UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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

ORDER ON MOTION

On January 26, 1998 EPA filed its Motion for Leave to File Second Amended Complaint. In this motion EPA set forth four reasons for filing the Second Amended Complaint:

1. To provide a more detailed factual basis for the alleged violations, including additional evidence of the alleged violations;

2. To declassify certain information as FIFRA Confidential Business Information, as Respondent has declassified the information now set forth in paragraph 11 by virtue of its Answer at paragraph 50(b);

3. To substitute in Paragraph 23 of the First Amended Complaint the phrase "in conjunction with," for the statutory phrase "as a part of," which phrase is derived from the statutory language of Section 12(a)(1)(B) of FIFRA, and;

4. To correct clerical errors related to shipment dates set forth in Paragraph 29 of the Amended Complaint, to correct the docket number reflected in the penalty calculation worksheets to conform to this docket, and to correctly reflect the effective date of the Civil Penalty Inflation Adjustment Rule as January 30, 1997.

Relying upon Section 22.14(d) of the Consolidated Rules of Practice, the Federal Rules of Civil Procedure, Rule 15(a), Foman v. Davis, 371 U.S. 178, 182 (1962), the Sixth Circuit's opinion in Hiar v. Hingston, 1996 U.S. LEXIS 25332 (September 5, 1996), and several decisions of the Environmental Appeals Board (EAB), for the proposition that leave to amend complaints should be freely given, absent undue delay or some nefarious intent by the complainant or undue prejudice to the Respondent, EPA notes that the alleged violations, as well as the proposed penalties, remain unchanged, and that the prehearing exchanges have not yet occurred nor has a date been established for the hearing.

On February 5, 1998 Respondent mailed its Opposition to EPA's Motion for the Second Amended Complaint, asserting that this was the EPA's second attempt to allege elements necessary to state a claim, that the "new" factual claims[1] alleged were based on information previously had in its files, and that in its "ever shifting version of events" EPA was attempting to "draft around" Microban's previous Answer. Respondent's Opposition at 1. Respondent asserted that it had been subject to "undue prejudice" and that, in any event, the amendments were futile.

In support of its claim of undue prejudice Microban asserts that it now must "retool its Answer" to deal with the "shifted factual allegations," and that this was particularly burdensome given its simultaneous obligation to pursue settlement efforts and comply with the Prehearing Order. Id. at 3. Microban makes the serious assertion that, as the information contained in the Second Amended Complaint was previously available, EPA tactically chose to make uninformed

[1]Microban concedes that the Second Amended Complaint does *not* raise additional legal claims. Respondent's Opposition at 3.

allegations, backing the Respondent into a factual and legal position, when it could have initially drafted one complete complaint. Respondent further asserts that this Motion to Amend the Complaint causes additional harm to the public's misconception regarding Microban's actions, which harm began with EPA's issuance of a press release with its initial complaint, and which is aggravated by each delay in the proceeding, further harming its position in the market.

More significantly, Microban maintains that, the amended complaint should be denied on the independent basis that EPA cannot prevail on the substance of its legal claim in any event, as the complaint and any of its amended forms are insufficient as a matter of law. Microban argues that the basis for the EPA complaint is that Respondent made "public health related" claims about its additive "B" registered pesticide, and that Respondent's use of the word "germs" is also prohibited, yet there is no legal authority defining what a "public health related" claim is under FIFRA nor does that Act prohibit the use of the word "germs." Thus, Microban argues at bottom that there has been no fair notice of what conduct is proscribed.

Thereafter, on February 9, 1998, EPA filed a very brief response to Microban's objection to the Second Amended Complaint, asserting that Microban's objection made false and misleading assertions. In an oral Order issued by the presiding judge on February 18, 1998 during a telephone conference call with the parties, and which was followed by a written order restating that oral order, EPA was directed to supplement its February 9th response.

The supplemental response was filed on March 2, 1998. Initially, EPA restated its position that administrative pleadings are easily amended, a proposition with which the undersigned wholeheartedly agrees. EPA then observes that Block v. First Blood Assoc., 988 F.2d 344, 350 (2d Cir. 1993) ("Block") is distinguishable from the present controversy as it

addressed the treatment of a *new* claim. In contrast, the statutory provisions alleged to have been violated in the present case remain unchanged from the original complaint. Responding to Microban's objection that it now will have to expend significant additional resources in discovery and trial preparation, EPA, citing to Walton & Lonsbury, Inc., Docket No. RCRA-I-89-1098 (May 30, 1991), In re City of Sioux Falls, S.D., Docket No. CWA-VIII-93-03-P-II, (July 13, 1994), notes that it has added only factual information which is similar to the original factual allegations and therefore in the nature of amplification of the originally pleaded facts. In addition, EPA states that the information is derived solely from Microban's own documents and that all of this is occurring well in advance of the hearing[2].

