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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

IN THE MATTER OF	)	
	)	
MICROBAN PRODUCTS COMPANY	)	
	)	Docket No. FIFRA 98-H-01
	)	
Respondent	)	

Order on Motions for Discovery, Filing of Sur-Reply and Partial Accelerated Decision

On July 15, 1998, Complainant, The United States Environmental Protection Agency ("EPA" or "Complainant") filed a Motion for Accelerated Decision as to Liability in this action under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C.136 et seq. ("FIFRA"). Subsequent to this, Respondent, Microban Products Company ("Microban" or "Respondent") filed, on July 20, 1998, a Motion for Further Discovery. Microban filed its Opposition to the Motion for Accelerated Decision on August 3, 1998. Thereafter the Court issued an Order, dated August 4, 1998, directing EPA to file a reply brief and postponing the hearing.(1) This was followed by Microban's Motion, filed on August 6, 1998, for a Limited Hearing on its Discovery Motion. Microban also filed, on August 21, 1998, a Motion for Leave to File a Sur-Reply regarding the Motion for Accelerated Decision.

The EPA Complaint Against Microban

The Second Amended Complaint ("Complaint")(2) asserts, in a single count, that Microban made 32 separate sales or distributions of its registered pesticide, Microban Plastic Additive "B," ("Microban B") in violation of Section 12 (a)(1)(B) of FIFRA, 7 U.S.C. § 136j (a)(1)(B), by making claims that were substantially different from claims made in connection with its registration.(3)

I. Microban's Motion for Further Discovery and Limited Hearing on Discovery

Microban's Motion has two aspects to it. First, it seeks information regarding the

Agency's definition of a "public health claim," and in particular information that provides instruction "as to the meaning of a 'direct public health claim' or 'indirect public health claim' within the meaning of FIFRA." Motion at 2. Underlying this request is Microban's assertion that EPA failed to provide "clear guidance . . . relating to the types of claims that could be made for Microban's bacteriostatic antimicrobial pesticide." Id. at 3. Second, Microban seeks information relating to "EPA's approval and evaluation of claims made *by other* manufacturers of antimicrobial pesticides *similar* to Microban's Additive "B."" Id. at 2. (Italics added).

In its Opposition, EPA, referring to the Consolidated Rules of Practice, 40 C.F.R. § 22.19(f)(1)(iii), argues that the requests fail to satisfy the "significant probative value" requirement for information sought beyond the pre-hearing exchange. As to the meaning of a "public health related claim," EPA refers to the Court's April 3, 1998 Order, holding 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.[c]oli, Strep. and Staph." Order at 11. Regarding Microban's request for EPA's actions relating to other companies, EPA again refers to the Court's April 3rd Order which set forth the basis for establishing a Section 12(a)(1)(B) violation, noting that a violation is determined by measuring the terms of EPA's approval against the registrant's claims. Thus it maintains EPA's actions relating to other companies has no probative value to this case. Opposition at 4.

As neither aspect of Respondent's Discovery Request and the attendant Request for a Limited Hearing satisfies the "significant probative value" requirement of 40 C.F.R. § 22.19(f)(1)(iii), the Motion is DENIED. Once again, Microban's Motion obfuscates what is involved in this case, to wit: whether the Respondent made claims as a part of its distribution or sale which substantially differ from those claims permitted with the registration. This does not require delving into what the Agency may or may not have said (if indeed it has said anything at all) about the meaning of "direct or indirect public health claims." If there are instances where it may not be clear whether an assertion amounts to a public health related claim, this is not one of them. As noted in the Court's April 3rd Order, no definition of what constitutes a "public health related claim" is needed, as applied here, since a person of ordinary intelligence would understand that such a claim applies to Salmonella, E.coli, Strep and Staph."

Microban's second aspect of discovery similarly fails the "significant probative value" requirement as it seeks information about unrelated matters: the inquiry into EPA's treatment of independent pesticide applications of *similar* pesticides by *other* manufacturers. This would amount to launching a fleet of fishing expeditions, serving no purpose beyond distraction from the issue to be decided.

II. Microban's Motion for Sur-reply Regarding Motion for Accelerated Decision

As noted earlier, the Court, on its own motion, requested a Reply Brief from EPA regarding the Motion for Accelerated Decision. Prior to receipt of that Order, EPA filed a Motion seeking leave to file a Reply Brief. On August 11, 1998, Microban sent a letter to the Court expressing its surprise that "the court, without consultation with the parties, ordered EPA to file a reply brief." Thereafter, on August 21st, Respondent filed a formal motion for leave to file such a reply brief, again noting the Court's failure to first consult with the parties before directing such a brief.

