

\$160,000 Civil Penalty for FIFRA Violation Reinstated Upon Landmark Appeal

In a landmark enforcement case, the Environmental Appeals Board (EAB) reversed a liability decision and assessed a \$160,500 civil penalty on Microban Products Co., a North Carolina plastics manufacturer, for violation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (*In re Microban Products Co.*, EPA EAB, No. FIFRA 98-H-01, 5/12/04).

Microban produced a product called Microban Plastic Additive “B,” which was registered by the EPA in 1983 and later sold to toymaker, Hasbro Inc., for incorporation into certain plastic toys, games, and juvenile products. Pesticide Enforcement alleged in its December 5, 1997 Complaint against Microban, that the company had committed thirty-two violations of FIFRA section 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B) by shipping products that the company claimed had antimicrobial effects.

Specifically, Pesticide Enforcement alleged of each of the thirty-two shipments of Additive “B” that Microban “in each instance sold or distributed a registered pesticide with claims that were substantially different from claims made in connection with its registration.” The relevant section of FIFRA provides that it is unlawful to distribute or sell a pesticide if any claims made as part of its distribution or sale differ from the approved claims under the product’s registration statement.

Pesticide Enforcement’s case centered on three questions: whether Microban’s claims differed from those made in the registration statement, whether the unapproved claims were made “as part of” the distribution or sale of Additive “B,” and whether the unit of violation and penalty assessment were appropriate and proportional to the gravity of the violation.

Three documents were at the heart of the EAB’s finding that Microban’s antimicrobial claims about Additive “B” substantially differed from claims made under its registration: 1) a document memorializing a Presentation to Hasbro, Inc. including the statement that Additive “B” was “the ultimate in germ-fighting protection”; 2) a draft toy label by Microban suggesting that the Hasbro toy labels state, “Only Playskool has the exclusive Microban germ-fighting technology built right into the toy. This unique technology inhibits the growth of germs on toys to help provide a healthier (or better) environment for your child”; and 3) a Questionnaire about Microban stating “Microban protection has been shown to be effective in virtually eliminating the growth of most common household germs, including E. coli, Salmonella, Staph. and Strep. as well as mold and fungus.”

Based on these documents, the appeals board found that EPA had produced sufficient evidence of a violation. Microban’s human health related antimicrobial claims differed from EPA’s explicit statement made in a July 1987 letter to the company regarding registration stating: “the data which you have submitted do not support health-related efficacy claims. The only claim which may be made is that the product is bacteriostatic with respect to bacteria not infectious to man.”

The second central question, whether the unapproved claims were made “as part of” the distribution or sale of Additive “B,” was more contentious. On remand, the Administrative Law Judge (ALJ) concluded that Pesticide Enforcement had not demonstrated a particularized link between the thirty-two shipment invoices and the unapproved claims in the Presentation, the Q&A document, and the Draft Label, thus finding no violations of FIFRA section 12(a)(1)(B).

On appeal, however, the EAB found that the fact that the sales agreement was entered into sometime after the presentation, and the shipments resulting from the agreement occurred sometime after that, does not change the underlying fact that a connection existed between the unapproved claims and the “distribution or sale” of the pesticide.

Resolution of the final question regarding the unit of violation and penalty assessment was also reinterpreted upon appeal. Microban argued that, when there is a sale and later shipments made pursuant to that sale, unless the unapproved claims physically accompany the subsequent shipments, there can only be one violation of FIFRA for the sale. Microban emphasized the fact that none of the documents at issue were sent with the thirty-two shipments to any of Hasbro’s contractors.

In his 1999 decision, the ALJ decision concluded that Microban had committed five violations of FIFRA section 12(a)(1)(B) based upon five documents in which he found Microban to have made unapproved claims. In the current decision, the EAB held that the ALJ had erred in his interpretation of section 12(a)(1)(B) of FIFRA because a unit of violation “must be based, not upon the number of documents containing unapproved pesticidal claims, but rather upon the number of proven distributions or sales of the pesticide, which in turn must be shown to be ‘linked’ to one or more of the unapproved claims.”

The appeals court found the gravity of the violations to be significant because Microban’s culpability was high and the company’s claim violations were blatant. The Board thus assessed the statutory maximum penalty per violation, which resulted in a total civil penalty of \$160,500.

The Appeal’s Board’s decision has several lasting implications. The Microban decision reinforces a broad interpretation of evidence demonstrating the existence of a nexus between unapproved claims and the distribution or sale of a pesticide. The penalty assessment also demonstrates the EAB’s willingness to issue the statutory maximum fine per FIFRA violation, especially in the case of a claim that “blatantly” departs from the scope of EPA’s approval.

In the current decision, the Board found that the language of FIFRA authorizes the Agency to consider each shipment as a violation of the Act, stating, “under the plain language of the statute, each shipment of Additive “B” constitutes one violation of FIFRA.” In the case of a FIFRA section 12(a)(1)(B) violation, the EPA is authorized to charge violations of either the sale(s) or the shipment(s) of a pesticide (but not both).

Thus, any egregiously written pesticide claims that depart from the scope of a pesticide's registration will meet a potential maximum statutory fine based on either the number of sales or shipments of the pesticide.

EPA penalty policy for assessment of administrative penalties for violations of FIFRA (Five-Stage Process):

- (1) Determine the gravity of the violation;
- (2) Determine the size of business category for the violator;
- (3) Use the FIFRA penalty matrices to determine the dollar amount associated with that gravity level and that size of business category;
- (4) Further adjust the gravity of the base penalty by considering the specifics of the pesticide involved, such as toxicity, the actual or potential harm to human health and/or the environment, the compliance history of the violator, and the culpability of the violator;
- (5) Consider the effect of the calculated payment on the ability of the violator to continue in business.