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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY BEFORE THE ADMINISTRATOR

IN THE MATTER OF)		
MI CROBAN PRODUCTS COMPANY, 01)	DOCKET NO.	FIFRA 98-H
RESPONDENT)		

INITIAL DECISION REGARDING PENALTY (1)

In this proceeding under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§136 et seq., EPA, in a single count, alleged that the Respondent, Microban Products Company, ("Microban") violated Section 12(a)(1)(B) of FIFRA, (7 U.S.C. § 136j), by making claims that were substantially different from claims permitted within the terms of its registration approval. $\frac{(2)}{2}$ At this juncture of the proceedings, the determination of liability and the number of violations having been previously determined, only the determination of an appropriate penalty remains for resolution.

However, prior to addressing the penalty issue, it is necessary for the Court to briefly revisit its prior ruling determining the number of violations, because of inaccuracies in Complainant EPA's Motion for Interlocutory Appeal, challenging the Court's determination on that issue.

The Court's February 18, 1999 Order the Court addressed whether the Complaint presented thirty-two independently assessable violations, as urged by EPA; one violation, as urged by Microban; or five violations, the last mirroring the number of offending documents which formed the basis for EPA's Complaint. In a nutshell, but without distortion, EPA took the position that the number of violations was determined simply by tallying the number of distributions or sales of the product, with each sale constituting a separate violation. In this instance it was

undisputed that Respondent made 54 shipments of the product in issue. EPA has referred the Court to the FIFRA Enforcement Response Policy ("ERP") which provides 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. Yet, describing it as within its enforcement discretion, EPA unilaterally disregarded the Response Policy's position by dropping 22 of the Microban sales invoices at the time the Complaint was filed, thereby conceding before any answer was filed, and before any exploration of settlement negotiation, \$121,000.00 in penalties.

Of concern is EPA's assertion in its March 22, 1999 Motion for Interlocutory Appeal that "...the Presiding Officer ruled that individual sales and shipments of a pesticide cannot trigger independent violations of Section 12(a)(1)(B) ... unless the unapproved claims physically accompany the pesticides during each sale and shipment." Motion for Interlocutory Appeal at 1. (emphasis in original). Further, EPA represented that "the Presiding Officer assumed that there is no incremental harm from each additional sale and shipment of a pesticide where each shipment does not 'carr[y] forth the misinformation on the product." Id. (emphasis in original).

The Court did not maintain that the unapproved claims must physically accompany the pesticides during each sale and shipment nor that there could not be instances of incremental harm from each sale or shipment. (3) Rather the Order explicitly stated that "... for any given case, determining the unit of violation for [12(a)(1)(B)] this Subsection requires a particularized inquiry into the surrounding facts." Order at 9. In fact the Court gave two, non-exclusive, examples of instances where a violation could be established for each sale or shipment. \underline{Id} . at 10. It went on to examine the "particular facts of [the] case and then observed that "[b]ased on the present record" the five offending documents were not particularly tied to the thirty-two sales or distributions. (4) \underline{Id} . at 9-10.

Beyond EPA's apparent misreadings of the February 18, 1999 Order, the Court merely restates that Section 12(a)(1)(B) nowhere expressly provides that each sale or distribution constitutes a separate violation, that the 1990 FIFRA Enforcement Response Policy emphasizes that the violation is about CLAIMS which differ from the approved registration and that EPA itself, in this case as well as in <u>Sporicidin International</u>, 1991 EPA App. LEXIS 3; 3 E.A.D. 589, June 4, 1991, has not adhered to its own putative policy.

The Determination of an Appropriate Penalty

The Environmental Appeals Board ("EAB" or "Board") has had occasion to address the judge's role in determining an appropriate penalty in FIFRA enforcement actions as well as in the context of other environmental statutes. See, for example, <u>In re: Predex Corporation</u>, FIFRA Appeal No. 97-8, 1998 EPA App. LEXIS 84, May 8, 1998 ("Predex") and <u>In the Matter of: Hall Signs, Inc.</u>, EPCRA Appeal No. 97-6, 1998 EPA App. LEXIS 113, December 16, 1998 ("Hall Signs").

In the context of FIFRA, the Board has observed that the statutory criteria to be considered in determining the appropriateness of the penalty are the size of the business, the effect on the ability to continue in business, and the gravity of the violation. Predex at 1998 EPA App. LEXIS 84, *13. Although the judge also must "consider" any civil penalties or policies issued by the Agency, 40 C.F.R. § 22.27(b), (5) the Board has made it clear that the judge has the discretion to assess a different penalty so long as the reasons for departure are adequately explained. Id. at *15. It has also observed that ultimately "any penalty assessed must 'reflect[] a reasonable application of the statutory penalty criteria to the facts of the particular violations." Id. , quoting from In re Employers of Wausau, 6

E.A.D. 735, 758 (EAB 1997).