Microban states in this Motion that EPA "continues to change its basis for [the] alleged violation," by asserting "for the first time that Microban has made 'self-sanitizing claims;'" and also that EPA's Reply Brief "provides new and novel interpretations of FIFRA § 12(a)(1)(B); offers new interpretations of its 1987 letter; has changed its position as to the purpose that Subdivision G Guidelines serves; and relies on evidence that has not heretofore been introduced into the record."

Complainant filed a Response in which it denied Microban's assertions and noted

that, as to the claim that EPA first raised "self-sanitizing claims" in the Reply brief, Microban had already claimed that "self-sanitizing claims" were first raised by EPA in its July 15, 1998 Motion for Accelerated Decision.(4)

It is noted that Microban's two page Motion for Leave to File a sur-reply makes one specific assertion and many general allegations. As to the one specific assertion, the record reveals that Microban is flatly wrong. At a minimum, EPA raised the "self-sanitizing" claim in its Motion for Accelerated Decision, as Microban itself acknowledged in its Response in Opposition.

The remaining general assertions fail to provide the Court with any specific references to EPA's Reply Brief to support Respondent's claims, apparently leaving it to the Court to search the Reply Brief for evidence of the four other allegations and then to make Microban's arguments concerning them. The Court is not so inclined, and particularly so given that the one specific allegation offered by Microban is without any basis.

In terms of Microban's assertion that the Court failed to first consult with the parties before ordering a Reply Brief, the Consolidated Rules do not impose such a requirement. Such matters, including granting leave to file a sur-reply lie within the sound discretion of the Court. In the exercise of that discretion, Microban's Motion to file a sur-reply is DENIED. American Forest & Paper Ass'n v. United States Environmental Protection Agency, 1996 U.S. Dist. LEXIS 13230, *11, Beaird v. Seagate Technology, 145 F.3d 1159, (10th Cir. 1998), 1998 U.S. App. LEXIS 10701, *8- *11, Lopez v. Garcia, 1998 U.S. App. LEXIS 7461, *4. However, the Court has reviewed EPA's Reply Brief and finds that it does not raise new points or assignments, but only responds to the points made by Microban. See, e.g., Robertson v. Johnson Cty., 896 F. Supp. 673 (ED Ky.1995). Cf. U.S. v. Jerkins, 871 F2d 598, 602 (6th Cir. 1989).

III. EPA's Motion for Partial Accelerated Decision

A. EPA's Argument

EPA first observes that Microban, in seeking registration approval for its pesticide, claimed that it was "A preservative, bacteriostatic agent for use in the manufacture of polymer plastic and latex products." EPA Approved Label for Microban Plastic Additive "B" (August 15, 1983). In approving the pesticide's registration on August 15, 1983, EPA informed Microban that the product was being accepted "*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.* EPA Motion at 6, (italics added.) On this basis EPA asserts that any claims that Microban Additive "B" is effective against microorganisms infectious to man, such as Salmonella, E.coli, Strep or Staph(5), would constitute claims that "substantially differ" from those approved with its registration. EPA points to five documents in which it alleges that such substantially differing claims were made.

The first document is a Microban promotional brochure which asserts:

> Microban has been proven to safely reduce the growth of many common harmful bacteria (including E.coli, Salmonella, Staph. and Strep.) **by 99.9 percent**.

Brochure at 6, EPA Exhibit 7, accompanying instant Motion. (Emphasis in original). EPA asserts that this represents a public health related claim, proclaiming effectiveness against harmful bacteria and, by asserting that it reduces the growth of harmful bacteria by the figure of 99.9 percent, constitutes a sanitizer or self-sanitizer claim, as that is the figure used by EPA for approving a claimed sanitizer of self-sanitizer pesticide.(6) In the same brochure EPA refers to Microban's use of charts displaying that "GERMS" are present in the home, workplace, and "EVERYWHERE

WE GO," and that Microban is effective against common harmful bacteria such as Staph and E. coli. Brochure at 3.

EPA next points to a Microban document identified as "Facts About Microban Antimicrobial Protection." EPA Exhibit 13, accompanying instant Motion. In this document, Microban describes the product's "protection" as addressing the public's concern:

> . . . over the prevalence of germs and bacteria , such as E. coli, Salmonella, Staph., and Strep. **Independent laboratory tests have shown conclusively that Microban can safely reduce the presence of bacteria on these products by 99.9 percent.**

Exhibit 13 at 1. (Bold in original). EPA asserts that, by claiming effectiveness against microorganisms infectious to man, this document constitutes a public health-related claim, and that it also amounts to a sanitizer or self-sanitizer claim.

