Thus, the ERP describes a violation of the section as follows:

FIFRA SECTION	VIOLATION
12(a)(1)(B)	CLAIMS made for a pesticide as part of sale or distribution differed substantially from those

accepted in connection with registration.

Id. at A-1. (Capitalization of "CLAIMS" in ERP) (FTTS Code and gravity level omitted.)

Beyond this observation, the EAB has observed that the ERP has never been subject to notice and comment and, accordingly, has described it as a "non-binding Agency policy whose application is open to attack in any particular case." In re: McLaughlin Gormley King Co. , FIFRA Appeal Nos. 95-2 through 95-7, 1996 EPA App. LEXIS 1, *23, 6 E.A.D. 339, March 12, 1996. The Board also noted that "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." Id. (emphasis added).

It is also noteworthy that EPA certainly has not been consistently applying a standard which measures the number of Section 12(a)(1)(B) violations according to the number of shipments or sales. For example, in Sporicidin, EPA did not even include an allegation that there were distributions or sales of the product until the administrative law judge required that the complaint be amended to include such an assertion. Even when amended, the number of counts in the complaint was not based on the number of sales or distributions involved. Similarly, in neither Johnson Pacific, Incorporated, 1993 EPA ALJ LEXIS 471, August 5, 1993 nor in J.C. Ehrlich Chemical Co., Inc., 1980 EPA ALJ LEXIS 8, February 11, 1980, was EPA concerned with the number of sales or distributions involved to determine the number of Section 12 (a)(1)(B) violations alleged.

While EPA's position overreaches, Microban's construction is too narrow. By seeking to have all five offending documents here linked to a single sale or distribution, Microban's interpretation would negate the individual harm created with each separate instance of making claims which are substantially different from those accepted with the pesticide's registration and ignore the particular circumstances surrounding the violations. Such a construction would be at odds with the purpose of Subsection 12(a)(1)(B). Therefore, the Court does not adopt either party's position in this matter.

While Section 12(a)(1) makes it unlawful to distribute or sell a registered pesticide if claims made for it as part of its distribution or sale substantially differ from those claims allowed under its registration, there is nothing that indicates *each sale* constitutes an independent violation. While a distribution or sale is a necessary element for each violation, the determination of the number of violations requires a contextual analysis of the circumstances surrounding each substantially differing claim, as opposed to engaging in a mechanical or slavish reading that focuses only upon the number of sales or distributions that occurred.[(1)]

Although addressing a different subsection, the EAB's decision in McLaughlin Gormley King Co. provides useful guidance in construing the subsection in issue. In that case the Board had to determine whether there was one or four separate violations of FIFRA subsection 12(a)(2)(Q), and its provision making it unlawful to falsify all or part of any information submitted to the Administrator relating to the testing of any pesticide.[(2)] The Board employed a "logical reading" of the statutory section in concluding that the "unit of violation" could not be smaller than each piece of information. Id. at *14.

Not only did the Board apply a logical reading of the statutory provision before it, but it also pointed out that it did not have to articulate the basis constituting a violation for every case under Subsection 12(a)(2)(Q). Rather, the EAB determined that, *as applied in that case only*, a unit of violation could not be smaller than an assertion that a particular study complied with EPA's Good Laboratory Practice Standards.

This Court subscribes to the EAB's logical interpretation of statutory provisions as well as to its sensible approach of construing a provision only as it applies to the particular case at hand. As noted by the Fourth Circuit:

> Although the task of statutory construction generally begins with the actual language of the provision in question, the inquiry does not end there. The Supreme Court has often emphasized the crucial role of context as a tool of statutory construction. For example, the Court has stated that when construing a statute, courts 'must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object or policy.'

Brown and Williamson Tobacco Corp. v. Food and Drug Administration, 153 F.3d 155, 162 (4th Cir. 1998).

