UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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

ORDER DENYING MOTION TO DISMISS ADMINISTRATIVE COMPLAINT

By pleading dated April 3, 1998, (with a substitute version dated April 6, 1998) Respondent Microban Products Company ("Microban") filed a Motion to Dismiss Administrative Complaint. Complainant Environmental Protection Agency ("EPA") timely filed a Response opposing this Motion. For the following reasons, Respondent's Motion is DENIED.

Respondent argues that the Complaint in this matter should be dismissed because:

(a) EPA lacks the authority to regulate microorganisms such as E. coli, Staph., Strep., Salmonella or "germs" because these organisms are on or in living humans or living animals, or on or in processed foods.

(b) EPA has not properly declared microorganisms such as E. coli, Staph., Strep., Salmonella or "germs" as "deleterious to man or the environment," "in[j]urious to man or the environment" or "infectious to man in any area of the inanimate environment," and therefore lacks authority to regulate Microban's product on that basis.

(c) EPA has failed to provide fair notice to Microban of its interpretation of "claims against microorganisms infectious to man" and/or "public health claims" such that Microban was not provided adequate notice to satisfy due process that its actions were prohibited.

(d) EPA cannot demonstrate that the statements it alleges were made by Microban are "claims" within the meaning of FIFRA, or that these claims substantially differ from claims approved by EPA.

(e) EPA cannot apply the treated article exception to Microban in this case because

Microban has never sold and/or distributed any treated articles, but sold only an antibacterial pesticide compound that was to be incorporated into a treated article manufactured by Microban's customer Hasbro, Inc. Moreover, each end product into which Microban additive "B" was incorporated had been approved and registered by EPA as an end-use product.

EPA counters that the central issue for determination at this juncture is whether Respondent has made claims as part of the distribution and sale of its product which substantially differ from the claims approved by the EPA as part of its registration. EPA asserts that the remainder of Respondent's claims amount to nothing more than a rehashing of the fair notice arguments rejected by the undersigned in the April 3, 1998 Order on Motion ("April 3 Order") issued in this case.

EPA filed a Second Amended Complaint in this case on April 7, 1998.

Discussion

Respondent's Motion to Dismiss was dated the same day as the undersigned's April 3 Order and as such presumably did not take into account the ruling made therein. Several of the arguments raised by Respondent in the present Motion have been ruled upon in the April 3 Order. It is not necessary to restate my views in this regard. However, to the extent necessary to address all of the allegations raised in Microban's Motion to Dismiss, these arguments will be briefly discussed.

In the April 3 Order I stated, with regard to whether a Section 12(a)(1)(B) violation of FIFRA, 7 U.S.C. § 136j(a)(1)(B) exists that;

> 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.
> April 3 Order at 11.

I did not make a determination then, nor do I now, as to whether such a violation of Section 12(a)(1)(B) exists in this case. What I *am* doing is reminding the Parties what the central issue for determination in this case is, namely, a determination of whether or not Respondent made claims in its efforts to sell and/or distribute its product, additive "B" which substantially differ from its EPA registration approval.

In addition, the April 3 Order also addressed the fair notice arguments raised by Respondent in its Opposition to EPA's Motion for Second Amended Complaint and similarly raised in its Motion to Dismiss. In rejecting these arguments I concluded then, as I do now, that Respondent's framing of the issue is in error. The issue is not whether there is sufficient legal authority defining the phrase "public health related" and the word "germs," the question instead is, as stated above, whether Microban's claims in its sale and/or distribution of additive "B" *substantially differ* from its EPA registration approval.

Further, the April 3 Order also addressed the substance of Respondent's claim as to whether sufficient legal authority exists defining the terms "public health related" claims and "microorganisms infectious to man." I concluded that these terms do not require definition at this time in history since "a person of ordinary intelligence would understand [them] as applying to Salmonella, E.[c]oli, Strep. and Staph. This conclusion is only strengthened by the fact that the Respondent is knowledgeable in the field of microbiology." The undersigned also took judicial notice of the fact that E.coli, Salmonella, Staph. And Strep. are widely recognized as microorganisms infectious to man.[(1)]

To prevail in a Motion to Dismiss, Respondent would have to show that no set of

facts would allow EPA to prevail in the underlying action or, in other words, that EPA has failed to state a prima facie case. This is simply not the case in the present action. While matters of fact and law remain in dispute, a plain reading of the Second Amended Complaint shows that if the facts as alleged did in fact occur and that an application of the applicable statutory and regulatory provisions are as Complainant alleges, then a violation exists.

The Second Amended Complaint alleges, in a single count, 32 violations of FIFRA Section 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B). This Section states:

> [i]t 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 136a of this title; (Emphasis added.)

The facts as alleged in this case, if proven, will support a claim that the above cited Section of FIFRA was violated.[(2)] Therefore, EPA's Second Amended Complaint in this matter survives Respondent's Motion to Dismiss.

For the foregoing reasons, Respondent Microban Products Company's Motion to Dismiss is hereby DENIED.

So Ordered.

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William B. Moran
Administrative Law Judge

Dated: May 18, 1998
Washington, D.C.

1. Respondent has requested an opportunity to be heard concerning the taking of Judicial Notice in this matter. This Request has been granted.

2. To the extent that Microban states that EPA cannot demonstrate that the statements made by them are "claims" as defined by FIFRA or that they substantially differ from the claims approved by EPA, this is a matter of fact to be determined at the appropriate juncture in these proceedings. To the extent that Microban asserts that the treated article exception does not apply to them since they did not sell an end-use product, this may also be a subject of a later determination.