The Motion also cites three other documents: Microban's Presentation to Hasbro, which refers to the product's germ fighting qualities against E.coli and Staph, EPA Exhibit 14, at page 18, accompanying instant Motion; Microban's suggested language to Hasbro on October 28, 1996, regarding the product's germ fighting and germ inhibiting qualities together with the assertion that this provides a healthier environment for children, EPA Exhibit 16, accompanying instant Motion; and a Microban public relations document, dated January 13, 1997, in which similar claims are made regarding the product's effectiveness against germs such as E. coli, Salmonella, Staph, and Strep, EPA Exhibit 12, accompanying instant Motion. EPA notes that these documents have been identified by Microban as documents pertaining to the sale or marketing of the product.

EPA argues that, consistent with the Federal Register Notice addressing the subject, case law and common understanding of the term, these statements constitute "claims" under Section 12(a)(1)(B) of FIFRA, and that the product was shipped to Hasbro during 1996 and 1997. Pointing to In the Matter of Sporicidin International, 1991 EPA App. LEXIS 3; 3 E.A.D. 589, June 4, 1991, ("Sporicidin"), EPA maintains that it was held that a claim is made as a part of a product's distribution or sale if it is intended to induce its purchase and use, and that the documents cited in the instant Motion were presented as marketing tools with the purpose of entering into business with Hasbro.

B. Microban's Opposition to the Motion for Accelerated Decision

Microban replies that, as a matter of undisputed fact and law, it has not been shown that it made "claims" which "substantially differ" from those approved by EPA in the product's registration and that it engaged in a reasonable interpretation of its registration.

Addressing EPA's assertion that Microban's marketing materials constitute "claims," Respondent states that in Sporicidin the Environmental Appeals Board held that a claim must be disseminated with the intent to induce the purchase and use of the product and that it recommends or suggests the purchase of pesticides for certain purposes. Opposition at 5, 6. Referring to the specific documents cited by EPA, Microban asserts that the January 13, 1997 Public Relations Questions & Answers document (EPA Exhibit 12) was drafted *after* the sale of Microban to Hasbro had already been made and at Hasbro's request for its own training program and therefor could not be construed as documents to induce the sale and use of the product. With the same reasoning, the draft label, being created *after* the sale, cannot be viewed as a purchase *inducement.* Opposition at 7, 8. Microban argues that, under the EPA interpretation, any utterance, regardless of the context in which it occurred, would be a "claim." It urges that the notion that these documents constitute *per se* sale or distribution claims be rejected, as they had nothing to do with inducing the Hasbro sale.

Further, Microban argues that the plain language of Section 12(a)(1)(B) nowhere requires that only the "exact recitation" of the registration may be used, and that only "material" (i.e. "substantial") differences are forbidden. It is Respondent's position that violations must be assessed in the context in which the claim under scrutiny is presented and, it asserts, this requires consideration of the purpose behind the alleged claim, a purpose they contend lacks that of inducing the sale and use of Microban. Opposition at 10. Respondent also maintains that the use of the terms "sale or distribution" must not be read in a vacuum and that this means the product " must be put into a channel of trade for further sale." Id. at 12. Microban maintains that it only delivered the product for incorporation into Hasbro products and that each of the 32 shipments, which form the basis for the 32 alleged incidents, were made *after* the decision to purchase and accordingly could not form any basis for inducement to purchase. Id.

Apart from these arguments, Microban takes the position that, in any event, its claims do not substantially differ from the language approved by EPA. Pointing to a July 10, 1987, letter from EPA's Jeff Kempter, it notes that the following phrases were deemed acceptable to the Agency: "provides a hygienic surface," "inhibits growth of bacteria," "resists bacterial growth," "inhibits/controls growth of odor-causing bacteria and mildew (fungus)," and "resists mildew and bacteria growth." Id. at 13, 14. EPA stood behind these five phrases in a March 14, 1997, Memorandum, and Microban asserts that the Agency is therefore bound by its "official action" approving this language.