Under this common sense approach, it seems clear that the offending conduct distinctly addressed by Section 12(a)(1)(B) involves claims which are at odds with those permitted under the pesticide's registration. While the unapproved claims must be associated with (i.e., *part of*) a pesticide's distribution or sale, nothing in that section directly ties the number of violations to the number of sales or distributions. Thus, the gravamen of the offense addressed by this provision is directed at the prevention of unapproved claims, not unapproved sales.

At least in this instance, this harm is not magnified with each additional sale. In fact, EPA has implicitly recognized the weakness of its position, by its unilateral decision to disregard twenty-two (22) additional Microban sales invoices, a number constituting 41% of the violations that EPA maintains it could have brought. Thus, on its own motion, without any settlement incentive to do so, EPA unilaterally elected to forego $121,000.00 in available fines under the suggestion that this is within its "enforcement discretion." If the matter really turned on the number of sales or distribution and not the number of unapproved claims, this would appear to exceed the bounds of any reasonable discretion, at least at the time the Complaint was initially filed.

The Chief Judicial Officer's statements in Sporicidin also support the view expressed here. As in this case, in Sporicidin claims were found to have been made for a registered product which were substantially different from those approved with its registration. The Chief Judge expressly recognized the distinctness of the sections within Section 12(a)(1), noting that a Section 12(a)(1)(E) claim has no bearing on the definition of a claim under Section 12(a)(1)(B) and that the two sections should not be confused. Id. at *29. Judge McCallum took note that the thrust of Section 12(a)(1)(B) "prohibits sellers and distributors from making pesticidal claims . . ." Id. The Judge also observed that the complaint itself stated it was the "*Respondent's act of making claims . . . which substantially differ from the statements accepted in connection with the . . . registration* [*that constitutes*] *a violation of the section*." 1991 EPA App. LEXIS 3, *20, (n.20) (emphasis added).

On the basis of the foregoing, I conclude that the determination of the appropriate unit of violation has to be examined within the context of each particular subsection of FIFRA Section 12(a)(1). Examining the particular subsection at issue here, the harm addressed by Subsection 12 (a)(1)(B) is the making of claims that substantially differ from those accepted with the pesticide's registration. Finally, for any given case, determining the unit of violation for this Subsection requires a particularized inquiry into the surrounding facts.

The five documents which form the heart of EPA's case in this instance were not particularly tied to the thirty-two Microban sales or distributions. Rather they existed independently of any particular sale or distribution. Based on the present record, as noted in the Court's September 18, 1998, Order, granting the Complainant's Motion for Accelerated Decision as to Liability, each of the five documents, as reflected in EPA Exhibits 7, 12, 13, 14, and 16, independently made claims which substantially differed from those permitted with its registration.

This is not to say that the sale or distribution element is irrelevant.(3) There must be a showing, as there was here, that there was at least some sale or distribution of the pesticide as a necessary element of establishing a Subsection 12(a)(1)(B) offense. Therefore, under the particular facts of this case, I conclude

that there were five violations committed here, one for each of the five documents cited in the Complaint.

II. Ruling on Respondent's Motion for Accelerated Decision as to Penalty and Complainant's Response Thereto.

Respondent filed its Motion for Accelerated Decision as to Penalty ("Respondent's Motion") along with a Memorandum in Support of that Motion on October 16, 1998. Microban views the total gravity-based penalty of $160,500.00 sought by EPA as "excessive, punitive, and not in keeping with Respondent's actions."(4) Respondent's Motion at 14. On November 6, 1998, Complainant filed its Opposition to Respondent's Motion for Accelerated Decision as to Penalty ("Complainant's Opposition"). In its Opposition, Complainant asserts that there are issues of material fact.(5)

Respondent challenges the following gravity criteria:

1. **Toxicity.** Microban takes the position that this factor is not applicable since the amount of the pesticide that can be incorporated into the final product is substantially diluted and because EPA recently reduced the signal warning for the same active ingredient in Additive "B" to "Caution" in place of the term "Danger." Further, Microban asserts that there is no evidence that its product, *in any strength*, is toxic and hence presents no risk of toxicity.

