



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

August 3, 2005

Mr. Warren Stickle, President
Chemical Producers & Distributors Association
P.O. Box 25793
Alexandria, VA 22313

Dear Mr. Stickle:

Thank you for your letter of July 11, expressing your concern about the potential impacts of the court's recent decision in *FMC Corp v. Control Solutions, Inc.* I share your concern about the potential impacts on EPA's Pesticide Program for the following program policy reasons.

First, it must be stressed that the pesticide label is an important part of a federally approved registration that provides necessary information and directions to users regarding the pesticide and how the pesticide must be used. The label also is an important element in EPA's analysis of whether a pesticide can be used without causing unreasonable adverse effects to human health and the environment. Accordingly, it is important for the protection of the environment and public health that products that are similar and intended for similar uses have clear and consistent labeling. It has been the practice of the Office of Pesticide Programs since the enactment of FIFRA section 3(c)(7)(A) in 1978 to strongly encourage "me-too" product labels to be identical or substantially similar to the labels of the products on which their registrations are based. When they are not, OPP may be unable to conclude that products meet the FIFRA section 3(c)(7)(A) standard for issuing "me-too" registrations. Thus, this is not merely a matter of convenience for OPP. Similar products need to communicate use instructions and warnings in a clear and consistent fashion to ensure that the products are used appropriately.

Conveying application instructions and safety messages for similar products in different ways increases the likelihood that the product will be misused. It also diminishes the Agency's ability to enforce pesticide labeling in a consistent manner and thus defeats the primary purpose of the labeling. For example, precautionary language on mosquito control products, which is intended to manage risks to aquatic life, has varied considerably from product to product, causing confusion among users and enforcement personnel. The Agency recently issued a Pesticide Registration Notice (PR Notice 2005-1), which recommends consistent environmental hazard label statements. The recommended language will help achieve the objective of effective mosquito control while protecting water and aquatic life.

Second, if the *FMC v. CSI* decision stands, EPA's Pesticide Program would likely be inundated with applications to amend thousands of "me-too" labels as their registrants endeavor to avoid potential copyright infringement claims. It is difficult to imagine how many different ways companies might come up with to convey the same information, and it is equally hard to imagine the amount of staff time that would be required to conduct a detailed review of each label. For example, there are over 650 2,4-D products, the majority of which are "me-toos". It is simply not reasonable to expect that each label could be sufficiently different from all others to avoid copyright infringement and yet ensure that users will not be confused. Users are bound to be confused if all of these products' labels convey their instructions for use in different ways. And, as you have pointed out, amendments to "me-too" labels are not subject to the payment of fees under the Pesticide Registration Improvement Act, but we are required by law to complete those reviews within 90 days. These applications would require us to devote significant resources to activities that are essentially administrative and do not enhance environmental protection. The result would be a major diversion of resources that would undermine our ability to protect human health and the environment.

We are continuing to analyze the FMC decision as we keep abreast of pending litigation on this issue. We are grateful that you have shared your own analysis with us.

Sincerely,

S/

Susan B. Hazen
Principal Deputy Assistant Administrator