EPA further notes that Microban's concerns about completing discovery before the prehearing exchange are at odds with the Consolidated Rules, which contemplate, under 40 C.F.R. § 22.19(f), "further discovery" *after* the exchange. EPA also discounts the assertion that the delay occasioned by the Second Amended Complaint has been aggravated by the EPA's press release concerning this matter and "strenuously objects" to claims that it deliberately employed a staging process in seeking amendments to the complaint as part of a litigative strategy. EPA Supplement at 11.

Addressing Microban's arguments concerning the futility of amendments to the complaint because, assertedly, it is unlikely that EPA can prevail as the claim is legally insufficient, EPA refers the presiding judge to Consolidated Rule § 22.20(a) and a test which is

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[2]EPA also notes that, while not present under these facts, motions to amend the complaint can be granted much later than the present juncture such as during and even after the hearing, where there is no unfair disadvantage, surprise, prejudice etc. EPA Supplement at 6-7.

comparable to that found in Rule 12(b)(6) of the Federal Rules of Civil Procedure. Under the standard set forth in these, an amendment is deemed futile only where it appears beyond doubt that no set of facts can be demonstrated to establish a right to relief.

Responding to the foundation of Microban's claim of futility, that EPA never provided "fair notice" of what it means by "public health related claims," EPA states that each of the complaints are based on the claim of Respondent's violations stemming from Microban's product claims concerning "microorganisms infectious to man." While EPA concedes that a reference to a "public health related" claim does appear in the Complaint, it exists only in the alternative pleading section of the complaint and that, in any event, it is only a more general term, encompassing "microorganisms infectious to man." EPA Supplemental Response at 12-14. EPA also observes that 40 C.F.R. § 158.640, n.1, requires that claims that a product controls *microorganisms infectious to man* must be backed by efficacy data for the product and such data must be submitted to the Agency. Referring to the standard for determining "fair notice" which requires that a reasonable person of ordinary intelligence be able to understand what conduct is prohibited, EPA states that such a person would understand that a prohibition against claims concerning microorganisms infectious to man necessarily bans claims about Staph, E. Coli, Strep., and Salmonella. Beyond this, EPA notes that, as Respondent is knowledgeable in the field of microbiology, it can be expected to have understood what these terms meant in its FIFRA registration. Id. at 14-16. For these reasons, EPA observes that the existence of a regulation which would define such term is irrelevant. Id. at 16, footnote 12.

Referring to 40 C.F.R. § 158.640 and its requirement that efficacy data be submitted to and accepted by the Agency for a product that claims to control pest microorganisms before such

claims are made about it, EPA asserts that it has notified Microban that the data it has submitted was not acceptable to support such claims. EPA states that on more than one occasion it expressly advised Microban that claims relating to products concerning the control of microorganisms infectious to man, such as Staphylococcus aureus, are claims directly related to human health and, beyond that, Respondent's own documents disclose its awareness of the nature of these microorganisms as illness causing germs. Id. at 19-20.

EPA refers to the Environmental Appeals Board decision in In re Sporicidin International, FIFRA Appeal Board No. 88-2, 3 E.A.D. 589 (EAB, June 4, 1991), observing that the standard for establishing claims which are made as part of the sale or distribution of a product under Section 12(a)(1)(B) is whether the claim is intended to induce the purchase and use of the product and that Microban's product literature to Hasbro is one example of such conduct. Last, referring to Microban's argument that Section 12(a)(1)(B) does not allow EPA to bring claims relating to "public health," EPA responds that the plain language broadly addresses and forbids any claims which substantially differ from the claims made in the pesticide's registration.

Thereafter, Microban filed, on March 12th, a reply to Complainant's Supplement, in which it largely reiterated the arguments it had already advanced. However, Microban also asserts that EPA omitted a "key statutory limitation" from its references to "microorganisms infectious to man," in that 40 C.F.R. 158.640, n.1 as well as EPA's "Pesticide Assessment Guidelines, Subdivision G" refer to "***pest***" microorganisms. Referring then to definitions of the term ***pest*** in FIFRA § 2(t), 7 U.S.C. § 136(t) and 40 C.F.R. § 152.5(d), Microban construes germs such as Strep, Staph, Salmonella and E. Coli as within the exception to the definition of ***pest*** as microorganisms found to be living on or in humans, animals or processed food. Following this

reasoning Microban asserts that should EPA want to cover these excepted germs, it must declare them to be ***pests*** under the FIFRA procedures set forth in § 25(c)(1), 7 U.S.C. § 136 w (c)(1) and, not having done so, has failed to provide fair notice to affected parties thereby violating the Due Process Clause of the Fifth Amendment. Thus EPA has failed to give notice as what claims, if any, can be made against "microorganisms infectious to man." Respondent also argues that EPA's alternative pleading, asserting that express or implied health related claims have been made about Microban's Plastic Additive "B," similarly fails to give fair notice as to what is a prohibited "health related claim." Respondent's Reply to Complainant's Supplement at 10-11.