Having fully considered the May 26 and May 27, 1999 testimony at the hearing on the issue of an appropriate penalty, as well as the parties post-hearing briefs and replies thereto, the Court, for the reasons which follow, departs from the EPA analysis and assesses a penalty of five thousand dollars (\$5,000.00) for each of the five violations for a total penalty of twenty-five thousand dollars (\$25,000.00).

In assigning a value of "2" for the toxicity because the product contained the signal word "danger," EPA was locked into that point value solely because of the signal word. The Court departs from the Agency's analysis because EPA conceded that it did not consider whether the product was in fact toxic, as used, but rather relied solely on the presence of the signal word "danger."

Tr. 286-287. In fact EPA Counsel conceded that it had no concerns relating to the product's toxicity. (7) Tr. 250.

Mindful that the statutory criteria to be considered are the size of the business, the penalty's effect on the Respondent's ability to continue in business, and the gravity of the violation, the Court first observes that Microban is undeniably large, with gross revenues for the applicable period of time exceeding a million dollars. Tr. 271. Second, Respondent's Counsel conceded that, even if it were determined that there were 32 violations, instead of the five violations found by the Court, and an attendant penalty of \$160,000.00 imposed, such a penalty would not have an effect on its ability to continue in business. Tr. 10. Therefore, with regard to the first two statutory criteria, the former criterion, which points to the imposition of a higher penalty for larger companies, directs that such an enhanced penalty be imposed against the Respondent, while the latter criterion, as applied to the facts of this case, directs that there be no reduction in the penalty on that account, as the penalty will not impair Microban's ability to continue in business.

However, it is the third criterion, the gravity of the violation, which, when considered with the Respondent's size and ability to continue in business, leads the Court to impose the \$5,000.00 penalty for each of the five violations. In the Court's view, the highest statutory penalty is warranted in this instance because of Microban's clear and stark departure from the terms of the registration approval. As noted in the Court's September 16, 1998 Order, the registration of Microban's Plastic Additive, dated August 15, 1983, accepted the product "...as a preservative and bacteriostatic agent effective only against non-health related organisms which may contribute to deterioration of the treated articles or to control odors by such organisms." Order at 14. Complainant's Exhibit 1(emphasis added). Yet, despite the clear terms of the registration $\frac{(8)}{}$, Microban's Promotional Brochure, its "Facts about Microban Antimicrobial Protection, the May 31, 1995 "Presentation to Hasbro, Inc.", the language it editorially urged for a Hasbro toy label, and its Public Relations Questions and Answers sent to Hasbro January 13, 1997, each blatantly departed from the scope of approval. See the Court's September 16, 1998 Order at 15-18.

To expound, as one example among the five offending documents, the May 31, 1995 Presentation to Hasbro is rife with health related associations or claims. From (among others in the document) the sample response that 73% of those surveyed felt Microban protected their children's health, to its references to antibiotics, killer microbes, growing germ awareness, staph and e coli, to the claim that it provided the "ultimate in germ fighting protection," Microban's departures were, in each of the five instances, egregious (9).

Further, the Court cannot ignore, in terms of evaluating the gravity of the departures, the fact that Microban's version of the 1983 EPA registration approval

conveniently omitted the critical limiting language that it was accepted only against non-health related organisms. EPA exhibits 1 and 46, Tr. 33-36, 152-153. The redacted approval may have been sent out to potential customers. Tr. 165-166. Nor can the Court overlook that the redacted form fit too well with Microban's subsequent unapproved claims and that the actual approval created obvious conflicts with those claims. In any event, even if it were assumed that somehow the redaction was innocent or that it occurred before the current owners acquired the company from Mr. Morrison, the Court still independently concludes, on the other gravity related grounds set forth in this decision, that the maximum penalty is warranted.

Given that the Court has determined that the nature and degree of the departures warrant, by themselves, maximum consideration of the gravity component in the penalty assessment, it is unnecessary and an unwarranted distraction to delve into Mr. Jordan's or Mr. Francis' personal views as to how consumers might react to Microban's unapproved representations nor to consider, in computing the penalty, the impact of the national opinion poll survey concerning whether consumers would still follow their usual washing and cleaning practices with cutting board's that had antibacterial protection. Tr.66-68, 228-229, Respondent's Exhibit 115.

Further, the Court does not subscribe to Microban's view that EPA "changed its interpretation of the claims approved for Microban Additive B but saw no reason to communicate its new interpretations to Microban, nor the assertion that EPA adopted a $laissez\ faire$ approach to telling the affected community as to what claims would violate FIFRA section 12(a)(1)(B), nor the notion that Microban was merely substituting specific named bacteria in its claims as a way to be more accurate than the general reference to bacteria. Microban Reply Brief at 5-7.