Microban also argues that its "General Corporate Brochure" and the "Fact Sheet" are "general corporate documents" constituting "general information sources" that describe the properties of Microban Additive "B." Microban takes the position that because of the purposes for which these documents were drafted (to address medical/hospital and pesticide uses) they cannot be deemed to contain "claims." Despite this stance, Microban goes on to assert that, in any event, these documents do not make claims that "substantially differ" from the claims permitted by EPA. Microban acknowledges that these documents make reference to the public's concern over bacteria like E. coli, Staph., Strep. and Salmonella, but asserts that this is the only such reference in the Fact Sheet and that it demonstrates that Microban meets FDA standards regarding antibacterial properties. The Brochure's reference to locations where germs live and breed and the observation that permanent antimicrobial protection can eliminate such harmful microbe growth is, according to Microban, merely a statement concerning where people can contact microorganisms together with the remark that products, like Microban's Additive "B," can reduce such microbe growth, but that this in no way implies any particular pesticidal claims regarding E. coli, Staph, Strep, or Salmonella. Opposition at 17,18.

Additionally, Microban takes issue with EPA's assertion that referring to "germs" and "microbes" connotes microorganisms which are infectious to man, and maintains that these are merely used as generic terms for bacteria, mold or mildew, and therefore consistent with the approved language that Microban Additive "B" inhibits the growth of bacteria, molds or mildew on plastic surfaces. Similarly, language referring to the elimination of growth of harmful microbes is, as Microban sees it, not substantially different from the approved language that Additive "B" provides a "hygienic surface." Id. at 19.

Microban also asserts that its product advertising is consistent with FDA approvals, and that EPA has no authority to prevent such advertising or to require separate FDA promotional materials merely because the language used in general materials might implicate EPA regulated products. Regarding its Hasbro presentation, Microban observes that the only microorganisms referred to in the photograph of petri dishes are E. coli and S. Aureus. Noting that no other specific microorganisms are mentioned in the presentation, Microban asserts that its use of the phrase "ultimate germ fighting protection" and the inclusion of consumers' perceptions of the type of protection that Microban provides, do not "directly imply" that the product is effective against microorganisms infectious to man since these passages (apart from the petri dish photograph) do not mention specific bacteria. The survey, Microban maintains, *only reflects the viewpoints of the women*

surveyed, and not Microban's words or impressions. In any event, the passages do not "substantially differ" from the approved EPA phrases of "provides a hygienic surface" and "inhibits the growth of bacteria." From its perspective, Microban has only used general statements referencing "health" and "germs" and since all pesticides have a general beneficial effect upon human health, such general remarks do not rise to the level of constituting prohibited claims regarding microorganisms infectious to man.

C. Microban's Response to the "Self-Sanitizing" Claim

Initially, Microban argues that, with the filing of the Motion for Accelerated Decision, EPA has raised the claim that Microban made "Self-sanitizing claims" for the first time in this proceeding and that, with no prior notice, it is too late to add such a claim, and accordingly is outside of the scope of the complaint. However, Microban also goes on to address the charge by asserting that there is no substantial difference between asserting that Microban Additive "B" provides a hygienic surface and asserting that it reduces the growth of bacteria to that degree. Nor, it adds, does the language cited by EPA fit within the Pesticide "G" guidelines which describes self-sanitizing claims in terms of a pesticide killing a certain number of bacteria within a specified time, as Microban made no claim that there was a 99.9% bacterial reduction over the control within 5 minutes. Apparently, without adding the 5 minute time factor to its claims, Microban believes that claiming a 99.9% bacterial growth reduction alone is not materially different from stating that its product provides a hygienic surface or inhibits the growth of bacteria. Id. at 22, 23.

IV Discussion

A. Determination of violation

The Consolidated Rules of Practice set forth the standard for review of a Motion for Accelerated Decision. 40 C.F.R. § 22.20. Such a motion may be granted "if no genuine issue of material fact exists and a party is entitled to judgment as a matter of law, as to all or any part of the proceeding. In re Green Thumb Nursery, 1997 EPA App. LEXIS 4; 6 E.A.D. 782, March 6, 1997.

Given the breadth of the arguments raised, it would be understandable for one to lose sight of the actual, straightforward, issue presented in this case. In a single count, Microban has been charged with violating Section 12(a)(1)(B) of the Federal Insecticide, Fungicide and Rodenticide Act[(7)] which 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 136a of this title;

As set forth in the EPA's registration of "Microban Plastic Additive," dated August 15, 1983, EPA registration number 42182-1, the product was:

> **accepted 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.**

EPA Exhibit 2, accompanying instant Motion[(8)]. (Italics and emphasis added). This

notice of pesticide registration represents the base line from which allegations of a Section 12(a)(1)(B) violation of FIFRA must be measured.