Finally, regarding Microban's claim of prejudice, Respondent refers to the differences between the descriptions of the alleged violations in the Complaint as compared to the EPA press release, with the latter referring to "public health claims," while the former refers to "microorganisms infectious to man." In response to the EPA's reply that these issues will be resolved through the hearing process, Microban maintains that this constitutes an additional reason to deny the Second Amended Complaint, as it operates to delay its opportunity to contest the allegations and present its defense through the hearing process. Id. at 12-13.

On March 19, 1998 EPA filed a Motion seeking leave to reply to Microban's March 12th Submission, which motion was granted on March 20th. Following this Motion, Respondent filed an objection to it and proposed an expedited briefing schedule for it to present a Motion to Dismiss and, in the alternative, a Motion for Summary Judgment.

On March 27, 1998 EPA submitted its Reply to Microban's March 12th submission. As several of the subjects in the Reply have already been exhaustively discussed by the parties in the previous submissions, only those new aspects which I consider important to this Order will be

mentioned here. EPA, after noting the distinction in the jurisdiction between EPA and the Food and Drug Administration in these matters, observes that Microban's assertion that EPA does not have authority to regulate Staph, Strep., etc., was addressed in Kenepp v. American Edwards Laboratories, 859 F.Supp. 809 (E.D. Pa. 1994), in which the court rejected the argument that a disinfectant fell outside the definition of "pesticide" under FIFRA. EPA Reply at 3.

In response to Microban's assertion that a footnote reference in 40 C.F.R. § 158.640 appears to be the basis of EPA's interpretation that references to Staph, Strep, etc. constitute "claims against microorganisms infectious to man," EPA clarifies its position as to Subheading C of its Supplement that in addition to the regulation, Microban was also put on notice by EPA's pre-enforcement efforts, including EPA's rejection of the efficacy data submitted by Microban.

Discussion

The law regarding the amendment of complaints is very clear and there is no need for an extensive discussion of principles already so well established. As a "liberal pro-amendment ethos dominates," courts freely grant leave to amend, absent a substantial reason to deny the amendment. The basis for this ethos is to achieve the underlying purpose of facilitating a decision on the merits. In the Matter of: Asbestos Specialists, Inc., 1993 EPA App. LEXIS 7; 4 E.A.D. 819, October 6, 1993. It is particularly important that a court allow amendments for the purpose of ensuring that all issues are before it. See Moore's Federal Practice 3D, Section 15.14. As noted by EPA, this case is still in the pretrial phase. While I recognize that there are exceptions to this general rule favoring allowance of amendments, I find that none of them are applicable here.

On the first page of this Order I noted that EPA set forth in its Motion four reasons for filing the Second Amended Complaint. Of these, the Respondent's objection is essentially directed only to the first reason: To provide a more detailed factual basis for the alleged violations, including additional evidence of the alleged violations. As noted, Microban does not allege that EPA is raising different legal claims. Microban's assertion that this created an undue burden because of its simultaneous efforts with settlement discussions and its duty to comply with the Prehearing Order, are unconvincing. A party always has the option to apply to the court for an extension of time to comply with an order and, when sufficient reasons are advanced in support thereof, they are usually granted. Further, the factual reality of the Second Amended Complaint dispels Respondent's unsupported allegation that EPA was intentionally making uninformed allegations in the original and Amended Complaints. In addition, the assertion that this had the effect of "backing" the Respondent into a factual and legal position, is curious since it suggests that the Microban's factual and legal positions are at the mercy of the EPA's assertions, even though the heart of EPA's allegations have remained unchanged. Finally, Respondent's claim that the amendment should be denied because it aggravates the public's misconception of Microban's actions mixes unrelated events that operate on independent levels. Whatever claims may be traded between the parties in the press is independent of the legal action here. Should Microban ultimately prevail on the alleged violations, that outcome will speak louder than any of the parties' thrusts and parries before the press.[3]

As to the second issue raised by Microban, the futility of any amendments on the theory

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[3]I note that, in any event, Microban seems to be holding its own to the extent that this matter is being discussed in the press. See The Washington Post, March 27, 1998, E1.

that they are all insufficient as a matter of law, I find no merit in the Respondent's contentions. The essence of Microban's argument in this regard is that there is no legal authority defining what constitutes a "public health related" claim nor does FIFRA prohibit the use of the word "germs."