In fact, EPA informed Microban from the outset that health related claims were not permitted and continued to do so in many subsequent written communications. It also should be noted that, under the facts here, EPA was under no obligation to repeat what was clearly stated in the original registration approval, which could not have been clearer in limiting the approval, as relevant here, as a "bacteriostatic $\frac{(10)}{10}$ agent effective only against non-health related organisms." Further the assertion that Microban was simply intending to more accurately describe specific bacteria, but only in the context of the allowable bacteriostatic claims, is disingenuous at best.

Last, in addition to the nature and degree of the departures from the registration, the Court also is of the view that, by making such claims, Microban interfered with the agency's ability to carry out its statutory mandate of protecting human health and consequently did harm to the regulatory program. See the testimony of Dr. Brenda F. Mosley, Tr. 275 and Mr. William Jordan, Associate Director of the Antimicrobials Division, Tr.80 -83. The EAB has observed that "harm to the program alone is sufficient to support a substantial penalty." In re: Arapahoe County Weed District, FIFRA Appeal No.98-3,1999 EPA App. LEXIS 18, June 14, 1999.

ORDER

- 1. A civil penalty in the amount of 25,000.00 is assessed against Respondent, Microban Products Company.
- 2. Payment of the full amount of the civil penalty assessed shall be made within sixty (60) days of the service date of the final order by submitting a certified

check or cashier's check payable to Treasurer, United States of America, and mailed to:

EPA- Washington (Hearing Clerk) Post Office Lock Box 360277M Pittsburgh, PA 15251-6277

- 3. A transmittal letter identifying the subject case and the EPA docket number, plus Respondent's name and address, must accompany the check.
- 4. Failure upon the part of the Respondent to pay the penalty within the prescribed statutory time frame after entry of the final order may result in the assessment of interest on the civil penalty. 31 U.S.C. § 3717; 40 C.F.R. § 102.13 (b), (c), (e).
- 5. Pursuant to 40 C.F.R. § 22.27, this Initial Decision shall become the final order of the Environmental Appeals Board (EAB) within forty-five (45) days after its service upon the parties and without further proceedings unless (1) an appeal to the EAB is taken from it by a party to this proceeding, pursuant to 40 C.F.R. § 22.30(a), within thirty (30) days after the Initial Decision is served upon the parties or (2) the EAB elects, upon its own motion, to review the Initial Decision.

So Ordered.

William B. Moran
United States Administrative Law Judge

Dated: November 4, 1999 Washington, D.C.

- 1. The Court issued an initial decision as to liability on September 16, 1998 in its Order on Motions for Discovery, Filing of Sur-Reply and Partial Accelerate Decision. This was followed, on February 18, 1999, by the Court's Order Determining Number of Violations and Ruling on Respondent's Motion for Accelerated Decision as to Penalty.
- 2. See Complainant's Second Amended Complaint, for which leave to file was granted on April 3, 1998.
- 3. The reader is directed to the full text of the Order which is found at 1999 EPA ALJ LEXIS 4.
- 4. EPA has never offered any evidence to demonstrate the occurrence of a distinct harm with each sale or distribution, a fact which remained unchanged throughout the entire proceeding, including the two day penalty phase hearing.
- 5. This provision remains unchanged as to cite and substance under the Revised Procedural Rules for 40 C.F.R. Part 22. 64 F.R. 40176 et seq., July 23, 1999.
- 6. The five violations were identified in the Court's September 16, 1998 Order.

- 7. Where the gravity of the harm has been overstated, gravity should be assessed without regard to the complex formulation used in the penalty policy. <u>In re:</u> <u>Johnson Pacific, Incorporated</u>, FIFRA Appeal No. 93-4, 1995 EPA App. LEXIS 4; 5 E.A.D. 696, at *14, February 2, 1995.
- 8. Microban's various arguments that EPA changed its interpretation of the claims approved for Microban's Additive B, that EPA made admissions which directly contradicted the prohibition of public health claims, and that it needed guidance about permissible claims, are, in the context of the claims at issue here, rejected.
- 9. Even though the chief issue on liability was whether, irrespective of issue of truthfulness, Microban departed from the terms of the registration approval, the Court is troubled by Microban's apparent continued insistence that EPA is objecting to its dissemination of truthful information: "Complainant has assumed a paternalistic role to protect consumers in this case against speculative misuse of truthful information." Microban Reply Brief at 4.(emphasis added). But that is exactly what caused EPA to file the Complaint in the first place. Microban did not demonstrate, to EPA's satisfaction, the truth of the product's health related claims and that is why the registration approval did not permit such claims then and continues to prohibit such claims now. Tr. 212-213.
- 10. The term "bacteriostatic" refers to an agent that inhibits the growth or multiplication of bacteria. Tr. 57, $\underline{Dorland's\ Illustrated\ Medical\ Dictionary}$, 182 (27th ed. 1988).

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