Therefore, as stated in my April 3, 1998, Order, establishment of this 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."[(9)] Order at 11. In the same Order, I also took judicial notice of the fact that E. coli, Salmonella, Staph. and Strep are widely recognized as microorganisms infectious to man[(10)], observing that, upon resort to authorities whose accuracy cannot reasonably be questioned, this is a fact not subject to reasonable dispute.

The Environmental Appeals Board ("EAB" or "Board") has addressed the provision at issue in this case: In the Matter of: Sporicidin International, 1991 EPA App. LEXIS 3; 3 E.A.D. 589, June 4, 1991. ("Sporicidin") There, the Board pointed out that a remedial statute is to be "construed liberally so as to effectuate its purposes" and, accordingly, that determining whether a pesticide claim was made as a "part of its distribution or sale" was to be broadly construed. It noted that the purpose at work in this provision is the health risks attributable to unsubstantiated and possibly misleading claims which are associated with the promotion of the product. The EAB pointed out that a Section 12(a)(1)(B) claim is not necessarily a claim about untruthfulness, but rather relates to claims that have been made prematurely, as pesticide sellers and distributors can not make claims about their products *until the EPA has determined* that they have been adequately substantiated by test data. Id. At 1991 EPA App. LEXIS 3, *30. The Board also observed that its construction did not make the phrase "part of its distribution or sale" so broad as to denominate all activity as promotional, noting that the dissemination of scientific information within the scientific community was an acceptable non-commercial setting to exchange information. Id. at *37.

Examination of Microban's Promotional Brochure; its document entitled "Facts about Microban Antimicrobial Protection;" its May 31, 1995, "Presentation to Hasbro, Inc.;" the language urged by Microban for a Hasbro Toy Label; and Microban's Public Relations Questions & Answers transmitted to Hasbro on January 13, 1997, identified, respectively, as Exhibit Numbers 7,13, 14, 16, and 12 in EPA's Motion, each independently demonstrate that Microban, despite elaborate arguments to the contrary, made claims that "substantially differ[ed]" from those approved with its registration and did so as part of its distribution or sale. Any one of these documents establish a violation of Section 12(a)(1)(B) of FIFRA. Thus the finding of liability rests entirely on Microban's own documents, which speak for themselves, in establishing a violation.[(11)]

Exhibit 7, a Microban promotional brochure, is plainly nothing other than a sales medium. The document is rife with departures from the terms of the approval, with its reference to the "microbe invasion" and its linkage with "illness causing germs." Further, the same document discusses petri dishes containing Staph. aureus and E. coli together with the claim that the areas treated with Microban's protection are free of these bacteria. It also makes the assertion that Microban's antimicrobial protection was developed to "neutralize germs virtually everywhere they can live and breed." Each of these statements go beyond the boundaries of the approval and its limitation to effectiveness against non-health related organisms. Association of Microban's effectiveness with terms like "illness causing germs" and their "neutralization" clearly exceeds the terms of the approval. Even without the more particular description of "illness causing germs," the term "germs" is clearly understood to mean a microorganism that is pathogenic, that is to say, something capable of causing disease. See Webster's II New College Dictionary, 1995[(12)]. Indeed, Microban's own documents reveal that they apply this common understanding of "germs" and associate the term as including the specific pathogens of E. coli, Salmonella, Staph. and Strep. Microban's January 13, 1997 "Public Relations Questions & Answers" document. EPA Exhibit 12 at p. 3. Exhibit 7 also contains the assertion that the product "utilizes germ-killing ingredients similar to those currently found in leading soaps and disinfectants offering antibacterial

protection." Further, the discussion of "GERM-RELATED ILLNESSES" with its reference to the many species of bacteria and viruses that "swarm around us wherever we go," food-borne illness and related fatalities are all about *health related organisms,* as is the subsequent discussion of consumers welcoming products with Microban's antibacterial protection and the sales pitch that they are willing to pay a premium price for the "peace of mind afforded by products with built-in, germ-fighting protection."

A similar tact is taken in the document entitled "Facts about Microban Antimicrobial Protection," (Exhibit 13), with its reference to Microban's protection for the purpose of "address[ing] the growing public concern over the prevalence of germs and bacteria, such as E. coli, Salmonella, Staph., and Strep.," coupled with the claim that "**[i]ndependent laboratory tests have shown *conclusively* that Microban can safely reduce the presence of bacteria on these products by 99.9 percent**[(13)]**.**" (Boldness in original, italics added) As with Exhibit 7, this document, touting Microban's protection, uses, safety, and current users is also, unmistakably, nothing other than promotional literature.