EPA responds that Microban Plastic Additive "B" was classified by EPA as being in Toxicity Category I because the product was assigned the signal word "danger," which word appears on the product's label. EPA submits that under its calculation process a gravity value of 2 was properly assigned because the product is in Toxicity Category I. As to Microban's claim that the gravity value of 2 fails to take into account that the product is actually distributed in a "substantially diluted form," EPA counters that most pesticides are substantially diluted prior to their use. Complainant's Opposition at 7.

It appears that there are issues concerning the degree of dilution of the product and whether it is diluted before or after its distribution as well as the appropriate signal word to be assigned, each of which will need to be explored further during the penalty determination phase of the hearing for possible consideration in evaluating the product's toxicity.

2. **Harm to Human Health and the Environment**. Microban asserts that this factor relates to "unreasonable risk to man or the environment" and that, as part of EPA's approval of the product, the agency had to determine that the product was "safe." Respondent's Memorandum at 15. Microban states that the sole basis for risk to human health advanced by EPA is that consumers, thinking that the product in fact has demonstrated antimicrobial properties, might fail to take the precautions they ordinarily would take. Based on polling data, Microban asserts that consumers would still exercise prudence and it notes that EPA has not produced any contrary data. While EPA selected a value of 3 for this factor, out of a maximum of 5, Microban maintains that the correct value should be zero. Id. at 17.

Noting that EPA also assigned a value of 3 for the environmental aspect of this gravity criterion, Microban maintains that by virtue of EPA's approval of Additive B in toys, EPA is estopped from asserting that there is any environmental harm. Microban also states that EPA has presented no evidence to support its claim of environmental harm.

In response, EPA maintains that a product label with unsubstantiated claims as to its efficacy may lull the public into erroneous assumptions about the product's sanitary or self-sanitizing properties and potentially cause a lapse in hygiene practices they would ordinarily follow. EPA also asserts that the potential for harm can be considered to be "major" even if no actual harm is demonstrated, where it can be shown that the violation harms the regulatory program. EPA claims that Microban's "willful disregard" of FIFRA's registration process creates such harm by

undermining the FIFRA registration process and that the program's requirement for substantiation of health claims with test data goes to the heart of the program. Further, Respondent's disregard, if not appropriately sanctioned, could encourage others to commit violations, further harming the program. Opposition at 8-10. On those grounds, EPA believes that an "adjustment value of 3 " is proper for the "harm to human health" and the "harm to the environment" factors. Complainant's Opposition at 11.

The Court is of the view that there appear to be factual issues as to these criteria which would benefit from hearing testimony and/or receiving exhibits.

3. **Culpability**. Microban notes that EPA assigned a value of 4 to this gravity criterion, but characterizes such a value as factually unsupportable in terms of demonstrating that Microban acted knowingly or willfully and that it was excessive and punitive as well. Microban maintains that EPA's letters do not form the basis for making such a conclusion and that it interpreted EPA's statements to other manufacturers as signaling that it was appropriate to use the term "germs" in place of "bacteria, fungus, or mildew." Respondent's Memorandum at 19. Respondent also claims that once it truly became aware of the problems EPA had with the language Microban employed, it acted promptly to make corrections.

EPA assigned a value of 4 for culpability on the basis of its determination that Microban had knowingly and willfully violated its registration terms. Respondent takes the position that such a rating is "excessive, punitive, and cannot be supported by the facts in this case." Id. at 18. EPA supports its culpability rating on the basis of the registration's explicit prohibition of claims asserting effectiveness against microorganisms infectious to man and the Court's determination that Microban's claims were an obvious departure from the registration's terms. Complainant's Opposition at 12. EPA also maintains that the assessment of culpability should take note that copies of the Notice of Pesticide Registration "had been altered to delete the claims-restricting language and that Microban was repeatedly advised that it could not make claims that the product was effective against microorganisms infectious to man." Id. at 12-13 and n.10. Apart from determining whether 4 is the correct culpability value to be assigned, EPA's observations, rebutting Microban's claims that it was not informed and did not understand EPA's position that references to microorganisms such as Salmonella and Staph were prohibited, are well taken. Testimony and exhibits on this issue are considered to be of value.