Microban loses sight of the what is charged here.[4] The single count, made up of 32 separate alleged violations, charges Microban with a violation of FIFRA Section 12 (a)(1)(B), 7 U.S.C. Section 136 j (a)(1)(B). That Section provides:

> ...it shall be unlawful for any person in any State to distribute or sell to any person--
>
> (B) any registered pesticide if ***any*** claims made for it as a part of its distribution or sale ***substantially differ*** from any claims for it as a part of the statement required in connection with its registration under section 136 a of this title; (Emphasis added.)

As alleged by EPA, in its Notice of Pesticide Registration dated August 15, 1983 and in subsequent letters, EPA notified Respondent that "bacteriostatic claims **made pursuant to the registration for Microban Plastic Additive "B," EPA Reg. No. 42182-1 are acceptable *only with respect to non-health related microorganisms not infectious to man*.**" (Emphasis added.) Second Amended Complaint, Paragraph 15.

Thus, rather than posing the question, as framed by Microban, inquiring whether the phrase "public health related" claims and the use of the term "germs" are without any defining legal authority and consequently whether there has been any lack of fair notice of the proscribed

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[4]Beginning with the Amended Complaint, EPA added an alternative pleading, asserting that if Respondent's sales or distribution of "Additive B" were not sales or distributions of a registered pesticide, then FIFRA section 12 (a)(1)(A) was violated.

conduct, the question before me is considerably less involved. In my view, establishment of a violation involves holding up, on the one hand, the terms of the EPA's registration approval and then, per Section 136j (a)(1)(B), determining whether Microban made any claims as a part of its distribution or sale which substantially differ from those made in connection with its registration approval. See, for example, In the Matter of Johnson Pacific, Incorporated, 1993 FIFRA LEXIS 148, August 5, 1993, in which Administrative Law Judge Frank W. Vanderheyden dealt with the same FIFRA section at issue here. In upholding the violation, the judge noted that "the product was only registered as Sanitizer for Swimming Pools," and accordingly claims that it "could be used in spas was a claim foreign to its registration." Id. at 26. See also In the Matter of: Sporicidin International, 1991 EPA App. LEXIS 3; 3 E.A.D. 589, June 4, 1991.

Even if it were necessary to reach Microban's "fair notice" arguments, I would reject them because I agree with EPA's position that no definition of the term "microorganisms infectious to man" or the term "public health related" claim is needed, as both of these are terms that, at this point in history, a person of ordinary intelligence would understand as applying to Salmonella, E. Coli, Strep. and Staph. This conclusion is only strengthened by the fact that the Respondent is knowledgeable in the field of microbiology. There is no debate within the medical community about the fact that each of these bacteria are microorganisms infectious to man. See, for example: Tierney, et al., Current Medical Diagnosis & Treatment, 1129-1146 (33rd ed. 1994), and The Merck Manual, 86-102, (16th ed. 1992). Even dictionaries routinely define three of these microorganisms.[5] See Webster's II New Riverside University Dictionary,

[5]Only Escherichia coli, better known as "E coli," does not appear in the general dictionaries consulted. The bacteria is defined in medical dictionaries. See, for example,

(1984).

The application of the concept of judicial notice is also appropriate here, as it involves a matter which is not subject to reasonable dispute: that the germs listed above are commonly known as microorganisms harmful to man. Thus it is a proposition of generalized knowledge which is beyond reasonable controversy. As stated by the United States District Court for the District of Maryland in United States of America v. Sean Sauls: "The Supreme Court has stated that firmly established scientific principles are properly the subject of judicial notice ... a judicially noticed fact is one that is not subject to reasonable dispute and is capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." 981 F. Supp. 909 at 920 (October 8, 1997).

Accordingly, I take judicial notice of the fact that E. Coli, Salmonella, Staph. and Strep. are widely recognized as microorganisms infectious to man. Indeed, at least as alleged by EPA in the Second Amended Complaint in documents represented to have been generated by Microban, Respondent asserts that its pesticide provides protection against "germs" such as E. Coli and Staph. Id. at paragraphs 24 and 25.

Accordingly, for the reasons stated, Complainant's Motion for Leave to File Second Amended Complaint is granted.

So Ordered.

William B. Moran
Administrative Law Judge

Dated: April 3, 1998
Washington, D.C.

Dorland's Illustrated Medical Dictionary, (27th ed.1988).

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

CERTIFICATE OF SERVICE

I certify that the foregoing **Order on Motion,** dated April 3, 1998, was sent in the following manner to the addressees below.

Original by Pouch Mail to: Headquarters Hearing Clerk

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Dated: April 3, 1998
Washington, D.C.