As reflected by its involvement with the language employed in Hasbro's Playskool toy label, Microban's suggested label editing continued the theme evidenced in the documents discussed above. Microban's involvement with the Hasbro product label has both sales and distribution qualities. In attempting to influence the label's wording, Microban was clearly making an effort to interject sales aspects onto the label. In addition to suggesting that the Microban name appear again on the label, for a total of seven times, by adding language touting the germ fighting/ antibacterial protection and the consequent healthier environment the product allegedly provides for children, Microban exceeded the terms of its registration. EPA Exhibit 16 accompanying instant Motion. The fact that it was attempting to piggyback its claims onto the Hasbro label does not diminish the sales aspect. Consumers do read labels. Labels, as Microban implicitly recognizes, help sell products. As observed by the EAB, distribution of a product includes its marketing and merchandising and merchandising encompasses sales promotion as a "comprehensive function." Sporicidin at *39. Therefore, under either aspect, the label satisfies the second element of a Section 12(a)(1)(B) violation.

Clearly these documents[(14)] show a consistency on Microban's part to achieve via a backdoor route what EPA had not approved: associating the effectiveness of the product against health related organisms. While not every claim in these documents runs afoul of the terms of the EPA's approval, that is not the test of compliance. Rather the question to be posed is whether *any* of the claims run contrary to the terms of the registration approval. Each of these documents, by substantially differing from the claims permitted with the registration, exceeded the approval.

B. Addressing Microban's Arguments Regarding the Motion for Accelerated Decision

Microban has argued that Sporicidin holds that a claim must be disseminated with the intent of inducing the purchase and use of the product and that documents such as the January 13, 1997 Public Relations Questions & Answers and the draft product label, being drafted *after* the sale and at the request of the buyer, can not be construed as inducing the product's sale and use. Using the same rationale, it argues that its general corporate brochure and fact sheet had no "claim" purpose, as they were only general corporate documents and general information sources.

Adoption of Microban's argument that a Section 12(a)(1)(B) violation can only be made out when a claim occurs in advance of, and in order to induce, a sale would create a loophole that would defeat the provision's clear purpose of barring unapproved claims. The obvious intent of the provision is to ensure that claims do not go beyond those approved. Further, the phrase prohibiting substantially differing claims made "as a part of its distribution or sale" contains no limiting language, such as "contemporaneous" sale, and, in any event is expressly broader than sales alone, covering unapproved claims made as part of the pesticide's distribution as well. The EAB has expressly avoided imposing such a narrow time stricture, noting that a claim can be "part of a future sale or distribution" and

that a time interval between a claim and subsequent sale is common. Sporicidin at *35. As noted above, the Board has observed that Section 12 (a)(1)(B) applies to claims made as part of *either* a sale or distribution and that distribution is a broad term which includes both marketing and merchandising. Merchandising refers to sales promotion as a "comprehensive function." Id. at *39. Rather than focusing on the time when a claim is made, the true inquiry is whether the unapproved claim is intended to persuade about the value of the product and to encourage its purchase and use. Id. at *34. Clearly each of the documents cited above meet that standard.

Microban's argument also ignores that the sales picture is actually a mural, which includes more than the actions which result in the closing of a present sale with Hasbro. Selling a product is an ongoing effort which involves current and future sales and secondary sales efforts aimed at consumers who, through purchases, may create additional demand by manufacturers to incorporate Microban's Additive "B" in its products.

While the Court agrees with Microban's assertion that Section 12(a)(1)(B) does not limit claims to those that are "exact recitation[s]" of the language approved in the registration and that only substantial differences are prohibited, their associated argument that such differences must be measured by considering whether the purpose behind the claim was to induce the sale and use of the product, amounts to little more than a repackaging of the argument that claims made after a sale is completed are exempt from the proscription against unapproved claims.

Similarly unpersuasive is Microban's argument that, in any event, the claims it used do not substantially differ from the phrases EPA approved. EPA's complaint is not based on the use of any of the phrases it deemed acceptable in the July 10, 1987, letter. On their face none of the EPA approved phrases imply effectiveness against health related organisms and Microban offers no rationale which links the substance of the approved phrases to the substance of the offending ones. Instead there seems to be an implicit suggestion that by permitting some phrases, EPA had somehow opened the door to either accepting all phrases Microban chose to use or that it was estopped from objecting to others. The distinction between the approved phrases and the phrases used in Microban's claims is basic and stark: while the approved phrases do not imply effectiveness against health related organisms, the offending phrases clearly do.