4. **The Assertion that the Penalty is Excessive and Punitive**. Pointing to the penalty of only $5,000.00 sought by EPA in Sporicidin, a case in which, as previously mentioned, claims substantially differed from those approved with the registration and about which EPA sent warning letters, Microban notes that, in contrast, it received no warning letter and it submits that the $160,500.00 sought here demonstrates an inflated penalty amount. As has been noted, today's ruling as to the number of violations will substantially affect the penalty computation. To the extent that Respondent still maintains that only a warning should have been issued, exhibits and testimony are considered to be useful on this issue.

Accordingly, there being factual issues in dispute, the Respondent's Motion is **DENIED**.

The Presiding Judge will initiate a conference call in the near future for the purpose of setting a date for hearing the remaining issues.

So Ordered.

_____

William B. Moran
United States Administrative Law Judge

Date: February 18, 1999
Washington, D.C.

1. Having the number of violations mechanically determined in all instances simply by counting the number of sales or distributions can produce unreasonable results in certain circumstances. For example, assume two pesticIde producers make five separate but virtually Identical claims which substantially differ from those permitted under their respective registrations. Assume further, that for each producer none of the claims are related to any particular sale or distribution. Under such circumstances if one producer happens to sell ten units of its product while the other sells one thousand, EPA's construction would allow it to impose a penalty for one producer that would be a hundredfold that of the other producer, even though the harm created by the unapproved claims was the same.

2. As in Microban, McLaughlin Gormley King Co. involved a single statutory provision, and the determination whether a single course of conduct could result in multiple violations. The Board therefore distinguished cases which employed the test set out in Blockburger v. United States, 284 U.S. 299 (1932), as those cases inquired whether a single act could violate several different statutory provisions.

3. For example, had the unauthorized claims been attached to each product by employing the advertising technique of adding a tag which repeated the claims or if they had been republished on the outsIde of the packing cartons distributing it, a separate 12(a)(1)(B) violation could have been made out for each product or carton repeating the unapproved claims.

4. Obviously, in view of the ruling today finding the number of violations to be five, the total penalty will need to be recalculated by EPA. However, the parties are reminded that the PresIding Judge has the authority to raise, adopt, or lower the proposed penalty.

5. Certain aspects of the Complainant's penalty calculation have not been challenged: Microban's compliance history (which the parties agree has a gravity value of zero ("0") inasmuch as the Respondent has no prior FIFRA violations); that the violation charged is a "Level 2" violation; and that Microban is a "Category I" size business. Respondent's Memorandum at 13, EPA's Opposition at 6.

In the Matter of Microban Products, Inc., Respondent
Docket No. FIFRA-98-H-01

CERTIFICATE OF SERVICE

I hereby certify that the foregoing Order Determining Number of Violations and Ruling On Respondent's Motion for Accelerated Decision as to Penalty, dated February 18, 1999, was sent in the following manner to the addressees listed below:

Original by Pouch Mail to:

Bessie Hammiel
Headquarters Hearing Clerk
U.S. EPA
401 M Street, S.W., Mail Code 1900
Washington, D.C. 20460

Copy by Regular Mail to:

Counsel for Complainant:

Robert W. Darnell, Esquire
Marc Borodin, Esquire
U.S. EPA
Toxics and Pesticides Enforcement Division (2245-A)
401 M Street, S.W.
Washington, D.C. 20460
Counsel for Respondent:

P. Susan Lively, Esquire
Gerald Yamada, Esquire
Paul, Hastings, Janofsky & Walker, LLP
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

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Elaine Malcolm
Legal Assistant

Dated: February 18, 1999
Washington, D.C.