



MEMORANDUM

Via E-Mail

DATE: August 4, 2005

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: EPA Responds to CPDA Regarding *FMC v. CSI*

Yesterday, the U.S. Environmental Protection Agency responded to the Chemical Producers & Distributors Association (CPDA) regarding the implications of the U.S. District Court for the Eastern District of Pennsylvania's May 16, 2005, decision to issue a preliminary injunction in *FMC Corporation v. Control Solutions, Inc.* As reported in our May 27, 2005, memorandum, which is available at <http://www.lawbc.com/updates/052705-fifra.pdf>, the court enjoined Control Solutions, Inc. (CSI) from selling its generic Bifen I/T pesticide, which "contains the exact ingredients, in the identical proportions as, and is thus functionally equivalent to, [FMC Corporation's (FMC)] TalstarOne product." Ms. Susan B. Hazen, top toxics decision-maker at EPA, wrote that EPA shares CPDA's concern about the potential impacts on EPA's pesticide program for two program policy reasons: "[s]imilar products need to communicate use instructions and warnings in a clear and consistent fashion to ensure that the products are used appropriately"; and, if the *FMC* 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."

Regarding the first issue, EPA's letter states that pesticide labels provide necessary information and directions to users regarding the pesticide and its use. EPA's letter also says that the pesticide label 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." The letter continues:

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"



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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.

According to EPA’s letter, if pesticide labels for similar products convey application instructions and safety messages in different ways, the likelihood that the product will be misused increases. Different labels for similar products also “diminishes [EPA’s] ability to enforce pesticide labeling in a consistent manner and thus defeats the primary purpose of the labeling.”

Regarding the second issue, that EPA would be inundated with applications to amend thousands of “me-too” labels, the letter states: “[i]t 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.” As an example, EPA’s letter notes that there are over 650 2,4-D products, the majority of which are “me-toos,” and says “[i]t 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.” EPA also agrees with CPDA’s comment that while amendments to “me-too” labels are not subject to the payment of fees under the Pesticide Registration Improvement Act, but EPA would be “required by law to complete those reviews within 90 days.”

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We hope this information is helpful. As always, please call if you have any questions.