Microban also argues that any offending references are inconsequential. By noting that it makes only one reference in its "Fact Sheet" regarding E.coli, Staph., Strep. and Salmonella, Microban infers that the making of an isolated reference to the public's concern over such health related organisms is insufficient to amount to a violation. Microban attempts to bolster this argument by adding that it has only made general observations about antimicrobial protection in general, without making any specific pesticidal claims and such isolated references only demonstrate that its product has satisfied the FDA's standards.

However, the prohibition against unauthorized claims is total. There is no provision allowing occasional or isolated unapproved claims. Further, Microban's assertion that these statements represent mere observations about where microorganisms live and breed and general concerns about such bacteria are not detached or divorced from the product itself. So too Microban's claim that its reference to "germs" and "microbes" is only a harmless generic allusion to non-health related organisms is belied by the unmistakable health related context in which these references appear.

Last, Microban's attempt to blur the issue of whether health-related claims were made by referring to FDA approval and by advancing the notion that the some of the statements only represent "consumers' perceptions," as opposed to Microban's words or impressions is unavailing and disingenuous. Regardless of the source of the consumers' comments, it was Microban that selected them and was using them to its advantage to imply its product's effectiveness against health related organisms. Nor can Microban bootstrap its claims into being approved by EPA merely because another federal agency may have approved its product. The issue is the terms of the EPA's registration approval, not that of some other agency. As noted by the EAB in Sporicidin, references to other federal agencies' approval of a pesticide has no

bearing on the definition of a claim under Section 12(a)(1)(B), as this section prohibits the making of unapproved pesticidal claims until the Agency (i.e. EPA) has made a determination that they have been adequately substantiated. Id. at *29-30.

Rather than concocting elaborate arguments to deny the obvious departure from the terms of the approval, Microban would have been wiser to have pursued, in the first instance, the course of providing (if it could) the required documentation, sufficient to satisfy EPA, that the health related claims it was asserting were valid.

C. The Sanitizing or Self-Sanitizing Issue

The Second Amended Complaint indirectly references "sanitization" only in paragraph 14, as background discussing EPA's requirements for antimicrobial pesticides. Paragraphs 23 through 25 provide specifics to the alleged violation, but these contain no mention of any sanitizer or self-sanitizer claims.

It appears to the Court that the issue of whether the documents referring to Microban's claimed ability to reduce bacteria on treated products by 99.9 percent amounts to a sanitizer or self-sanitizer claim was not alleged in the complaint, is unnecessary to decide in any event, and ultimately creates a distraction from the violation charged. There is nothing talismanic about any determination that Microban made "sanitizer" claims, in terms of establishing a Section 12(a)(1)(B) violation. If, for example, Microban's promotional brochure (EPA Exhibit 7) had asserted that "Microban has been proven to safely reduce... harmful bacteria (including E. coli, Salmonella, Staph and Strep) by **50** percent," this would still establish the claim element of the offense as completely as one asserting a growth reduction of **99.9** percent, as both assertions transgress the terms of the registration approval by making health related claims. Therefore, while sanitizer claims were not alleged in the complaint, the absence of this allegation has no impact upon the establishment of a violation in this case.

Conclusion

For the reasons stated, EPA's Motion for Accelerated Decision as to Liability is GRANTED. The determination of an appropriate penalty has yet to be made. In this regard the Court has questions concerning whether it is appropriate to view this as 32 separate violations of Section 12(a)(1)(B) of FIFRA, based on 32 separate sales or as 5 violations, representing the five offending Microban documents cited in the Complaint. Preliminarily, it would seem that each offending claim by Microban would form the basis for a separate violation, not each individual Microban sale or distribution made to Hasbro. However, unless the parties are able to stipulate as to the appropriate penalty in this matter, the Court directs that briefs be submitted on this issue by October 16, 1998. A hearing, limited to the determination of an appropriate penalty, will then be scheduled.

So Ordered.

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William B. Moran
United States Administrative Law Judge

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

1. On August 5, 1998 EPA filed a Motion for leave to file a Reply Brief to Respondent's Opposition and Respondent filed its Opposition the following day, August 6, 1998. In view of the Court's own prior direction for a Reply Brief, the Motion and Opposition are moot.

2. Complainant's Motion for Leave to File Second Amended Complaint was granted on April 3, 1998.

3. As an alternative pleading, the Complaint asserts that, *if* the Respondent's actions were not sales or distributions of a *registered* pesticide, then Microban engaged in 32 incidents of the sale or distribution of the unregistered pesticide, Microban Plastic Additive "B," in violation of Section 12(a)(1)(A) of FIFRA. The protective, alternative pleading, apparently stems from the language used in the EPA's Notice of Pesticide Registration, dated August 15, 1983, which described the product as "conditionally registered," and set forth three conditions. Following the numbered conditions, the registration continued with the language that is in issue in this case, by providing that the "product is being accepted as a preservative and bacteriostatic agent effective only against non-health related organisms..." Microban does not assert that its product was not registered. Apart from the numbered conditions, a failure to adhere to the terms of acceptance is viewed as a Section 12(a)(1)(B) violation, as the language in issue, while describing the parameters of the acceptance, does not act as a condition precedent to acceptance of the registration.

4. The record confirms that in fact Microban *did assert,* in its Opposition to Complainant's Motion for Accelerated Decision as to Liability, that EPA first raised a "self-sanitizing" claim with the filing of the Motion for Accelerated Decision. Microban Opposition at 21.

5. Except for Salmonella, these terms are the short hand expressions used in common parlance but, formally, "E. coli" refers to "Escherichia coli," "Staph" refers to "Staphylococci" and "Strep" refers to "Streptococci." Current Medical Diagnosis & Treatment, Thirty-third Edition, 1994.

6. EPA's Pesticide Assessment Guidelines, Subdivision G, 91-2(j)(2), (1)(5)(October 1982). EPA Exhibit 10, accompanying instant Motion.

7. 7 U.S.C. § 136j(a)(1)(B).

8. Although EPA references several letters sent subsequent to August 15, 1983, which reaffirm its position that Microban was not permitted to claim that its product was effective against microorganisms infectious to man (EPA Motion at 6), these are considered relevant in determining the gravity of the violation.

9. There is no dispute that Respondent is a "person" and located in a "state," nor that Hasbro is a "person."

10. EPA has, since 1979, clearly distinguished between microorganisms infectious to man and microorganisms of economic or aesthetic (i.e. bacteriostatic) significance. REQUIREMENTS FOR ANTIMICROBIAL PESTICIDES: Determination of Health-Related and Non-Health-Related Uses, DIS/TSS-16, June 26, 1979. Complainant's Prehearing Exchange, Exhibit 31.

11. Accordingly, no part of this decision on liability relies upon the affidavit of Walter C. Francis.

12. Dorland's Illustrated Medical Dictionary, 27th Edition, 1988, echoes this common understanding that a "germ" connotes a pathogenic organism.

13. As discussed more fully infra, apart from whether particular language can be described as making a "sanitizer or self-sanitizer claim," the language employed can be assessed independently of that determination by simply analyzing whether the language *itself* amounts to a claim which substantially differs from that permitted by the registration.

14. There is no need for an extended discussion of the two other documents EPA refers to in its Motion for Accelerated Decision as to Liability: the May 31, 1995 Presentation to Hasbro (EPA Exhibit 14, accompanying instant Motion); and the Public Relations Questions and Answers for Hasbro (EPA Exhibit 12, accompanying instant Motion) because it would be redundant. It is sufficient to note that, by referencing the product's effectiveness against microorganisms "like E. coli, Salmonella, Staph. and Strep."(which are also referred to as "household germs" by Microban) (See Exhibit 12), and by the pervasive connection between these germs and health related illness, they continue the themes discussed supra for the first three documents (Exhibits 7, 13, 16). Both of these documents make claims that go beyond those permitted by the registration and, by their very nature, Exhibits 14 and 16, as sales strategy documents, satisfy the "distribution or sale" element of Section 12(a)(1)(B).

In the Matter of Microban Products Company, Respondent

Docket No. FIFRA-98-H-01

CERTIFICATE OF SERVICE

I hereby certify that the foregoing Order on Motion for Discovery, Filing of Sur-Reply and Partial Accelerated Decision, dated September 18, 1998, was sent in the following manner to the addressees listed below:

By Pouch Mail to:

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

By Regular Mail to:

Counsel for Complainant:

Robert W. Darnell, Esquire
Marc Borodin, Esquire
Toxics and Pesticides Enforcement Div. (2245-A)
Office of Enforcement and Compliance
U.S., EPA
401 M Street, S.W.
Washington, D.C. 20460

Counsel for Respondent:

P. Susan Lively, Esquire
Gerald H. Yamada, Esquire
Charles A. Patrizia, Esquire
Paul, Hastings, Janofsky & Walker, LLP
1299 Pennsylvania Avenue, N.W.
Washington, DC. 20004

_____

Elaine Malcolm
Legal Assistant

Date: September 18, 1998
Washington, D.C.

Last updated on March 24, 2014